Laboratory Approval Program – General Policies & Procedures

1. Purpose

Laboratory approval programs are developed at the request of industry, other Federal agencies, or foreign governments in support of domestic and international trade. The Laboratory Approval Service approves, or accredits, laboratories to perform testing services to verify that the analysis of food and agricultural products meet country and customer-specified requirements and that the testing of products marketed is conducted by qualified and approved laboratories. This document describes the general policies and procedures for a laboratory to apply for and maintain status in a Laboratory Approval Program (LAP) administered by the Laboratory Approval Service (LAS). Program specific requirements are outlined in program specific documents.

The Laboratory Approval Service programs are provided by the United States Department of Agriculture (USDA), Agricultural Marketing Service (AMS), Science and Technology Program (S&T), Laboratory Approval and Testing Division (LATD).

2. Scope

The provisions of this document apply to all laboratory approval programs administered by LAS. It applies to a laboratory seeking to apply or maintain status in a laboratory approval program. LAS provides due notice of any change to its requirements, and verifies that applicants carry out any necessary adjustments.

3. Table of Contents

4. References

The references listed are used in the application of this document. For dated references, only the cited edition applies. For undated references, the latest edition available (including any amendments) applies.

4.1. 5 USC §552. Freedom of Information Act (FOIA). Public Information; Agency Rules, Opinions, Orders, Records, and Proceedings. United States Code, Title 5 – Government Organization and Employees.

4.2. 7 USC 38, Agricultural Marketing Act of 1946. Distribution and Marketing of Agricultural Products. Title 7 – Agriculture.

4.3. 7 CFR Part 90. Introduction. Subchapter E – Commodity Laboratory Testing Programs. Chapter 1 – Agricultural Marketing Service (Standards, Inspections, Marketing Practices). Subtitle B – Regulations of the Department of Agriculture. Title 7 – Agriculture.

4.4. 7 CFR Part 91. Services and General Information. Subchapter E – Commodity Laboratory Testing Programs. Chapter 1 – Agricultural Marketing Service (Standards, Inspections, Marketing Practices). Subtitle B – Regulations of the Department of Agriculture. Title 7 – Agriculture.

4.5. ISO 17011. Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies (2004 or 2017).

4.6. ISO/IEC 17025. General requirements for the competence of testing and calibration laboratories (2005 or 2017).

4.7. ISO/IEC 19011:2011. Guidelines for auditing management systems.

4.8. LAS-QM. United States Department of Agriculture, Agricultural Marketing Service, Science and Technology Program, Laboratory Approval and Testing Division, Laboratory Approval Service Quality Manual.

4.9. LAP-PR.06. Laboratory Approval Program – Fees

4.10. LAP-WI.03. Client Response to Nonconformance

4.11. USDA AMS LATD LAS Website, https://www.ams.usda.gov/services/lab-testing/lab-approval

5. Nondiscrimination

Services are provided to applicants without discrimination as to race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity.

6. Confidentiality

Documentation submitted by applicants and maintained by LAS is subject to disclosure under the Freedom of Information Act (FOIA) (5 USC §552). FOIA applies to documents that are in the control of or maintained by a government agency. Any portion of the documentation that the applicant considers proprietary must be identified to LAS at the time the information is submitted. LAS makes appropriate provisions to protect the information from disclosure to the extent possible under existing federal laws.

7. Contact Information

Contact information is located on the Laboratory Approval Service Website. The Program Manager is the primary point of contact. The Branch Chief and LATD Director are the secondary points of contact and may be contacted when the Program Manager is unavailable or there may be conflict with the Program Manager.

General contact information for LAS:

USDA, AMS, S&T, LATD
1400 Independence Avenue, SW, Room 3533-S
Washington, D.C. 20250-0272

Fax: 202-720-4361
Email: LAS@ams.usda.gov
Website: https://www.ams.usda.gov/services/lab-testing/lab-approval

8. Responsibilities of LAS

LAS administers its laboratory approval programs under the authority of 7 USC 38, 7 CFR Part 90, and 7 CFR Part 91, and in compliance with the ISO 17011 and ISO 19011 standards, and LAS Quality Manual.

9. Who May Apply

Any laboratory (U.S. or international) may apply provided they are performing testing services within the scope of a laboratory approval program administered by the Laboratory Approval Service.

The Laboratory Approval Service Website provides information about the available laboratory approval programs.

10. Requirements for Approval

LAS requires the laboratory to conform to the following:

a) The laboratory must commit to continually fulfilling the requirements set by LAS for the areas where approval is sought or granted. This includes agreement to adapt to a programmatic change.

b) The laboratory must keep LAS up-to-date on all matters of the laboratory related to the program where approval is sought or granted.

c) The laboratory must permit LAS access to its facilities, personnel, procedures, and records to enable verification that requirements are met, upon request. Records must be maintained for at least three years.

d) The laboratory must provide access to those records and documents that provide insight into the level of independence and impartiality of the laboratory from its related bodies, where applicable (e.g., conflict of interest policy and procedure).

e) The laboratory must claim approval only with respect to the scope for which it has been granted approval.

f) The laboratory must not use its approval in such a manner as to bring LAS into disrepute.

g) The laboratory must pay fees as determined by LAS.

Laboratory Approval Program – General Policies & Procedures

11. Letter of Application

A letter of application is used to notify the Program Manager of a laboratory's interest in the program and to ensure the laboratory fully understands the LAP general policies and procedures and program requirements before submitting an application package.

A duly authorized representative of the laboratory must make formal application, by email, to the Program Manager. The authorized representative is the laboratory's point of contact responsible for (1) the commitment to conditions of approval, (2) ensuring compliance with the LAP general policies and procedures and program requirements, and (3) the information provided in the application package.

The application letter and accompanying information must include:

a) A clearly defined, request for a specific scope of approval of a specific approval program;

b) General information concerning the laboratory such as its activities, its relationship in a larger corporate entity if any, and addresses of all its physical location(s) to be covered by the scope of approval;

c) Billing Information to include, business' legal name, billing address, taxpayer identification number (Federal W-9 Form or Federal W-8BEN), and accounts payable point of contact (i.e. name, phone number, and email address).

d) An agreement to fulfil LAS general policies and procedures and program requirements.

The Program Manager acknowledges receipt of the letter and communicates with the laboratory to ensure they understand the LAP general policies and procedures and program requirements and application package inclusions.

12. Application Package Requirements

The application package inclusions are used to evaluate whether a laboratory has a quality management system in place and records to support compliance with the LAP general policies and procedures and program requirements. All information received will remain confidential and protected (see §6).

The application package includes, but not limited to,

12.1. A clearly defined, request for a specific scope of approval of a specific approval program.

12.2. Laboratory Information:

a) Laboratory's legal name;

b) Physical address and mailing address if different;

c) Authorized representative's name, title, phone number, and email address;

d) Approved signatories of test reports that reference "USDA approved-laboratory" (name, title, phone number, and email address); and

e) Organizational Chart.

12.3. Policies and procedures however named or organized:

a) Master List of documents (internal and external procedures, forms, lists, etc.);

b) Quality Manual;

c) Conflict of Interest Statement and procedure;

d) Document Control procedure;

e) Records Control procedure;

f) Corrective Action procedure;

g) Internal Audit procedure;

h) Management Review procedure;

i) Training procedure;

j) Equipment handling, calibration, calibration verification schedule and procedure;

k) Method validation and verification procedure;

l) Test Method procedure(s) including method quality controls, how to handle nonconforming quality controls, and calculated measurement uncertainty;

m) Proficiency Testing procedure;

n) Control Charting procedure; and

o) Test Report procedure.

12.4. Records:

a) Copy of certificate of accreditation and scope from an accreditation body recognized by the International Laboratory Accreditation Cooperation (ILAC);

b) Test method validation and verification study(ies);

c) Equipment calibration or calibration verification certificates/records;

d) Test report (Certificate of Analysis) and supporting analytical data;

e) Staff training records and authorizations;

f) Last internal audit report and associated corrective action and correction;

g) Last management review report and associated status of action items;

h) Last proficiency test results and associated corrective action and correction (if relevant). At least one proficiency test round, with satisfactory results is required prior to granting approval;

i) Test method control charts; and

j) Equipment inventory.

13. Submission of Application Package

A duly authorized representative of the applicant laboratory submits the application package to the Program Manager (preferably electronically).

The Program Manager notifies the laboratory, in writing, of package receipt and reviews applications in the order in which they are received.

14. Assessment of Application Package

A desk audit (see §17.5) of the application package is performed to ensure the LAP general policies and procedures and program requirements are fully addressed. The auditor uses appropriate program checklist and audit tools to record observations, findings, and decision recommendation.

a) If the applicant's documentation is adequate and the majority of the LAP general policies and procedures and program requirement are met, the initial onsite audit (see §16) may be scheduled.

b) If the applicant's documentation requires minimal clarification or additional information, the auditor obtains the clarification or additional information. Once the applicant's documentation is adequate and the majority of the LAP general policies and procedures and program requirements are met, the initial onsite audit (see §16) may be scheduled.

c) If the applicant's documentation does not conform to the majority of the LAP general policies and procedures and program requirements or if evidence shows the applicant would not successful the initial onsite audit (see §16), the auditor prepares and submits a desk audit report (see §18) itemizing the deficiencies to the Program Manager. The Program Manager sends the report to the applicant discussing the action they must take before continuing the application process. The laboratory may reapply as a new applicant after resolving the itemized deficiencies.

15. Withdrawal of Application Package

An application may be withdrawn, all or in part, by a duly authorized representative at any time; provided that the duly authorized representative notifies LAS in writing of their desire to withdraw the application and pays any expenses LAS has incurred in connection with the application. The laboratory may reapply as a new applicant after a withdrawal.

16. Onsite Audit of Laboratory

The Program Manager coordinates the onsite audit (see §17.6) (ideally within 6 months of application package desk audit). After the onsite audit, an audit report is issued within 30 days (see §18). If there is a nonconformance, the laboratory must respond within 30 days (see §19). When the Program Manager grants approval, a certificate or letter of approval is issued (see §20) and the laboratory is added to the Official Listing of the USDA-Approved Laboratories (see §22).

Thereafter, the laboratory may use the term "USDA-approved laboratory" and use USDA Symbols (see §23) and must maintain its status in the program (see §24).

17. Audits

An audit is a systematic, independent, and documented process for obtaining evidence and evaluating it objectively to determine if the criteria are fulfilled. Each audit is planned and conducted according to a defined and agreed upon objective, criteria, and scope. LAS uses three primary processes for auditing, desk audit (see §17.5), onsite audit (see §17.6), and surveillance (see §17.7) in accordance with ISO 19011:2011. A written report (see §18) of the audit findings is issued to the laboratory at the conclusion of an audit.

17.1. Audit Objective: The audit objective explains the reason for the audit. For example, 1) initial onsite audit to approve a laboratory after an application package is accepted, 2) routine onsite audit to ensure continued compliance with the LAP general policies and procedures and program requirements.

17.2. Audit Criteria: The audit criteria is the set of policies, procedures or requirements used as a reference against which audit evidence is compared. The audit criteria must include, at least, the Laboratory Approval Program Requirements – [Program Name] (LAS website) and ISO 17025:2005.

Note: Program requirements may not require formal accreditation; however, LAS reviews for compliance to the standard to ensure fair and equal assessment. See applicable approval program to determine if formal accreditation is required.

17.3. Audit Scope: The audit scope defines the boundaries of an audit. It generally includes a description of the physical location, organizational units, activities and processes, as well as the period of records covered.

17.4. Audit Plan and Audit Schedule (Desk, Onsite): The audit plan outlines the audit objective, criteria, and scope for an audit. The audit schedule outlines the date, agenda, and logistical expectations for the audit.

a) The Program Manager defines the audit objective, criteria, and scope. They must approve any change to audit objective, criteria, and scope requested by the laboratory.

b) The Branch Chief, or designee, assigns the auditor(s) to conduct the audit. A single auditor or a two-member team typically conducts an audit.

c) The Program Manager introduces the laboratory to their auditor.

d) The laboratory has five business days from receipt of notification of assigned auditor to submit written objections regarding any audit team member(s) (see §36).

e) The auditor works with the laboratory to schedule the onsite audit date and review the audit objective, criteria, and scope. Based upon the agreed upon audit plan, an agenda and logistical expectations are outlined (audit schedule). The auditor ensures the laboratory has relevant program documents available, and requests and obtains records and documentation needed to prepare for the audit.

17.5. Desk Audit: A desk audit is a review of documents and records, away from the place of business. The audit is to ensure the LAP general policies and procedures and program requirements are fully addressed in documentation and records. The auditor uses the appropriate program checklist and audit tools to record observations and findings.

17.6. Onsite Audit: An onsite audit is conducted on the premises of a business and involves reviewing documents and records, and witnessing processes. Where relevant, the audit includes other locations where the laboratory operates to gather objective evidence that laboratory is competent and conforms to the relevant program requirements for approval.

a) The auditor must witness the performance of a representative number of laboratory staff to provide assurance of the competence of the laboratory across the scope of approval.

b) The laboratory must process a sample from receipt to reporting for the auditor to witness.

c) The auditor must interview laboratory staff.

d) The auditor must review relevant records and documentation.

e) The auditor must collect relevant evidence, as necessary, to support audit findings during the audit.

f) The auditor will identify preliminary findings and inform the laboratory. Audit findings are not final until communicated via an official audit report (see §18). The auditor must not give recommendations.

17.7. Surveillance: Data is collected over time to monitor continued compliance with certain program requirements. Surveillance activities are outlined in the program requirements.

Laboratory Approval Program – General Policies & Procedures

18. Audit Report

An audit report is the written summary of an audit containing a statement about competence and compliance, and audit findings. Audit findings are categorized as either a nonconformance or a continuous improvement point. The auditor must not give recommendations.

The auditor writes the audit report and submits it for review and approval.

The Program Manager issues the final report to the laboratory within 30 days.

a) Nonconformance (NC): is a nonfulfillment or failure to meet a requirement.

b) Continuous point of improvement (CIP): Observations or areas not identified as a nonconformance but have the potential to become a nonconformance if not addressed.

19. Addressing Nonconformance

A nonconformance is a nonfulfillment or failure to meet a requirement.

The laboratory must submit a response to LAS for each nonconformance within 30 calendar days, or timeframe specified. The response must include record of the investigation, identification of root cause(s), corrective action and correction taken, and evidence of implementation. Guidance for formatting the response back to LAS is described in LAP-WI.03, Client Response to Nonconformance.

a) Correction: Action to eliminate a detected nonconformance. Correction does not address the root cause of the nonconformance, but rather the specific nonconforming product.

b) Corrective Action: Action taken to eliminate the cause of a detected nonconformance. Corrective action is taken to prevent recurrence. This often involves revision of a policy and/or procedure.

The Program Manager reviews the laboratory's response, including evidence of implementation, to determine if the action appears sufficient and effective. If the laboratory response is insufficient, further information will be requested. LAS must provide a letter of decision upon completing the review. Additional desk audits (see §17.5) and/or onsite (see §17.6) audits may be needed.

The reviewed status of a nonconformance may be:

c) Not Accepted: The response to the nonconformance, corrective action, and correction is not sufficient.

d) Accepted: The response to the nonconformance, corrective action, and correction is sufficient, and may change to "Cleared" upon verification through a combination of desk and onsite audits and surveillance records, as applicable.

e) Cleared: The corrective action and correction is verified as implemented and appears effective, preventing recurrence of the nonconformance.

Laboratory Approval Program – General Policies & Procedures

20. Application Decision

20.1. Acceptance

The Program Manager may grant approval when the applicant satisfies the LAP general policies and procedures and program requirements, demonstrated with audit evidence (desk (see §17.5) and onsite (see §17.6)). The Program Manager issues an approval certificate or letter (see §21) to the laboratory and adds the laboratory to the Official Listing of USDA-Approved Laboratories (see §22) on the LAS website.

20.2. Denial

The Program Manager may deny approval, and issue a letter of decision, to an applicant that fails to conform to the LAP general policies and procedures and program requirements.

An application may be denied for failure to:

a) Adequately address any of the LAP general policies and procedures and program requirements resulting in a nonconformance;

b) Demonstrate capability to conform to any of the LAP general policies and procedures and program requirements resulting in a nonconformance;

c) Address each nonconformance identified in the desk audit report of the application package;

d) Present truthful and accurate information to any auditor or other USDA official;

e) Allow access to facilities and records within the scope of the program.

21. Certificate or Letter of Approval

The certificate or letter of approval describes a laboratory's approval status and scope of approval. The Program Manager issues an approval certificate or letter to an approved laboratory. A new certificate or letter is issued when approval status, change in scope, or approval is continued past the expiration date.

The certificate or letter identifies the:

a) Unique identity of the approved laboratory;

b) Premises (all) from which one or more key activities are performed and which are covered by the approval;

c) Effective date of granting of approval and, as applicable, the expiry date;

d) Scope of approval including program and tests or types of tests performed and materials or products tested and, where appropriate, the methods used;

e) Statement of compliance and a reference to the standard(s) or other normative document(s), including issue or revision used for the assessment of the laboratory.

22. Official Listing

The Official Listing of the USDA-Approved Laboratories is made publicly available on the LAS website. It contains the laboratory name, address, and contact information, scope of approval, approved signatories, and approval expiry date. The Program Manager maintains the listing.

23. Referencing USDA-Approval and Using USDA Symbols

The laboratory may use of the term "USDA-approved laboratory" or USDA Symbols for the limited purpose of announcing an approved status and for use on reports or certificates that describe the testing within the scope of approval only. The laboratory must submit communication materials for review by LAS prior to its use. The Program Manager will take suitable action to address incorrect references to approval status or misleading use of approval terms found in advertisements, catalogues, etc.

The approved laboratory may use the term "USDA-approved laboratory" if it:

a) Fully conforms to the requirements of LAS, when referring to its approval in communication media such as the internet, documents, brochures, or advertising;

b) Only uses the approval statement for the premises of the laboratory that is specifically included in the approval;

c) Does not make any statement regarding its approval that the approval body may consider misleading or unauthorized;

d) Takes due care that no report or certificate nor any part thereof is used in a misleading manner;

e) Upon suspension, withdrawal, or dismissal of its approval (however determined), discontinues its use of all advertising that contains any reference to an approval status; and

f) Does not allow its approval to be used to imply that a product, process, system or person is approved by LAS.

24. Maintaining Program Status

The laboratory must maintain program status by continuous compliance with the LAP general policies and procedures and program requirements.

LAS uses a combination of desk and onsite audits (see §17.5 and §17.6), surveillance records (see §17.7), program records, and experience gained during previous audits to assess a laboratory's continued compliance.

a) After initial approval into the LAP, LAS performs an onsite audit (see §16) the next calendar year. Thereafter, the onsite audits are scheduled on a biennial basis, unless otherwise specified to be more frequent in the program requirements.

b) Onsite audits (see §16) are scheduled on a biennial basis, unless otherwise specified to be more frequent in the program requirements.

c) Additional audits, at the expense of the laboratory, in response to a complaint, verification of resolution to nonconformance, or significant change, will be conducted. These may be unannounced.

25. Exceptions

A duly authorized representative of the laboratory may request an exception to a LAP general policy or procedure or program requirement. Submit this request in writing, to the Program Manager, on letterhead. Describe the exception requested and provide supporting records and documentation.

The Program Manager will acknowledge receipt of the request. The Program Manager reviews the request to determine whether to grant the exception and issues the decision in a letter.

26. Significant Change

A significant change is a change that may have an effect on the laboratory's approval status or capability of the laboratory to conform to any of the LAP general policies and procedures and program requirements.

A duly authorized representative of the laboratory must provide notification of a significant change, in advance if possible. Submit this request in writing, to the Program Manager, on letterhead. Describe the change, and include the effective date of the action.

A significant change may include:

a) Legal, commercial, ownership, or organizational status;

b) Top management (e.g. Laboratory Manager/Director), and key personnel (e.g. Quality Manager, analysts, etc.);

c) Analytical method procedures (preparation, extraction, detection, measurement, etc);

d) Relocation of premises;

e) Extending the scope of approval (see §27);

f) Change in ISO 17025 accreditation status; and

g) Other matters that may affect the ability of the laboratory to fulfil requirements for the program.

The Program Manager will acknowledge receipt of the request. The Program Manager advises the laboratory if an approval status change (e.g., suspension) will be necessary, and of any actions that need to be taken to maintain compliance with the LAP general policies and procedures and program requirements due to the change, in a letter.

27. Extending Scope of Approval

An extension of the scope of approval is a significant change (see §26(e)).

A duly authorized representative of the laboratory, in good standing, may submit an application to extend its scope of approval at any time. A scope expansion is treated like a new application (see §13).

The Program Manager reviews the application to determine whether to grant the extension (see §14).

28. Suspending Approval

Suspension is the status used for a laboratory not conforming to the LAP general policies and procedures and program requirements. During suspension, the laboratory is given the opportunity to remedy its nonconformance. In a suspended status, the laboratory must cease reporting test results as coming from a "USDA-approved laboratory" upon notification of suspension. The Official Listing of the USDA-Approved Laboratories is revised accordingly on the LAS website to show the laboratory as suspended and include the date of suspension.

28.1. Voluntary: The laboratory initiates the action.

A duly authorized representative of the laboratory may submit a voluntary request to suspend its approval, or portion of it at any time, for any reason. Submit this request in writing to the Program Manager, on letterhead. Describe the scope of the suspension, and include the effective date of the action.

The Program Manager will issue a letter to the laboratory acknowledging the requested action and the actions required to be reinstated (see §29).

28.2. Involuntary: LAS initiates the action.

The Program Manager may place a laboratory on involuntary suspension if it fails to conform to the LAP general policies and procedures and program requirements while it works to remedy its nonconformance. The Program Manager issues a letter to the laboratory detailing the suspension and the actions required to be reinstated (see §29).

Program suspension may occur for failure to:

a) Adequately address any of the LAP general policies and procedures and program requirements resulting in a nonconformance, including audit findings that compromise the defensibility of data;

b) Demonstrate capability to conform to any of the LAP general policies and procedures and program requirements resulting in a nonconformance;

c) Follow and maintain its approved scope of approval or procedures;

d) Provide corrective action and correction as applicable in the time-frame specified;

e) Submit notification of a significant change and seek LAS approval prior to implementation of a significant change to an approved scope including top management and key personnel (see §26(b)), analytical method procedures (see §26(c)), or other matters that may affect the ability of the laboratory to fulfil requirements for the program (see §26(g)).

f) Allow access to facilities and records within the scope of approval;

g) Accurately represent the eligibility of the laboratory results or services distributed under an approved program;

h) Remit payment for LAS services;

i) Abstain from any fraudulent or deceptive practice in connection with an application or request for service; or

j) Allow any auditor or other USDA official to perform their duties.

29. Reinstatement of Suspended Approval

A fee may be charged for review of records and documentation for reinstatement.

29.1. Voluntary Suspension

A duly authorized representative of the laboratory, under a voluntary suspension, may submit a request for reinstatement of its approval, or portion of it at any time. Submit the request in writing, to the Program Manager, on letterhead. Include records and documentation supporting the reinstatement, and the effective date of the action.

The Program Manager reviews the request, and supporting records and documentation (see §28.1). If satisfactory, the laboratory is immediately reinstated. The Program Manager will issue a letter to the laboratory for the reinstatement. The Official Listing of the USDA-Approved Laboratories will be revised accordingly on the LAS website.

29.2. Involuntary Suspension

The laboratory must address each nonconformance identified in the letter of suspension (see §19).

The Program Manager will issue a letter of reinstatement when a nonconformance is "Accepted" and if no additional onsite audits are needed. The Official Listing of the USDA-Approved Laboratories will be revised accordingly on the LAS website.

30. Withdrawing from Program

Withdrawal is the voluntary removal of a laboratory from a program. At any time, a "USDA approved-laboratory" may voluntarily withdraw from all or part (reduce scope) of the program. The laboratory must cease reporting test results as coming from a "USDA-approved laboratory" upon notification of withdrawal.

A duly authorized representative of the laboratory may request to withdrawal from the program or any part. Submit this request in writing, to the Program Manager, on letterhead. Describe whether to laboratory is withdrawing entirely or reducing its scope, and include the effective date of the action.

The Program Manager will issue a letter to the laboratory acknowledging the requested action and revise the Official Listing of the USDA-Approved Laboratories accordingly on the LAS website. Additionally, LAS notifies the appropriate commodity committee, board, or representative organization(s).

31. Reinstatement of Withdrawal from Program

The laboratory may apply as a new applicant at any time for reinstatement (see §12).

32. Dismissal from Program

Dismissal is when LAS removes (involuntary) its approval from a laboratory. Upon dismissal, no certificate of analysis or report of analysis may include the "USDA-approved laboratory" term or statement thereof, and reference to USDA-Approval and use of USDA symbols must be discontinued immediately, as of the date of the involuntary action letter. The Official Listing of the USDA-Approved Laboratories is revised accordingly on the LAS website. Additionally, LAS notifies the appropriate commodity committee, board, or representative organization(s).

The laboratory must comply with the instructions in the notification of pending dismissal issued by the Program Manager.

The Program Manager begins the dismissal process by notifying the laboratory, in writing, that it is danger of dismissal from the program with reasons identified, and places the laboratory in suspended status, if it is not already in suspended status. An additional onsite audit (see §16) is performed to substantiate reason for dismissal. An audit report is issued (see §18). If the reason for dismissal cannot be substantiated and there is no nonconformance, the laboratory will be reinstated to approved status. If the reason for dismissal is substantiated the laboratory will be immediately dismissed.

Program dismissal may occur for any of the following reasons:

a) Persistently failing to conform to the LAP general policies and procedures and program requirements;

b) Persistently failing to maintain satisfactory performance in proficiency test programs. Three unsatisfactory proficiency attempts in four consecutive rounds of proficiency samples, regardless of the approval year, is grounds for immediate involuntary withdrawal;

c) Persistently failing to perform corrective action and correction in a timely manner and/or provide satisfactory resolutions with accompanying evidence;

d) Failure to submit notification of a significant change to legal, commercial, ownership, or organizational status (see §26(a)); relocation of premises (see §26(d)); extending the scope of approval (see §26(e)); or change in ISO 17025 accreditation status (see §26(f));

e) Denying access to the laboratory facilities and records within the scope of the program;

f) Persistently failing to pay fees;

g) Failure to pay annual fees when in a suspended status;

h) Deliberately misrepresenting the laboratory's approval;

i) Confirmed finding of falsification of analytical results;

j) Fraudulent or deceptive practice in connection with any application or request for service; or

k) Use of program approval in such a manner as to bring LAS into disrepute.

33. Reinstatement after Dismissal from Program

A laboratory dismissed from the program may reapply after six months as a new applicant (see §12). The laboratory must submit an application package and include records and documents of corrective action and correction proving the reason for removal is remedied.

34. Appeal - Dismissal

The laboratory has the right to submit an application of appeal for a dismissal action.

34.1. Application for Appeal

A duly authorized representative of the laboratory may make an application of appeal within 30 days of receipt of the decision. Submit the request in writing, to LAS, on letterhead. Identify the action or decision appealed from and give a concise, but complete statement of the facts, with supporting documentation, relied upon and the relief sought. Note: During the appeal process, the laboratory will remain in an unapproved status. The laboratory may withdraw an application for an appeal at any time before the decision is delivered.

The laboratory must direct the application for appeal to next higher management level in the organization than the level issuing the original decision.

a) The Branch Chief handles appeals of decision made by a Program Manager.

b) The LATD Director handles appeals of a decision made by the Branch Chief.

c) The Science and Technology Program Deputy Administrator handles appeals of decisions made by the LATD Director.

34.2. Review and Decision of Application for Appeal

LAS may refuse an application for an appeal if the reasons for the appeal are frivolous or cannot be substantiated or there is a noncompliance with the LAP general policies and procedures and program requirements.

A person or panel assigned to investigate the appeal determines the validity of the appeal and, if appropriate, makes the decision. In some cases, an ad hoc expert or advisory panel may be called upon to address the technical issues of appeals.

LAS will respond, in writing, with a decision and method available for further appeal to a first application within 30 days and for a second, within 90 days, upon receipt.

35. Complaints

Complaint: An objection to policies, procedures, and/or performance.

35.1. A laboratory has the right to submit a complaint regarding the Laboratory Approval Services policies, procedures, and/or performance.

a) The laboratory must submit the complaint, in any format, to the Program Manager, Branch Chief, or LATD Director. The complaint must include enough information for LAS to investigate.

b) The Program Manager records the complaint, investigates, and finds a resolution.

35.2. A third party has the right to submit a complaint regarding a USDA or USDA-approved laboratory's performance or activities.

a) The third party must submit the complaint, in any format, to the Program Manager, Branch Chief, or LATD Director. The complaint must include enough information for LAS to investigate.

b) The Program Manager records the complaint, investigates, and finds a resolution.

36. Objection of Assigned Auditor

36.1. A laboratory has the right to object to any assigned auditor(s).

a) A duly authorized representative of the laboratory must submit an objection, in writing, to the Program Manager within five business days after notification of the assigned auditor. The objection must include the basis for the objection and the requested alternative decision or action.

b) The Program Manager reviews the objection and notifies the laboratory of the decision within five business days of receiving the objection.

36.2. The laboratory has the right to appeal the decision issued by the Program Manager.

a) A duly authorized representative of the laboratory must submit the application of appeal, in writing, to the Branch Chief within five business days of the date of the original decision. The application of appeal must include the basis of the appeal and the requested alternative decision or action.

b) The Branch Chief reviews the application of appeal and notifies the laboratory of the final decision within five business days from receipt of the appeal.

37. Fees

LAS charges a fee-for-service to administer the LAPs. Fees are the responsibility of the applicant or approved laboratory. The fee schedule is described in *Laboratory Approval Program – Fees,* LAP-PR.06, located on the LAS website.

38. Quality Assurance

This document must be reviewed by the Branch Chief and the LATD Director every two years, or as needed.

39. Revision History

New Rev. Date	Description of Change	Prepared by
03/28/18	Original	Grace Vaillant Branch Chief
11/16/18	§1: edited. §4: Add subsection numbers. §9 changed "analysis" to "testing services". §10 c): added record retention of 3 years. §12.3 k) added. §12.4 b): added "verification". §14 Header: Changed "desk audit" to "assessment". §15: edited and changed to "any time". §17: added "independent, and documented" to the audit definition. §28 added c), f), i), and j). Throughout changed "shall" to "must," "meet" to "conform," "nonconformances" to "nonconformance," and "changes" to "change."	Grace Vaillant Branch Chief

40. Review / Approvals

GRACE VAILLANT Digitally signed by GRACE VAILLANT Date: 2018.11.20 09:28:17 -05'00'

Grace Vaillant
Branch Chief
(Author)

KERRY SMITH Digitally signed by KERRY SMITH Date: 2018.11.30 14:44:57 -05'00'

Kerry R. Smith, Ph. D
Director, LATD
(Approve)