Designation: D6792 – 21

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D4182 Practice for Evaluation of Laboratories Using ASTM Procedures in the Sampling and Analysis of Coal and Coke (Withdrawn 2010)[6]

D4621 Guide for Quality Management in an Organization That Samples or Tests Coal and Coke (Withdrawn 2010)[6]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 and Liquid Fuels (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, Liquid Fuels, 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, records, and document management and control (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, Records, and Document Management and Control

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, clearly, objectively, and unambiguously contains all the information in accordance with the test method reporting, specification, customer, or accreditation authority requirements, or combinations thereof, and all other relevant information required for interpretation of the results.

NOTE 3—Reports are typically printed or electronic for external customers, however reports for internal customers may just be an entry in a Laboratory Information Management System (LIMS) or equivalent system.

7.1.2 The intent of the report should be to meet 7.1.1; however, some report requirements may be specified by the customer or an accreditation authority and if so these shall be followed. Other items in the lab report may include:

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 contact information of the customer,

7.1.2.4 Order identification number (if relevant for the work undertaken),

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

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

7.1.2.7 Identification of the test specification, test method(s), or testing procedures used,

7.1.2.8 Description of the sampling procedure, and or subsampling (where relevant to the application of the results),

7.1.2.9 Any deviations, additions to or exclusions from the specified test method requirements,

7.1.2.10 Disclosure of any nonstandard sampling procedure, 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 Product or sample specifications or limits, if applicable,

7.1.2.13 The test results with units of measurement and, where relevant, a statement of the measurement uncertainty,

7.1.2.14 Identification of any test results provided by an external laboratory,

7.1.2.15 Identification of the person(s) authorizing the final report, and

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

7.1.3 Items to be 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.

7.2.3 The test results should be reviewed and authorized before reporting to the customer.

7.3 *Records of Calibration, Verification, and Maintenance:*

7.3.1 Procedures shall be established for the management of instrument calibration records. The procedures used shall be in compliance with that required in the test method reported. Such records usually indicate the instrument calibrated, method or procedure used for calibration, the dates of last and next scheduled calibrations, the person performing the calibration, the values obtained before and after calibration, permissible tolerances, and the metrological traceability (if applicable) of the calibration materials used (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 where it has been identified as a QC tool. The QC procedures used shall be in compliance with that required in the test method reported. It is recommended that such records include the QC sample name, material, and source (if known), the test method(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 the date the QC material was put into active use in the laboratory be documented, along with the expiration date (if applicable).

7.4.2 Procedures for initial setup and re-evaluation of the chart control limits, ongoing evaluation of the control charts, and 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 and Disposal:*

7.5.1 The record retention and disposal 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, archived, and disposed according to laboratory, company, customer, or regulatory agency requirements, or a combination thereof.

7.5.3 Procedures for retaining and disposal of 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, and if changes have been made from the original record then these changes can be tracked to a previous or original record.

7.5.4 The original records shall be held in a suitable environment to prevent loss, damage, deterioration, unauthorized access, or amendment. A system shall exist that allows locating the required documents in a reasonable period of time.

7.5.5 All issued reports should be retained and disposed of in line with customer or regulatory requirements.

7.6 *Document Control:*

7.6.1 Document, implement, and maintain procedures to describe the control of documents in the laboratory. These procedures shall establish the process by which only authorized

and appropriate (typically the most current) version of documents are available to the staff in the area of use. 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, unique identification, authorization for use by relevant personnel, review and update period, and a system whereby unintended use of obsolete documents is prevented.

7.7 *Laboratory Information Management System (LIMS):*

7.7.1 The LIMS system in use should suit the laboratory's circumstances and can be electronic or non-electronic in nature or a mixture of both.

7.7.2 Procedures for backup and recovery of electronic data shall be established.

7.7.3 Procedures shall be established for changes to LIMS system and should include authorization, documentation, and validation of the change.

7.7.4 Procedures shall be established to protect the system from unauthorized access and tampering to maintain the integrity of the data reported.

7.7.5 Calculations and data transfers performed directly from instruments should be validated as accurate on a periodic basis.

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.

[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.

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.

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

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

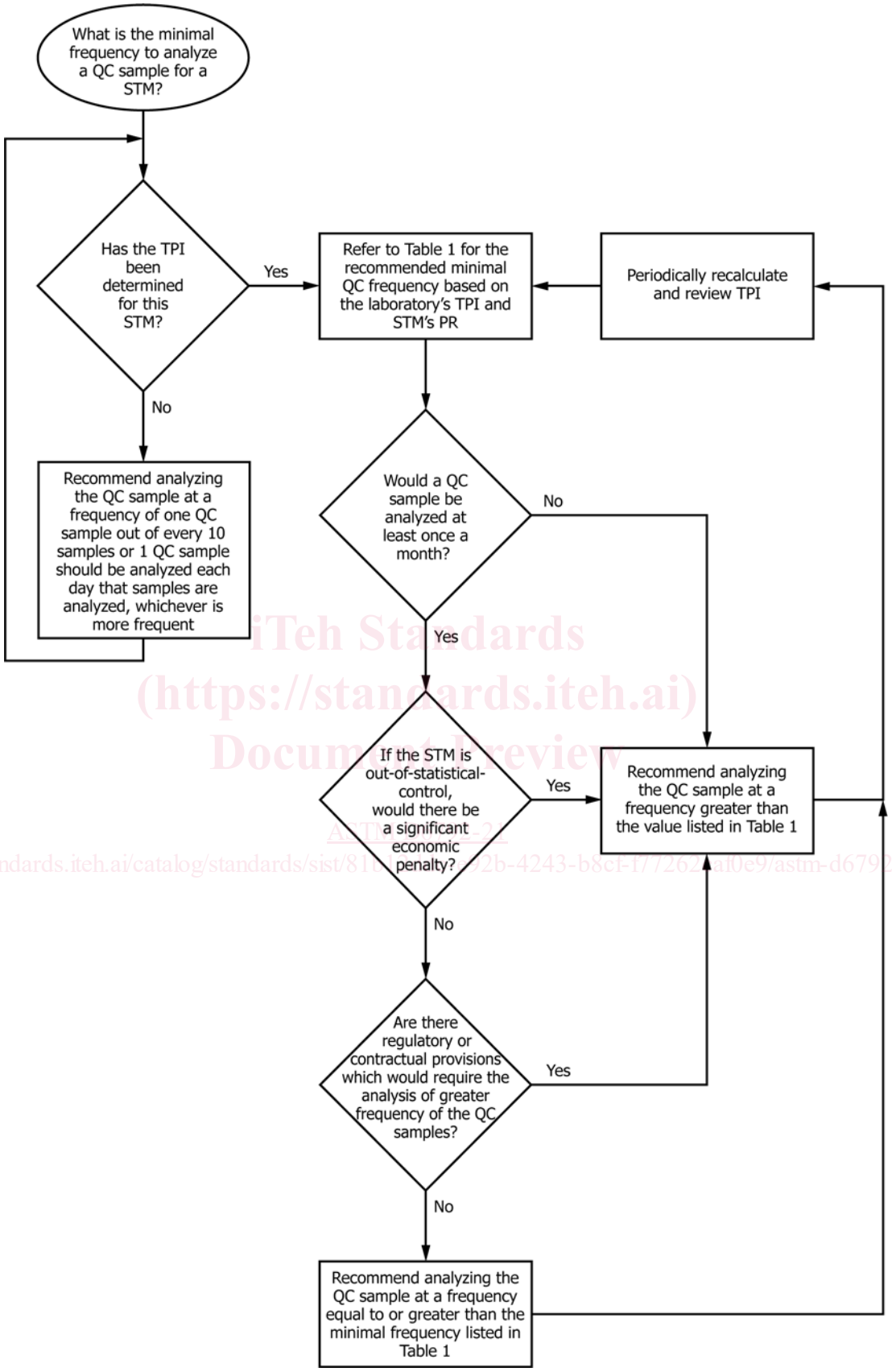

FIG. 1 Flowchart for QC Frequency

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:*

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.

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

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.

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 accredited to ISO/IEC 17025. There are a number of similarities between the ISO/IEC standard and this practice in terms of managing laboratory quality. For example:

Requirement	ASTM Practice D6792	ISO/IEC 17025:2017
Quality Management System	5.1; 5.2; 5.3	5.1; 5.2; 5.3; 5.4; 5.5; 5.6
Management Reviews	5.3	8.9
Contract Review	5.4.9	7.1
Sampling and Sample Management	6.2	7.3; 7.4
Reports of Analysis	7.1; 7.2	7.8
Control of Records	7.3; 7.4; 7.5; 9.6	8.4
Document Control	7.6; 8.1; 8.3; 8.4	8.3
Laboratory Information Management System	7.7	7.11
Test Methods	8.2; 8.3; 8.4	7.2.2
Calibration	9.2	6.5
Equipment	9.2; 9.3; 9.4; 9.5; 9.7	6.4
Validity of Results	10.1; 10.2; 10.3; 10.4	7.7
Internal Audits	11.1	8.8
Proficiency Testing	11.2	7.7.2
Corrective Action	13; Appendix X1	7.10; 8.6; 8.7
Preventive Action	13.4	8.5; 8.6
Complaints	14.1	7.9
Training	15.1; 15.2	6.2

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—References to ASTM Practice D6792 are not exclusive to those sections indicated as there may be related requirements found throughout the document. Only the key sections for comparison to ISO/IEC 17025:2017 were included.

NOTE 19—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