Designation: D 6792 – 02

An American National Standard

Standard Guide for A Quality System in Petroleum Products and Lubricants Testing Laboratories[1]

This standard is issued under the fixed designation D 6792; 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 guide covers the establishment and maintenance of the essentials of a quality system in laboratories engaged in the analysis of petroleum products and lubricants. It is designed to be used in conjunction with Practice D 6299.

NOTE 1—This guide is based on the quality management concepts and principles advocated in ANSI/ISO/ASQ Q9000 standards, ISO Guide 17025, ASQC Manual,[2] and ASTM standards such as D 3244, D 4182, D 4621, D 6299, D 6300, E 29, E 177, E 456, E 548, E 882, E 994, E 1301, E 1323, 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.*

2. Referenced Documents

2.1 *ASTM Standards:*

D 3244 Practice for Utilization of Test Data to Determine Conformance with Specifications[5]

D 4182 Practice for Evaluation of Laboratories Using ASTM Procedures in the Sampling and Analysis of Coal and Coke[6]

D 4621 Guide for Quality Management in an Organization that Samples or Tests Coal and Coke[6]

D 6299 Practice for Applying Statistical Quality Assurance Techniques to Evaluate Analytical Measurement System Performance[7]

D 6300 Practice for Determination of Precision and Bias Data for Use in Test Methods for Petroleum Products and Lubricants[7]

D 6617 Practice for Laboratory Bias Detection Using Single Test Result from Standard Material[8]

E 29 Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications[9]

E 177 Practice for Use of the Terms Precision and Bias in ASTM Test Methods[9]

E 456 Terminology Relating to Quality and Statistics[9]

E 548 Guide for General Criteria Used for Evaluating Laboratory Competence[9]

E 691 Practice for Conducting an Interlaboratory Study to Determine the Precision of a Test Method[9]

E 882 Guide for Accountability and Quality Control in the Chemical Analysis Laboratory[10]

E 994 Guide for Calibration and Testing Laboratory Accreditation Systems General Requirements for Operation and Recognition[9]

E 1301 Guide for Proficiency Testing by Interlaboratory Comparisons[9]

E 1323 Guide for Evaluating Laboratory Measurement Practices and the Statistical Analysis of the Resulting Data[9]

2.2 *ISO Standards:*[11]

ISO Guide 30 Terms and Definitions Used in Connection with Reference Materials

ISO Guide 17025 General Requirements for the Competence of Calibration and Testing Laboratories

ISO Standard 4259 Petroleum Products—Determination and Application of Precision Data in Relation to Methods of Test

ANSI/ISO/ASQ Q9000 Quality Management System Standards

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

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

Current edition approved April 10, 2002. Published August 2002.

[2] "Quality Assurance for The Chemical and Process Industries: A Manual of Good Practices," 1987, available from American Society for Quality Control, 611 E. Wisconsin Ave., Milwaukee, WI 53292.

[3] *ASTM STP 15D*, "ASTM Manual on Presentation of Data and Control Chart Analysis," available from ASTM International Headquarters.

[4] *ASTM STP 1209*, "ASTM Manual on Total Quality Management," available from ASTM International Headquarters.

[5] *Annual Book of ASTM Standards*, Vol 05.02.

[6] *Annual Book of ASTM Standards*, Vol 05.06.

[7] *Annual Book of ASTM Standards*, Vol 05.03.

[8] *Annual Book of ASTM Standards*, Vol 05.04.

[9] *Annual Book of ASTM Standards*, Vol 14.02.

[10] *Annual Book of ASTM Standards*, Vol 03.06.

[11] Available from American National Standards Institute, 25 W. 43rd St., 4th Floor, New York, NY 10036.

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. **E 456**

3.1.2 *accuracy*, *n*—the closeness of agreement between a test result and an accepted reference value. **E 456**

3.1.3 *audit*, *n*—a systematic examination of a laboratory's quality system procedure and related activities by an internal or external team to determine whether these procedures or activities are implemented according to the documented system.

3.1.4 *bias*, *n*—the difference between the population mean of the test results and an accepted reference value. **E 456**

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 *outlier*, *n*—a result far enough in magnitude from other results so as to be considered not a part of the set. **D 6300**

3.1.8 *precision*, *n*—the closeness of agreement between test results obtained under prescribed conditions. **E 456**

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

3.1.9.1 *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.

3.1.10 *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.

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

3.1.11 *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.

3.1.12 *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. **D 6299**

3.1.13 *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.

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

3.1.14 *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. **D 6300**

3.1.15 *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 the defined as the 95 % confidence limit for the difference between two such single and independent results. **D 6300**

3.1.16 *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. **D 6299**

3.1.17 *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 from the same sample of material over an extended period of time spanning at least a 15 day interval. **D 6299**

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

3.3 *Acronyms:*

3.3.1 *NIST*, *n*—National Institute of Standards and Technology (formerly called National Bureau of Standards), Gaithersburg, MD.

4. Significance and Use

4.1 A petroleum products 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 system in a laboratory.

5. General Quality Requirements for the Laboratory

5.1 Establishment and maintenance of a quality 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 system in the laboratory.

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

5.4 The quality system shall have documented processes for:

5.4.1 Sample management (see Section 6),

5.4.2 Data and record management (see Section 7),

5.4.3 Producing accurate, reliable, and properly represented test results (see Section 8),

5.4.4 Audits and proficiency testing (see Section 9),

5.4.5 Corrective and preventive action (see Section 11),

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

5.4.7 Ensuring that personnel are adequately trained to obtain quality results.

6. Sample Management

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

6.1.1 Procedures for unique sample identification.

6.1.2 Criteria for sample acceptance.

6.1.3 Procedures for sample handling.

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

6.1.4.1 Applicable government—local, state, or national—regulatory requirements for shelf life and time-dependent tests that set product stability limits,

6.1.4.2 Type of sample containers required to preserve the sample,

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

6.1.4.4 Storage conditions,

6.1.4.5 Required safety precautions, and

6.1.4.6 Customer requirements.

6.1.5 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,

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,

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, 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),

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.

7.2.2 If rounding is performed, the rounding protocol of Practice E 29 should be used unless otherwise specified in the method or procedure.

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, 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, the dates of last and next maintenance, and the person performing the maintenance. Records may be electronic.

NOTE 4—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.