Designation: D6792 – 17

An American National Standard

Standard Practice for Quality Management Systems in Petroleum Products, Liquid Fuels, and Lubricants Testing Laboratories[1]

This standard is issued under the fixed designation D6792; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope*

1.1 This practice covers the establishment and maintenance of the essentials of a quality management system in laboratories engaged in the analysis of petroleum products, liquid fuels, and lubricants. It is designed to be used in conjunction with Practice D6299.

NOTE 1—This practice is based on the quality management concepts and principles advocated in ANSI/ISO/ASQ Q9000 standards, ISO/IEC 17025, ASQ Manual,[2] and ASTM standards such as D3244, D4182, D4621, D6299, D6300, D7372, E29, E177, E456, E548, E882, E994, E1301, E1323, STP 15D,[3] and STP 1209.[4]

1.2 *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 requirements prior to use.*

1.3 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[5]

D86 Test Method for Distillation of Petroleum Products and Liquid Fuels at Atmospheric Pressure

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

D4057 Practice for Manual Sampling of Petroleum and Petroleum Products

D4182 Practice for Evaluation of Laboratories Using ASTM Procedures in the Sampling and Analysis of Coal and Coke (Withdrawn 2010)[6]

D4621 Guide for Quality Management in an Organization That Samples or Tests Coal and Coke (Withdrawn 2010)[6]

D5191 Test Method for Vapor Pressure of Petroleum Products (Mini Method)

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

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

D6300 Practice for Determination of Precision and Bias Data for Use in Test Methods for Petroleum Products and Lubricants

D6617 Practice for Laboratory Bias Detection Using Single Test Result from Standard Material

D6708 Practice for Statistical Assessment and Improvement of Expected Agreement Between Two Test Methods that Purport to Measure the Same Property of a Material

D7372 Guide for Analysis and Interpretation of Proficiency Test Program Results

E29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

E177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods

E456 Terminology Relating to Quality and Statistics

E548 Guide for General Criteria Used for Evaluating Laboratory Competence (Withdrawn 2002)[6]

E882 Guide for Accountability and Quality Control in the Chemical Analysis Laboratory

E994 Guide for Calibration and Testing Laboratory Accreditation Systems General Requirements for Operation and

[1] This practice is under the jurisdiction of ASTM Committee D02 on Petroleum Products, Liquid Fuels, and Lubricants and is the direct responsibility of Subcommittee D02.94 on Coordinating Subcommittee on Quality Assurance and Statistics.

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[2] "Quality Assurance for The Chemical and Process Industries: A Manual of Good Practices," 1987, available from American Society for Quality (ASQ), 600 N. Plankinton Ave., Milwaukee, WI 53203. www.asq.org.

[3] ASTM STP 15D, *ASTM Manual on Presentation of Data and Control Chart Analysis*, ASTM International, W. Conshohocken, PA.

[4] ASTM STP 1209, *ASTM Manual on Total Quality Management*, ASTM International, W. Conshohocken, PA.

[5] 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.

[6] The last approved version of this historical standard is referenced on www.astm.org.

*A Summary of Changes section appears at the end of this standard

Recognition (Withdrawn 2003)[6]
E1301 Guide for Proficiency Testing by Interlaboratory Comparisons (Withdrawn 2012)[6]
E1323 Guide for Evaluating Laboratory Measurement Practices and the Statistical Analysis of the Resulting Data
2.2 *ISO Standards:*[7]
ISO Guide 30 Terms and Definitions Used in Connection with Reference Materials
ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories
ISO 4259 Petroleum Products—Determination and Application of Precision Data in Relation to Methods of Test
ANSI/ISO/ASQ Q9000 Quality Management System Standards
2.3 *Other Standards:*
40 CFR 80 Regulation of Fuels and Fuel Additives[8]

3. Terminology

3.1 *Definitions:*

3.1.1 *accepted reference value, ARV, n*— a value that serves as an agreed upon reference for comparison, and which is derived as: (*1*) a theoretical or established value, based on scientific principles, (*2*) an assigned value, based on experimental work of some national or international organization such as the U.S. National Institute of Standards and Technology (NIST), or (*3*) a consensus value, based on collaborative experimental work under the auspices of a scientific or engineering group. **E456**

3.1.2 *accuracy, n*—the closeness of agreement between a test result and an accepted reference value. **E456**

3.1.3 *audit, n*—a systematic examination of a laboratory's quality management system documentation and related activities by an internal or external team to determine conformance to the applicable quality management system standard, such as described in this practice.

3.1.4 *bias, n*—the difference between the population mean of the test results and an accepted reference value. **E456**

3.1.5 *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.

3.1.6 *certified reference material, CRM, 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. **ISO Guide 30**

3.1.7 *measurand, n*—the measurable quantity subject to measurement.

3.1.8 *outlier, n*—a result far enough in magnitude from other results so as to be considered not a part of the set. **D6300**

3.1.9 *precision, n*—the closeness of agreement between test results obtained under prescribed conditions. **E456**

3.1.10 *proficiency testing, n*—determination of a laboratory's testing capability by evaluating its test results in interlaboratory exchange testing or crosscheck programs.

3.1.10.1 *Discussion*—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 hundred laboratories.

3.1.11 *quality assurance (QA), n*—a system of activities, the purpose of which is to provide to the producer and user of a product, measurement, or service the assurance that it meets the defined standards of quality with a stated level of confidence.

3.1.11.1 *Discussion*—Quality assurance includes quality planning and quality control.

3.1.12 *quality control (QC), 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.

3.1.13 *quality control sample (QC sample), n*— for use in quality assurance program to determine and monitor the precision and stability of a measurement system; a stable and homogenous material having physical or chemical properties, or both, similar to those of typical samples tested by the analytical measurement system. The material is properly stored to ensure sample integrity, and is available in sufficient quantity for repeated long-term testing. **D6299**

3.1.14 *reference material (RM), 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.

3.1.14.1 *Discussion*—Sometimes these may be prepared "in-house" provided the reference values are established using accepted standard procedures.

3.1.15 *repeatability, n*—the quantitative expression of the random error associated with a single operator in a given laboratory obtaining repetitive results with the same apparatus under constant operating conditions on identical test material. It is defined as the difference between two such results at the 95 % confidence level. **D6300**

3.1.16 *reproducibility, n*—a quantitative expression of the random error associated with different operators using different apparatus, and so forth, each obtaining a single result on an identical test sample when applying the same method. It is then defined as the 95 % confidence limit for the difference between two such single and independent results. **D6300**

3.1.17 *site precision (R'), n*—the value below which the absolute difference between two individual test results obtained under site precision conditions may be expected to occur with a probability of approximately 0.95 (95 %). It is defined as 2.77 times the standard deviation of results obtained under site precision conditions. **D6299**

3.1.18 *site precision conditions, n*—conditions under which test results are obtained by one or more operators in a single site location practicing the same test method on a single measurement system using test specimens taken at random

[7] Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036, http://www.ansi.org.
[8] Available from U.S. Government Printing Office, Superintendent of Documents, 732 N. Capitol St., NW, Washington, DC 20401-0001, http://www.access.gpo.gov.

from the same sample of material over an extended period of time spanning at least a 15 day interval. D6299

3.1.19 *traceability, n*—property of the result of a measurement or the value of a standard whereby it can be related to stated references, usually national or international standards, through an unbroken chain of comparisons all having stated uncertainties.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *precision ratio (PR), n*—an estimate of relative magnitude of repeatability and reproducibility. The PR for a given standard test method can provide information on the relative significance between variation caused by different operators and laboratories compared to a single operator in a laboratory performing the standard test method.

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

3.3 *Acronyms:*

3.3.1 *NIST*—National Institute of Standards and Technology, Gaithersburg, MD.

4. Significance and Use

4.1 A petroleum products, liquid fuels, and lubricants testing laboratory plays a crucial role in product quality management and customer satisfaction. It is essential for a laboratory to provide quality data. This document provides guidance for establishing and maintaining a quality management system in a laboratory.

4.1.1 The word 'customer' can refer to both customers internal and external to the laboratory or organization.

5. General Quality Requirements for the Laboratory

5.1 Establishment and maintenance of a quality management system shall include stated objectives in the following areas: a laboratory's adherence to test method requirements, calibration and maintenance practices, and its quality control program. Laboratory quality objectives should encompass the laboratory's continuous improvement goals as well as meeting customer requirements.

5.2 Management shall appoint a representative to implement and maintain the quality management system in the laboratory.

5.3 Laboratory management shall review the adequacy of the quality management system and the activities of the laboratory for consistency with the stated quality objectives at least annually.

5.4 The quality management system shall have documented processes for:

5.4.1 Sampling and sample management (see Section 6),

5.4.2 Data and record management (see Section 7),

5.4.3 Control and implementation of test methods (see Section 8),

5.4.4 Equipment calibration and maintenance (see Section 9),

5.4.5 Quality control (see Section 10),

5.4.6 Audits and proficiency testing (see Section 11),

5.4.7 Corrective and preventive action (see Section 13),

5.4.8 Handling of customer complaints (see Section 14),

5.4.9 Ensuring that procured services and materials meet the contracted requirements, and

5.4.10 Ensuring that personnel are adequately trained to obtain quality results (see Section 15).

6. Sampling and Sample Management

6.1 When samples are obtained by laboratory staff, these samples shall be obtained in accordance with applicable industry standards.

6.2 The elements of sample management shall include at a minimum:

6.2.1 Procedures for unique identification of samples submitted to the laboratory.

6.2.2 Criteria for sample acceptance.

6.2.3 Procedures for sample handling.

6.2.3.1 In cases where industry standards for sample handling (for example, Practoce D5854) are applicable and referenced within industry standard test methods, they shall be utilized.

6.2.4 Procedures for sample storage and retention. Items to consider when creating these procedures include:

6.2.4.1 Applicable government—local, state, or national—regulatory requirements or customer contract agreements.

6.2.4.2 Type of sample containers required to preserve the sample,

6.2.4.3 Control of access to the retained samples to protect their validity and preserve their original integrity,

6.2.4.4 Storage conditions,

6.2.4.5 Required safety precautions, and

6.2.4.6 Customer requirements.

6.2.5 Procedures for sample disposal in accordance with applicable government regulatory requirements.

NOTE 2—This may be handled through a separate chemical hygiene or waste disposal plan.

7. Data and Record Management

7.1 *Reports of Analysis:*

7.1.1 The work carried out by a laboratory shall be covered by a certificate or report that accurately and unambiguously presents the test results and all other relevant information.

NOTE 3—This report may be an entry in a Laboratory Information Management System (LIMS) or equivalent system.

7.1.2 The following items are suggested for inclusion in laboratory reports:

7.1.2.1 Name and address of the testing laboratory,

7.1.2.2 Unique identification of the report (such as serial number) on each page of the report including version identification if the report has been updated,

NOTE 4—Occasionally, a report may be updated and a version identification will enable one version of the report to be distinguished from another. This is necessary to determine which report version was the original and which is the most current. Simple conventions such as last updated date are useful means of version identification.

7.1.2.3 Name and address of the customer,

7.1.2.4 Order number,

7.1.2.5 Description and identification of the test sample including comments on the sample condition particularly if it is likely to have an adverse effect on the sample integrity,

7.1.2.6 Date of receipt of the test sample and date(s) of performance of test, as appropriate,

7.1.2.7 Identification of the test specification, method, and procedure,

7.1.2.8 Description of the sampling procedure, where relevant,

7.1.2.9 Any deviations, additions to or exclusions from the specified test requirements, and any other information relevant to a specific test,

7.1.2.10 Disclosure of any nonstandard test method or procedure utilized,

7.1.2.11 Measurements, examinations, and derived results including units of measurement, supported by tables, graphs, sketches, and photographs as appropriate, and any failures identified,

7.1.2.12 Minimum-maximum product specifications, if applicable,

7.1.2.13 A statement of the measurement uncertainty (where relevant or required by the customer),

7.1.2.14 Any other information which might be required by the customer,

7.1.2.15 A signature and job title of person(s) accepting technical responsibility for the test report and the date of issue, and

7.1.2.16 A statement on the laboratory policy regarding the reproduction of test reports.

7.1.3 Items actually included in laboratory reports should be specified by laboratory management or agreements with customers, or both.

7.1.4 Procedures for corrections or additions to a test report after issue shall be established.

7.2 *Reporting and Rounding the Data:*

7.2.1 The reporting requirements specified in the test method or procedure shall be used (unless specifically required otherwise by the customer or applicable regulations).

7.2.2 If rounding is performed, the rounding protocol of Practice E29 should be used unless otherwise specified in the method, procedure, or governing specification.

7.3 *Records of Calibration and Maintenance:*

7.3.1 Procedures shall be established for the management of instrument calibration records. Such records usually indicate the instrument calibrated, method or procedure used for calibration, the dates of last and next calibrations, the person performing the calibration, the values obtained during calibration, permissible tolerances, and the nature and traceability (if applicable) of the calibration standards (that is, certified values). Records may be electronic.

7.3.2 Procedures shall be established for the management of instrument maintenance records. Such records usually indicate the instrument maintained, description of the maintenance performed, the dates of last and next maintenance, and the person performing the maintenance. Records may be electronic.

NOTE 5—For instruments that require calibration, calibration and maintenance records may be combined.

7.4 *Quality Control (QC) Testing Records:*

7.4.1 The laboratory shall have documented procedures for creating and maintaining records for analysis of QC samples. It is recommended that such records include the sample name and source, the test(s) for which it is to be used, the assigned values and their uncertainty where applicable, and values obtained upon analysis. Additionally, it is recommended that the receipt date or date put into active QC use in the laboratory be documented, along with the expiration date (if applicable).

7.4.2 Procedures for retaining completed control charts should be established. It is recommended that these records include the date the control charts were changed and the reason for the change.

7.5 *Record Retention:*

7.5.1 The record system should suit the laboratory's particular circumstances and comply with any existing regulations and customer requirements.

7.5.2 All data shall be maintained according to laboratory, company, customer, or regulatory agency requirements, or a combination thereof.

7.5.3 Procedures for retaining records, including electronic, of all original observations, calculations and derived data, calibration records, and final test reports for an appropriate period shall be established. The records for each test should contain sufficient information to permit satisfactory replication of the test and recalculation of the results.

7.5.4 The records shall be held in a safe and secure storage. A system shall exist that allows locating the required documents in a reasonable period of time.

7.6 *Document Control*—A document control process shall be established. As a minimum, for laboratory procedures (for example, standard operating procedures, SOPs) and laboratory test procedures (if used), a document control process shall address version/revision identification and management approval.

8. Test Methods

8.1 The laboratory shall have documented test methods and procedures for performing the required tests.

8.2 The test methods that are stated in the product specifications or agreed upon with customers shall be used for sample analysis.

8.3 These test methods shall be maintained up-to-date and be readily available to the laboratory staff.

NOTE 6—Some specifications or regulations may require the use of a specific year version of a test method.

8.4 The laboratory shall have procedures for the approval, documentation, and reporting of deviations from the test method requirements or the use of alternative methods.

9. Equipment Calibration and Maintenance

9.1 *Calibration:*

9.1.1 Procedures shall be established to verify the measuring and testing equipment in-calibration status, at a scheduled frequency.

9.1.2 Items to consider when creating these procedures include:

9.1.2.1 Records of calibration and maintenance (see 7.3),

NOTE 7—The calibration verification frequency and protocol may vary with the instrument type and its frequency of use.

9.1.3 Traceability to national or international standards,

NOTE 8—Where the concept of traceability to national or international standards of measurement is not applicable, the testing laboratory shall provide satisfactory evidence of test result accuracy (for example, by participation in a program of interlaboratory comparisons).

9.1.4 Requirements of the test method or procedure,

9.1.5 Customer requirements, and

9.1.6 Corrective actions (see Section 13).

9.2 *Maintenance:*

9.2.1 Laboratories shall have procedures to ensure that measuring and testing equipment is properly maintained,

9.2.2 An inventory of measuring and testing equipment is established and maintained,

9.2.3 A reliability strategy is developed which may include the following:

9.2.3.1 Equipment age,

9.2.3.2 Back-up equipment justification based on utilization,

9.2.3.3 Critical spare parts, and

9.2.4 A maintenance schedule is established and followed.

9.3 The performance of apparatus and equipment used in the laboratory but not calibrated in that laboratory (that is, pre-calibrated, vendor supplied) should be verified by using a documented, technically valid procedure at periodic intervals.

9.4 Calibration standards shall be appropriate for the method and characterized with the accuracy demanded by the analysis to be performed. Quantitative calibration standards should be prepared from constituents of known purity. Use the primary calibration standards or CRMs specified or allowed in the test method.

9.4.1 Where appropriate, values for reference materials should be produced following the certification protocol used by NIST[9,10,11] or other standards issuing bodies, and, should be traceable to national or international standard reference materials, if required or appropriate.

9.4.2 The materials analyzed in proficiency testing programs meeting the requirements of Practice D6300 or ISO 4259 may be used as reference materials, provided no obvious bias or unusual frequency distribution of results are observed. The consensus value is most likely the value closest to the true value of this material; however, the uncertainty attached to this mean value will be dependent on the precision and the total number of the participating laboratories.

9.5 The laboratory shall establish procedures for the storage of reference materials in a manner to ensure their safety, integrity, and protection from contamination (see 6.2.4).

9.6 Records of instrument calibration shall be maintained (see Section 7).

9.7 If an instrument is found to be out of calibration, and the situation cannot be immediately addressed, then the instrument shall be taken out of operation and tagged as such until the situation is corrected (see Section 13).

10. Quality Control

10.1 *Quality Control Practices:*

10.1.1 Quality control practices shall be established to assess applicable test methods used by the laboratory.

10.1.2 Use of appropriate quality control charts or other quality control practices shall be established for each test method performed by the laboratory unless specifically excluded (see Practice D6299). Document cases where quality control practices are not employed and include the rationale.

10.1.3 This practice advocates the regular testing of quality control samples with timely interpretation of test results. This practice also advocates using appropriate control charting techniques to ascertain the in-statistical-control status of test methods in terms of precision, bias (if a standard is being used), and method stability over time. For details concerning QC sample requirements and control charting techniques, refer to Practice D6299. The generally accepted practices are outlined in 10.1.4 through 10.4.4.

10.1.4 QC sample testing frequency shall be established for each applicable test method. Principal factors to be considered for determining the frequency of testing shall include: (*1*) frequency of use of the analytical measurement system, (*2*) criticality of the parameter being measured and business economics, (*3*) established system stability and precision performance based on historical data, (*4*) regulatory requirements, (*5*) contractual provisions, and (*6*) test method requirements. Minimum QC sample testing specified in regulations or in the test method shall prevail over any larger interval determined below in 10.1.4.1 – 10.1.4.4.

10.1.4.1 If site precision for a specific test has not been established as defined by Practice D6299, then the recommended frequency for analysis of QC samples is one QC out of every ten samples analyzed. Alternatively, one QC sample is analyzed each day that samples are analyzed, whichever is more frequent.

10.1.4.2 Once the site precision has been established as defined by Practice D6299, and to ensure similar quality of data is achieved with the documented method, the minimal QC frequency may be adjusted based on the Test Performance Index (TPI) and the Precision Ratio (PR).

10.1.4.3 Table 1 provides recommended minimal QC frequencies as a function of PR and TPI. For those tests, which are performed infrequently, for example less than 25 samples are analyzed monthly, it is recommended that at least one QC sample be analyzed each time samples are analyzed.

10.1.4.4 In many situations, the minimal QC frequency as recommended by Table 1 may not be sufficient to ensure adequate statistical quality control, considering, for example, the significance of use of the results. Hence, it is recommended that the flowchart in Fig. 1 be followed to determine if a higher QC frequency should be used.

[9] Cali, J. P., *Anal. Chem.*, Vol 48, 802A, 1976.

[10] Uriano, G. A., and Gravatt, C. C., *CRC Crit. Revs, in Anal. Chem.*, Vol 6, 361, 1977.

[11] Alvarez, R., Rasberry, S. D., and Uriano, G. A., *Anal. Chem.*, Vol 54, 1226A, 1982.

TABLE 1 Minimal QC Frequency as a Function of Test Performance Index

TPI for Standard Test Methods with PR<4	TPI for Standard Test Methods with PR≥4	Nominal QC Frequency (1 QC out of every X Samples) Values of X	Approximate Percentage of QC Samples/ Total Analyses
Not determined	Not determined	10	9
<0.8	<1.6	10	9
0.8–1.2	1.6–2.4	20	5
1.2–2.0	2.4–4.0	35	3
>2.0	>4.0	40	2

10.1.4.5 The TPI should be recalculated and reviewed at least annually. Adjustments to QC frequency should be made based on the recalculated TPI by following sections 10.1.4.1 and 10.1.4.2.

10.1.5 QC testing frequency, QC samples, and their test values shall be recorded.

10.1.6 All persons who routinely operate the system shall participate in generating QC test data. QC samples should be treated as regular samples.

NOTE 9—Avoid special treatment of QC samples designed to "get a better result." Special treatment seriously undermines the integrity of precision and bias estimates.

10.1.7 The laboratory may establish random or blind testing, or both, of QC or other known materials.

10.2 *Quality Control Sample and Test Data Evaluation:*

10.2.1 QC samples should be stable and homogeneous materials having physical or chemical properties, or both, representative of the actual samples being analyzed by the test method. This material shall be well-characterized for the analyses of interest, available in sufficient quantities, have concentration values that are within the calibration range of the test method, and reflect the most common values tested by the laboratory. For QC testing that is strictly for monitoring the test method stability and precision, the QC sample expected value is the control chart centerline, established using data obtained under site precision conditions. For regular QC testing that is intended to assess test method bias, RMs, or CRMs with independently assigned ARVs should be used. The results should be assessed in accordance with Practice D6299 requirements for check standard testing. For infrequent QC testing for bias assessment, refer to Practice D6617.

NOTE 10—It is not advisable to use the same sample for both a calibrant and a QC sample. It is not advisable to use the same chemical lot number for both a calibrant and a QC sample.

10.2.2 If the QC material is observed to be degrading or changing in physical or chemical characteristics, this shall be immediately investigated and, if necessary, a replacement QC material shall be prepared for use.

NOTE 11—In a customer-supplier quality dispute, it may be beneficial to provide the customer with the laboratory's test results on QC material to demonstrate testing proficiency. Practice D3244 may be useful.

10.3 *Quality Control Charts:*

10.3.1 QC sample test data shall be promptly plotted on a control chart and evaluated to determine if the results obtained are within the method specifications and laboratory-established control limits. The charts used should be appropriate for the testing conditions and statistical objectives. Corrective action should be taken and documented for any analyses that are out-of-statistical-control (see Section 13).

NOTE 12—Charts such as individual, moving average and moving range, exponentially weighted moving average, or cumulative summation charts may be used as appropriate. Refer to Practice D6299 for guidance on plotting these charts.

10.3.1.1 The charts should indicate the test method, date when the QC analyses were performed, and who performed them. Test samples should not be analyzed or results for samples should not be reported until the corresponding QC data are assessed and the testing process is verified to be in-statistical-control. (See 10.1.)

10.3.2 Adequate training shall be provided to the organizational entity that is responsible for the generation and interpretation of control charts.

10.3.3 It is suggested that the charts be displayed prominently near the analysis workstation or be readily retrievable from a computer workstation, so that all can view and, if necessary, help in improving the analyses.

10.3.4 Supervisory and technical personnel assigned this task shall periodically review the QC charts.

10.3.5 The laboratory shall establish written procedures outlining the appropriate interpretation of QC charts and responses to out-of-statistical-control situations observed.

10.3.5.1 When an out-of-statistical-control situation has been identified, an investigation shall be conducted and remedial action (if needed) should be taken before analyzing further samples. In all such cases, document any actions taken and retest the QC sample and ensure that a satisfactory result can be obtained before analyzing *unknown* samples.

NOTE 13—A generic checklist for investigating the root cause of unsatisfactory analytical performance is given in Appendix X1.

10.3.6 Out-of-statistical-control situations may be detected by one or more analyses. In these situations, procedures shall be documented to determine when it may be necessary to retest samples analyzed during the period between the last in-statistical-control QC data point and the QC data point that triggered the out-of-statistical-control notice (or event) using retained samples and equipment known to be in control. If the new analysis shows a difference that is statistically different from the original results, and the difference exceeds the established site precision of that test, the laboratory shall decide on what further actions are necessary (see Section 13).

10.4 *Revision of Control Charts*—QC chart revision is covered in detail in Practice D6299. Control charts shall be revised only when the existing limits are no longer appropriate. As a guideline, revisions may be needed when:

10.4.1 Additional information becomes available,

10.4.2 The process has improved,

10.4.3 A new QC material is initiated and the mean value is different than the previous QC material, or

10.4.4 There are major changes to the test procedure.

11. Audits and Proficiency Testing

11.1 *Audits:*

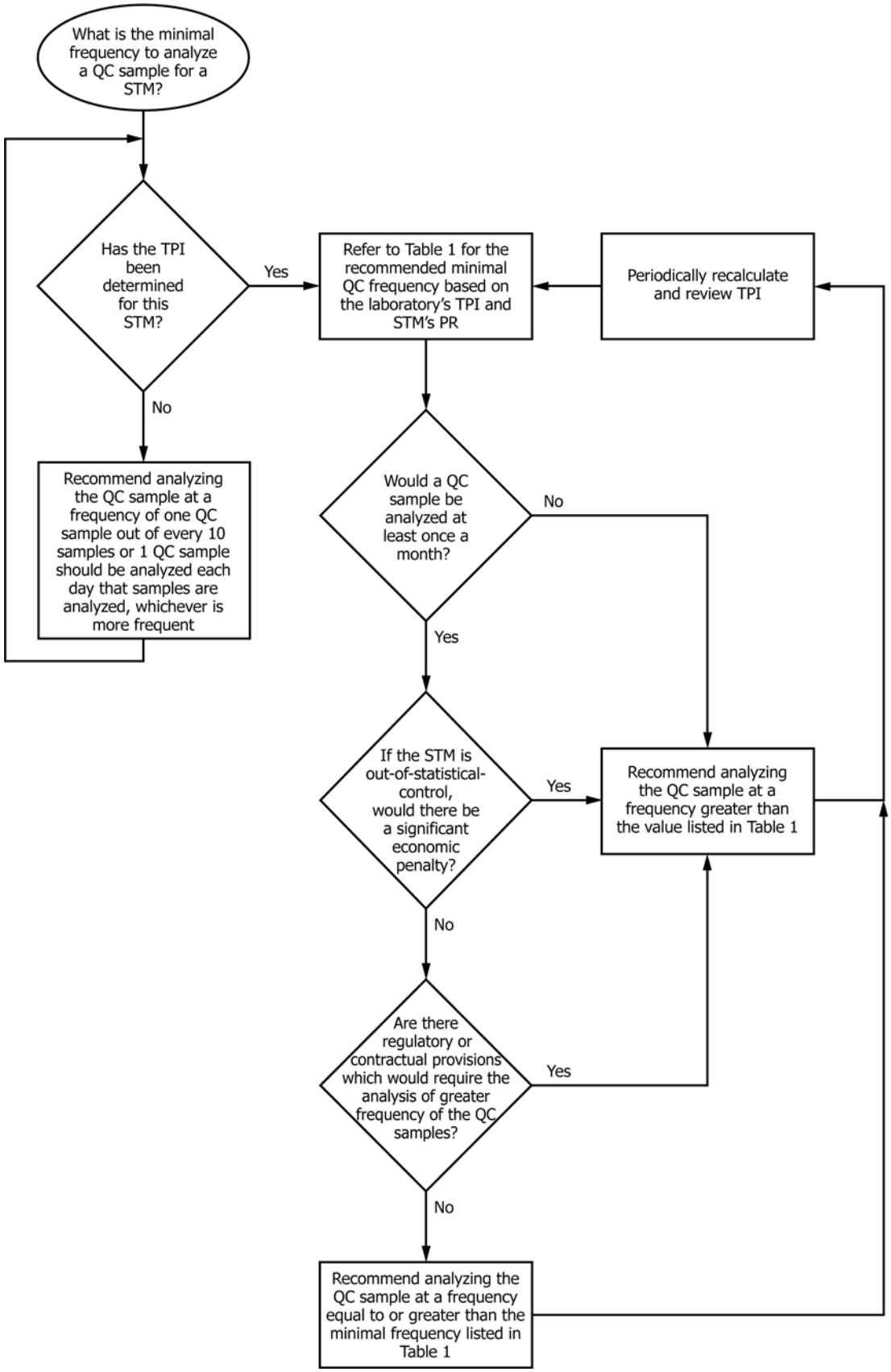

FIG. 1 Flowchart for QC Frequency

11.1.1 A laboratory shall have a system to periodically review its own practices to confirm continued conformance to the laboratory's documented quality management system. Even if the laboratory is subjected to a formal external audit (for example, as a requirement of ANSI/ISO/ASQ Q9000), it is important to have internal audits since the internal reviewers may be more familiar with their laboratory's requirements than the external auditors. An assessment checklist based on this standard is provided in Appendix X2.

11.1.2 Audits of test methods (sometimes referred to as test method assessments) shall be conducted to confirm adherence to the documented test methods and test method procedures. The performance of the entire test should be observed and checked against the official specified test method. The frequency of test method assessments should be specified in the quality management system; an annual audit of test methods is recommended.

NOTE 14—These audits may be part of the quality management system audits or may be separate.

11.1.3 Audit results shall be promptly documented. The team shall report the audit results to laboratory personnel having the authority and responsibility to take corrective action and to its management.

11.1.4 The findings and recommendations of these internal audits shall be reviewed by the laboratory management and acted upon to correct the deficiencies or nonconformances.

11.1.5 The effectiveness of any corrective actions taken in response to an audit shall be verified. The follow-up results shall be documented as required by the quality management system procedures or laboratory policy, or both.

11.2 *Proficiency Testing:*

11.2.1 Regular participation in interlaboratory proficiency testing (PT) programs, where appropriate samples are tested by multiple test facilities using a specified test protocol, shall be integrated into the laboratory's quality control program. Proficiency test programs shall be used as appropriate by the laboratory to demonstrate testing proficiency relative to other industry laboratories.

NOTE 15—Document the rationale for not participating in a proficiency test program.

11.2.2 The laboratory shall establish criteria for guiding their participation in interlaboratory testing programs. Such criteria may include factors such as the frequency of use of the target test method, the critical nature of how the customer uses the data, and regulatory considerations. Participation in proficiency test programs can provide a cost-effective alternative to regular CRM testing.

11.2.3 Participants may plot their deviations from the consensus values established by the proficiency test program averages on a control chart to ascertain if their measurement processes are non-biased. The precision of these exchange performance data can also be assessed against precision established by in-house QC sample testing for consistency (see Practice D6299 for details).

11.2.4 Additional guidance related to the analysis and interpretation of proficiency test program results is provided in Guide D7372.

11.2.5 Participation in proficiency testing shall not be considered as a substitute for a quality control program, as described in 10.1, and vice versa.

12. Test Method Precision Performance Assessment

12.1 The test performance index (TPI) can be used to compare the precision of the laboratory measurements with the published reproducibility of a standard test method. The term TPI is defined as:

$$\text{test performance index} = \frac{\text{test method reproducibility}}{\text{site precision}} \quad (1)$$

NOTE 16—The ASTM International Committee D02 sponsored Interlaboratory Crosscheck Program employs a test performance index based on the ratio of the published ASTM reproducibility to the reproducibility calculated from the program data. This index is termed the TPI (Industry) to distinguish from the definition in 12.1.

12.2 A precision ratio (PR) is determined for a given published test method so that the appropriate action criteria may be applied for a laboratory's TPI. The PR for a published test method estimates the influence that non-site specific variations has on the published precision. The PR can be calculated by dividing the test method's reproducibility by the repeatability as shown in Eq 2.

$$\text{Precision Ratio, PR} = \frac{\text{Test Method reproducibility (R)}}{\text{Test Method repeatability (r)}} \quad (2)$$

where the ratio of R/r is calculated to the nearest integer (that is, 1, 2, 3, 4, …).

12.2.1 A test method with PR greater than or equal to 4, for the purpose of this practice, is deemed to exhibit a significant difference between repeatability and reproducibility. For further explanation on why the greater than or equal to 4 criterion was chosen, please see Appendix X3.

12.3 A laboratory's TPI may be a function of the sample type being analyzed and variations associated with that laboratory. As general guidelines Table 2 may be used once the TPI of that laboratory and the PR of the published standard test method has been calculated. Similar information to that provided in Table 2 is provided in 12.3.1 through 12.3.2.3.

12.3.1 For a published standard test method with a PR less than 4 the following TPI criteria should be applied.

12.3.1.1 A TPI greater than 1.2 indicates that the performance is probably satisfactory relative to ASTM published precision.

12.3.1.2 A TPI greater than or equal to 0.8 and less than or equal to 1.2 indicated performance may be marginal and the laboratory should consider method review for improvement.

12.3.1.3 A TPI less than 0.8 suggests that the method as practiced at this site is not consistent with the ASTM published precision. Either laboratory method performance improvement is required, or ASTM published precision does not reflect achievable precision. Existing interlaboratory exchange performance (if available) should be reviewed to determine if the latter is plausible.

12.3.2 For a published standard test method with a PR greater than or equal to 4 the following TPI criteria should be applied.

TABLE 2 Guidelines for Action Based on TPI

TPI for Standard Test Methods with PR<4	TPI for Standard Test Methods with PR≥4	Recommended Quality Improvement Action
>1.2	>2.4	Indicates that the performance is probably satisfactory relative to ASTM published precision.
>0.8 and <1.2	>1.6 and <2.4	Indicates that the performance is probably satisfactory relative to ASTM published precision, however a method review could be necessary to improve its performance.
<0.8	<1.6	This condition suggests that the method as practiced at this site is not consistent with the ASTM published precision. Either laboratory method performance improvement is required, or the ASTM published precision does not reflect precision achievable. Existing interlaboratory exchange performance (if available) should be reviewed to determine if the latter is plausible.

12.3.2.1 A TPI greater than 2.4 indicates that the performance is probably satisfactory relative to ASTM published precision.

12.3.2.2 A TPI greater than or equal to 1.6 and less than or equal to 2.4 indicated performance may be marginal and the laboratory should consider method review for improvement.

12.3.2.3 A TPI less than 1.6 suggests that the method as practiced at this site is not consistent with the ASTM published precision. Either laboratory method performance improvement is required, or ASTM published precision does not reflect precision achievable. Existing interlaboratory exchange performance (if available) should be reviewed to determine if the latter is plausible.

12.3.3 A laboratory may choose to set other benchmarks for TPI, keeping in mind that site precision of an adequately performing laboratory cannot, in the long run, exceed the practically achievable reproducibility of the method when PR is less than 4 or approaches repeatability when PR is much greater than 4.

NOTE 17—Experience has shown, for some methods, published reproducibility is not in good agreement with the precision achieved by participants in well-managed crosscheck programs. Users should consider this fact when evaluating laboratory performance using TPI.

12.4 A laboratory should review their precision obtained for multiple analyses on the same sample. The site precision of the QC samples can be compared with the reproducibility or repeatability given in the standard test methods to indicate how well a laboratory is performing against the industry standards.

12.5 A laboratory's site precision (R') that is significantly worse than the published test method reproducibility may indicate poor performance. An investigation should be launched to determine the root cause for this performance so that corrective action can be undertaken if necessary. Such a periodic review is a key feature of a laboratory's continuous improvement program.

13. Corrective and Preventive Action

13.1 A corrective and preventive action process shall be established. The need for corrective and preventive action may be indicated by one or more of the following unacceptable situations:

13.1.1 Equipment out of calibration,

13.1.2 QC or check sample result out-of-statistical-control,

13.1.3 Test method performance by the laboratory does not meet performance criteria (for example, precision, bias, and the like) documented in the test method,

13.1.4 Product, material, or process out of specification data,

13.1.5 Outlier or unacceptable trend in an interlaboratory cross-check program,

13.1.6 Nonconformance identified in an external or internal audit,

13.1.7 Nonconformance identified during review of laboratory data or records,

13.1.8 Customer complaint.

13.2 When any of these situations occur, the root cause should be investigated and identified. Procedures for investigating root cause should be established. Items to consider when creating these procedures include:

13.2.1 Determining when the test of equipment was last known to be in control,

13.2.2 Identifying results that may have been adversely affected,

13.2.3 How to handle affected results already reported to a customer,

13.2.4 What to do if the root cause cannot be determined, and

13.2.5 What to do if it is determined that the original data is correct.

13.2.6 It is possible that the analytical results are correct, even if they don't meet specifications. Procedures should consider this possibility.

13.2.7 See Appendix X1 for a checklist for investigating the root cause of unsatisfactory analytical performance.

13.3 Procedures should also be established for the identification and implementation of appropriate corrective and preventive action so that the situation does not reoccur. This may involve:

13.3.1 Training or retraining personnel,

13.3.2 Reviewing customer specifications,

13.3.3 Reviewing test methods and procedures,

13.3.4 Establishing new or revised procedures,
13.3.5 Instrument maintenance and repair,
13.3.6 Re-preparation of reagents and standards,
13.3.7 Recalibration of equipment,
13.3.8 Re-analysis of samples, and
13.3.9 Additional QC sample analysis.

13.3.10 The situation, root cause, and corrective/preventive action taken should be documented promptly. A corrective and preventive action report is a suitable format for documentation.

13.3.11 The report should be reviewed and approved by management and then verified for effectiveness of corrective and preventive actions.

13.4 Quality control charts (see 10.3) are a method of preventive action and should be evaluated on a regular basis to prevent, when possible, out-of-statistical-control situations.

14. Customer Complaints

14.1 A procedure shall exist to follow-up on customer complaints or non-conformances brought to the laboratory's attention by a client. The result of such investigation should be communicated to the customer as soon as practical. This procedure may be incorporated into a corrective and preventive action process (see Section 13).

15. Training

15.1 Laboratory management shall ensure that all staff performing testing or interpreting data, or both, are appropriately trained.

15.2 Laboratory training should cover at a minimum the following areas: safety, test methods, and company policies and procedures. Training is specifically required as specified in: 5.4.10, 10.3.2, 13.3.1, and X1.1.11.

15.3 Records of training and the determination of competence shall be maintained.

16. Relationship with Other Quality Standards

16.1 Some laboratories in the petrochemicals testing area have been registered to ISO/IEC 17025. There are a number of similarities between the ISO standard and this practice in key areas of managing laboratory quality. For example:

Requirement	ISO/IEC 17025	ASTM Practice D6792
Quality Management System	4.2	5.1
Document Control	4.3	7.6; 8.1; 8.4
Contract Review	4.4	5.4.9
Complaints	4.8	14.1
Corrective Action	4.10	13; Appendix X1
Preventive Action	4.11	13.4
Control of Records	4.12	7.3.1; 7.4; 7.5; 7.6
Internal Audits	4.13	11.1
Management Reviews	4.14	5.3
Personnel	5.2	5.4.10, 15.1, 15.2
Calibration	5.6.2.1	9.2–9.7
Sample Handling	5.8	6.2
Quality Control Procedures	5.9	10.1
Use of Quality Control Materials	5.9.a	10.2
Proficiency Testing	5.9.b	11.2
Data Reports	5.10	7.1

16.2 *Measurement Uncertainty*—For test methods under the jurisdiction of Committee D02, measurement uncertainty as required in ISO/IEC 17025, as practiced by a laboratory, can be estimated by multiplying 2× the site precision standard deviation as defined in Practice D6299.

NOTE 18—The complexity and empirical nature of the majority of D02 methods preclude the application of rigorous measurement uncertainty algorithms. In many cases, interactions between the test method variables and the measurand cannot be reasonably estimated due to the covariance of the variables that affect the measurand. The site precision approach estimates the combined effects of these variables on the total uncertainty for the measurand.

16.3 The practice of using QC materials and control charts to estimate measurement uncertainty assumes that the laboratory bias is not statistically or practically significant. This assumption should be validated periodically using check standards. See Practice D6617 or Practice D6299 for further guidance.

17. Keywords

17.1 audit; calibration; control charts; proficiency testing; quality assurance; quality control; test performance index

APPENDIXES

(Nonmandatory Information)

X1. CHECKLIST FOR INVESTIGATING THE ROOT CAUSE OF UNSATISFACTORY ANALYTICAL PERFORMANCE

X1.1 To identify why a laboratory's data may have been considered a statistical outlier or to improve the precision, or both, the following action items (not necessarily in the order of preference) are suggested. There may be additional ways to improve the performance.

X1.1.1 Check the results for typos, calculation errors, and transcription errors.

X1.1.2 Reanalyze the sample; compare results to site precision, or, if not available, to test method repeatability.

X1.1.3 Check the sample for homogeneity or contamination, and that a representative sample has been analyzed.

X1.1.4 Review the test method and ensure that the latest version of the ASTM test method is being used. Check the procedure step-by-step with the analyst.

X1.1.5 Check the instrument calibration.

X1.1.6 Check the statistical quality control chart to see if the problem has been developing earlier.

X1.1.7 Check the quality of the reagents and standards used, and whether they are expired or contaminated.

X1.1.8 Check the equipment for proper operation against the vendor's operating manual.

X1.1.9 Perform maintenance or repairs, or both, on the equipment following guidelines established by the vendor.

X1.1.10 After the problem has been resolved, analyze a certified reference material if one is available, or the laboratory quality control sample, to ascertain that the analytical operation is under control.

X1.1.11 Provide training to new analysts and, if necessary, refresher training to experienced analysts.

X1.1.12 Document the incident and the learnings for use in the future if a similar problem occurs.

X2. ASSESSMENT CHECKLIST TO EVALUATE COMPLIANCE WITH PRACTICE D6792

X2.1 See the checklist in Table X2.1. The requirements covered in D6792 are summarized in checklist Table X2.1. For most items in the checklist, a reference to the corresponding text in D6792 is included in (). Note that requirements listed in the checklist with an asterisk (*) are mandatory ("shall"). See X2.3 for a discussion on possible rating schemes. To make the best possible use of this checklist, it is recommended that the assessor provide comments for each item. The comments should include a description of the documents, data and activities observed and should indicate any gaps, omissions, or incorrect actions.

X2.2 Table X2.2 presents the actions and/or questions that the assessor could use to supplement their use of the checklist (Table X2.1). This table is intended as a general guide to provide additional information to assist the auditor in completing the Checklist. This table is not intended to be all inclusive nor to have every item apply to all petroleum, petroleum product, liquid fuel, and lubricant laboratories. Auditors are expected to use their professional judgement in applying this supplemental guide.

X2.3 Rating Schemes

X2.3.1 *General*—Professional auditors often use rating schemes developed by their respective organization, so there a number of ways to approach developing an overall rating for a laboratory based on the Table X2.1 checklist. Two generalized schemes are discussed below, without any recommendation of one over the other.

X2.3.2 *Non-Numeric Rating*—Some audits/assessments are conducted with the sole purpose of demonstrating compliance. The purpose of such audits could be for a laboratory manager to identify gaps in their efforts to satisfy D6792 or the audit could be conducted to satisfy a regulatory compliance. In both cases, the identification of all gaps, omissions or incorrect activities are important to note. The auditor would use professional judgement and the relative seriousness of any gaps (for example, did it involve a mandatory requirement) and the frequency of occurrence (often versus a one-off event) to rank the findings. The objective of the laboratory following an audit would be close all gaps giving priority to the more significant findings.

X2.3.3 *Numeric Rating Schemes*—Numeric scores might be useful with a network of laboratories or in cases where quantifiable means are needed to show progress from one audit to another. In general numeric rating schemes involve assigning points to each checklist item based on how completely a requirement is satisfied. For example, one could develop a scoring profile by assigning a rating number to indicate that the laboratory fully met all the requirements of an item and then a lower numbers to indicate partial completion or satisfaction of the requirement with the lowest rating of 0 (zero) indicating that the requirement was not met. In cases where this type of scheme is used the numeric rating can be weighted by the relative importance of a requirement or group of requirements. For example, one could adopt a weighted scheme as demonstrated in Table X2.3. The final audit score would result from the use of this or a similar table. The decision or guidance on whether or not a given final score was sufficient to meet the needs of the auditing organization or the laboratory management would also need to be developed.

TABLE X2.1 Assessment Checklist to Evaluate Compliance with Practice

	Requirements	Rating	Assessor Comments
1.0	**QUALITY MANAGEMENT SYSTEM (QMS)**		
1.1	*A quality management system is established and maintained. (5.1)		
1.2	*Management has appointed a representative to implement and maintain the quality management system in the laboratory. (5.2)		
1.3	*The quality management system includes stated objectives in the following areas: (5.1) • Laboratory's adherence to test method requirements, • Calibration and maintenance practices, • Quality control program, • Continuous improvement goals, • Meeting customer requirements.		
1.4	*The quality management system has documented processes for: (5.4) Sample management, • Data and record management, • Producing accurate, reliable, and properly represented test results, • Audits and proficiency testing, • Test Method, • Corrective and preventive action, • Ensuring that procured services and materials meet the contracted requirements, • Ensuring that personnel are adequately trained to obtain quality results		
1.5	*Laboratory management reviews the adequacy of the quality management system and the activities of the laboratory for consistency with the stated quality objectives at least annually. (5.3)		
2.0	**TEST METHODS**		
2.1	*Laboratory has documented, up-to-date and readily available (to the laboratory staff) test methods and procedures for performing the required tests. (8.1)		
2.2	*Test methods used for customer sample analyses are those stated in respective product specifications, regulations, or are those agreed upon with the customer. (8.1)		
2.3	*Laboratory has documented procedures for the approval, documentation, and reporting of deviations from the published test method requirements. (8.2)		
2.4	*Laboratory has documented procedures for obtaining customer approval for the use of alternative or substitute test methods for product certification. (8.2) (See Practice D6708 for applicable procedures.)		
3.0	**SAMPLING AND SAMPLE MANAGEMENT**		
3.1	*A sample management process or system is established and maintained. (6.1)		
3.2	*Sample management system addresses procedures for unique sample identification and criteria for sample acceptance. (6.2.1, 6.2.2)		
3.3	*Sample management system addresses procedures for sample handling, retention and storage. The system addresses the following items when applicable: (6.2.3, 6.2.4) Government (local, state, or national) regulatory requirements for shelf life, • Data or information regarding sample stability with respect to tested parameters, • Type of sample containers required to preserve the sample, • Sample storage conditions before testing, • Sample storage conditions for sample retention, • Required safety precautions, • Customer requirements, • Control of access to the retained samples to protect their validity and preserve their original integrity.		
3.4	*Procedures for sample disposal are in accordance with applicable regulatory requirements. (This may be handled through a separate chemical hygiene or waste disposal plan.) (6.2.5)		
4.0	**CALIBRATION**		
4.1	A laboratory calibration system or program is established. (5.1) The calibration system addresses: (9.1) • Creation and use of calibration records, • Lab calibration schedule, • Corrective actions.		
4.2	Calibration procedures are established for each instrument or test method as appropriate. (9.1) The calibration procedures address the following: • Calibration schedules, (The calibration frequency may vary with the instrument type and its frequency of use, some needing calibration before each set of analyses, others requiring calibration at less frequent periods or triggered by a QC chart out-of-statistical-control situation.) • Special requirements of the test method or procedure, • Customer requirements.		
4.3	The performance of apparatus and equipment used in, but not calibrated in the laboratory (that is, pre-calibrated, vendor supplied), is verified using a documented, technically valid procedure at periodic intervals. (9.2)		

TABLE X2.1 *Continued*

4.4	*Calibration standards meet the following requirements or conditions when appropriate: (9.3) • Are appropriate for the method and are characterized with the accuracy demanded by the analysis to be performed, • Are traceable to national or international standards or are derived from constituents of known purity, when prepared by the laboratory, • Where the concept of traceability to national or international standards of measurement is not applicable, the testing laboratory provides, satisfactory evidence of test result accuracy, for example, by participation in a program of interlaboratory comparisons, (Note 8) • Primary calibration standards or CRMs are used when specified or allowed by the test method, • Where appropriate, values for reference materials are produced following appropriate (NIST or other standards issuing body) certification protocol, (9.4.1) • The materials analyzed in proficiency testing programs meeting the requirements of Practice D6300 or ISO 4259 are used as reference materials, provided no obvious bias or unusual frequency distribution of results are observed. (The consensus value is most likely the value closest to the true value of this material; however, the uncertainty attached to this mean value will be dependent on the precision and the total number of the participating laboratories.) (9.4.2)		
4.5	*The laboratory has procedures for the storage of calibration and reference materials in a manner to ensure their safety, integrity, and protection from contamination (see 6.2.4). (9.5)		
4.6	*Calibration records are maintained. (9.6)		
4.7	Procedures are established for the management of instrument calibration records. (7.3.1) Such records indicate the following when applicable: • Instrument calibrated, • Method or procedure used for calibration, • Dates of last and next calibrations, • Person performing the calibration, • Values obtained during calibration, • Nature and traceability (if applicable) of the calibration standards, • Records may be electronic.		
4.8	*When found to be out of calibration and the situation cannot be immediately addressed, then instruments are taken out of operation and tagged as such until the situation is corrected (see Section 13). (9.7)		
5.0	**MAINTENANCE**		
5.1	*A laboratory maintenance system or program is established. (5.1)		
5.2	*Maintenance procedures are established for all measuring and testing equipment as appropriate. (9.1)		
5.3	*Procedures are established for the creation and management of instrument maintenance records. Such records indicate the instrument being maintained, the dates of last and next maintenance and the person performing the maintenance. Records may be electronic. (7.3.2, 9.1)		
6.0	**QUALITY CONTROL PROGRAM**		
6.1	*Laboratory has established Quality Control system or practices for: (10.1) • Regularly testing quality control samples, • Timely interpretation of test results using appropriate control charting techniques, • Determining the in-statistical-control status of test methods in terms of the method stability over time, the precision and the bias.		
6.2	*Laboratory has documented procedures for creating and maintaining records for QC samples. (7.4.1) QC sample records should include: • Sample name and source, • Test(s) for which it is used, • Assigned values (ARV) and their uncertainty where applicable, • Receipt date or date put into active QC use in the laboratory, • Expiration date of QC sample (if applicable).		
6.3	*Procedures are established for QC Sample testing frequency. (10.1.3)		
6.4	*All persons who routinely operate the test system participate in generating QC test data. (10.1.5)		
6.5	QC samples are treated as regular samples. (10.1.6)		
6.6	The laboratory uses random and/or blind testing to evaluate performance (optional). (10.1.6)		
6.7	*Procedures are established for obtaining and handling QC samples. QC samples meet the following: (10.2.1) • Stable and homogenous materials having physical or chemical properties, or both, representative of the actual samples being analyzed by the test method, • Well-characterized for the analyses of interest, • Available in sufficient quantities, • Have concentration values (or other measured characteristics) within the calibration range of the test method and reflects the most common values tested by the laboratory, • The same material is not used as both a QC sample and a calibration standard. It is not advisable to use the same chemical lot number for both a calibrant and a QC sample.		
6.8	For QC testing that is strictly for monitoring the test method stability and precision, the QC sample expected value is the control chart centerline, established using data obtained under site precision conditions. (10.2.1)		
6.9	RM or CRM with independently assigned ARVs are used for QC testing intended to assess test method bias. These results are assessed in accordance with Practice D6299 requirements for check standard testing. For infrequent QC testing for bias assessment, refer to Practice D6617. (10.2.1)		
6.10	*An investigation is conducted when the QC material is observed to be degrading or changing in physical or chemical characteristics. A replacement QC material is prepared for use. (10.2.2)		

TABLE X2.1 *Continued*

6.11	QC data are promptly plotted on a control chart. (10.3.1) • Charted data are evaluated to determine if the results obtained are without significant bias and are within laboratory established control limits (see Practice D6299 for guidance). • Charts used are appropriate for the testing conditions and statistical objectives. (May include charts such as individual, moving average and moving range, exponentially weighted moving average, or cumulative summation charts, as appropriate.) • Corrective actions are taken and documented for any datum or data that are out-of-statistical-control.		
6.12	Results for test samples are not reported until the QC data are assessed and the testing process is verified to be in- statistical- control. (10.3.1.1)		
6.13	*Control charts contain the following information (10.3.1.1): • Test method, • Date QC analyses performed, • Initials/name of person performing test.		
6.14	Adequate training is provided to the analysts enabling them to generate and interpret the charts. (10.3.2)		
6.15	QC charts are displayed prominently near the analysis workstation or are readily available at computer terminal or PC station. (10.3.5)		
6.16	*Quality control charts are preventive action tools. Supervisory and technical personnel periodically review the QC charts and ensure relevant actions are taken to possibly prevent or respond to out-of-statistical-control situations. (10.3.4)		
6.17	*The laboratory established written procedures outlining the appropriate interpretation of QC charts and responses to out-of-statistical-control situations observed. (10.3.5)		
6.18	When an out-of-statistical-control situation has been identified, remedial action is taken before analyzing further samples. In all such cases, the QC sample is run to ensure that a satisfactory result can be obtained before analyzing unknown samples. (10.3.5.1)		
6.19	*Out-of-statistical-control situations are detected by one or more analyses of the QC sample. For these cases, the lab has procedures to retest samples analyzed during the period between the last in-statistical-control QC data point and the QC data point that triggered the out-of-statistical-control notice (or event) using retained samples and equipment known to be in-statistical-control. If the new analysis shows a difference that is statistically different from the original results, and the difference exceeds the established site precision of that test, the laboratory has procedures to decide on what further actions are necessary. (10.3.6)		
6.20	The laboratory uses the test performance index (TPI) to compare the precision of the laboratory measurements from the QC charts (that is, the site precision) with the published precision for the standard test method. (12.1)		
6.21	The laboratory periodically reviews their TPI values and takes appropriate action in accordance with their documented procedures. (12.2 to 12.4)		
6.22	*The laboratory has procedures for revision of QC chart parameters (as covered in detail in ASTM Practice D6299). Control charts are revised when the existing limits are no longer appropriate. (10.4) (Guidelines for when QC chart revisions are needed may include: additional information becomes available; the process has improved; a new QC material is initiated and the mean value is different than the previous QC material; there are major changes to the test procedure.)		
6.23	Procedures are established for retaining completed control charts. (7.4.2) (These procedures also address situations when a retained control chart is altered for any reason, to include recording the date of change or alteration and the reason.)		
7.0	**BIAS MANAGEMENT AND PROFICIENCY EVALUATIONS**		
7.1	*Laboratory participates in regularly conducted interlaboratory exchanges or crosscheck programs, where typical samples are tested by multiple test facilities using a specified (for example ASTM) test protocol. (11.2.1) Participation in proficiency testing is not considered as a substitute for inhouse quality control. (11.2.5)		
7.2	Crosscheck results (that is, deviations from the consensus values) are monitored with control charts to ascertain if their measurement processes are non-biased. (11.2.3) (Could be mandatory based on regulation)		
7.3	The laboratory assesses the precision of these exchange data against precision established by in-house QC sample testing to determine consistency and adequacy of performance. (11.2.3)		
8.0	**DATA MANAGEMENT**		
8.1	*Procedures are established for collecting and retaining records of original observations, calculations and derived data. (7.5.3)		
8.2	*The records for each test contain sufficient information to permit satisfactory replication of the test and recalculation of the results. (7.5.3)		
8.3	*All data are maintained according to laboratory, company, or regulatory agency requirements, or a combination thereof. (7.5.2)		
8.4	*A certificate or report communicates test results and all other relevant information from the laboratory accurately and unambiguously. (This report may be an entry in a Laboratory Information Management System (LIMS) or equivalent system.) (7.1.1)		

TABLE X2.1 *Continued*

8.5	The format and content of the laboratory certificate or report is specified by lab management and/or in customer agreements. Laboratory reports include the following: (7.1.2) (7.1.3) • Name and address of testing laboratory (for external customer reports), • Description and identification of the test sample, • Identification of the test specification, if any, • Test results with appropriate units of measure, • Identification of test method(s) used (including reference to any deviations), • Signature and job title of person(s) accepting technical responsibility for the test report laboratory (allowances made for electronic signatures or email reports), • Date of issue, • Other information as required by the customer. [Other information for consideration in the report includes: unique identification of the report (such as serial number) on each page of the report; name and address of the customer; order number; date of receipt of the test sample and date(s) of performance of test; description of the sampling procedure; any other information relevant to a specific test; disclosure of nonstandard test method or procedure utilized; measurements, examinations and derived results, supported by tables, graphs, sketches, and photographs as appropriate; any failures identified; minimum-maximum product specifications; statement of the measurement uncertainty; statement on the laboratory policy regarding the reproduction of test reports.]		
8.6	*Procedures are established for corrections or additions to a test report after issue. (7.1.4)		
8.7	*Laboratory uses reporting requirements (for example, format, significant figures, and units) specified in the test method or procedure. (7.2.1)		
8.8	The rounding protocol of Practice E29 is used when data rounding is employed, unless otherwise specified in the method or procedure. (7.2.2)		
8.9	The record retention system is documented and suits the laboratory's particular circumstances and complies with existing regulations and customer specifications. (7.5.1)		
8.10	*The records are held in a safe and secure storage. A system allows locating the required documents in a reasonable period of time. (7.5.4)		
8.11	*A document control process is established. As a minimum, for laboratory procedures (for example, standing operating procedures, SOPs) and laboratory test procedures (if used), the document control process addresses version/revision identification and management approval.		
9.0	**TRAINING**		
9.1	*Laboratory training program addresses the following areas: safety, test methods, company policies and QA/QC procedures. (15.1 to 15.2)		
9.2	*Training records are maintained. (15.3)		
10.0	**ASSESSMENTS**		
10.1	*Laboratory has a system to periodically review its own practices to confirm continued conformance to the laboratory's documented quality management system. (11.1.1)		
10.2	*Test Method Assessments are conducted to confirm adherence to the documented test methods. The performance of the entire test is observed and checked against the official specified test method. Test methods are audited annually or as specified by laboratory management. (11.1.2)		
10.3	*Audit results are promptly documented. The assessment team reports the audit results to management having the authority and responsibility to take corrective action and to its management. (11.1.3)		
10.4	*The findings and recommendations of these internal audits are reviewed by the laboratory management and acted upon to correct the deficiencies or nonconformances. (11.1.4)		
10.5	*The effectiveness of any corrective actions taken in response to an audit is verified. The follow-up results are documented as required by the quality management system procedures or laboratory policy, or both. (11.1.5)		
11.0	**CORRECTIVE AND PREVENTIVE ACTIONS**		
11.1	*Corrective and preventive action systems and procedures are established. (13.1)		
11.2	The situations for implementing corrective and preventive actions are defined by the laboratory and may include one or more of the following unacceptable situations: • Equipment out of calibration, • QC sample out-of-statistical-control, • Results out of specification (generally investigated by customer and not necessarily by the laboratory), • Outlier or unacceptable trend in an interlaboratory cross-check program, • Nonconformance identified in an external or internal audit, • Nonconformance identified during review of laboratory data or records, • Customer complaint.		
11.3	The corrective action procedures include an investigation to determine the root cause. (13.2) Procedures are available to guide in the investigation of root causes. (13.3)		
11.4	Corrective action procedures also consider the following: (13.2) • Determining when the test of equipment was last known to be in-statistical-control, • Identifying results that may have been adversely affected, • How to handle affected results already reported to a customer, • What to do if the root cause cannot be determined, • What to do if it is determined that the original data is correct.		
11.5	Corrective action reports are documented promptly and include the situation, root cause, and corrective/preventive action taken. The corrective and preventative action reports are reviewed and approved by management and then verified for effectiveness of the actions.		

TABLE X2.1 *Continued*

12.0	**CUSTOMER INTERACTIONS**		
12.1	*A procedure is established to follow-up on customer complaints or nonconformances brought to the laboratory's attention by the customer. (12.1)		
12.2	*Results of any investigation and associated corrective actions involving customer complaints or inquiries are documented and communicated to the customer as soon as practical. (12.1)		
13.0	**CONTINUOUS IMPROVEMENT**		
13.1	*The laboratory has established continuous improvement goals. (5.1)		

TABLE X2.2 Supplemental (Optional) Auditor Actions/Questions to Support Table X2.1 Checklist

NOTE 1—This table is intended as a general guide to provide additional information to assist the auditor in completing the Table X2.1 Checklist. This table is not intended to be all inclusive nor to have every item apply to all petroleum, petroleum product, liquid fuel, and lubricant laboratories. Auditors are expected to use their professional judgement in applying this supplemental guide.

1.0	**Quality Management System**
1.1	• Verify that the laboratory has a documented Quality System (for example, Quality Assurance Manual—QAM) and that it complies with D6792. • Obtain a list of referenced and associated laboratory test procedures (LTP), laboratory procedures (LP) and standard operating procedures (SOP) and verify that they exist. • Verify that there is a management approved policy, directive, or endorsement for the goals and operations of the laboratory. • Obtain an organization chart for the lab and verify that there are clear lines of authority. • Verify that job descriptions are available for all laboratory staff positions. • Is there a procedure for reviewing and/or updating procedures (that is, QAM, LTPs, and LPs)? Verify that the procedure is followed. • Verify that a document control process exists to designate or identify the latest (up to date), official copy/version of key documents like the QAM, LTPs, LPs, etc. and that these are readily available to laboratory staff. (See Checklist §8.11)
1.2	• Who is designated to oversee quality in the Lab and where is this documented? • Are these responsibilities covered in their job description?
1.3	• Review the lab's mission statement. • Verify that the objectives listed in Checklist §1.3 are addressed.
1.4	• Verify that the QA Manual addresses each of these topics: sample management, data and record management, audits and proficiency testing, corrective and preventive actions, ensuring that procured services and materials meet the contracted requirements, ensuring that personnel are adequately trained to obtain quality results. • Verify that training records cover the QAM and related SOPs.
1.5	• Verify that the requirements for a management review are documented in the QA Manual. • Verify that a recent review was performed and documented. • Was the review approved by management? • Verify that corrective actions were identified and completed.
2.0	**Test Methods**
2.1	• Verify that the laboratory has procedures for documenting, approval, and reviewing/updating test methods. • Verify that these procedures specifically define a process to ensure that other ASTM test methods allowed by any future amendments to regulations or specifications will be incorporated into the respective laboratory test procedures. • Verify that the version or revision of the test method (or LTP) used by the laboratory is current, meaning that it corresponds to the latest ASTM version, the ASTM version required by regulation or by specification. • Determine how the LTPs are made available to the lab staff and confirm that this constitutes "readily available." • Verify from training records that the technicians have been trained on the latest test method version available in the laboratory (see Training). • Verify from records or other evidence that the technicians are using the respective LTPs or copy of the ASTM test method.
2.2	• As determined above, verify that the test methods used are those stated in the respective product specifications, regulations, or customer agreement. • Are all tests specified in the product specifications being performed (by the product quality laboratory). • Verify for each test method that any LTP conforms (exactly) to the corresponding ASTM test method.
2.3	• Determine if the laboratory is using a modified version of the specified test method. If so, has it been shown that the modified method gives results equivalent to those obtained by the specified method? • Verify that the lab has a procedure for approval, documentation and reporting of deviations from the published test method. • For any LTP that acknowledges deviations from the ASTM test method, verify that the approval process was followed and that the potential impact of the deviation was addressed.
2.4	• Verify that the laboratory has procedures for obtaining approvals for use of alternative or substitute test method from the customer. • If an alternative/substitute procedure is used, verify that Practice D6708 was used to assess the expected agreement between the alternative procedure and the required method. (Note D6708—Use of this practice requires results from an interlaboratory study involving both standard test methods.)
3.0	**Sampling and Sample Management**
3.1	• Verify that sample management process is documented in QA Manual or associated SOPs or LPs. • Verify that this process addresses topics from 3.2 to 3.4 below. • Verify that this procedure has been updated as per QA system requirements. • Verify that the appropriate sampling and sample handling practices specific for the sample type (for example, gasoline, diesel, aviation turbine fuel, LPG, coke, pitch, lube oil, used oils, etc.). NOTE—*It is the responsibility of the laboratory (and auditor) to determine the appropriate sampling and sample handling practices that apply.*
3.2	• Verify that criteria for sample acceptance are established and documented. • Verify that these criteria consider sample labeling, time and date sample collected, person who collected sample, sample material identification, sample location, sample temperature and sample containers. • Verify that the sample management procedures outline steps to be taken if criteria requirements are not met. • Verify that sample acceptance criteria are posted at sample receiving and/or that the receiving technicians are aware of the acceptance criteria. • Review sample receiving records to verify conformance with sample acceptance criteria. • Observe sample receiving to verify sample acceptance criteria are being followed. • Review sample tags to verify completeness of information in accordance with the lab procedure. • Verify that the sample management process addresses the sample login process and the process to assign unique sample IDs to samples entering the lab. • Verify that each batch of conventional gasoline produced at the refinery is assigned a batch number. Verify that each batch will have a unique sample identifier. • Verify that there are procedures for handling and identifying (with a unique ID) non-routine (unscheduled) samples • Verify that the sample management procedures describe how sample residuals (sample remaining in original sample bottle following completion of testing), extracts, digestates, duplicates, and excess sample containers are addressed within the system. • Verify that all samples are properly identified.

TABLE X2.2 *Continued*

3.3	• Verify that the sample management procedures address items listed below as appropriate. • Samples are logged into system prior to analysis • Sample containers comply with requirements of respective test methods. • Facilities and equipment are available for proper storage of samples prior to analysis. • Samples are handled and stored in accordance with regulations and appropriate ASTM practices (for example, D4057, D5842, and D5854). • Are appropriate safety procedures in place? • Containers for volatile materials are filled only to the amount specified for the test method (for example, D86, D5191, D4057, D5842) • The volume of sample collected for retain conforms to specifications, SOPs or regulations. • Verify that the inventory or retain samples held for each product conforms to SOPs and/or regulations. • Retain samples are adequately secured, including off hours. Verify that retain samples are held for the appropriate period. • Verify that retained samples are being disposed following their maximum retention time.
3.4	• Verify that there are procedures to address sample disposal. (These procedures may be addressed in a site chemical hygiene plan and/or waste disposal plan.) • Have applicable regulatory requirements been identified? • Do these plans cover applicable procedures within the laboratory environment? • Verify that the procedures applicable to laboratory operations are being followed.
4.0	**Calibration**
4.1	• Verify that the calibration system/program is documented (in QAM or LP). • Verify that the documented calibration program provides sufficient guidance to address items in this section. • Verify that a calibration schedule is established. • Verify that required calibrations are completed when needed or scheduled.
4.2	• Calibration procedures are established for balances and thermometers and other equipment not covered by a test method. • Confirm if balances are used for analytical purposes, they are calibrated using relevant ASTM procedures. • Confirm if thermometric measuring devices are used, they are calibrated using relevant ASTM procedures. • Verify that calibration procedures identified within test methods are properly reflected in the corresponding LTP (evaluated here or in 2.2). • Verify that analytical calibration standards are prepared appropriately. For example, there are standards for: calibration of ICP-AES and XRF instruments for metals analysis, preparation of liquid blends for use as analytical standards, preparation of low-pressure gas blends, handling of crude oil samples for mercury analysis, validation of process stream analyzers, calibration of moisture analyzers. NOTE—*It is the responsibility of the laboratory (and auditor) to determine the appropriate practices for preparation of calibration standards that apply to their test methods.*
4.3	• Verify that the calibration procedure addresses verification of vendor calibrated equipment/instruments. • Verify that such verifications are documented.
4.4	• Verify that calibration standards for balances and thermometers are appropriate and traceable to national standards. • Verify that calibration standards identified in the test methods are the ones being used and meet the specification in the test method. [This could be accomplished as part of the comparing LTP versus the ASTM test method in 2.2] • Verify that primary calibration standards or CRMs are used when specified or allowed by the test method. • Verify that where appropriate, values for reference materials are produced following appropriate (NIST or other standards issuing body) certification protocol. • Verify that the material analyzed in proficiency testing programs meeting the requirements of Practice D6300 or ISO 4295 are used as reference materials, provided no obvious bias or unusual frequency distribution of results are observed.
4.5	• Verify there are procedures for the storage of calibration and reference materials in a manner to ensure their safety, integrity, and protection from contamination. • These materials include purchased standards, chemicals, product standards, prepared standards, and working standards. • Verify that calibration or reference materials are labeled and stored as per documented procedures.
4.6	• Verify that calibration records are maintained for general laboratory equipment like balances, thermometers, etc. • Verify that calibrations identified for test methods are being performed at the intervals required and that the corresponding calibration records are being properly maintained.
4.7	• Review the calibration records for each test method and determine whether they comply with the key components listed in D6792, subsection 7.3.1. • Such records usually indicate the instrument calibrated, method or procedure used, dates of last/next calibrations, person performing calibration, values obtained, permissible tolerances, and traceability of the standards. Applies to thermometers, balances. .• Verify that the calibration records for calibrations specified in test methods (see 4.6 above) comply with these requirements.
4.8	• Determine if any instrument or equipment is out-of-calibration or are past due calibrations (for example, review calibration schedule; observations during walkabouts in the laboratory; review of calibration records). • Determine if out-of-calibration instruments are properly tagged as such.
5.0	**Maintenance**

5.1	• Verify that a maintenance program is documented (in QAM, LP, or SOP).
	• Verify that a maintenance schedule been established for all equipment in the lab as appropriate.
	• Determine if an equipment inventory list available and is up-to-date.
	• Determine if major instruments are included in service contracts.
	  • Verify that the service performed as contracted.
	  • If not under service contract, determine if arrangements have been made to get the instrument speedily repaired or use of a back-up lab for analysis.
	  • Verify that there is a procedure or backup system in case of instrument failure.
	• Determine if there is plan for upgrading and replacing older instrumentation.

5.2	Verify that procedures are available for performing the maintenance identified for lab instruments and equipment.
5.3	• Verify that procedures are established for creation and management if instrument maintenance records. • Verify that maintenance records are maintained (log books used or some other mechanism). • Verify that maintenance records are current. • Verify that the maintenance records indicate the instrument being maintained, the dates of last and next maintenance and the person performing the maintenance. • Verify that logs are kept of all downtime and service problems for instruments.
6.0	**Quality Control Program**
6.1	• Verify that a QC program is documented (in QAM and LPs). • Verify that the QC program includes regular QC sample testing, timely interpretations, use of appropriate control charting techniques, and determination of in-statistical-control status. See Practice D6299 A1.5 for control charts.

TABLE X2.2 *Continued*

6.2	• Verify that the QC Program describes the documentation and recordkeeping practices for the QC samples. • Verify that individual QC sample records include (as appropriate): sample name and source, test(s) for which it is used, assigned values (ARV) and their uncertainty, receipt date or date put into active QC use in laboratory, and expiration date of QC sample. • Determine who is assigned to maintain the QC sample records. • Verify training records.
6.3	• Verify that there are procedures to establish the QC Sample testing frequency for each test method within the QC program. • For each QC Sample program, verify that the QC Sample testing frequency has been established in accordance with the following as appropriate: • When site precision (see Practice D6299, section 9.1) is not established then the recommended frequency one QC out of every ten samples analyzed, • Alternatively, one QC sample is analyzed each day that samples are analyzed, whichever is more frequent, • When site precision is established the minimal QC frequency may be adjusted based on the TPI and the PR (see D6792Table 1). • For tests performed infrequently at least one QC sample be analyzed each time samples are analyzed, • Use the flow chart in D6792Fig. 1to determine if a higher QC frequency should be used. • Recalculate and reviewed TPI at least annually and adjust QC frequency as appropriate. • Assess whether the QC sample testing frequency provides adequate control for each test method. • Verify that the QC testing frequencies are followed as evidenced from the control charts.
6.4	Verify that all technicians routinely running a test also participate in generating QC chart data.
6.5	Review QC chart records to verify that there is no evidence to support that running any QC sample is given special treatment that would invalidate the control.
6.6	Verify the laboratory QC Program addresses random or blind testing schemes. A blind/random program either exists (documented) or such a program is not run but is explained in the QA Manual.
6.7	• Verify that procedures exist describing how QC samples are obtained and handled. • Verify for each QC sample that the material meets the following requirements: stable and homogeneous, representative of the actual samples being analyzed by the test method, source of material known and batch data available, sufficient quantity, concentration values within calibration range and within regulatory limits, concentration reflects the most common values tested, and not used as both a QC sample and a calibration standard.
6.8	Verify that the expected value for the QC sample is determined in accordance with Practice D6299. Applies to all QC charts (See Practice D6299 Annex A1.5).
6.9	• Verify that there is a procedure for using RM/CRM material in QC testing to assess test method bias. • Verify that the results of such assessments are in accordance with D6299, Section 9.2 • Determine if D6617 is used for infrequent QC testing for bias assessments. D6617 covers a methodology for establishing an acceptable tolerance zone. • Determine if the same sample is used for calibration and QC Sample—verify rationale.
6.10	• Verify that an investigation is conducted when the QC material is observed to be degrading or changing in physical or chemical characteristics (leading to the eventual replacement of the QC material). • Verify how QC samples are replaced. • Review records associated with control chart investigations?
6.11	• Verify that the QC data are promptly plotted; • Compare date/time stamp for QC data with corresponding date/time stamp for entry of data on chart. • If captured directly into LIMS verify from the program description that the charts are available in a timely manner for evaluation. • Verify for each QC sample that the QC chart type used is appropriate and complies with Practice D6299 (see Annex A1.5). • Verify that corrective actions were taken and documented for any out-of-statistical-control datum.
6.12	• Verify that the QC program procedure assures that QC results are assessed prior to reporting results on production samples. • Validate that this process is followed.
6.13	Verify that the control charts (see LIMS chart) list the test method, date QC analyses performed, and initials/name of person performing test.
6.14	Verify from training records that analysts are trained to generate and interpret control charts.
6.15	Verify that the control charts are readily available. [Readily available can be defined as the time for the data to be plotted on the control chart and showing any flags within the time frame necessary to decide whether the test method is in-statistical-control and can be used to analyze product.]
6.16	• Verify that a review of control charts by supervisory personnel is defined in the QC program. • Verify that these reviews are carried out and documented? • Verification of timely reviews might be determined from chart trends or out-of-statistical-control events that are not addressed in timely manner.
6.17	• Verify that procedures are available for outlining the appropriate interpretation of QC charts and response to outof-statistical-control situations. • Verify that these procedures generally comply with D6299 (see Annex A1.5) or otherwise provides adequate control for test method. • Verify that the procedures are followed and documented?
6.18	• Verify that corrective actions are taken for any out-of-statistical-control event prior to analyzing samples. (See 6.12) • For out-of-statistical-control events, verify that a QC sample is run following corrective actions. Determined from inspections of QC chart data for audit cycle
6.19	• Verify that the lab has a procedure to address the decision whether or not to retest samples analyzed during the period between the last in-statistical-control QC data and the QC data that triggered the out-of-statistical-control flag. • Verify that if an analysis of a retain sample shows a difference that is statistically different from the original result, and the difference exceeds the established site precision of that test, the laboratory has procedures to decide on what further actions are necessary.
6.20	• Determine if the laboratory uses the TPI to compare the precision observed from the QC charts (that is, the site precision) with the published precision for the standard test method. • Determine if the laboratory uses the PR along with TPI to estimate the influence that non-site specific variations has on the published precision.
6.21	• Verify that the laboratory periodically reviews their TPI values and takes appropriate action in accordance with their documented procedures. • How often does this data get reviewed? • Verify that the laboratory compares the site precisions (from QC charts) versus the test methods repeatability and reproducibility. • Verify that the laboratory investigates situations where QC chart precision is significantly worse than the test method reproducibility to determine the root cause for this performance so that corrective action can be undertaken if necessary.
6.22	• Verify that the laboratory has procedures for revision of QC chart parameters (as covered in D6299, Section 8.6). • Confirm that these procedures include guidelines for when QC chart revisions are needed. These may include: additional information becomes available, the process has improved, new QC material is initiated and the mean value is different than the previous QC material, or there are major changes to the test procedure. • Verify that QC chart parameters (limits) have been revised when data indicated the need.
6.23	Verify that there are procedures for retention of completed control charts and they are followed.
7.0	**Bias Management and Proficiency Evaluations**

TABLE X2.2 *Continued*

7.1	• Verify that there is a process or procedure covering the participation in PT programs, the analysis and interpretation of the statistical reports, investigation of out-of-statistical-control or warning flags, and corrective actions. • Verify that the data analysis and interpretation process references appropriate tools described in Guide D7372 (subsection 5.2.1) • Verify that the laboratory participates in a PT program like the ASTM ILCP. • Verify that the laboratory provided PT results for all the test that they run. • Verify that the lab maintains QC Charts (or other appropriate QC tools) for the test methods covered in the PTPs as required by regulation. • Verify that participation in a PT program is not a substitute for in-house QC.
7.2	• Verify that the lab follows their process to monitor and evaluate their PT results as presented in the PTP reports in accordance with Guide D7372. • Verify that the lab has taken corrective actions as appropriate.
7.3	Verify that the laboratory assesses the precision of these exchange data against precision established by in-house QC sample testing to determine consistency and adequacy of performance (see Practice D6299, subsection 7.6.2)
8.0	**Data Management**
8.1	Verify that there are procedures (in QAM or LP) dealing with the collection and retention of laboratory generated data. Verify that there are procedures for maintaining records containing the results of tests performed to meet fuels regulations - see 40 CFR 80.101(i).
8.2	Verify from a review of the records maintained for each of the regulatory test methods that sufficient information are recorded and maintained to permit satisfactory replication of the test and recalculation of the results.
8.3	• Verify that the lab is maintaining all the data records required by regulations and company requirements. • Verify that RVP results are reported to the nearest hundredth psi unit (for example, 0.01 psi). • Determine if all required records kept for required period of time?
8.4	Verify that the final/released reports are clear, unambiguous, and accurate.
8.5	• Verify that there are laboratory procedures for accurately reporting test values and properties as required by SOPs and regulations. • Determine if there are any key items missing from these reports.
8.6	Does the procedure for correcting an issued report provide sufficient guidance?
8.7	Do the test units, significant figures and rounding conventions meet regulatory requirements and/or test method?
8.8	See 8.7.
8.9	• Verify that there is a process (QAM or relevant LPs) for addressing retention of records and that the process is compliant with company policy and regulatory (40 CFR 80) requirements. • Verify that the record retention process (in 8.9.1) ensures that original records concerning tests of gasoline properties are maintained for five years from the date the test was performed.
8.10	• Verify that the record storage facility provides safe and secure storage. • Verify that records are held for the minimum period and that they can be retrieved in a reasonable time.
8.11	• Verify that a document control process is in place. Verify that SOPs and LTPs have version/revision numbers or are dated and that they are approved by laboratory management.
9.0	**Training**
9.1	• Verify that the laboratory has procedures to address staff training and covers key areas such as safety, test methods, company policies, and QA/QC procedures. • Verify that the training program identifies any external certifications required for certain staff functions. Verify that these certifications are current and available for each case. • Verify that the training program addresses training for all staff performing testing or interpreting data. A matrix showing which technicians perform the various test methods would be useful in ensuring that the appropriate test method procedure training was conducted for each staff member. • Verify that training being conducted as scheduled or as needed. • Determine if any of the training requires a verification test or other qualifier. • Determine if external courses used to supplement internal training. Verify that course description and training certificates are available.
9.2	Verify that training records are maintained and are complete.
10.0	**Assessments**
10.1	• Verify that there is a process for internal assessment of laboratory operations and that it addresses the following: identification, qualifications and/or training of lead assessors and assessors, establishing an assessment schedule or frequency, assessments of contract laboratories used by refinery, assessment reports, management review of reports, verification of effectiveness of corrective actions. • Verify that the process is followed.
10.2	• Verify that there is a process for conducting Test Method Assessments (TMA) and that it addresses the following: observing the performance of the entire test and checked against the corresponding LTP and/or ASTM test method, TMA schedule for all regulatory tests, TMA assessor qualifications and training. • Verify from records that TMAs are conducted as scheduled.
10.3	• Verify from a review laboratory and test method assessment reports that they are complete and were timely. • Verify that corrective actions were identified for any deficiencies.
10.4	Verify that the laboratory assessment and TMA reports have been reviewed by management and that any corrective actions were completed.
10.5	Verify that the effectiveness of corrective actions from assessments and TMAs are verified and documented by the laboratory.
11.0	**Corrective and Preventive Actions**
11.1	• Verify that there are procedures to provide adequate guidance for addressing corrective and preventative actions. • Verify that these guidelines include an investigation to determine root causes. • How are CARs tracked?
11.2	• Verify the situations for implementing corrective and preventive actions are defined by the laboratory. • These may include one or more of the following unacceptable situations: equipment out of calibration, QC sample out-of-statistical-control, results out of specification (generally investigated by customer and not necessarily by the laboratory), outlier or unacceptable trend in an interlaboratory cross-check program, nonconformance identified in an external or internal audit or TMA, nonconformance identified during review of laboratory data or records, and customer complaint or inquiry. • Verify that target dates established for completing corrective actions.
11.3	Verify that corrective action reports include investigations of root cause.
11.4	• Determine that the lab's corrective action procedures (for QC charts) consider the following: determining when the test of equipment was last known to be in-statistical-control, identifying results that may have been adversely affected, how to handle affected results already reported to a customer, what to do if the root cause cannot be determined, what to do if it is determined that the original data is correct. • Verify that completed CARs include investigations on these items.
11.5	• Verify that corrective action reports are documented promptly and include the situation, root cause and corrective/preventive action taken. • Verify that management reviews and approves CARS. • Determine that corrective actions are verified for effectiveness of the actions.
12.0	**Customer Interactions**

TABLE X2.2 *Continued*

12.1	• Verify that a procedure is established to follow-up on customer complaints or nonconformances brought to the laboratory's attention by the customer. • Customer complaints may be handled as a category of CARs.
12.2	• Verify documentation of customer inquiries. • Was outcome of any investigation or corrective action reported back to the customer?
13.0	**Continuous Improvement**
13.1	Verify that the laboratory has established continuous improvement goals.
13.2	Determine how often these goals are reviewed.

TABLE X2.3 Example Weighted Scoring Practice

Checklist Section	Title	Max Points[A]	Weighted, %
1	Quality Assurance System		10
2	Test Methods		5
3	Sampling and Sample Management		8
4	Calibration		12
5	Maintenance		5
6	Quality Control Program		20
7	Bias Management and Proficiency Evaluations		12
8	Data Management		8
9	Training		4
10	Assessments		8
11	Corrective and Preventive Actions		4
12	Customer Interactions		2
13	Continuous Improvement		2

[A] Maximum points depend on the number of items in the checklist section and the scoring profile selected.

X3. COMPARISON OF REPEATABILITY, REPRODUCIBILITY, PRECISION RATIO AND VARIANCE RATIO TEST OF VARIOUS ROUND ROBINS

X3.1 Practice D6300, subsection A1.7 on Variance Ratio Test (F-Test), provides a detailed discussion of how to determine when significant bias exists for two data sets using the variance ratio. Both the variance ratio, F value and precision ratio, PR were calculated for 38 round robin data sets. Generally, the correlation between F and R/r is not statistically significant to suggest that PR could be used to accurately predict the existence of laboratory-laboratory bias for a given test method. However, this practice is not intended as a detailed statistical analysis of bias between laboratories, rather, the purpose of this practice is to provide some general guidelines for assessing the performance on a laboratory.

X3.2 Generally, for a typical ASTM test method (for example, a typical number of laboratories, six or more, and a typical number of samples studied, ten or more) a F value of 5 or greater exceeds the 5 % critical value given in Practice D6300, Table A1.6 on critical 5 % values of F, suggesting a bias exists between the laboratories. In addition, when the PR value is equal to or greater than 4, the F value is greater than 5. This suggests that some laboratory bias may exist in the test method's reproducibility statement. This observation was the rationale for selecting equal to or greater than 4 as the criterion for switching to more severe performance assessment criteria.

X3.3 The relationship of repeatability, Reproducibility and Site Precision as it relates to performance assessment criteria of a test method with PR<4 for a laboratory is represented in Fig. X3.1. This figure illustrates that a laboratory may have a site precision less than Reproducibility and is similar in magnitude to the published method's repeatability.

X3.4 In Fig. X3.2, there is a similar relationship of repeatability, Reproducibility and Site Precision for a test method with PR>4 as shown in Fig. X3.1. However, the illustration shown in Fig. X3.2 has performance assessment criteria for when PR<4 and PR>4 applied to demonstrate the difference between these two criteria.

X3.4.1 Reviewing Fig. X3.2, a laboratory may have a site precision similar to the test method's reproducibility, that is significantly greater than the published methods repeatability, but based on the PR<4 performance assessment criteria, is still considered to be generating acceptable results. Using the PR>4 performance criterion forces acceptable site precision to be more evenly distributed between repeatability and reproducibility so that a more thorough review of the lab performance may be assessed.

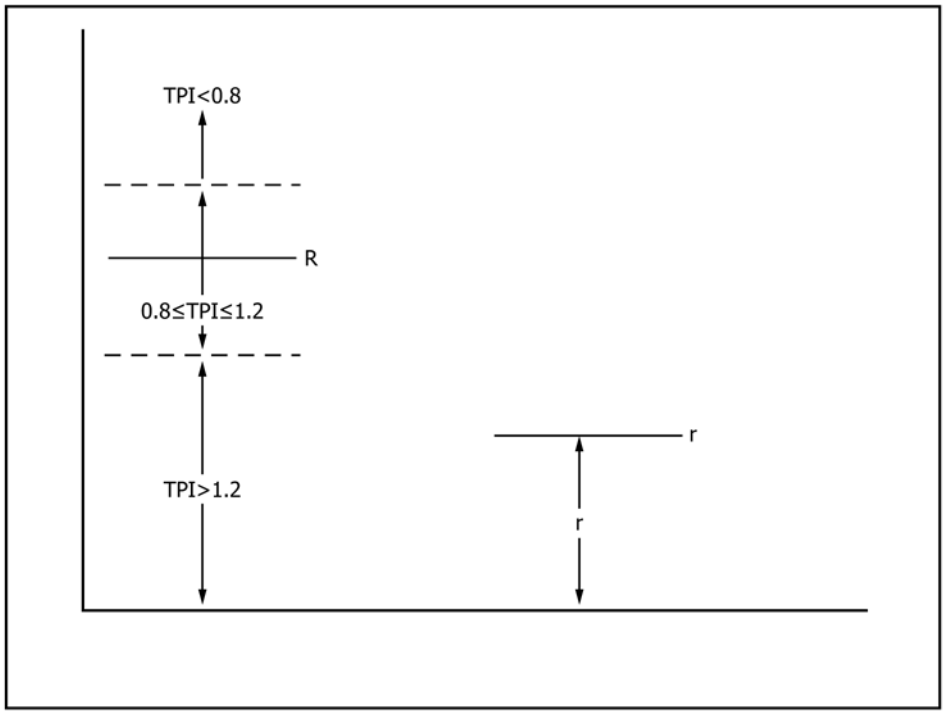

FIG. X3.1 Comparison of Reproducibility, Repeatability and TPI Guideliens for Action for a Test Method with PR<4

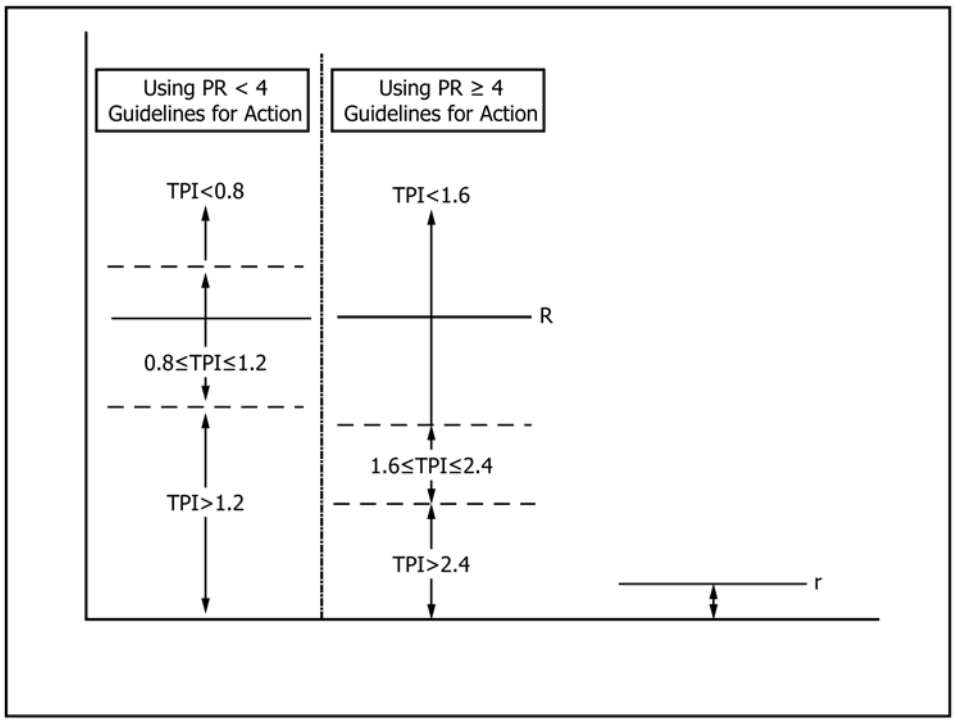

FIG. X3.2 Comparison of Reproducibility, Repeatability and TPI PR<4 and PR≥4 Guidelines for Action for a Test Method with PR≥4

SUMMARY OF CHANGES

Subcommittee D02.94 has identified the location of selected changes to this standard since the last issue (D6792 – 13) that may impact the use of this standard. (Approved May 1, 2017.)

(1) Changes made throughout to better align this standard with industry best practices, and to include the contents of Guide D7776.