

LABORATORY APPROVAL PROGRAM – GENERAL POLICIES & PROCEDURES

1. Purpose

The purpose of this document is to outline the general policies and procedures for administration of Laboratory Approval Programs (LAPs) by the Laboratory Approval Service (LAS). LAPs are developed at the request of industry, other Federal agencies, or foreign governments in support of domestic and international trade. LAS 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.

[LAS](#) is part of 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 LAPs administered by LAS. It applies to a laboratory seeking to apply or maintain status as a USDA-approved laboratory. LAS provides due notice of any changes to its requirements.

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4. References

- 4.1. The following articles are references listed in this document. Dated references apply to the cited edition and undated references apply to the latest edition published (including any amendments).
- a) [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.
 - b) [7 USC 38](#), Agricultural Marketing Act of 1946. Distribution and Marketing of Agricultural Products. Title 7 – Agriculture.
 - c) [7 CFR Part 62](#). Agricultural Marketing Service Audit Verification and Accreditation Programs (AVAAP). Subchapter C – Requirements and Standards Under the Agricultural Marketing Act of 1964 and the Egg Products Inspection Act. Chapter 1 – Agricultural Marketing Service (Standards, Inspections, Marketing Practices), Department of Agriculture. Subtitle B – Regulations of the Department of Agriculture. Title 7 – Agriculture.
 - d) [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.
 - e) ISO 17011. Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies.
 - f) ISO/IEC 17025. General requirements for the competence of testing and calibration laboratories.
 - g) ISO/IEC 19011. Guidelines for auditing management systems.

- h) LAS-QM. United States Department of Agriculture, Agricultural Marketing Service, Science and Technology Program, Laboratory Approval and Testing Division, Laboratory Approval Service Quality Manual.
- i) [LAP-PR.06](#). Laboratory Approval Program – Fees.
- j) USDA Non-Discrimination Statement Webpage, <https://www.usda.gov/non-discrimination-statement>.
- k) USDA AMS LATD LAS Website, <https://www.ams.usda.gov/services/lab-testing/lab-approval>.
- l) USDA AMS Laboratory Standards of Practice.

5. Nondiscrimination

- 5.1. 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 (§4.1.j).

6. Confidentiality

- 6.1. Documentation submitted by applicants and/or participants and maintained by LAS is subject to disclosure under the Freedom of Information Act (FOIA) (§4.1.a). 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

- 7.1. The Program Manager is the primary point of contact. The Branch Chief and LATD Director are the secondary points of contact.
- 7.2. General contact information for LAS:
- a) Address: USDA, AMS, S&T, LATD, 1400 Independence Avenue, SW, Room 2910-S, Washington, D.C. 20250-0272
 - b) Email: LAS@usda.gov
 - c) Website: <https://www.ams.usda.gov/services/lab-testing/lab-approval>

8. Responsibilities of LAS

- 8.1. LAS administers LAPs under the authority of 7 USC 38, 7 CFR Part 91, and 7 CFR Part 62; and in compliance with the ISO 17011 and ISO 19011 standards, and LAS Quality Manual.
- 8.2. LAS maintains information about available LAPs on the [LAS website](#).

9. Voluntary Participation & Fees

- 9.1. LAS administers LAPs as voluntary programs.
- 9.2. LAS charges a fee-for-service to administer a LAP; and the fee schedule is outlined in [Laboratory Approval Program – Fees](#) (§4.1.i).
- 9.3. The laboratory is responsible for paying service fees as invoiced.

10. Who May Apply

- 10.1. Any laboratory, including international and domestic government agencies, private agricultural business, and any financially interested person, may apply provided they are performing testing services within the scope of a LAP.

11. Approval Requirements

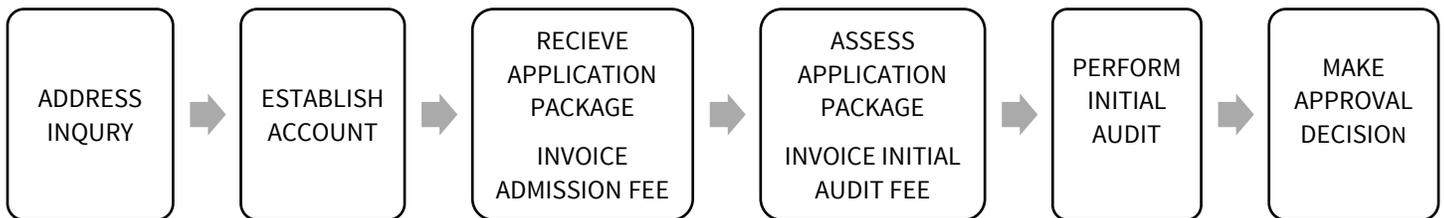
- 11.1. The laboratory must comply with all requirements set forth in this document to be granted approval into a LAP and to maintain approval as a USDA-approved laboratory, including:
 - a) Committing to continually fulfilling the requirements set by LAS (i.e., these general policies and procedures and LAP requirements) for the areas where approval is sought or granted;
 - b) Agreeing to adapt to programmatic changes;
 - c) Cooperating as necessary to enable LAS to verify requirements are met;
 - d) Permitting LAS access to its facilities, personnel, procedures, equipment, information, documents and records as necessary to enable verification that requirements are met (§15);
 - e) Providing 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., laboratory owned by a processor) (§14.4.b);
 - f) Informing LAS of significant changes (§23);
 - g) Arranging the witnessing of business operations when requested to enable verification that requirements are met (§15.4.b);

- h) Complying with laboratory quality assurance practices of the ISO 17025 standard (see individual LAP requirements about specific third party accreditation requirements);
- i) Retaining records for at least three years;
- j) Claiming USDA approval only with respect to the scope for which it has been granted (§21);
- k) Committing to use the USDA term ‘USDA-approved laboratory’ and USDA symbols appropriately (§21);
- l) Not using its approval in such a manner as to bring LAS into disrepute;
- m) Paying fees as determined by LAS (§9).

12. Application Process

12.1. LAS administers the application process as outlined in Figure 12-1 and as described below for entry into a LAP, scope expansion (§24), and reinstatement after a withdrawal or dismissal (§29).

Figure 12-1. LAS’ actions for the LAP application process.



12.2. A laboratory may begin the application process by contacting LAS.

12.3. LAS ensures the inquirer understands the application process.

12.4. LAS collects information to establish an Account, including but not limited to:

- a) Business’ legal name (as registered with the IRS), doing business as (if applicable), its relationship in a larger corporate entity (if applicable), taxpayer identification number (Form W-9 or Form W-8BEN), billing address, physical address, and accounts payable contact (i.e., name, title, phone, email);
- b) Identification of the Authorized Representative, the point of contact responsible for ensuring compliance with the approval requirements (§11) and the information provided in the application package (§14);
- c) Contact information for other key points of contact (e.g., Laboratory Manager, Quality Manager) including name, title, phone, and email.

12.5. LAS establishes understanding of inquirer’s timeframe for completing the application process.

12.6. The applicant’s Authorized Representative must submit an application package (§14) electronically to initiate an application assessment.

- 12.7. LAS notifies the applicant of application package receipt, in writing.
- 12.8. LAS invoices the applicant for the admission fee (\$9).
- 12.9. LAS assesses applications (\$15) in the order received and issues an audit report (\$16). LAS may reject an application or terminate the assessment process if there is evidence of fraudulent behavior, if false information was intentionally provided, or if information was intentionally concealed.
- 12.10. LAS schedules an initial onsite audit when evidence shows conformance to the requirements.

13. Application Withdrawal Process

- 13.1. An applicant's Authorized Representative may withdraw an application, all or in part, at any time by outlining the request on company letterhead (or equivalent). The applicant is responsible for paying any expenses LAS incurred up until recognition of an application's withdrawal.
- 13.2. LAS notifies the applicant of receipt for request to withdraw an application and any fees due, in writing.
- 13.3. The laboratory may submit a new application after withdrawing an application.

14. Application Package Requirements

- 14.1. A clearly defined request for a specific scope of approval in a LAP.
- 14.2. A signed commitment from the Authorized Representative to comply with the requirements (§11.1).
- 14.3. Laboratory Information:
 - a) Laboratory's legal name;
 - b) Physical address and billing address if different;
 - c) Name, title, phone, and email for Authorized Representative and other key points of contact (e.g., Laboratory Manager, Quality Manager, Accounts Payable, Approved Signatories) and
 - d) Organizational Chart.
- 14.4. Documents addressing policies and procedures (however named or organized) that make up the quality management system including, but not limited to:
 - a) Quality Manual;
 - b) Impartiality and managing conflict of interest;
 - c) Document Control;
 - d) Records Control;
 - e) Corrective Action;

- f) Internal Audit;
- g) Management Review;
- h) Training;
- i) Equipment handling and performance verification (e.g., calibration, intermediate checks);
- j) Test Method addressing preparation and use of method quality controls, how to handle nonconforming quality controls, and applying measurement uncertainty;
- k) Proficiency Testing;
- l) Control Charting; and
- m) Reporting.

14.5. Records:

- a) Master list of documents (e.g., internal and external procedures, forms, lists, etc.)
- b) Certificate of accreditation and scope from a third-party accreditation body recognized by the International Laboratory Accreditation Cooperation (ILAC) (if applicable);
- c) Test method validation / verification data packages;
- d) Equipment calibration or calibration verification;
- e) Test report and supporting analytical data;
- f) Staff training records and authorizations;
- g) Last internal audit report and associated corrective action(s) and correction(s);
- h) Last management review report and associated status of action items;
- i) Proficiency test results;
- j) Test method control charts; and
- k) Equipment inventory.

15. Assessment Process

15.1. LAS administers assessments as outlined in Figure 15-1 and as described below to ensure laboratory's meet the requirements for the scope of approval.

Figure 15-1. LAS' actions for the LAP assessment process.



- 15.2. LAS performs audits to assess compliance to the requirements. Audit terms are defined as follows:
- a) **Audit:** 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.
 - b) **Audit Trigger:** Reason or event that requires an audit (i.e., new application, scope expansion application, due for calendar year, for-cause, information submission, nonconformance, significant change).
 - c) **Audit Type:** Describes what the audit is in relation to the audit trigger and audit objective (i.e., application package, application initial onsite audit, first year, for cause, evaluation for corrective action response, evaluation for data package, ongoing participation, QMS gap analysis).
 - d) **Audit Plan:** Outlines the objective, criteria, and scope.
 - e) **Audit Schedule:** Outlines the date, audit time, agenda, and logistical expectations.
 - f) **Audit Objective:** Outlines the goal.
 - g) **Audit Criteria:** Policies, procedures, and requirements used as a reference against which audit evidence is compared, including but not limited to these general policies and procedures, ISO 17025, the LAP requirements, and analytical methodology.
 - h) **Audit Scope:** Boundaries, including but not limited to physical location, organizational units, activities, processes, and timeframe of records covered.
- 15.3. LAS uses onsite and remote auditing methods taking the forms of desk audit, onsite audit, virtual audit, and surveillance in accordance with ISO 19011. Audit method terms are defined as follows:
- a) **Desk Audit:** Conducted remote from the place of business to review documentation of policies, procedures, and records.
 - b) **Onsite Audit:** Conducted on the premises of a business to review, witness, observe, and interview, where LAS must:
 - Perform an opening meeting;
 - Witness the performance of a representative number of laboratory staff to provide assurance of competence;
 - Witness the laboratory process a sample from receipt to reporting;
 - Interview laboratory staff;
 - Review relevant records and documentation;
 - Collect relevant evidence to support audit findings;
 - Identify and share preliminary findings, and advise that findings are not final until communicated in an audit report;
 - Refrain from making recommendations;

- Perform a closing meeting.

- c) Virtual audit: Conducted remote from the place of business using audio/video applications in lieu of an onsite visit for situations including; but not limited to travel restrictions.
- d) Surveillance: Collection of data over time to monitor continued compliance with requirements (e.g., proficiency test results, marketing materials).

15.4. LAS uses:

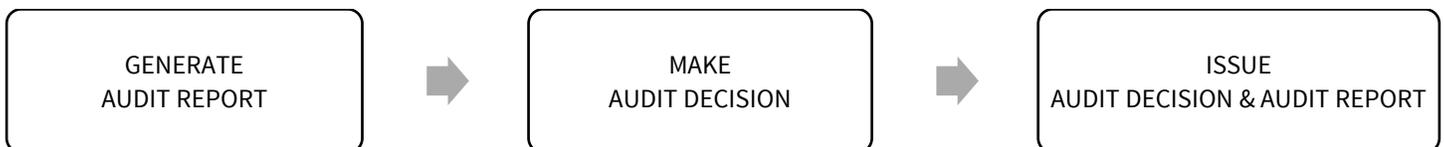
- a) Desk audits for evaluating application packages for new approval, scope expansion, reinstatement from suspension, reinstatement from withdrawal, and reinstatement from dismissal; preparation for onsite and/or virtual audits, evaluation of corrective action responses, evaluation of method verification / validation data packages, evaluation of significant changes, and others.
- b) Onsite audits for an application (initial onsite), for the next calendar year after initial approval (first-year); and thereafter on a biennial basis, unless otherwise specified to be more frequent in a LAP; and unscheduled audits at the expense of the laboratory and potentially unannounced, in response to a complaint, verification of resolution to nonconformance, or significant change.

15.5. The laboratory may object to an auditor assignment for an onsite audit (§32).

16. Audit Report & Audit Decision Process

16.1. LAS administers the audit report and audit decision process as outlined in Figure 16-1 and described below to record and communicate audit findings, outcome, and next steps.

Figure 16-1. LAS' actions for the LAP for the audit report and audit decision process.



16.2. LAS generates an audit report for each audit event; makes an audit decision for each audit report; and issues the audit report and audit decision letter together. Audit report and audit decision terms are defined as follows:

- a) Audit decision: Record (letter) of an audit outcome and specification of next steps for an audit report.
- b) Audit report: Record summarizing date, audit team, objective, criteria, scope, findings, and outcome for the audit event.

Outcome: Statement about competence and compliance to the audit criteria.

- c) Findings: An observation based on evidence collected relevant to the audit criteria; a nonconformance is a type of finding.

d) Nonconformance: Nonfulfillment or failure to meet a requirement.

16.3. LAS issues the audit report for an onsite audit within 30 days of the onsite visit.

16.4. LAS issues a request for corrective action when findings include nonconformances.

17. Corrective Action Process

17.1. LAS administers the corrective action process as outlined in Figure 17-1 and as described below to ensure a laboratory remediates a detected nonconformance to a requirement.

Figure 17-1. LAS' actions for the LAP for the evaluation of corrective action response process.



17.2. The laboratory must provide a response and implement corrective action for each nonconformance identified in an audit report. The corrective action response is due within 30 calendar days from the day the audit decision with audit report is issued, or timeframe specified. Corrective action terms are defined as follows:

- a) Corrective action response: Record of an investigation, root cause analysis, corrective action or correction or, if warranted due to time, a corrective action plan and evidence of implementation.
- b) Correction: Action to eliminate a detected nonconformance. Correction does not address the root cause of the nonconformance, but rather the specific nonconforming product.
- c) Corrective Action: Action taken to eliminate the cause of a detected nonconformance to prevent recurrence. This often involves revision of a policy and/or procedure.
- d) Corrective Action Plan: Step by step plan, including timeline, towards realization of the selected corrective action to eliminate the cause of a detected nonconformance.

17.3. LAS evaluates each corrective action response to determine if the nonconformance has been resolved and assigns an outcome of Not Accept, Accept, or Accept & Follow-up.

17.4. LAS may conduct additional audits as needed to verify resolution of a nonconformance.

18. Assessment Decision Process

18.1. LAS administers the assessment decision process as outlined in Figure 18-1 and Figure 18-2 as described below to record and communicate changes to a laboratory's USDA-approved status.

Figure 18-1. LAS' actions for the LAP for the approval decision process.



Figure 18-2. LAS' actions for the LAP for the exit decision process.



18.2. LAS issues an assessment decision (letter) about a laboratory's status as a USDA-approved laboratory using an approval decision or an exit decision. Assessment decisions record the favorable or unfavorable outcome. Assessment decision terms are defined as follows:

- a) Assessment decision: Based on a combination of evidence collected through audits, surveillance records, program records, and experience gained during previous audits to assess compliance to the requirements.
- b) Approval decision: Record of new, revised, or renewed approval status as a USDA-approved laboratory.
- c) Exit decision: Record of withdrawal or dismissal from a LAP.
- d) Favorable outcome: Conformance to the requirements including:
 - Granting approval for entry, continued approval, scope expansion, or an exception to a requirement;
 - Accepting a sufficient application package, corrective action response, corrective action response with follow-up on implementation, or method verification / validation package.
- e) Unfavorable outcome: Failure to conform to the requirements including:
 - Denying approval for entry, continued approval, scope expansion, or an exception to a requirement;
 - Not accepting an insufficient application package, corrective action response, or method verification / validation data package;
 - Suspending approval;
 - Dismissing a laboratory.

19. Scope of Approval Process

- 19.1. LAS issues a scope of approval document with an approval decision. The scope of approval document includes the:
- a) Unique identity of the laboratory;
 - b) Premises (all) from which one or more key activities are performed;
 - c) Effective date and, as applicable, the expiry date;
 - d) Description of approval including LAP name, commodity, market, analyte, and the test 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.

20. Official Business Listing Process

- 20.1. LAS publishes information about the USDA-approved laboratory in the Official Business Listing of the USDA-Approved Laboratories on the [LAS website](#) as a resource for stakeholders to find qualified laboratory services. The Official Business Listing contains the laboratory name, address, and contact information, products or services covered under the scope of approval, approved signatories (if applicable).

21. Referencing USDA-Approval

- 21.1. An approved 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 test reports for analysis within the scope of approval only if it:
- a) Fully conforms to the requirements 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 test report nor any part thereof is used in a misleading manner;
 - e) Upon scope reduction, suspension, withdrawal, or dismissal of its approval, discontinues use of all advertising that contains any reference to that approval; and informs affected clients; and,
 - f) Does not allow its approval to be used to imply that a product, process, system, or person is approved by LAS.

- 21.2. LAS may take suitable action to address incorrect or unauthorized claims of approval status, or misleading or unauthorized use of USDA symbols.

22. Exception Process

- 22.1. The laboratory's Authorized Representative may request an exception to a requirement by outlining the request on company letterhead (or equivalent) and providing supporting records and documentation.
- 22.2. LAS acknowledges receipt of the request, evaluates the supporting records or documents, and issues an assessment decision (§18).

23. Significant Change Process

- 23.1. The laboratory's Authorized Representative must provide notification of a significant change and effective date on company letterhead (or equivalent). A significant change may include:
- a) Legal, commercial, ownership, or organizational status;
 - b) Top management and key personnel (e.g. Authorized Representative, Laboratory Manager, Quality Manager, analysts, etc.);
 - c) Analytical method procedures;
 - d) Relocation of premises;
 - e) Extending the scope of approval;
 - f) Change in ISO 17025 accreditation status; and
 - g) Other matters that may affect the ability of the laboratory to fulfil the requirements.
- 23.2. LAS acknowledges receipt of the notification, reviews, and advises the laboratory if an approval status change is necessary, and of any actions required to maintain compliance with the requirements in writing.
- 23.3. LAS may suspend (§26) or dismiss (§28) a laboratory when there is a failure to provide notification of a significant change.

24. Extending Scope Process

- 24.1. The laboratory's Authorized Representative may apply (§12) to extend its scope of approval at any time.
- 24.2. LAS processes scope expansion requests using the application process.

25. Reducing Scope Process

- 25.1. The laboratory's Authorized Representative may submit a request to reduce the scope of approval at any time and for any reason by outlining the request and effective date on company letterhead (or equivalent).
- 25.2. LAS issues an approval decision to record the scope reduction (§18).

26. Suspending Approval Process

- 26.1. The laboratory's Authorized Representative may submit a voluntary request to suspend its approval, or portion of it, at any time and for any reason by outlining the request and effective date on company letterhead (or equivalent).
- 26.2. LAS may place a laboratory on involuntary suspension to provide an opportunity to conform to the requirements, including but not limited to a failure to:
 - a) Address, adequately, any of the requirements, thereby resulting in a nonconformance, including audit findings that compromise the defensibility of data;
 - b) Demonstrate capability to conform to any of the requirements, thereby 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 timeframe 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 (§23.1.b), analytical method procedures (§23.1.c), or other matters that may affect the ability of the laboratory to fulfil requirements for the LAP (§23.1.g).
 - f) Allow LAS access to facilities and records within the scope of approval;
 - g) Represent, accurately, the eligibility of the laboratory results or services distributed under a LAP;
 - 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 LAS or other USDA official to perform their duties.
- 26.3. LAS issues an approval decision to record the suspension (§18).
- 26.4. A laboratory in suspended status must cease reporting test results as coming from a 'USDA-approved laboratory' upon the effective date of suspension.

27. Withdrawal Process

- 27.1. The laboratory's Authorized Representative may request to withdraw, voluntarily remove itself, from participation in the LAP at any time by outlining the request and effective date on company letterhead (or equivalent).
- 27.2. LAS issues an exit decision to record the withdrawal (§18).
- 27.3. The laboratory must discontinue using reference to USDA-approval and issuing test results as coming from a 'USDA-approved laboratory' upon the effective date of withdrawal.

28. Dismissal Process

- 28.1. LAS may dismiss, involuntarily remove, its approval from a laboratory for any of the following reasons:
 - a) Failing, persistently, to conform to the requirements;
 - b) Failing persistently, to maintain satisfactory performance in proficiency test programs, where three unsatisfactory attempts in four consecutive rounds of proficiency samples, regardless of the approval year is grounds for immediate dismissal;
 - c) Failing, persistently, to perform corrective action and correction in a timely manner and/or provide satisfactory resolutions with accompanying evidence;
 - d) Failing to submit notification of a significant change to legal, commercial, ownership, or organizational status (§23.1.a); relocation of premises (§23.1.d); extending the scope of approval (§23.1.e); or change in ISO 17025 accreditation status (§23.1.f);
 - e) Denying access to the laboratory facilities and records within the scope of the LAP;
 - f) Failing, persistently, to pay fees;
 - g) Failing to pay annual fees when in a suspended status;
 - h) Misrepresenting, deliberately, the laboratory's approval;
 - i) Falsifying analytical results;
 - j) Engaging in fraudulent or deceptive practices in connection with any application or request for service; or
 - k) Using approval in such a manner as to bring LAS into disrepute.
- 28.2. LAS processes an immediate exit decision of dismissal for persistently unsatisfactory proficiency test performance (§28.1.b); and for all other reasons by the following process:
 - a) Notifying the laboratory that it is danger of dismissal including justification, in writing;
 - b) Placing the laboratory in suspended status;

- c) Performing an additional audit (§15) to substantiate the reason for dismissal; and
- d) Issuing an assessment decision (§18).

28.3. The laboratory must discontinue using reference to USDA approval and issuing test results as coming from a 'USDA-approved laboratory' upon the effective date of suspension and/or dismissal.

29. Reinstatement Process

- 29.1. The laboratory's Authorized Representative may submit a request for reinstatement from suspension at any time by outlining the request on company letterhead (or equivalent) and including supporting documentation and records (e.g., corrective action response, §17).
- 29.2. A laboratory's Authorized Representative may apply (§12) for reinstatement from a withdrawal at any time.
- 29.3. A laboratory's Authorized Representative may apply (§12) for reinstatement of dismissal after six months as a new applicant.
- 29.4. LAS may charge a fee to process an application for reinstatement (§9).

30. Appeal (Dismissal) Process

- 30.1. The laboratory's Authorized Representative may make an application of appeal to LAS for a dismissal decision by identifying the action or decision appealed from and giving a concise, but complete statement of the facts with supporting documentation, and the relief sought on company letterhead (or equivalent) within 30 days of receipt of the decision.
- 30.2. LAS processes an application for appeal through the next higher management level in the organization than the level issuing the original decision (i.e., Program Manager, Branch Chief, LATD Director, S&T Program Deputy Administrator); and may assign a person or panel to investigate and determine the validity of the appeal.
- 30.3. The laboratory may withdraw an application for an appeal at any time before the decision is delivered.
- 30.4. 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 requirements.
- 30.5. LAS responds with a decision and method available for further appeal to a first application of appeal within 30 days and for a second, within 90 days, upon receipt, in writing.

31. Complaint Process

- 31.1. A laboratory has the right to submit a complaint regarding the LAS policies, procedures, and/or performance. The complaint must include enough information for LAS to investigate.
- 31.2. A third party has the right to submit a complaint regarding a USDA or USDA-approved laboratory's performance or activities. The complaint must include enough information for LAS to investigate.
- 31.3. LAS records the complaint, investigates, and finds a resolution.

32. Objection of Assigned Auditor Process

- 32.1. A laboratory's Authorized Representative object to an assigned Auditor by submitting an objection describing the basis for the objection and the requested alternative decision or action on company letterhead (or equivalent) within five business days after notification of the assigned Auditor.
- 32.2. LAS reviews the objection and notifies the laboratory of the decision within five business days of receiving the objection.

33. Revision History

03/28/18 Original

Prepared by Grace Vaillant, Branch Chief

11/16/18 Throughout changed 'shall' to 'must', 'meet' to 'conform', 'nonconformances' to 'nonconformance', and 'changes' to 'change'. §1: Edited. §4: Add subsection numbers. §9 Changed 'analysis' to 'testing services'. §10c): Added record retention of 3 years. §12.3k) 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). Prepared by Grace Vaillant, Branch Chief

11/01/23 Throughout: Changed header, replaced abbreviation 'LAP' for 'laboratory approval program', replaced 'Program Manager' for 'LAS', replaced 'Branch Chief' for 'LAS', replaced 'LAP general policies and procedures' for 'requirements', edited sentence structure to begin statements with role followed by an action and then definitions as needed, incorporated cross-references for citations, added '(or equivalent)' after company letterhead. §4: Added 7 CFR Part 62, removed 7 CFR Part 90, added link to USDA Non-Discrimination webpage, added USDA AMS Laboratory Standards of Practice. §7: Updated address room number. §8: Moved statement about where LAP documents are maintained. §9 Moved information about voluntary participation and fees into its own section. §11: Consolidated requirements for approval (application and maintain) and renamed section. §12: Added flow diagram outlining key steps, consolidated requirements for the application process. §14: Removed requirement to provide QMS procedure for method validation procedure, moved master list to records section. §15: Renamed to 'Assessment Process', added flow diagram, consolidated requirements about audits, added definitions for new terms 'audit trigger', 'audit type', 'virtual audit', removed procedural steps for audit objective, criteria, scope, auditor assignment, auditor introduction, and scheduling, revised definition of 'audit objective' to align with use of 'audit trigger' and 'audit type', added language for 'remote' to support virtual audits, added bullet point about opening meeting and closing meeting, moved 'marketing materials' up to definition of 'surveillance'. §16: Added term 'audit decision'; removed 'continued point of improvement', clarified that only onsite audit reports have a defined time limit for issuance, added clarification to explain where LAS request for corrective action originates. §17: Added definition for 'corrective action plan', added term 'approval decision' and 'exit decision', clarified



description of 'favorable outcome' and 'unfavorable outcome'. §25: Consolidated process for reducing scope into its own section. §29: Consolidated information about reinstatement processes. §32: removed language about appealing the first decision made for addressing an objection to an assigned auditor. End of document: Added OMB control number and PRA burden statement per OMB decision of information collection package decision ICR reference number 202009-0581-002. Prepared by Grace Vaillant, Branch Chief

34. Review / Approvals

Grace Vaillant
Branch Chief
Author

Kerry R. Smith, Ph.D.
Director, LATD
Approver

According to the Paperwork Reduction Act of 1995, an agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0581-0251. The time required to complete this information collection is estimated to average 18.5 hours per year, including the time for reviewing instructions, searching existing data sources, gathering, and maintaining the data needed, completing and reviewing the collection of information.