Laboratory Approval Program General Information

Laboratory Approval Program General Information

Note

The authorized contact must read this document and be familiar with this information before submitting an application.

Introduction

The South Coast Air Quality Management District (SCAQMD) Laboratory Approval Program (LAP) is an approval program that focuses on test facilities that collect and report data to the District either directly or through another firm. Test facilities are approved on a method-by- method basis. Approval means that the test facility's management, personnel, policies, facilities, methods, equipment, documentation, quality assurance, and audit performance have been evaluated and found to meet District criteria.

Who needs approval?

Approval is required for compliance tests for RECLAIM NOx and RECLAIM SOx, and regulations such as Rules 1111, 1121, 1138, 1146.1 (NOx emissions from boilers and heaters), Rule 1138 (restaurant emissions), Rule 1174 (charcoal ignition products), Rule 1420 (lead emissions). Otherwise, approval is voluntary.

What does the LAP do?

The LAP has three purposes: to allow test facilities to distinguish themselves through LAP approval, to assist the business community in locating test firms that meet District requirements, and to improve the quality of data and reports submitted to the District.

What does approval do for me?

Approved test facilities are encouraged to advertise their approved status on test reports, and in trade, technical, and professional publications. Test facilities are issued a Letter of Approval and identified in District database. The District makes this information available on request.

What doesn't approval mean?

Approval is not an endorsement by SCAQMD or product certification. Advertising may not imply endorsement, product certification, or guarantee of results by SCAQMD. No reference to approval may be placed on labels, containers, or packaging material. Advertising in consumer media is not allowed. Approval does not waive the requirement for SCAQMD review of protocols and reports, nor does it guarantee that protocols and reports will be accepted by SCAQMD. It does not cover draft methods.

What does approval require?

The approval process begins when you request an application package for the method(s) you want approved. You receive, complete and submit a General Application and Method- Specific Application(s) which request detailed information on your management, personnel, location, facilities, policies, methods, equipment, documentation and quality assurance. Your applications are reviewed by District staff for completeness and conformance to District requirements. When deficiencies are resolved, we will schedule an inspection or your facility. Audits may also be required. Finally, you must pay required fees. You will find details under **What is the approval process?** and **What does the LAP look for?** later in this document.

How long does approval last?

The approval period is specified in the Letter of Approval, but is generally from the first day of the month following approval. It lasts for one year, or until significant changes are made in test facility operations. The approved test facility retains its assigned approval date as long as it remains in the program. Approval expires and may be renewed on that date. The approval date may be adjusted by the test facility with a written request to LAP. It may also be adjusted by LAP for operational reasons; for example, to "bundle" certain methods together, but in this case is always adjusted by extension.

How do I renew?

Your approved test facility is notified ahead of the expiration date and will receive a renewal package before its approval expires. The Renewal Package consists of a Declaration of No Change, which must be signed by the authorized contact. This Declaration of No Change affirms that there have been no changes in management, personnel, policies, facilities, location, methods, equipment, documentation, or quality assurance, since your last approval. If you have changed operations during the approval

period, the renewal is handled as a Revision (see below). However, approval may lapse while the revision is being reviewed, so timely notice of changes is strongly recommended.

What if changes are made during the approval period?

Changes in any of the conditions of approval may have negative impact on operations and void the approval. You are required to notify LAP within 60 days of any change by sending a letter to the LAP coordinator that describes these changes in detail. If we receive the notice within 60 days, your approval is automatically extended while the changes are evaluated and the review is performed at no charge. If you do not notify LAP within 60 days of making operational changes you will be billed for the review. Furthermore, if you are near your expiration date, your Approval will not be extended during the review. If you file a fraudulent Declaration of No Change, or you declare the wrong dates of changes you made, or LAP learns that you changed operations, personnel, etc. more than 180 days previously and no notice was received, your approval will be revoked.

What is the approval process?

Details of the approval process are as follows:

Application and Review
On request, you will be sent a package that consists of a

- Brochure, which gives an overview of the LAP program
- Applications and Fees sheet, which show available applications and applicable fees
- General Information sheet (this document) which details LAP procedures
- General Application Form, which requests general information about your test facility
- Method-specific application forms by request

The Application forms are based on the checklist that LAP assessors use for subsequent site inspection. By reviewing and filling out these forms, you will become familiar with the areas that concern our assessors.

The authorized contact reads the General Information sheet, fills out the General and Method-Specific Application(s) and sends the entire package to LAP. You are encouraged to apply for one than one method at a time. Once received, your test facility is assigned a LAP Number. This number is used for ID, filing, and database

management, and you are encouraged to use this number on all correspondence with LAP. You will receive a letter of acknowledging that we have received your applications.

Your Applications are reviewed for completeness and conformance to District requirements for management, personnel, policies, facilities, equipment, methods, documentation, and quality assurance. During this review, you may be contacted informally to supplement, clarify or correct information in your Applications. If you have been contacted, LAP staff will wait approximately one month for additional information, clarifications or corrections before beginning a formal review. After that time, they will formally review your Applications.

Once your Applications have been reviewed, you will receive a letter from the LAP describing the findings. Your Application may be acceptable, it may have correctable deficiencies, or it may be unacceptable. An invoice for application review is sent with the letter of findings. If correctable deficiencies are found, you will be required to make the corrections within a reasonable time frame, generally within 180 days after notification, or your approval may be denied. When deficiencies are corrected and your application is acceptable, the process can continue.

Site inspection

A site inspection is conducted after your application has been accepted. All sites used for LAP work must be inspected, including your main test facility, outlying sites and mobile laboratories. Site inspections are conducted using a checklist based on your application. This checklist ensures that all facilities are evaluated for the same items, however, the assessor has considerable latitude in identifying problems. The goal of the inspection is to identify deficiencies that may have a *significant* impact on test results or applicability of results. The inspection is arranged on a mutually agreeable date during normal work hours. Typically, a site inspection takes one day, and involves more than one assessor.

The site inspection begins with a meeting between you, your supervisors, management and the assessment team to familiarize the assessors with your operations and to give your staff an overview of what to expect. The assessors then conduct a physical examination of facilities and equipment; examine raw data, methods, and other documents; interview staff; and observe techniques. The history of a single sample may be traced. Assessors may at the same time bring audit samples for later analysis. The inspection ends with an interview with you, facility supervisors and management, who are informed of any deficiencies that were found. This is followed by a written report and invoice sent to the test facility. Your test facility may be acceptable, it may have correctable deficiencies, or it may be unacceptable. If correctable deficiencies are found, deficiencies must be corrected within a reasonable time frame, generally within 180 days after notification of

findings, or the approval may be denied. Once deficiencies are corrected, the process can continue. Correction may be verified by follow-up visits.

Performance audit
Performance audit samples are designed to be typical of samples or sampling procedures encountered in SCAQMD. One set of analytical performance audits is delivered for each analyst who will be performing that LAP analysis. You are encouraged to request audits for each analyst who will or might be performing that analysis in the coming year. You may not contract out the analysis. You must use your normal procedures plus any special instructions that may come with the audit samples, and to submit your results to LAP within one month. LAP evaluates the results. You will be notified if your results were "acceptable" or "unacceptable", along with an invoice. If the results are not acceptable, experienced LAP staff is available to consult with the test facility about possible problems and solutions. A second audit can be sent on request for an additional fee. If the results are still unacceptable, Approval may be denied.

This process is required with your initial application and periodically thereafter. Random inspections and audits may be conducted for cause or at random, at no cost to test facility. Failure to cooperate will result in revocation.

What does the LAP look for?

The actual areas of concern are shown in both the General and Method-Specific Applications. Criteria are discussed in general terms here.

Ownership and identification
The test facility must be a legally recognized entity and have a recognized owner. It must have a regular place of business and a mailing address.

Organization
The test facility must have an authorized LAP contact, a technical director (however named) who has overall responsibility for technical operations, report signatories, staff who have day to day oversight of work and data quality, and a QA officer (either in-house on contracted) to audit QA performance. In small test facilities these positions may be occupied by one person, except the QA officer, who must not engage in data production. The span of supervision is also reviewed.

Personnel
The QA Officer, technical manager, report signatories, reviewers and those with day to day supervision of work are expected to have relevant degrees and five years of experience. Analysts, technicians, etc. are expected to have education and experience in line with their duties and responsibilities.

Integrity
Your test facility must have policies and practices that assure that there is no inducement (either positive or negative) that affects the quality or credibility of the data or results. This includes organizational or individual conflict of interest and pace of work that undercuts staff's ability to perform necessary QA. Your test facility must have policies on falsification of data and data selection, and staff must be aware of them.

Facilities
The test facility must be large enough to accommodate the size and scope of work. LAP work areas must be freely accessible only to regular employees of the test facility; this includes equipment storage, report preparation and data storage areas. Furthermore each work area must meet the technical requirements of the method.

Methods
SCAQMD Methods or SCAQMD-approved methods are expected to be performed as adopted, except for improvements required or allowed by LAP and described in the Method-Specific Applications. Significant method deviations have the option of being reviewed for equivalence. If your test facility has deviations from the adopted methods that are considered to be insignificant, you may discuss the technical merits with LAP staff. Methods, SOPs or other forms of instruction must be freely accessible to the personnel who perform them.

Quality Control
Your test facility must be firmly committed to performing all quality control required by method, and must routinely review QC results.

Sample Receipt and Storage, Chain of Custody, Evidence Retention
Samples must be properly identified and stored on receipt. Chain of Custody must track outgoing prepared equipment, field sampling staff, and incoming samples. Those who sign the chain of custody are required to keep the equipment and/ or samples under their immediate observation or locked in a secure location. For compliance tests, unused portions of samples, raw data and documents must be securely maintained until it is determined that either the source passes or no that legal action will be taken, or until the case has been resolved.

Equipment, Instruments, Reagents and Standards
These must meet the requirements of the method and be traceable.

Documentation
Tests must be documented completely. It must be possible to reconstruct all pertinent aspects of the test and sample including equipment, instruments, reagents and standards, procedures, calibrations, calculations, analyst, sample, date and time etc. Data may be recorded or referenced. Data, reports and related information must be maintained in hardcopy in a secure location. If logbooks, SOPs etc. are referenced, they must be identifiable by date, version number, or other unique identifier. The test facility must have version control on all of its documents.

Quality Assurance (QA)
Your QA program must demonstrate the ability to detect, correct, and document problems in any aspect of sampling or analysis that may affect data quality.

Audit performance
Analytical audit samples have a numeric acceptable range. Results must be within this range to be acceptable.

LAP status

Experienced SCAQMD staff evaluates the test facility and recommends the following final actions. The recommendations are based on

Organization;
Presence of data integrity policies;
Adherence to standard methods or approved equivalent methods;
Facilities, equipment, reagents, instruments and other physical requirements;
Completeness and traceability of documentation, including raw and calibration data and reports;
Suitability of quality assurance for the tests in question;
Actions taken by the test facility to correct deficiencies;
Results of audit tests;
Other information such as test reports submitted to SCAQMD, follow-up visits, random audits etc.

LAP status may be as follows:

Approved
If your test facility has been approved for performance of a method and has paid all required fees, a Letter of Approval is sent and the status listed in the SCAQMD database. Approval means that your test facility has met all requirements, paid all necessary fees, and is within the approval period.

Denied
Your test facility has failed to meet requirements or has not corrected deficiencies within 180 *days* of notification. *These deficiencies may be found through evaluation of applications, audit samples, submitted protocols or reports, observed during testing or site inspection etc.* If approval has been denied, a letter will be sent to test facility with the specific reason(s) for denial. Status will be posted in the SCAQMD database for six months, then removed, after which the test facility may reapply. Test facility may voluntarily withdraw or appeal.

Suspended
Failure to produce LAP-quality work or failure to correct deficiencies within 180 days of notification will result in suspension. These deficiencies may be found through evaluation of applications, audit samples, submitted protocols or reports, observed during testing or site inspection etc. If the approval has been suspended, a letter of suspension will be sent along with the reason(s) for suspension and the action(s) required to have approval reinstated. During suspension, the test facility must cease advertising its approved status or using the LAP logo, and must cease performing work that requires LAP approval. Status and applicable suspension period (if any) will be posted in SCAQMD database until test facility ahs changed status. Test facility may voluntarily withdraw or appeal.

Lapsed
Approval lapses when the test facility fails to renew before the expiration date. If approval has lapsed, the status will be posted for six months or until the test facility has renewed. While lapsed, the test facility must cease advertising its approved status or using the LAP logo and must cease performing work that requires LAP approval.

Withdrawn
Test facility may choose to withdraw from the approval process by sending a letter to the LAP coordinator. If the test facility withdraws, it must return its Letter of Approval (if in force), cease advertising its approved status or using the LAP logo and must cease performing work that requires LAP approval. Status will be posted for six months in the

District database, then the listing will be removed, after which time the test facility may reapply.

Extended
Approval period has been extended by the SCAQMD for a period of up to one year. The extended date will be posted until the test facility changes status.

Revoked
Reasons for revocation include fraud or misrepresentation to LAP or clients, including fraudulent application material or Declaration of No Change, falsification of data, refusal of inspector or audit, threats against LAP or its personnel, *more than one suspension in five years,* or other serious violations of law of LAP agreement. If approval is revoked, a letter of revocation and specific reason(s) will be sent. *During suspension, the test facility must cease advertising its approved status or using the LAP logo, and must cease performing work that requires LAP approval.* Under these circumstances, the test facility may elect to voluntarily withdraw or appeal.

Appeal
If an Approval has been denied, suspended, or revoked the test facility has the right to appeal the decision to the LAP Appeals Committee in 30 days, specifying in writing the reasons for the appeal. A meeting is arranged between the test facility, the Appeals Committee and the evaluator(s), and a decision is made at the meeting. The Appeals Committee consists of the Director of Monitoring & Analysis Division, the Public Advisor, and a staff member of SCAQMD Legal Counsel.

Fees

District costs are reimbursed at a labor rate specified in District Rules 304 and 304.1 up to a cap defined by the Rules. Test facilities are invoiced separately for application review, site inspection, and audit preparation and review. *Payment is due with receipt of a written report and invoice from the District. Checks are payable to SCAQMD Laboratory Approval Program.*

All test facilities will be reviewed annually by LAP, which will charge at least an annual renewal fee. Inspections and audits will be required periodically at additional cost.

Test facilities that have changed their operations during their Approval period may need review of new operations. If LAP is notified by letter within 60 days of operational changes, these changes will be reviewed at no cost. However, if notice is received after

60 days, test facility will be billed for the review, based on the number of hours required and limited by the same caps in place .

Test facilities that have had their Approval denied, suspended, or revoked, or that voluntarily withdraw from the program, are responsible for charges up to the time of the finding or withdrawal.

Random inspections and audits that are initiated by the District are at no charge to the test facility.

Travel costs will be defrayed at rates that conform to travel by government employees, and will be prorated among several applicants wherever possible.

There will be a service charge of $25 for returned checks, checks that have been stopped, or other withheld payment.

Method Equivalence

Test facilities occasionally want to use a modified method that cannot be easily evaluated from the method description. If the test facility chooses, the modified method can be evaluated for equivalence to the standard method. If the modified method is found to be equivalent, it can then be submitted for LAP Approval. The Equivalence Procedure is different from the Approval Procedure, and is handled by the Laboratory Services Manager. The applicant test facility will be notified by letter of this problem, and given additional information on how equivalence can be determined.

Authorized Contact

The authorized contact is a person from the test facility who has authority to enter into agreement with SCAQMD LAP and can commit to fulfilling LAP requirements. Only the authorized representative can initiate or terminate an Approval or change its scope.

Compliance with existing laws

Approval does not relieve the test facility the need to observe and comply with existing Federal, State, and local statutes, ordinances and regulations including consumer protection and anti-trust laws.

Questions? Comments?

We welcome your questions and comments!

If you have questions, comments, or need more information, please feel free to call

LAP Coordinator
SCAQMD
21865 Copley Dr.
Diamond Bar, CA 91765
909-396-2271