# Petroleum Test Laboratory Accreditation Program

API STANDARD 1512
FIRST EDITION, OCTOBER 1995

**American Petroleum Institute**
1220 L Street, Northwest
Washington, D.C. 20005

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**Industry Services Department**

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Institute

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## FOREWORD

This standard is under the jurisdiction of the API Fuels Committee. It shall become effective on the date printed on the cover, but may be used voluntarily from the date of distribution. The API Fuels Committee has established a voluntary Petroleum Test Laboratory Accreditation Program (PTLAP) for independent commercial and petroleum company laboratories to ensure consistent quality of test results in view of federal and state regulations. This program includes a provision for accredited laboratories to use the API Petroleum Test Laboratory Accreditation Program logo. It is not intended in any way to inhibit the use of laboratories not licensed to use this logo.

It is essential that the refining, distribution, and marketing sectors be assured that testing is conducted properly, and results are accurate. Good quality control programs are an essential element for compliance with these regulations.

API produced this document under standardization procedures that ensure appropriate notification and participation in the developmental process and is designated as an API *standard.* Questions concerning the interpretation of the content of this standard or comments and questions concerning the procedures under which this standard was developed should be directed in writing to the API Industry Services Department.

API standards may be used by anyone desiring to do so. Every effort has been made by the Institute to ensure the accuracy and reliability of the data contained in them; however, the Institute makes no representation, warranty, or guarantee in connection with the publication and hereby expressly disclaims any liability or responsibility for loss or damage resulting from their use or for any violation of any federal, state, or municipal regulation with which an API standard may conflict.

Suggested revisions are invited and should be submitted to the Industry Services Department, American Petroleum Institute, 1220 L Street, N.W., Washington, D.C. 20005.

# Petroleum Test Laboratory Accreditation Program

## 0 Introduction

The API Petroleum Test Laboratory Accreditation Program (PTLAP) is a voluntary accreditation program open to all laboratories doing tests on petroleum products. It is a result of cooperation between the petroleum industry and independent laboratories to reduce the need to continue or establish multiple audits by petroleum companies.

The PTLAP objective is to verify the quality of test results from petroleum product testing. Program participants must pass an on-site assessment before accreditation is awarded and must have an established quality system that complies with the requirements in Sections 12-19. To maintain accreditation, the laboratory must pass a periodic assessment during the accreditation period and participate in the appropriate ASTM Interlaboratory Crosscheck Program(s). Laboratories with "outlier" results must follow up with appropriate corrective action per the requirements in Paragraph 16.2.

## 1 Scope

This standard sets forth the program requirements for laboratories that wish to be recognized by the American Petroleum Institute as meeting specific industry requirements for testing, measuring, and inspecting petroleum products. The requirements are structured to prevent nonconformance during every stage of the testing process and are applicable in all situations when doing API accredited tests.

This standard provides criteria for the qualification and selection of assessors, the conduct of on-site assessments, the evaluation of laboratories leading to accreditation, the continuance of accreditation, and the ongoing monitoring and surveillance of accredited laboratories.

This standard outlines requirements for a quality system to control the testing of petroleum products performed by independent and petroleum company laboratories. It complements ISO 9002 and ISO Guide 25, *General Requirements for the Competence of Calibration and Testing Laboratories.* PTLAP adds the requirement to observe the tests for which the laboratory seeks accreditation, as they are performed by laboratory personnel.

## 2 References

**2.1** Unless otherwise specified, the most recent editions or revisions of the following standards, codes, and specifications shall, to the extent specified herein, form a part of this standard.

API

| | |
|---|---|
| Policy 104 | *Standarization* |
| Spec Q1 | *Specification for Quality Programs* |

ANSI[1]

| | |
|---|---|
| Q1 | *Generic Guidelines for Auditing of Quality Systems* |

ASQC[2]

| | |
|---|---|
| | *Quality Systems—Model for Quality Assurance in Design, Development, Production, Installation, and Servicing* |

ASTM[3]

| | |
|---|---|
| D975 | *Standard Specification for Diesel Fuel Oils* |
| D1655 | *Standard Specification for Aviation Turbine Fuels* |
| D4814 | *Standard Specification for Automotive Spark-Ignition Engine Fuel* |
| E1187 | *Standard Terminology Relating to Lab Accreditation* |

EPA[4]

| | |
|---|---|
| 40 | *Code of Federal Regulations* Part 80.46 |

ISO[5]

| | |
|---|---|
| 9002 | *Quality Systems—Model for Quality Assurance in Production and Installation* |

[1]American National Standards Institute, 1430 Broadway, New York, New York 10018

[2]American Society for Quality Control, 611 East Wisconsin Avenue, Milwaukee, Wisconsin 53201-3005

[3]American Society for Testing and Materials, 100 Bar Harbor Drive, West Conshohocken, Pennsylvania 19428

[4]Environmental Protection Agency. The *Code of Federal Regulation* is available from the U.S. Government Printing Office, Washington, D.C.

[5]International Organization for Standardization, Geneva, Switzerland.

Guide 25 *General Requirements for the Competence of Calibration and Testing Laboratories*

### 2.2 OTHER REFERENCES

The following standards and codes are also referred in this publication.

ASTM

D4057 *Manual Sampling of Petroleum Products*
E548 *Standard Practice for Preparation of Criteria for use in the Evaluation of Testing Laboratories and Inspection Bodies*
E994 *Standard Guide for Lab Accreditation System*
E1322 *Selection, Training, and Evaluation of Assessors*

ISO

8402 *Quality Vocabulary*
10011-1 *Guidelines for Auditing Quality Systems*
10011-2 *Qualifications for Auditors*
10011-3 *Management of Auditing Programs*
Guide 2 *General Terms and Their Definitions Concerning Standardization and Their Related Activities*

## 3 Definitions

The relevant definitions from ISO/IEC Guide 25 and ASTM E1187 are applicable; the most relevant being quoted below, with additional definitions applicable for the purposes of this standard.

**3.1 acceptance criteria:** Defined limits placed on characteristics of materials, products, and services.

**3.2 accreditation criteria:** A set of requirements used by an accrediting body that a testing laboratory must meet to be accredited.

**3.3 accredited laboratory:** Testing laboratory to which accreditation has been granted.

**3.4 accrediting organization:** A body that conducts and administers a laboratory accreditation system and grants accreditation.

**3.5 assessment:** The activity of evaluating a laboratory's compliance with accreditation criteria.

**3.6 assessor:** An individual under contract to API who carries out some or all functions related to laboratory assessment.

**3.7 authorized representative:** An individual who is authorized by the laboratory to sign the PTLAP application form and commit the laboratory to fulfill program requirements.

**3.8 calibration:** Comparison and adjustment to a standard of known accuracy.

**3.9 calibration method:** Defined procedure for performing a calibration.

**3.10 certified reference material (crm):** A reference material whose property values are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation that is issued by a certifying body.

**3.11 client:** Any person or organization that engages the services of a laboratory.

**3.12 deficiency:** The nonfulfillment of PTLAP conditions and/or criteria for accreditation.

**3.13 inspection:** Process of measuring, examining, testing, gauging, or using other procedures to ascertain the quality or state, detect errors or defects, or otherwise appraise materials, products, services, systems, or environments to a preestablished standard.

**3.14 laboratory:** Body that calibrates and/or tests. In cases where a laboratory forms part of an organization that carries out other activities besides calibration and testing, the term "laboratory" refers only to those parts of that organization involved in the calibration and testing process.

**3.15 nonconformance:** Any nonfulfillment of or deviation from specified requirements.

**3.16 proficiency testing:** Determination of the laboratory testing performance by means of the ASTM Interlaboratory Crosscheck Program.

**3.17 quality:** Conformance to specified requirements.

**3.18 quality assurance:** The activity of providing the evidence needed to establish confidence that data provided by a laboratory are of the requisite precision and accuracy.

**3.19 quality control:** The process through which a laboratory measures its performance, compares it with standards, and acts on any differences.

**3.20 quality manual:** A document stating the quality policy, quality system, and quality practices of an organization.

**3.21 quality system:** The organizational structure, responsibilities, control features, processes, and resources needed to manage quality.

**3.22 standard material:** A material or substance having one or more properties that are sufficiently well estab-

lished to be used for the calibration of an apparatus or the assessment of a measurement method.

**3.23 satellite facility:** A laboratory operating under the technical direction and quality system of a main facility that is accredited.

**3.24 subcontractor:** Any individual or organization that provides testing services to the laboratory.

**3.25 test:** Determination of the characteristics or performance of a given product by a specified procedure.

**3.26 test method:** A defined technical procedure to determine one or more specified characteristics of a material or product.

**3.27 testing laboratory:** Laboratory that measures, examines, tests, calibrates, or otherwise determines the characteristics or performance of materials or products.

**3.28 traceability:** The property of a result of a measurement that can be related to appropriate standards through an unbroken chain of comparisons.

**3.29 verification:** Confirmation by examination and furnishing of evidence that specified requirements have been met.

## 4 Responsibility

### 4.1 API RESPONSIBILITY

**4.1.1** API shall publish and maintain a document describing laboratory accreditation procedures.

**4.1.2** API shall publish and maintain the accreditation criteria and evaluation procedures that will allow petroleum testing laboratories to become licensed to use the API PTLAP logo.

**4.1.3** API shall process the application for accreditation and carry out the accreditation process in a timely manner.

**4.1.4** API shall have a policy and procedure to prevent accreditation from being misrepresented as product certification.

**4.1.5** API shall specify the scope of accreditation in terms of specific tests and products.

**4.1.6** When the laboratory has satisfied the requirements for accreditation, API shall issue a certificate.

**4.1.7** API shall protect the integrity of the program and ensure that only accredited labs are using the API accreditation symbol. API shall promptly advise all licensees when revisions or addenda are made to accreditation procedures.

**4.1.8** API shall verify that accredited laboratories are operating in conformance with the prescribed procedures, and have documented policies for revoking the accreditation from laboratories failing to comply.

**4.1.9** API shall publish a directory of accredited laboratories, showing the specific scope of each accreditation.

**4.1.10** API shall maintain records of reported problems encountered with the laboratories.

**4.1.11** API shall have an appeals procedure to resolve disputes, minimize conflicts of interest, and ensure that accreditation is based on recognized competence.

**4.1.12** API shall have a documented policy and procedure for the resolution of complaints received from testing laboratories concerning either the accreditation process or the assessor. A record shall be maintained of all complaints and of the action carried out by API to resolve the issues in dispute.

**4.1.13** API shall establish an interindustry advisory group to advise on enhancements and improvements to the program.

**4.1.14** API shall have a procedure that solicits and encourages feedback from participants. in order to promote uniform application of these requirements among accredited laboratories.

**4.1.15** API shall document and maintain rules defining the procedures of the accreditation process, including the requirements of any contractual arrangements between API and the accredited laboratories.

**4.1.16** API shall perform an assessment of laboratories through an on-site review according to the prescribed assessment guidelines and the issuance of a written report.

**4.1.17** API shall document and maintain evaluation procedures for initial and announced follow-up assessments, with a means for identifying that corrective action was implemented.

**4.1.18** API will maintain a system for monitoring and improving the accreditation program.

### 4.2 LABORATORY RESPONSIBILITY

**4.2.1** The laboratory shall comply with the requirements of this standard.

**4.2.2** The laboratory shall claim that it is accredited only in respect to testing services for which it has been granted accreditation.

**4.2.3** The laboratory shall pay fees for application, assessment, audits, and other services required to comply with this standard.

**4.2.4** The laboratory shall not use its accreditation in a way that is misleading.

**4.2.5** Upon the end of its accreditation, the laboratory shall cease use of the PTLAP logo in all advertising.

**4.2.6** The laboratory shall in no way suggest or imply product approval by API, and shall instruct its clients to do likewise.

**4.2.7** The laboratory shall promptly inform API of any changes affecting its compliance with this standard.

**4.2.8** An API accredited testing laboratory may relinquish accreditation by giving written notice to API.

# 5 Technical Requirements

Test methods subject to API accreditation are listed in Appendix A. If a laboratory wishes to become accredited for only some of these tests, they may do so by indicating this on the application form.

# 6 Accreditation Process

## 6.1 ACCREDITATION CRITERIA

**6.1.1** The procedures under which the API operates shall be administered in a nondiscriminatory manner and shall be designed to protect the integrity of the program. Access to this accreditation program will not be conditional upon membership in any association or group.

**6.1.2** The competence of an applicant laboratory will be determined by API against the specifications in Sections 12-19 and those tests listed in Appendix A of this standard. If the tests cannot be performed to the satisfaction of API assessors, accreditation will not be granted.

**6.1.3** API shall confine its requirements, assessments, and decisions on accreditation to those matters specifically related to the scope of the accreditation considered.

**6.1.4** To attain and maintain accreditation, an applicant must agree to:

a. Adhere to all requirements for accreditation.
b. Be assessed initially and as required.
c. Demonstrate, on request, that the tests for which accreditation is sought can be performed according to the test method.
d. Pay all required API fees.
e. Participate in the appropriate ASTM Interlaboratory Crosscheck Program and implement corrective action as required by API.
f. Limit representation of its accreditation to only those tests for which accreditation was granted.
g. Adhere to the requirements for use of the API PTLAP logo.
h. Resolve all deficiencies.
i. Discontinue the use of the logo if it is unable to comply with these conditions.
j. Report to API within 30 days any changes involving the location, management structure, ownership, facilities, or authorized representative.
k. Notify API in writing of its intention not to continue its accreditation.

## 6.2 APPLICATION

A laboratory applies for accreditation by completing and submitting the API application package that includes:

a. Corporate entity, name, address, and ownership of the laboratory.
b. Name, address, telephone, and fax number of the authorized representative of the laboratory.
c. A designation on the application form of the specific tests (see Appendix A) for which accreditation is desired.
d. Submittal of a quality manual for the evaluation by the API Quality Review Panel.
e. Names and titles of persons responsible for approving test reports.
f. An organization chart defining relationships that are relevant to performing testing covered in the accreditation request.
g. An agreement to comply with the accreditation procedure, especially to receive the assessment team, and to pay the applicable fees regardless of the result of the assessment.

## 6.3 QUALITY MANUAL REVIEW

A copy of the laboratory's quality system manual shall be submitted with the PTLAP application. A review panel consisting of API personnel will review the manual to evaluate compliance to the quality system requirements outlined in Sections 12-19 of this document.

## 6.4 ON-SITE ASSESSMENT

An on-site assessment will be scheduled once a completed application is submitted, the quality manual is judged acceptable, and the appropriate fees have been paid. On-site assessments must be successfully passed to attain accreditation. Deficiencies identified during the assessment shall be corrected according to an approved corrective action plan before accreditation can be awarded.

## 6.5 DECISION ON ACCREDITATION

The decision to accredit a laboratory shall be made by API based on the assessment report. Any decision shall be stated in writing. A decision to refuse or limit the scope of accreditation shall be made by API, after which the laboratory has the opportunity to appeal.

## 6.6 PROFICIENCY TESTING

An API accredited laboratory must enroll in the appropriate ASTM Interlaboratory Crosscheck Program for each test method for which it seeks accreditation. This proficiency testing program enables API and accredited laboratories to compare their performance with other program participants.

Laboratories shall bear the cost of any fees charged to participate in this program.

### 6.7 PERIOD OF ACCREDITATION

The period of accreditation for a laboratory in good standing is three years. Accreditation remains in effect until revoked by API, discontinued by the accredited laboratory, or until expiration of the accreditation date. The loss of accreditation will occur upon not fulfilling any of the conditions outlined in 6.8.

### 6.8 MAINTAINING ACCREDITATION

To maintain accreditation, the laboratory shall comply with the following requirements:

a. Successful completion of periodic proficiency testing requirements outlined in Section 8.
b. Successful completion of at least one periodic assessment during the accreditation period.
c. Payment of fees required to maintain accreditation within established deadlines.
d. Compliance with the quality system requirements outlined in Sections 12-19.
e. Compliance with the terms and conditions specified in the license agreement.

### 6.9 RENEWAL OF ACCREDITATION

API will notify an accredited laboratory at least 60 days before its accreditation expires and will send each accredited laboratory a renewal application package, allowing sufficient time to complete the renewal process before the expiration date. Renewal fees and completed paperwork must be received by API prior to expiration of the laboratory's current accreditation to avoid a lapse in accreditation.

### 6.10 SUSPENSION, REVOCATION, AND DENIAL OF ACCREDITATION

**6.10.1** If API decides to deny or revoke accreditation of a laboratory, API shall inform the laboratory of the reasons for the denial or revocation and the procedure for appealing such a decision.

**6.10.2** Suspension shall mean the temporary removal of a laboratory's accreditation for a minimum of 30 days. A suspended laboratory does not have to reapply for accreditation if cause and corrective action is approved by API within the established deadline. A laboratory's accreditation may be suspended in total or in part.

**6.10.3** Revocation shall mean the withdrawal of a laboratory's accreditation by API. The laboratory will not be eligible to reapply for accreditation for six months, in which time the cause of the revocation must be corrected. Reasons for suspension and/or revocation shall include, but are not limited to, the following:

a. Failure to participate or repeated unsatisfactory performance in the proficiency testing program.
b. Misrepresentation of any material fact pertinent to receiving initial accreditation.
c. Denial of entry on the agreed-upon date for on-site assessments.
d. Falsification of any report relating to laboratory testing covered by PTLAP accreditation.
e. Failure to pay accreditation fees.
f. Failure to comply with the terms and conditions specified in the license agreement.
g. Repeated unsatisfactory performance as identified by validated client complaints.
h. Failure to submit and implement corrective action for deficiencies found during assessments.
i. Loss of personnel with the required education, training, experience, and performance on the job.
j. Failure to correct repeated infractions.

**6.10.4** The laboratory shall cease using the API PTLAP logo during any period of suspension or revocation of accreditation.

### 6.11 WARNING LETTERS

Warning letters may be issued for infractions not requiring suspension or revocation of accreditation.

### 6.12 REINSTATEMENT

Laboratories who have been subject to suspension or revocation will be reinstated only after taking remedial actions that are deemed appropriate by API.

### 6.13 SATELLITE FACILITIES

When a parent laboratory is accredited, any of its satellite facilities must also seek accreditation independently if use of the PTLAP logo is desired at the satellite facility.

## 7 On-Site Assessment

### 7.1 GENERAL

The on-site assessment is the primary means of determining a laboratory's capabilities and qualifications. Its objective is to establish whether a laboratory complies with the API requirements for accreditation and can properly perform the tests for which accreditation is sought. The assessment team will collect information and make observations that will be used to evaluate the laboratory's conformance to established accreditation criteria. API shall arrange assessments of laboratories in such a way as to minimize potential conflicts of interest.

## 7.2 ASSESSMENT ELEMENTS

One or more assessors will be assigned to conduct an on-site assessment that may last from one to several days. To ensure uniformity, the assessment is conducted per the guidelines in a checklist developed by API. The assessment must be held at the site where testing will take place. It generally involves:

a. An entry briefing with laboratory management.
b. Review of quality documentation, sample handling, and records.
c. Witnessing performance of the test methods designated on the application form.
d. Interviews with staff.
e. Examination of equipment and calibration records.
f. A written report of assessor findings.
g. An exit briefing, including the specific identification of any deficiencies.

## 7.3 ON-SITE ASSESSORS

### 7.3.1 Assessor Training

API will specify the minimum qualifications for assessors and develop criteria for training requirements. The assessor training course will be provided by API and performed by individuals who have displayed proficiency in petroleum testing methods and quality system indoctrination. API will be the sole judge of an assessor's qualifications.

### 7.3.2 Qualifications

Each assessor must successfully complete the API assessor training course and meet the following qualifications:

a. Familiarity with API accreditation criteria and ISO Guide 25 requirements.
b. Demonstrated ability to communicate effectively and professionally both verbally and in writing.
c. Absence of interest or bias that would prevent impartiality.
d. Knowledge of pertinent standards and regulations.
e. Knowledge of basic concepts, principles, and techniques of auditing.
f. Ability to travel among laboratories.

#### 7.3.2.1 Technical Assessors

An individual selected to do on-site technical assessments shall have at least a bachelor of science degree in chemistry or chemical engineering or be an experienced laboratory technician with no less than five years of experience in supervising or performing laboratory tests. The following additional qualifications must also be met:

a. Proficiency and technical competence in each of the test methods specified in Appendix A.
b. General knowledge of relevant assessment methods and documents.
c. Expertise in ASTM Section 5 Standards, Volume 05.01, .02, and .03 Fuel Test Methods.
d. Experience in proficiency testing and ASTM reproducibility and repeatability limits and protocols.
e. Experience in petroleum laboratory quality control and inspection.
f. Experience in field auditing and reporting.

#### 7.3.2.2 Quality System Assessors

An individual selected to do on-site quality system assessments shall have the following additional qualifications:

a. Thorough knowledge of relevant assessment methods and documents.
b. General knowledge of the test methods specified in Appendix A.
c. A minimum of five years of experience in quality assurance activities.
d. Training in statistical quality control.
e. Experience in field auditing and reporting.
f. Training in API accreditation requirements. (Other certifications are also desirable.)

### 7.3.3 Appointment of Assessors

The applicant laboratory shall be provided with the name(s) of the qualified assessor(s) selected to carry out the on-site assessment. The assessors shall be qualified and appointed by API. A confirmation letter outlining the scope and details of the assessment will be sent to the applicant laboratory.

## 7.4 LABORATORY COOPERATION

The laboratory desiring accreditation shall afford the assessor such cooperation as is necessary to enable the assessor to monitor compliance with the requirements detailed in this standard. This cooperation shall include:

a. Allowing the assessor access to relevant areas of the testing laboratory for the witnessing of tests during normal business hours.
b. Undertaking any reasonable check to enable the assessor to verify the testing capability of the testing laboratory.
c. Allowing the assessor to review the results of the testing laboratory's internal audits and interlaboratory proficiency tests.

## 7.5 FREQUENCY OF ASSESSMENTS

### 7.5.1 Application for Accreditation

Upon submittal of the completed application, quality system manual, and the appropriate application fees to API, an initial assessment will be scheduled at a mutually agreed-

upon time. This assessment ensures that the laboratory can do analyses to the level, precision, and accuracy required by each method for which accreditation is being sought.

### 7.5.2 Periodic Assessments

In addition to the initial assessment, an accredited laboratory must successfully pass at least one periodic assessment during each accreditation period. These assessments may include all or some of the elements described in 7.2. Failure to be found in compliance with the requirements of accreditation will result in suspension of accreditation, unless appropriate corrective action is taken within the specified time. Laboratories will generally be notified three business days prior to the assessment.

### 7.5.3 Conditions for Reassessment

Partial reassessments will be conducted whenever major changes that may affect the reliability of its services occur in a laboratory.

### 7.6 ASSESSMENT REPORTS

The assessor will review assessment findings with laboratory management and will issue a report to the laboratory that reflects deficiencies identified during the assessment and indicates those that were acknowledged by both parties. As soon as possible after the assessment, the assessors shall prepare and forward a written report to API summarizing the on-site visit. The assessor's report will include:

a. Identification of observed nonconformities relating to the accreditation criteria.
b. The assessor's checklist and all supporting documentation.
c. A copy (to be forwarded to API by the assessor) that contains recommendations on specific tests for which accreditation should or should not be granted, with supporting reasons.

### 7.7 CODE OF ETHICS

Assessors appointed by API must comply with standards of conduct specified by API, when performing assessment activities associated with the API PTLAP.

## 8 Proficiency Testing

**8.1** A laboratory must enroll within a period of time specified by API in the appropriate ASTM Interlaboratory Crosscheck Program for those tests for which it is accredited. This proficiency testing program enables API to compare performance among participating laboratories.

**8.2** Proficiency testing identifies problem areas and provides a means by which the overall effectiveness of the laboratory can be measured. Proficiency testing data are analyzed by ASTM and the results are reported to the participants, maintaining the confidentiality of individual laboratories.

**8.3** Where required, API will identify for participating laboratories a statistical correlation for each accredited test. Laboratories will be allowed to compare their individual data against the consensus results of other PTLAP-accredited laboratories. Data from these reports will be used to improve ASTM reproducibility limits, while maintaining the confidentiality of the fuel supplier and testing laboratory.

**8.4** API will issue a warning letter to the laboratory for a test result that falls outside the ASTM Crosscheck compliance range in any given month. The laboratory will have 30 days from the date of notification to respond to API with cause, corrective action, and a resolution date for the problem.

**8.5** Two successive samples that fall outside the ASTM Crosscheck compliance range will result in immediate and automatic suspension of accreditation for the specific test(s). Reinstatement can occur only when cause and corrective action has been submitted in writing to API and the next proficiency results are acceptable. Failure in four of seven consecutive samples will result in automatic suspension of accreditation. Repeated or significant failures over a period of time may also result in suspension or revocation of accreditation.

**8.6** Failure by a laboratory to participate in a regularly scheduled round of proficiency testing for which it has received instructions and/or materials shall be tantamount to an unsatisfactory test sample result.

**8.7** Upon reinstatement from a suspension of accreditation, the laboratory will be subject to periodic assessment by API.

## 9 Accreditation for Additional Testing

An accredited laboratory that wishes to broaden the scope of accreditation must apply to API and include payment of the appropriate fees. Upon acceptance, API will arrange for an assessment of those test methods to be added.

## 10 Promotion of PTLAP Accreditation

**10.1** The API PTLAP logo may only be used in conjunction with the API certificate number. The following statement must appear with the API PTLAP logo: "API Accredited for the Tests Specified in Certificate #_____."

**10.2** Use of the PTLAP logo is conditional on and limited

to test reports that describe testing within the scope of PTLAP accreditation. Any questions regarding use of the PTLAP logo should be submitted to API prior to its intended use.

**10.3** The laboratory's test reports must differentiate between PTLAP-accredited test results and results from tests that fall outside the scope of PTLAP accreditation.

## 11 Appeals

When API denies, suspends, or revokes an accreditation, the laboratory may appeal the decision. Appeals must be submitted in writing to the Director of the API Industry Services Department. The appeal shall include a statement of the basis for the objection. It must be filed with API within 45 days of the date of notification of the denial, suspension, or revocation of the accreditation. (See API Policy 104.)

## 12 Quality System

### 12.1 MANAGEMENT RESPONSIBILITY

**12.1.1** The laboratory shall identify management positions that have the responsibility and authority to:

a. Initiate action to prevent the occurrence of test nonconformance.
b. Identify and record any quality problems.
c. Verify the implementation of solutions.
d. Control subsequent nonconforming testing until the deficiency or unsatisfactory condition has been corrected.

**12.1.2** The laboratory shall have a quality manager (however named) who, irrespective of other responsibility, shall be assigned total responsibility and authority to plan, implement, and maintain the quality system. This person shall have direct access to the highest level of management at which decisions are made on laboratory policy and procedures. Additional managerial duties shall include:

a. Ensuring that the laboratory supervisors are familiar with the test methods, procedures, the objective of the test, and the assessment of the results.
b. Having documented policies and procedures to ensure the protection of a client's confidential information and proprietary rights.

### 12.2 ORGANIZATION

The laboratory shall clearly document its organizational structure with defined responsibilities, authority, and lines of communication. It will be organized so that confidence in its independence of judgment and integrity is maintained at all times. Personnel performing the quality functions shall have the organizational freedom to identify and evaluate quality problems and to initiate, recommend, or provide solutions through designated channels.

### 12.3 QUALITY POLICY

The laboratory's policy and objectives for and commitment to quality shall be defined, documented, and approved by management. Management shall ensure that this policy is understood, implemented in a clearly defined mission statement, and maintained at all levels in the organization.

### 12.4 QUALITY PLANNING

Quality assurance activities shall be planned and developed as an integral part of the laboratory's calibration and testing operation. The laboratory shall consider the following activities in meeting the technical requirements for specific tests:

a. Identifying and acquiring any controls, processes, equipment, testing resources, and skills that may be needed to achieve the required quality.
b. Ensuring the compatibility of the processes, inspection, test procedures, and applicable documentation.
c. Updating, as necessary, quality control, inspection, and testing techniques, including the development of new instrumentation.
d. Identifying and preparing quality records.

### 12.5 QUALITY MANUAL

The laboratory shall establish and maintain a documented quality system whose elements are described in a quality manual. The quality documentation shall be readily available for use by laboratory personnel. The quality system shall provide for:

a. Preparation of quality plans according to specified requirements.
b. Identification, acquisition, or availability of any controls, processes, test equipment, fixtures, laboratory resources, and skills needed to achieve test requirements.
c. The identification and preparation of quality records.

### 12.6 MANAGEMENT REVIEW

The quality system shall be systematically reviewed annually by the laboratory's management to evaluate its continuing suitability and effectiveness. A management review shall include, but not be limited to, the results of internal audits, changes in API-specified requirements, trends of nonconformance, and corrective actions. Records of such reviews shall be maintained.

### 12.7 INTERNAL QUALITY AUDITS

The laboratory shall arrange for audits of its activities at appropriate intervals to verify that its operations continue to comply with the requirements of the quality system. Such

audits shall be carried out by trained and qualified staff who are, whenever possible, independent of the activity to be audited. Where the audit findings cast doubt on the accuracy or validity of the laboratory's test results, the laboratory shall take immediate corrective action and shall immediately notify, in writing, any client whose work may have been affected.

### 12.8 DOCUMENT AND DATA CONTROL

#### 12.8.1 Control, Issue, and Retention

**12.8.1.1** The laboratory shall establish and maintain written procedures to control all documentation and data that relate to the requirements of this standard, including where possible documents of external origin, such as standards and subcontracted test results.

**12.8.1.2** The laboratory shall ensure that test methods, instructions, and specifications, including revisions, are reviewed and approved for adequacy by authorized personnel prior to issue and use. Responsibilities for approval of these documents shall be specified.

**12.8.1.3** All original observations, calculations and derived data, calibration records and certificates, test reports, and test certificates shall be retained for a period no less than five years. Original observations shall be entered at the time of testing into bound notebooks or properly designed work sheets.

#### 12.8.2 Document Changes/Modifications

The laboratory shall establish and maintain written procedures to control changes to documents. These changes shall be reviewed and approved by the same functions/organizations that performed the original review and approval. Those responsible for review and approval shall have access to pertinent background information on which to base their decisions. Changes shall be identified in the document or appropriate attachments.

## 13 Process Control

### 13.1 EQUIPMENT AND REFERENCE MATERIALS

**13.1.1** The laboratory shall be furnished with all items of equipment (including reference materials) required for the correct performance of tests. In those cases where the laboratory needs to use equipment outside its permanent control, it shall ensure that the relevant requirements of this standard are met.

**13.1.2** All equipment (including testing software) shall be properly maintained, and maintenance procedures shall be documented. Any item of equipment that has been subject to overloading or mishandling, or gives suspect results, or has been shown by verification to be defective shall be taken out of service. Out-of-service equipment shall be clearly identified and wherever possible stored at a specified place until it has been repaired and shown by calibration, verification, or test to perform satisfactorily. The laboratory shall examine the effect of this defect on previous tests.

**13.1.3** All equipment and reference materials shall, when appropriate, be labeled, marked, or otherwise identified to indicate its calibration status.

**13.1.4** Records shall be maintained for each item of equipment and all reference materials significant to the tests performed. The records shall include:

a. The name of the equipment.
b. The manufacturer's name, type identification, and serial number or other unique identification.
c. Date received and date placed in service.
d. Current location, where appropriate.
e. Condition when received (for example, new, used, reconditioned).
f. Copy of the manufacturer's operating instructions, where appropriate.
g. Dates and results of calibrations and/or verifications and date of next calibration and/or verification.
h. Details of maintenance carried out to date and planned for the future.
i. History of any damage, malfunction, modification, or repair.

**13.1.5** Documented procedures shall be established to control equipment calibrations. These procedures shall contain details of equipment type, identification number, location, frequency and type of calibration methods, acceptance criteria, and corrective action taken when results are unsatisfactory.

### 13.2 MEASUREMENT TRACEABILITY AND CALIBRATION

**13.2.1** All measuring and test equipment having an effect on the accuracy or validity of tests shall be calibrated and/or verified before being put into service. The laboratory shall have an established program for the calibration and verification of its measuring and test equipment at prescribed intervals.

**13.2.2** The calibration/verification program shall be designed and operated to ensure that measurements made by the laboratory are traceable to nationally or internationally recognized standards. Calibration certificates shall, wherever applicable, indicate the traceability to these standards and shall provide the measurement results and associated uncertainty of measurement and/or a statement of compliance with an identified metrological specification.

**13.2.3** Where no national or international standard materials exist, the basis used for calibration shall be documented

and shall provide satisfactory evidence of correlation of results.

**13.2.4** Standard materials held by the laboratory shall be used for calibration only and for no other purpose.

**13.2.5** Standard materials shall be certified by a body that can provide traceability to a national or international standard of measurement.

**13.2.6** Where relevant, reference standards and measuring and testing equipment shall be subjected to in-service checks between calibrations and verifications.

## 13.3 TEST METHODS

**13.3.1** The laboratory shall have documented instructions on the use and operation of all relevant equipment, handling and preparation of items, and testing, where the absence of such instructions could jeopardize the tests. All instructions, standards, manuals, and reference data relevant to the work of the laboratory shall be up-to-date and readily available to the staff.

**13.3.2** The laboratory shall use appropriate methods and procedures for all calibrations, tests, and related activities within its responsibility (including sampling, handling, transport and storage, preparation of items, estimate of uncertainty of measurement, and analysis of calibration and/or test data). They shall be consistent with the accuracy required and with any standard specifications used for the tests concerned.

**13.3.3** Where sampling is carried out as part of the test method, the laboratory shall use documented procedures and appropriate statistical techniques to select samples.

**13.3.4** Calculations and data transfers shall be subject to appropriate checks.

**13.3.5** Where computers or automated equipment are used for the capture, processing, manipulation, recording, reporting, storage, or retrieval of test data, the laboratory shall ensure that:

a. The requirements of this standard are complied with.
b. The computer software is documented and adequate for use.
c. Procedures are established and implemented for protecting the integrity of data. Such procedures shall include, but not be limited to, integrity of data entry or capture, data storage, data transmission, and data processing.
d. Computer and automated equipment is maintained to ensure proper operation and provided with the environmental and operating conditions necessary to maintain the integrity of calibration and test data.
e. It establishes and implements appropriate procedures for the maintenance and security of data including the prevention of unauthorized access to, and the unauthorized amendment of, computer records.

## 13.4 ACCOMMODATION AND ENVIRONMENT

**13.4.1** Laboratory accommodation, calibration and test areas, energy sources, lighting, heating, and ventilation shall facilitate proper performance of tests.

**13.4.2** The environment in which testing activities are undertaken shall not invalidate the results or adversely affect the required accuracy of measurement. Particular care shall be taken when such activities are undertaken at sites other than the permanent laboratory premises.

**13.4.3** The laboratory shall provide facilities for the effective monitoring, control, and recording of environmental conditions as appropriate. Attention appropriate to the tests concerned shall be paid to dust, electromagnetic interference, humidity, main voltage, and ambient pressure and temperature.

**13.4.4** There shall be effective separation between neighboring areas when the activities therein are incompatible.

**13.4.5** Access to and use of all areas affecting testing quality shall be defined and controlled.

**13.4.6** Adequate measures shall be taken to ensure good housekeeping in the laboratory.

## 13.5 HANDLING OF TEST ITEMS

**13.5.1** The laboratory shall have a documented system for uniquely identifying the items to be tested, to ensure that there will be no confusion regarding the identity of such items at any time.

**13.5.2** Upon receipt, the condition of the test item, including any abnormalities or departures from standard condition as prescribed in the relevant test method, shall be recorded. Where there is any doubt as to the item's suitability for test (for example, if the item does not conform to the description provided, or the test required is not fully specified), the laboratory shall consult the client for further instruction before proceeding. The laboratory shall establish whether the item has received all necessary preparation, or whether the client requires preparation to be undertaken or arranged by the laboratory.

**13.5.3** The laboratory shall have documented procedures and appropriate facilities to avoid deterioration or damage to the test item during storage, handling, preparation, and test; any relevant instructions provided with the item shall be followed. Where items must be stored or conditioned under specific environmental conditions, these conditions shall be maintained, monitored, and recorded where necessary. Where a test item or portion of an item is to be held secure, the laboratory shall have storage and security arrangements that protect the condition and integrity of the secured items or portions concerned.

**13.5.4** The laboratory shall have documented procedures, or reference to state, federal, or international guidelines for

the receipt, retention, or safe disposal of test items, including all provisions necessary to protect the integrity of the laboratory.

### 13.6 STATISTICAL TECHNIQUES

The laboratory shall use statistical planning, analysis, tests, and quality control techniques whenever such techniques are suitable to maintain the required control of quality. The procedures to implement and control the application of these techniques shall be documented in the quality manual.

### 13.7 OUTSIDE SUPPORT SERVICES AND SUPPLIES

**13.7.1** The laboratory shall use only those outside support services and supplies that are of adequate quality to sustain confidence in the laboratory's tests.

**13.7.2** Documented procedures shall exist for the purchase, reception, and storage of consumable materials used for the technical operations of the laboratory.

**13.7.3** Wherever possible, the laboratory should ensure that purchased equipment and consumable materials are not used until they have been inspected, calibrated, or otherwise verified as complying with any standard specifications relevant to the tests concerned.

**13.7.4** The laboratory shall maintain records of all suppliers from whom it obtains support services or supplies required for testing.

## 14 Personnel

**14.1** The laboratory shall employ sufficient personnel with the necessary education, training, technical knowledge, and experience for their assigned functions.

**14.2** The laboratory shall identify the training needs of all personnel responsible for calibration and/or testing activities. Training requirements shall provide for quality system indoctrination and up-to-date job training of personnel.

**14.3** Records on the relevant qualifications, training, skills, and experience of the calibration and/or testing personnel shall be maintained by the laboratory.

## 15 Subcontracting of Testing

**15.1** An API-accredited laboratory shall ensure and be able to prove its subcontractor is competent to perform the activities in question and complies with the same criteria of competence as the laboratory in respect to the work being subcontracted.

**15.2** The laboratory shall record and retain details of its investigation of the competence and compliance of its subcontractors and maintain records of all subcontracting.

**15.3** An API-accredited laboratory intending to subcontract testing that will be represented as meeting PTLAP requirements must:

a. Have subcontracting procedures in its quality manual that are compatible with PTLAP policy.
b. Place the subcontracted work with a laboratory that maintains a current PTLAP accreditation.
c. Clearly identify in its records, and in the test report to the client, exactly which data were obtained by the PTLAP-accredited laboratory and by the subcontractor, PTLAP-accredited or not.
d. Include in the test report the name, address, contact person of the subcontracted laboratory(ies), and the statement: "This report contains data produced by a PTLAP-accredited subcontracted laboratory (PTLAP Certificate # ) for the test methods indicated."

**15.4** Any testing performed by a subcontracted laboratory that is not accredited by PTLAP must not be represented as meeting PTLAP criteria. The test report must also include the following statement: "This report contains data produced by a subcontracted laboratory NOT PTLAP-ACCREDITED for the test methods indicated."

**15.5** A PTLAP-accredited laboratory that uses a subcontractor to perform PTLAP-accredited testing is responsible for the action of the subcontractor.

## 16 Nonconformance Controls

### 16.1 NONCONFORMANCE REVIEW AND EVALUATION

The responsibility for nonconformance review and the authority for the disposition of nonconforming test results shall be defined. Procedures shall be established for evaluation of nonconforming services that do not meet the established proficiency testing criteria.

### 16.2 CORRECTIVE AND PREVENTIVE ACTION

**16.2.1** The laboratory shall establish and document procedures for identifying, investigating, and documenting the cause of repetitive nonconformances and the corrective action needed to prevent recurrence.

**16.2.2** The laboratory shall analyze processes, work instructions, quality records, specifications, and customer complaints to detect and eliminate potential causes of nonconforming test results.

**16.2.3** Corrective or preventive actions to eliminate the causes of actual or potential nonconformances to a degree appropriate to the magnitude of problems shall be implemented. Controls shall be applied to ensure that these corrective actions are effective and the resulting changes in procedures are recorded.

### 16.2.4 Corrective Action

The procedures for corrective action shall include:

a. The effective handling of customer complaints and reports of product nonconformities.
b. Investigation of the cause of nonconformities relating to product, process, and quality system, and recording the results of the investigation.
c. Determination of the corrective action needed to eliminate the cause of nonconformities.
d. Application of controls to ensure that corrective action is taken and that it is effective.

### 16.2.5 Preventive Action

The procedures for preventive action shall include:

a. The use of appropriate sources of information such as processes and work operations which affect product quality, concessions, audit results, quality records, service reports, and customer complaints to detect, analyze, and eliminate potential causes of nonconformities.
b. Determination of the steps needed to deal with any problems requiring preventive action.
c. Initiation of preventive action and application of controls to ensure that it is effective.
d. Confirmation that relevant information on actions taken is submitted for management review.

## 17 Records

**17.1** The laboratory shall have a record system that retains all original observations, calculations and derived data, calibration records and certificates, and test reports or certificates for a minimum of five years. Records for each test shall contain sufficient information to allow their repetition and shall include the identity of personnel involved in sampling, preparation, or testing. The records shall show conformance to good scientific and technical practices, and the effective operation of the quality system.

**17.2** All quality records (including those pertaining to calibration and test equipment) shall be stored so that they are readily retrievable in facilities that provide an environment that minimizes the possibility of deterioration, damage, or loss.

**17.3** Retention times of quality records shall be established and documented.

**17.3.1** Records required by process specifications shall be retained for the period specified in those documents.

**17.3.2** Records specified to demonstrate conformance to the effective operation of the quality system shall be retained for a minimum of five years.

## 18 Certificates and Reports

**18.1** The results of each individual or series of tests shall be reported accurately, clearly, unambiguously, and objectively, according to any instructions in the test methods. The results should normally be reported in a test report or test certificate, and should include the information necessary for the interpretation of the test results and all information required by the method used.

**18.2** Each certificate or report shall include at least the following information:

a. Name and address of the laboratory and the location where the test was carried out (if different from the address of the laboratory).
b. A unique identification of the certificate or report (such as serial number).
c. The name and address of client, where appropriate.
d. A description, condition, and unambiguous identification of the item tested.
e. The date of receipt of the test item and date(s) of performance of the test, where appropriate.
f. A reference to sampling procedure, where relevant.
g. Any deviations from, additions to, or exclusions from the test method, and any other information relevant to a specific test, such as environmental conditions.
h. Measurements, examinations, and derived results, supported by tables, graphs, sketches, and photographs as appropriate, and any failures identified.
i. A statement of the estimated uncertainty of the test result (where relevant to the customer);
j. A signature and title or an equivalent identification of the person(s) accepting responsibility for the content of the certificate or report (however produced), and the date of issue;
k. A statement that the certificate or report shall not be reproduced except in full, without the written approval of the laboratory.
l. An indication of which tests were performed under PTLAP accreditation.

**18.3** Results of tests done by subcontractors shall be clearly identified.

**18.4** The format of the report shall be carefully and specifically designed for each type of test carried out, and the headings standardized as much as possible.

**18.5** Material amendments to a test report after issue shall be made only in the form of a further document, or data transfer including the statement "Supplement to Test Report, serial number (or as otherwise identified)," or equivalent wording. Such amendments shall meet all the relevant requirements of Section 10 of this document.

**18.6** The laboratory shall notify clients promptly, in writing, of any event such as the identification of defective mea-

suring or test equipment that casts doubt on the validity of results given in any test report or amendment to a report.

**18.7** The laboratory shall ensure that, where clients require transmission of test results by telephone, telex, facsimile, or other electronic means, staff will follow documented procedures that ensure that the requirements of this document are met and that confidentiality is preserved.

## 19 Complaints

**19.1** The laboratory shall have a documented policy and procedures for the resolution of complaints received from clients or other parties about the laboratory's activities. A record shall be maintained of all complaints and of the actions taken by the laboratory.

**19.2** Where a complaint or any other circumstance raises doubt concerning the laboratory's compliance with their policies or procedures or with the requirements of this standard, or otherwise concerning the quality of tests, the laboratory shall ensure that those areas of activity and responsibility involved are promptly audited according to 12.7.

# APPENDIX A—PETROLEUM TEST LABORATORY ACCREDITATION PROGRAM TESTING LIST

| Method | Description | EPA Required Test |
|---|---|---|
| D 86-90* | Distillation of Petroleum Products | Yes |
| D 287-92<br>D 4052-91 | API Gravity of Crude Petroleum and Petroleum Products | No |
| D 1298-90 | Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum Products and Liquid Petroleum Products by Hydrometer Method | No |
| D 1319-93* | Hydrocarbon Types in Liquid Petroleum Products by Fluorescent Indicator Adsorption | Yes |
| D 2622-92 | Sulfur in Petroleum Products by X-ray Spectrometry | Yes |
| D 3606-92 | Determination of Benzene and Toluene in Finished Motor and Aviation Gasoline by Gas Chromatography | Yes |
| EPA | Oxygenates in Gasoline by Gas Chromatography/Oxygenate Flame Ionization Detector (GC/OFID) | Yes |
| EPA | Total Aromatics by Gas Chromatography/Mass Spectrometry | Yes |
| D 4815-93 | Oxygenates in Gasoline by Gas Chromatography | Yes |
| D 4953-93 | Vapor Pressure of Gasoline and Gasoline-Oxygenate Blends | No |
| D 5191-93a* | Vapor Pressure of Petroleum Products (With Environmental Protection Agency Modifications) | Yes |

Note: The scope of Appendix A currently pertains only to EPA required testing of reformulated gasoline (RFG). Additional tests for conventional diesel, and aviation fuels and lubricants will be added in the future.

*Test method revision year stipulated by EPA in 40 CFR Part 80.46.

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