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An American National Standard

# Standard Guide for Self-Assessment of Quality System Practices in Petroleum Products and Lubricant Testing Laboratories[1]

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## 1. Scope

1.1 This guide covers and provides direction for the self-assessment of the quality system practices in a laboratory testing petroleum products and lubricants in the oil industry. This guide is intended to satisfy requirements of international laboratory quality standards to conduct periodic self-assessments. It is not intended for comparing laboratory performance among a laboratory group or for use in external certification programs.

1.2 Other forms of assessment formats may also be acceptable as long as they cover the essential elements of this guide regarding laboratory capability.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

## 2. Referenced Documents

2.1 *ASTM Standards:*[2]

D94 Test Methods for Saponification Number of Petroleum Products

D445 Test Method for Kinematic Viscosity of Transparent and Opaque Liquids (and Calculation of Dynamic Viscosity)

D892 Test Method for Foaming Characteristics of Lubricating Oils

D1265 Practice for Sampling Liquefied Petroleum (LP) Gases, Manual Method

D3244 Practice for Utilization of Test Data to Determine Conformance with Specifications

D3700 Practice for Obtaining LPG Samples Using a Floating Piston Cylinder

D3764 Practice for Validation of the Performance of Process Stream Analyzer Systems

D4051 Practice for Preparation of Low-Pressure Gas Blends

D4057 Practice for Manual Sampling of Petroleum and Petroleum Products

D4177 Practice for Automatic Sampling of Petroleum and Petroleum Products

D4178 Practice for Calibrating Moisture Analyzers

D4296 Practice for Sampling Pitch

D4306 Practice for Aviation Fuel Sample Containers for Tests Affected by Trace Contamination

D4307 Practice for Preparation of Liquid Blends for Use as Analytical Standards

D4378 Practice for In-Service Monitoring of Mineral Turbine Oils for Steam, Gas, and Combined Cycle Turbines

D4418 Practice for Receipt, Storage, and Handling of Fuels for Gas Turbines

D5185 Test Method for Multielement Determination of Used and Unused Lubricating Oils and Base Oils by Inductively Coupled Plasma Atomic Emission Spectrometry (ICP-AES)

D5842 Practice for Sampling and Handling of Fuels for Volatility Measurement

D5854 Practice for Mixing and Handling of Liquid Samples of Petroleum and Petroleum Products

D6046 Classification of Hydraulic Fluids for Environmental Impact

D6122 Practice for Validation of the Performance of Multivariate Online, At-Line, and Laboratory Infrared Spectrophotometer Based Analyzer Systems

D6299 Practice for Applying Statistical Quality Assurance and Control Charting Techniques to Evaluate Analytical Measurement System Performance

D6304 Test Method for Determination of Water in Petroleum Products, Lubricating Oils, and Additives by Coulometric Karl Fischer Titration

D6595 Test Method for Determination of Wear Metals and Contaminants in Used Lubricating Oils or Used Hydraulic Fluids by Rotating Disc Electrode Atomic Emission Spectrometry

D6596 Practice for Ampulization and Storage of Gasoline and Related Hydrocarbon Materials

[1] This guide is under the jurisdiction of ASTM Committee D02 on Petroleum Products, Liquid Fuels, and Lubricants and is the direct responsibility of Subcommittee D02.94.01 on Task Group A: Quality Assurance and Quality Control.

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[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

D6792 Practice for Quality System in Petroleum Products and Lubricants Testing Laboratories
D6849 Practice for Storage and Use of Liquefied Petroleum Gases (LPG) in Sample Cylinders for LPG Test Methods
D6969 Practice for Preparation of Calcined Petroleum Coke Samples for Analysis
D6970 Practice for Collection of Calcined Petroleum Coke Samples for Analysis
D7235 Guide for Establishing a Linear Correlation Relationship Between Analyzer and Primary Test Method Results Using Relevant ASTM Standard Practices
D7260 Practice for Optimization, Calibration, and Validation of Inductively Coupled Plasma-Atomic Emission Spectrometry (ICP-AES) for Elemental Analysis of Petroleum Products and Lubricants
D7343 Practice for Optimization, Sample Handling, Calibration, and Validation of X-ray Fluorescence Spectrometry Methods for Elemental Analysis of Petroleum Products and Lubricants
D7372 Guide for Analysis and Interpretation of Proficiency Test Program Results
D7482 Practice for Sampling, Storage, and Handling of Hydrocarbons for Mercury Analysis
E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications
E77 Test Method for Inspection and Verification of Thermometers
E548 Guide for General Criteria Used for Evaluating Laboratory Competence (Withdrawn 2002)[3]
E882 Guide for Accountability and Quality Control in the Chemical Analysis Laboratory
E898 Test Method of Testing Top-Loading, Direct-Reading Laboratory Scales and Balances
E994 Guide for Calibration and Testing Laboratory Accreditation Systems General Requirements for Operation and Recognition (Withdrawn 2003)[3]
E1323 Guide for Evaluating Laboratory Measurement Practices and the Statistical Analysis of the Resulting Data
IEEE/ASTM SI 10 American National Standard for Metric Practice

2.2 *ISO Standards:*[4]
ISO 4259 Petroleum Products – Determination and Application of Precision Data in Relation to Methods of Test
ISO 9000 Quality Management Standards
ISO 17025 General Requirements for the Competence of Testing and Calibration Laboratories

## 3. Terminology

3.1 *Definitions:*

3.1.1 *bias, n*—a systematic error that contributes to the difference between a population mean of the measurements or test results and an accepted reference or true value. **D6299**

3.1.2 *calibration, n*—the determination of the values of the significant parameters by comparison with values indicated by a set of reference standards. **D6595**

3.1.3 *calibration standard, n*—a material with a certified value for a relevant property, issued by or traceable to a national organization such as NIST, and whose properties are known with sufficient accuracy to permit its use to evaluate the same property of another sample. **D6792**

3.1.4 *certificate of analysis (COA), n*—a document provided by a supplier to a customer giving results from analyses of required parameters to show how the material is in conformance with the product specifications or not.

3.1.5 *certified reference material, n*—a reference material one or more of whose property values are certified by a technically valid procedure, accompanied by a traceable certificate or other documentation which is issued by a certifying body. **D6792**

3.1.6 *control limits, n*—limits on a control chart that are used as criteria for signaling the need for action or for judging whether a set of data does or does not indicate a state of statistical control. **D6299**

3.1.7 *good laboratory practices, n*—guidelines for the management of laboratory experiments which are published by regulatory agencies or other recognized groups and are concerned with the organizational process and the conditions under which laboratory studies are planned, performed, monitored, recorded, and reported. **D6046**

3.1.8 *ICP-AES, n*—a high temperature discharge generated by passing an ionizable gas through a magnetic field induced by a radio frequency coil surrounding the tubes that carry gas. The light emitted by this process is measured at fixed wavelengths specific to elements of interest and converted to their concentrations in a sample.

3.1.9 *proficiency testing, n*—determination of a laboratory's testing capability by evaluating its test results in interlaboratory exchange testing or crosscheck programs. One example is the ASTM D02 Committee's proficiency testing programs in a wide variety of petroleum products and lubricants, many of which may involve more than a 100 laboratories. **D6792**

3.1.10 *quality control, n*—a planned system of activities whose purpose is to provide a level of quality that meets the needs of users; also the uses of such a system. **D6792**

3.1.11 *reference material, n*—a material with accepted reference value(s), accompanied by an uncertainty at a stated level of confidence for desired properties, which may be used for calibration or quality control purposes in the laboratory. Sometimes these may be prepared "in-house" provided the reference values are established using accepted standard procedures. **D6792**

3.1.12 *sigma, n*—a measure of variance; also called standard deviation.

3.1.13 *test performance index (TPI), n*—an approximate measure of a laboratory's testing capability, defined as the ratio of test method reproducibility to site precision. **D6792**

3.1.14 *traceable, n*—property of the result of a measurement or the value of a standard whereby it can be related to stated

[3] The last approved version of this historical standard is referenced on www.astm.org.
[4] Available from International Organization for Standardization (ISO), 1, ch. de la Voie-Creuse, CP 56, CH-1211 Geneva 20, Switzerland, http://www.iso.org.

references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties. D6792

3.1.15 *Z-score, n*—standardized and dimensionless measure of the difference between an individual result in a data set and the arithmetic mean of the data set, re-expressed in units of standard deviation of the data set (by dividing the actual difference from the mean by the standard deviation for the data set). D7372

3.2 *Acronyms:*

3.2.1 *ILCP*—ASTM D02 Committee proficiency testing program for interlaboratory cross-check program.

3.2.2 *ISO*—International Organization for Standardization based in Geneva, Switzerland.

3.2.3 *MSDS*—Material Safety Data Sheet.

3.2.4 *NIST*—National Institute of Standards and Technology based in Gaithersburg, MD.

3.2.5 *TMC*—ASTM Test Monitoring Center headquartered in Pittsburgh, PA.

## 4. Summary of Guide

4.1 Petroleum products and lubricants are regularly analyzed in refinery and plant laboratories using specified standard test methods. This guide provides management with a tool to assist in determining how well their laboratory is performing relative to established laboratory quality practices. A scoring scheme is suggested to assist the laboratory in identifying essential elements and to prioritize corrective actions.

## 5. Significance and Use

5.1 This guide can be used to evaluate the performance of a laboratory with regards to its adherence to established laboratory quality practices for the essential elements of managing a well-performing laboratory. The suggested scoring system can be used to identify the laboratory areas which need improvement in performance.

5.2 The assessment guide (Table 1) should be adjusted or modified to reflect the specific laboratory quality system that the laboratory follows. This guide is based on Practice D6792.

5.3 Similar but more generic schemes can be found in other ASTM standards such as Guide E548, E882, E994, and E1323. But this guide is the first one to attempt a numerical evaluation for the petroleum products and lubricants testing laboratories in the oil industry.

## 6. Scoring System

6.1 The suggested scoring system is given in Table 2. Laboratory areas to be self-assessed are arranged by rational groups. The areas and maximum aggregate scores for these are given in Table 2.

6.1.1 Usually safety practices in a laboratory would be covered by a separate organizational structure. However, given that safety should be an integral part of laboratory operations, brief and salient points from this aspect are included in this guide, but without a corresponding numerical score. A separate and more complete safety assessment would be desirable.

6.1.2 It is recognized that a laboratory's performance can be measured by other criteria such as customer satisfaction which involves other factors than those assessed here.

6.1.3 Judgment must be used by an assessor regarding whether the laboratory practice fully meets, partially meets, or does not meet the stated requirements. Thus, partial credit can be given depending upon the extent of compliance. A weight should be given to each question based on its importance since not all requirements are of the same critical nature. Thus, the assessor's observation associated with a specific to a question from Table 1 could be:

| | | |
|---|---|---|
| Yes | Good | All : Max Score |
| Partially | Satisfactory | Most : < Max Score |
| No | Poor | Some : Zero |
| N/A | N/A | None : N/A |

6.2 Most of the questions in Table 1 have been assigned a maximum of 10 or 20 rating points. Calibration and quality control sections carry the greatest total weight in the scoring since these two areas are perhaps the most important ones associated with producing accurate and precise data. All answers should be supported by available documents in the laboratory.

6.3 If a particular question does not apply to the activity of the laboratory in question, the maximum score possible should be reduced by the test score allocated to that item.

6.4 In many cases notes are provided at the end of the Table 1 to help the assessor to understand the intent of the questions.

6.5 For scoring purposes guide in Table 3 may be used. The laboratory may find it necessary to provide additional guidance for scoring when there is only a partial fulfillment of the requirement.

6.6 An assessment grade can be established as indicated in Table 4. The grade can be based on either a maximum possible score of 1300, or as a percentage of the maximum score for a modified scheme.

6.7 A laboratory or an assessor may use a different scoring system so long as it remains consistent with the essential elements cited in this Guide and weighting provided in Table 2.

6.8 Appendix X1 provides examples responses for some of the questions from Table 1 as it may relate to a hypothetical issue.

6.9 For some questions in this guide there is no quantitative answer. The assessor should use discretion in reviewing such answers. An assessor should particularly pay attention whether the laboratory response is adequate as a good practice.

6.10 The most critical areas for a laboratory's proficiency are test method compliance, calibration and statistical quality control. Thus, these three areas carry 650 points in this scheme (about 50 % of total).

## 7. Report

7.1 Laboratories and assessors should document their investigations. In the spirit of continuous improvement, laboratories are encouraged to share their findings from the investigations, and take steps to implement changes to improve the laboratory technical management.

**TABLE 1 Laboratory Assessment Guide to Good Laboratory Practices**

NOTE 1—When the sampling is within the control of the laboratory, documents other than quoted above may detail the sampling process (not only ASTM). For example, company procedures. These should be assessed as well to check compliance to industry standards and then to ensure the laboratory complies with these procedures.

NOTE 2—Samples, when received by the laboratory from customers, should question the integrity of the sample and make some reference on the final test report to the fact that tests were completed on samples as received. If sample container was not appropriate, a similar caveat should be included. Instruction/procedure on how to deal with these situations should be documented and the laboratory assessed against it.

NOTE 3—In-house instructions/operating procedures also need to be assessed where used/written for each test method.

| Number | Issue | Comment | Maximum Score |
|---|---|---|---|
| **1.0 PERSONNEL & TRAINING** | | | |
| 1.1 | Is there an organization chart available for the lab? | | / 5 |
| 1.2 | Is there a management approved policy, directive, endorsement or the like for the goals and operations of the laboratory? | | / 10 |
| 1.3 | Are job descriptions provided for all laboratory associates? | | / 5 |
| 1.4 | Are personnel qualification records including training maintained for all lab personnel? | | / 5 |
| 1.5 | Are technicians trained in all pertinent tests? | | / 10 |
| 1.6 | Are newly hired technicians trained by approved trainers? | | / 10 |
| 1.7 | Before new technicians perform routine analysis, are they evaluated to produce correct results by analyzing quality control standards? | | / 10 |
| 1.8 | Are technicians provided instrument training courses where necessary? | | / 10 |
| 1.9 | Are there back-up technicians for each test? | | / 5 |
| 1.10 | Is there a documented system for training and is it being followed? | | / 5 |
| 1.11 | Is there a system to recognize innovative ideas from technicians? | | / 5 |
| 1.12 | Are there quality improvement teams organized in the lab? | | / 5 |
| 1.13 | Are results of these teams' work readily available? | | / 5 |
| 1.14 | Does management review the work of these quality teams? | | / 5 |
| | | **TOTAL** | **/195** |
| **2.0 SAMPLE PREPARATION** | | | |
| 2.1[A] | Has a representative sample been obtained per Practice D4057 or D4177 protocols? | | / 5 |
| 2.2[B] | If the sample analysis involves LPG, does the sampling and storage follow instructions in Practice D6849? | | / 5 |
| 2.3[B] | Are LPG samples obtained according to Practice D3700 if using a floating piston cylinder? | | / 5 |
| 2.4[B] | Are LPG samples collected using manual method Practice D1265? | | / 5 |
| 2.5[B] | For the analysis of calcined petroleum coke, is Practice D6969 followed for sample preparation? | | / 5 |
| 2.6[B] | For collection of calcined petroleum coke, is Practice D6970 followed? | | / 5 |
| 2.7[B] | For ampulization and storage of gasoline is Practice D6596 being followed? | | / 5 |
| 2.8[B] | If volatility measurements are conducted on fuel samples, is Practice D5842 being followed? | | / 5 |
| 2.9[B] | Is Practice D4296 being followed in sampling of pitch? | | / 5 |
| 2.10[B] | Are aviation fuel samples stored in containers suitable according to Practice D4306 | | / 5 |
| 2.11[B] | Are gas turbine fuels handled in accordance with Practice D4418? | | / 5 |
| 2.12[B] | If in-service monitoring of fluids is done, is Practice D4378 being followed? | | / 5 |
| 2.13 | Are appropriate sample containers being used, checked for their integrity, cleanliness, and compatibility? | | / 5 |
| 2.14[B] | Is liquid sample mixing done using Practice D5854 protocol? | | / 5 |

**TABLE 1** *Continued*

| Number | Issue | Comment | Maximum Score |
|---|---|---|---|
| | | **TOTAL** | **/ 175** |
| **3.0 TEST METHOD COMPLIANCE** | | | |
| 3.1 | Are all test methods used in the lab available to all staff members? | | / 10 |
| 3.2 | Is a current site specific lab manual available? | | / 10 |
| 3.3 | Are the methods specified in the product specifications used for analysis? | | / 10 |
| 3.4 | Are all tests performed in the lab following the exact language of the written test methods? | | / 30 |
| 3.5[C] | Has the lab modified any of the specified test methods? | | ? |
| 3.6 | If so, has it been shown that the modified method gives results equivalent to those obtained by the specified method? | | / 20 |
| 3.7 | If a method is modified, is the customer informed about this change? | | / 5 |
| 3.8 | Are all tests specified in the product specifications performed? | | / 10 |
| 3.9 | If not, has approval been given in writing by the process leaders and/or customers not to carry out all tests? | | / 5 |
| 3.10 | Does the lab have appropriate instrument for the analysis? | | / 10 |
| 3.11 | Is an equipment inventory list available and is it up-to-date? | | / 5 |
| 3.12 | Are major instruments included in service contracts? | | / 5 |
| 3.13 | If not, has arrangement been made to get the instrument speedily repaired or use of a back-up lab for analysis? | | / 5 |
| 3.14 | Are logs kept of all downtime and service problems of all instruments? | | / 5 |
| 3.15 | Is there a system of backup in case of instrument failure? | | / 5 |
| 3.16 | Is there a long range plan of upgrading and replacing older instrumentation? | | / 5 |
| 3.17 | Has a maintenance schedule been established for all equipment in the lab? | | / 10 |
| 3.18 | Is a record of special or routine or preventive maintenance kept and is it up-to-date? | | / 5 |
| 3.19 | If a duplicate analysis is done for some reason, are the results checked to see that they meet Practice D3244 or ISO 4259 criteria for replicate testing? | | / 10 |
| 3.20 | In reporting the results, are protocols given in Practice E29 and IEEE/ASTM SI 10 standards followed regarding rounding of the test results? | | / 10 |
| | | **TOTAL** | **/ 175** |
| **4.0 CALIBRATION OF INSTRUMENTS** | | | |
| 4.1 | Are all pertinent calibration standards available in the lab? | | / 10 |
| 4.2 | Are they all stored in clean, safe, and contamination-free environment? | | / 10 |
| 4.3[B] | Is Practice D4307 followed for preparing liquid blends for use as analytical standards? | | / 5 |
| 4.4[B] | Is Practice D4051 used for the preparation of low-pressure gas blends? | | / 5 |
| 4.5 | Are the calibration standards traceable to national or international standards? | | / 5 |
| 4.6 | Where appropriate, are the values for reference materials produced by following the appropriate NIST or other standards issuing body certification protocol? | | / 10 |
| 4.7[B] | If used, are crude oil samples for mercury analysis handled as per Practice D7482? | | / 5 |
| 4.8 | Is relevant calibration done on all instruments before sample analysis? | | / 10 |
| 4.9 | Has a calibration schedule been established for lab equipment? | | / 5 |
| 4.10 | Are calibration procedures documented and available to all lab personnel? | | / 10 |

**TABLE 1** *Continued*

| Number | Issue | Comment | Maximum Score |
|---|---|---|---|
| 4.11 | If the calibration is done through a vendor, is it checked that it meets the requirements? | | / 10 |
| 4.12 | Are all calibration records maintained containing all necessary information? | | / 10 |
| 4.13 | When found to be out of calibration, is the instrument taken out of operation until the problem is fixed? | | / 10 |
| 4.14[B] | Was the performance of process stream analyzer, if used, validated using Practice D3764 or D6122, whichever is applicable? | | / 5 |
| 4.15[B] | If used, are moisture analyzers calibrated per Practice D4178? | | / 5 |
| 4.16[B] | If analyzers are used has a linear correlation been established between the analyzer and primary ASTM test methods using Guide D7235? | | / 15 |
| 4.17[B] | If metals are analyzed using ICP-AES, is Practice D7260 followed for ICP-AES operation? | | / 10 |
| 4.18[B] | If metals are analyzed using XRF, is Practice D7343 followed for XRF operation? | | / 10 |
| 4.19[B] | If balances are used for analytical purposes, are they being calibrated using Test Method E898? | | / 10 |
| 4.20[B] | If thermometric measuring devices are being used, are they calibrated using Test Method E77? | | / 10 |
| 4.21[B] | If timers are used for measurement purposes, are they being calibrated or verified using the relevant standard test method? | | / 10 |
| | | **TOTAL** | **/ 180** |
| **5.0 STATISTICAL QUALITY CONTROL** | | | |
| 5.1 | Is a QC program set up for each routine test performed in the lab, if pertinent? | | / 10 |
| 5.2 | Has a schedule of QC frequency been established and followed? | | / 10 |
| 5.3 | What is the frequency of QC testing? | | / 10 |
| 5.4[D] | Is a QC samples analyzed with each "batch" of samples? | | / 10 |
| 5.5 | Is a list available showing tests with QC program, standards, frequency, and the analyst responsible for running it? | | / 10 |
| 5.6 | Are control charts used in the lab for all appropriate tests? | | / 10 |
| 5.7 | Are the control charts being plotted in real time? | | / 10 |
| 5.8[E] | Are the control charts plotted manually or electronically? | | / 5 |
| 5.9[F] | Are the control charts plotted by technicians or supervisors? | | / 10 |
| 5.10[G] | Are the control charts displayed near the test stations or filed in cabinets? | | / 5 |
| 5.11 | Are all relevant data recorded on the QC charts (e.g., analyst name or initial, date, numerical value, etc.)? | | / 10 |
| 5.12 | Are the values reported on the control chart consistent with the reporting resolution in the test method? | | / 5 |
| 5.13 | Are the mean ± standard deviation values assigned to the QC sample based on at least 20 replicate measurements? | | /10 |
| 5.14 | If starting the chart with 15 or less data points, is it revised after obtaining 20 -30 data points? (D6299) | | /10 |
| 5.15[H] | How many statistical run rules are used for control charts? | | / 10 |
| 5.16 | Have any run rules been violated? | | / 10 |
| 5.17 | What action was taken in such cases? Is the action taken documented? | | / 0 –10 |
| 5.18 | If a QC data point is found to be out-ofcontrol, are the samples analyzed between the last good QC data point and the first bad data point reanalyzed? | | / 10 |
| 5.19 | Are appropriate QC samples being used for specific tests and relevant to the matrices being analyzed? | | / 5 |
| 5.20 | Are QC samples prepared from stable, homogenous and well-characterized materials similar to the samples being analyzed? | | / 5 |
| 5.21[I] | Is the same material used both for calibration and QC? | | / 10 |
| 5.22 | Is QC material available in sufficiently large quantities? | | / 10 |

**TABLE 1** *Continued*

| Number | Issue | Comment | Maximum Score |
|---|---|---|---|
| 5.23 | Is a program in place to replace the depleting QC material with a new lot of material? | | / 10 |
| 5.24 | Is action taken when the control chart displays an upset? | | / 10 |
| 5.25 | Is the action taken noted on the control chart? | | / 10 |
| 5.26 | Does it appear that the corrective action taken has improved the chart? | | / 5 |
| 5.27 | Does every test have a control chart? -If not, why not? | | / 10 |
| 5.28 | Are sigmas calculated and updated from the control chart data? (D6299) | | / 10 |
| 5.29 | Are they equivalent or better than the ones quoted in the standard test methods? | | / 10 |
| 5.30 | If TPIs calculated are below the expected level in the standard methods, is any action taken to improve this situation? | | / 10 |
| 5.31[J] | Are the sample results reported to the customers if the QC analysis is found to be out of control? | | / 0 – 10 |
| 5.32 | Does the laboratory use random and/or blind testing to evaluate the performance? | | / 5 – 0 |
| 5.33 | Are procedures in place to revise or replace the QC charts with new ones? (Practice D6792) | | / 10 |
| | | **TOTAL** | **/ 295** |
| **6.0 QUALITY MANAGEMENT PROCESS** | | | |
| 6.1 | Does the laboratory have or is it a part of site ISO 9000 registration? | | / 10 |
| 6.2 | Does the laboratory have ISO 17025 accreditation? | | / 10 |
| 6.3 | Does the laboratory have any other quality accreditation? Specify. | | / 10 |
| 6.4 | Is there a specific quality manager (or other designation) overseeing the quality activities in the laboratory? | | / 10 |
| 6.5 | Is there a written quality manual? | | / 10 |
| 6.6 | Are all staff trained in the quality principles and manual? | | / 10 |
| 6.7 | Is a sample Analysis schedule available? | | / 10 |
| 6.8 | Are all test method files up-to-date with current version? | | / 10 |
| 6.9 | Does the laboratory conduct periodic internal audits to check that the expected quality systems are working? | | / 20 |
| 6.10 | Are audits of test methods conducted to confirm adherence to documented test methods? | | / 20 |
| 6.11 | Are the results promptly documented and action, if necessary, taken to correct the deficiencies? | | / 10 |
| 6.12 | If deficiencies are observed in external audits (e.g., ISO 9000), are prompt corrective actions taken and documented? | | / 20 |
| 6.13 | Is there a procedure for following up on any customer complaints and documenting the results? | | / 10 |
| 6.14 | Has the laboratory established continuous improvement goal and teams to implement them? | | / 10 |
| 6.15 | Are the activity reports of such teams available showing continuous improvement? | | / 10 |
| | | **TOTAL** | **/180** |
| **7.0 PARTICIPATION IN PROFICIENCY TESTING** | | | |
| 7.1 | Does the laboratory take part in pertinent round robins or cross-checks? | | / 10– 0 |
| 7.2 | What is the frequency of the laboratory's participation in such round robins? | | ? |
| 7.3 | How many outliers did the lab have in the last three proficiency test programs?<br>- How many tests were found with consecutive outliers in them? | | /0 –10 |
| 7.4 | What corrective actions, if any, are taken to follow up on the unsatisfactory proficiency testing results? | | /0 – 10 |
| 7.5 | Does the lab participate in ASTM ILCP cross checks? | | / 0 – 10 |
| 7.6 | Are the Z-scores assigned to lab results satisfactory? | | / 10 |

**TABLE 1** *Continued*

| Number | Issue | Comment | Maximum Score |
|---|---|---|---|
| 7.7[B] | Does the lab take part in TMC surveillance panel analysis? | | / 0 – 10 |
| 7.8[B] | If the lab takes part in TMC surveillance, how well was the lab rated by TMC? / | | NA-10 |
| | | **TOTAL** | **/ 70** |
| **8.0 INFORMATION MANAGEMENT SYSTEM** | | | |
| 8.1 | Are all samples submitted to lab logged in before the analysis? | | / 10 |
| 8.2 | Does each submitted sample receive an unique identification number? | | / 5 |
| 8.3 | Does the system produce backlog and turnaround time reports? | | / 5 |
| 8.4 | Are all analyzed samples logged out? | | / 5 |
| 8.5 | Are certificates of analysis printed out when the analysis is complete? | | / 5 |
| 8.6 | Do all COAs have all necessary information (e.g., analyst name or initials, day/time, sample identification name or number, test method used, numerical or other results)? | | / 10 |
| 8.7 | Does the system plot quality control charts? | | / 10 |
| 8.8 | Does the system flag out-of-statistical control data? | | / 10 |
| 8.9 | Are all staff members familiar with the IMS? | | / 10 |
| 8.10 | Does the lab have a documented system for sample retention? | | / 5 |
| 8.11 | Are all data (e.g., weights, volumes, dilutions, analyst, results, etc.) produced in the lab permanently recorded? | | / 10 |
| 8.12 | Are all required records kept for required period of time? | | / 5 |
| 8.13 | Is there a document control system established in the lab? | | / 5 |
| 8.14 | If some analyses are done by subcontracting to another lab is this clearly indicated in the COA? | | / 5 |
| 8.15 | Before using an outside lab for analysis, has it been audited for its suitability to do the analysis? | | / 5 |
| 8.16 | Are all various records kept in a secure place with only authorized personnel being admitted therein? | | /5 |
| | | **TOTAL** | **/ 110** |
| **9.0 NON-CONFORMANCE AND CORRECTIVE ACTIONS** | | | |
| 9.1 | Does the lab have a documented procedure for corrective actions and non-conformances, including Corrective Action Report (CAR)? Were they documented? Approximate number of CARs per year? | | / 20 |
| 9.2 | What items are addressed by the corrective action system? | | / 10 |
| 9.3 | Are roles and responsibilities for initiation, investigation, root cause analysis, corrective action, review, and approval identified and documented? | | / 20 |
| 9.4 | Is reviewer and/or approver separate from the initiator/investigator if possible? | | / 10 |
| 9.5 | Is there a target date for CAR closure? | | / 10 |
| 9.6 | Are CARs closed in a timely manner? | | / 10 |
| 9.7 | Do CAR forms have all appropriate signatures? | | / 10 |
| 9.8 | How does the lab tract status of active CARs? | | / 10 |
| 9.9 | Activities that demonstrate review or continuous improvement. | | / 20 |
| | | **TOTAL** | **/ 120** |
| **10.0 SAFETY PRACTICES** | | | |
| 10.1 | Are all lab personnel trained in safety and emergency procedures? | | |
| 10.2 | Do all personnel have and use personal protective equipment (e.g., safety glasses, lab coats, gloves, safety shoes, etc.)? | | |
| 10.3 | Are fire extinguishers, safety showers, eye washers working properly? | | |
| 10.4 | Is there a regularly scheduled safety inspection? | | |
| 10.5 | Are chemicals and solvents stored in proper safety cabinets? | | |
| 10.6 | Are hoods properly ventilated? | | |
| 10.7 | Are gas cylinders properly secured and safety valves inspected? | | |

**TABLE 1** *Continued*

| Number | Issue | Comment | Maximum Score |
|---|---|---|---|
| 10.8 | Are MSDS sheets or other safety information on chemicals in the lab readily available? | | |
| 10.9 | Are used chemicals and samples properly disposed off in accordance with government regulations? | | |
| 10.10 | Does the lab have a clean and neat appearance? | | |
| 10.11 | Does the lab environment meet regulations regarding temperature range, dust, noise, radiation, drafts, etc.? | | |

[A] In some organizations, the sampling activity may be outside the control of the laboratory unit. For some products these standards may not be applicable.
[B] If these specific products are not analyzed in the lab, these questions do not apply.
[C] If the lab has not modified any of the test methods, credit should be given for that. If the laboratory has modified test methods, questions 3.5 and 3.6 would be pertinent.
[D] At least 5 % of the samples analyzed should be QCs. However, in each batch QC should accompany the samples.
[E] This is an informational question. Either answer is satisfactory.
[F] Control charts should be plotted by the person who performs the analysis.
[G] It is preferable that the charts be displayed near the test station, if possible.
[H] Ideally 4 to 5 run rules should be used. See Practice D6792 for details.
[I] The same material should not be used for both calibration and QC.
[J] The sample results should not be reported to the customers if QC is out of control.

**TABLE 2 Suggested Scoring System**

| Section in Table 1 | Area | Maximum Points | Weighted (% of Total Points)[A] |
|---|---|---|---|
| 1. | Personnel and Training | 95 points | 7.0 |
| 2. | Sample Preparation | 75 points | 6.0 |
| 3. | Test Method Compliance | 175 points | 10.0 |
| 4. | Instrument Calibration | 180 points | 15.0 |
| 5. | Statistical Quality Control | 295 points | 25.0 |
| 6. | Quality Management Process | 180 points | 15.0 |
| 7. | Proficiency Testing Participation | 70 points | 5.0 |
| 8. | Information Management | 110 points | 8.0 |
| 9. | Non-Conformances and Corrective Actions | 120 points | 9.0 |
| 10. | Safety Practices | NA | |
| | **Total** | **1300 points** | |

[A] Approximate.

**TABLE 3 Scoring Guide**

| Requirement | Score |
|---|---|
| Documents fully meet the requirements | Max Score 5, 10, or 20 |
| Partially meets the requirements | ¼, ½, or ¾ × Max Score |
| Does not meet the requirements | 0 |

**TABLE 4 Assessment Grade**

| Score | % Range | Compliance Status |
|---|---|---|
| 1200–1300 | 92–100 | Meets requirements (Excellent) |
| 1040–1200 | 80–92 | Some improvement needed (Above Average) |
| 715–1040 | 55–80 | Substantial improvement needed (Below Average) |
| < 715 | < 55 | Implementation is minimal (Unsatisfactory) |

## 8. Keywords

8.1 calibration; calibration standards; certificates of analysis; laboratory manual; proficiency testing; quality control; quality control charts; quality control standards; safety practices; sampling; significant figures; statistical quality control; test methods; test performance index; training; Z-score

# APPENDIX

## X1. EXAMPLES OF NONCONFIRMATORY ANALYSIS

X1.1 Some typical examples are given in Table X1.1 for illustration purposes since they represent situations that can occur in a laboratory. These examples are not meant to be comprehensive or all-inclusive.

**TABLE X1.1 Typical Examples**

| | Problem | Correct Resolution |
|---|---|---|
| 1. | The test method requires use of an Erlenmeyer flask. The laboratory interprets this to mean use any container with a graduated scale for measuring the product. The lab should have:<br><br>– Discussed with ASTM about the interpretation,<br><br>– Used the literal requirement from the original method,<br><br>– The lab decision was correct for measuring since graduated flask has the measurements too. | The first two are the correct answers. Always use the literal wording of the test method and consult with ASTM, when in doubt. |
| 2. | The laboratory traditionally uses an AAS instrument for metal analysis. Recently, it purchased an ICP-AES instrument. After the vendor installed the instrument, and lab was satisfied that it was running properly.<br><br>I. The laboratory can use the ICP-AES data for product analysis and COA generation since the instrument appears to run o.k.<br><br>II. The laboratory discussed this with the customers, and they were enthusiastic about the modern instrument and ICP-AES COAs were fine with them.<br><br>III. The laboratory collected at least 12 data points on one or more days with a CRM and got proper approval from product managers and customers before using the new method. | The correct answer is III. It is always a good idea to statistically prove that the new instrument performs as well as the older one and gives equivalent results. |
| 3. | The laboratory uses Test Method D892 foam test. It requires cleaning the diffusers successively with different solvents.<br><br>IV. The lab has seen in the past that petroleum distillate can be substituted for xylene in other test methods, so they use xylene instead of petroleum distillates in the foam test.<br><br>V. The solvents suggested in the method are used in the exact sequence.<br><br>VI. The laboratory experiments with alternate solvents, documents that the easily available alternates work just as well, and start using the modified procedure. | The correct answer is V. Always follow the test method exactly. If there is a better way to do the test, provide the data to ASTM and revise the method. |
| 4. | Saponification number Test Method D94 takes much too long, holding up the product shipment. The laboratory chemist developed an elegant yet extremely quick alternate test.<br><br>VII. Multiple samples were analyzed multiple times by the proposed method. It gave data well within the product specifications. Based on this, the laboratory authorized the use of the new method for product certification, and informed the plant manager and the customer that the lab was now using a better test method.<br><br>VIII. The laboratory conducted side-by-side both tests on a series of plant samples multiple times and sent the data to a statistician for nonbias confirmation.<br><br>IX. The laboratory ran side-by-side both tests on a series of plant samples multiple times, statistically analyzed the data, and on finding both tests technically equivalent, documented this in the site ISO manual, thus authorizing its use in product certification. | The correct answer is IX. Always use protocol of Practice D3244 to implement changes. |

**TABLE X1.1** *Continued*

| | Problem | Correct Resolution |
|---|---|---|
| 5. | A new flash point instrument is purchased for the lab. The lab should:<br><br>– Run at least 12 data points collected on two or more days with a CRM and study the data to determine if the instrument is in control and if it is use the instrument for sample analysis;<br><br>– Collect at least 12 data points on both old (if still working) and the new instrument. Compare the bias of the two, and if found equivalent, use the new instrument for routine analysis. | The second is the correct answer. Always follow the protocol of Practice D3244 for implementing changes. |
| 6. | The plant unit supervisor knows by experience that the Karl Fischer water (Test Method D6304) data coming from the lab is unreliable. A result of 0.50 m% water was reported by the lab in today's sample.<br><br>X. The supervisor asked the laboratory to reanalyze the sample. They report 0.45 m% water. The supervisor dries the batch and sends in a new sample for analysis. This time the analysis is 0.1 m% and within the product specifications. The product is released.<br><br>XI. The reanalysis on the first sample comes as 0.1 m% and within product specifications. The unit supervisor knew the first analysis had to be wrong. Based on the second analysis the product is released.<br><br>XII. Since the water analysis is always unreliable, the lab and the unit decide not to worry about it, and release the product since the rest of the analyses are within specifications. | All responses are wrong. The protocol given in Practice D3244 should be used for deciding which result to report. |
| 7. | The laboratory's productivity falls because the calibration needs to be done too often in ICP-AES Test Method D5185.<br><br>XIII. Calibrations are done each time the plasma is lit irrespective of productivity.<br><br>XIV. There is ample data to show that the frequent calibration is unnecessary; hence, the lab chemist decides to calibrate the instrument only once a week.<br><br>XV. The laboratory writes their new protocol in their site ISO manual and is endorsed by the site manager for use. | XIII is the correct answer. Test Method D5185 and all other ICP-AES test methods always require recalibrations after shutting down the plasma and restarting. |
| 8. | After performing the analysis, the technician noted while plotting the data that the point was outside the three sigma limits (action line). He/she should:<br><br>XVI. Immediately remove/isolate the out-of-control instrument, determine the root cause, take the necessary actions to bring the instrument back into control, review all previous analysis performed on the instrument since the last QC analysis that was in control to determine the validity of the results.<br><br>XVII. Immediately remove/isolate the out of- control instrument, determine the root cause, take necessary action to bring the instrument back into control and notify others in the lab that the instrument is back in control.<br><br>XVIII. Immediately remove/isolate the out-of-control instrument, determine the root cause, take necessary corrective action to bring the instrument back into control and rerun the QC analysis. | The correct answer is XVI. Good lab practice requires stopping the use of the instrument until the perceived problem is solved. |

**TABLE X1.1** *Continued*

| | Problem | Correct Resolution |
|---|---|---|
| 9. | Since the calibrations are always in control, the laboratory wishes to reduce QC sample analysis for Test Method D445 kinematic viscosity determination to once a week.<br><br>XIX. Once a week QC looks perfect, so this is established as the new lab protocol.<br><br>XX. The laboratory uses one QC sample every 20 real samples; but submits long range data to statistician for possible reduced QC testing.<br><br>XXI. No customer has ever complained about the viscosity data; so why waste time running a QC each day? | The correct answer is XX. It is a good lab practice to have all samples in a batch of analysis accompanied by a QC sample. |