Designation: D6792 – 23a

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]

D630 Specification for Olive Oil Chip Soap (Type A, Straight; Type B, Blended) (Withdrawn 1979)[6]

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

D4057 Practice for Manual Sampling of Petroleum and Petroleum Products

D4175 Terminology Relating to Petroleum Products, Liquid Fuels, and Lubricants

D4182 Practice for Evaluation of Laboratories Using ASTM Procedures in the Sampling and Analysis of Coal and Coke (Withdrawn 2010)[6]

D4621 Guide for Quality Management in an Organization That Samples or Tests Coal and Coke (Withdrawn 2010)[6]

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

D7372 Guide for Analysis and Interpretation of Proficiency Test Program Results

D8428 Guide for Establishing Analyst Competence to Perform a Test Method

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 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

[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**

E2476 Guide for Risk Assessment and Risk Control as it Impacts the Design, Development, and Operation of PAT Processes for Pharmaceutical Manufacture

2.2 *ISO Standards:*[7]

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

ISO Guide 73 Risk Management – Vocabulary

ISO 4259-3 Petroleum and related products – Precision of measurement methods and results – Part 3: Monitoring and verification of published precision data in relation to methods of test

ISO 4259-4 Petroleum and related products – Precision of measurement methods and results – Part 4: Use of statistical control charts to validate 'in-statistical-control' status for the execution of a standard test method in a single laboratory

ISO 9000 Quality Management Systems – Fundamentals and Vocabulary

ANSI/ISO/ASQ Q9000 Quality Management System Standards

ISO/IEC 17000 Conformity Assessment – Vocabulary and general principles

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

ISO 31000 Risk Management – Guidelines

2.3 *Other Standards:*

40 CFR 80 Regulation of Fuels and Fuel Additives[8]

3. Terminology

3.1 *Definitions:*

3.1.1 For a more extensive list of terms used by laboratories engaged in the analysis of petroleum products, liquid fuels, and lubricants refer to Terminology D4175.

3.1.2 More extensive lists of terms related to quality management systems are found in ISO 9000 and ISO/IEC 17000, terms related to risk management are found in ISO Guide 73 and ISO 31000, and terms related to quality and statistics are found in Practice D630 and Terminology E456.

3.1.3 *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**

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

3.1.5 *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.

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

3.1.7 *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.

3.1.8 *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**

3.1.9 *correction, n*—action to eliminate a detected nonconformity. **ISO 9000**

3.1.9.1 *Discussion*—A correction may be performed before, during, or after corrective action. **ISO 9000**

3.1.9.2 *Discussion*—Corrections are typically one-time fixes that immediately address the nonconformity, but may not prevent recurrence.

3.1.10 *corrective action, n*—action taken to eliminate the cause of a nonconformity and to prevent recurrence. **ISO 9000**

3.1.10.1 *Discussion*—There can be more than one cause for a nonconformity. **ISO 9000**

3.1.10.2 *Discussion*—Corrective action is taken to prevent recurrence whereas preventive or continuous improvement actions are taken to prevent occurrence. **ISO 9000**

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

3.1.12 *nonconformity, n*—non-fulfillment of a requirement. **ISO 9000**

3.1.12.1 *Discussion*—The non-fulfilment of the requirement may render the quality of the product or service unacceptable, indeterminate, or not according to specified requirements and may be identified through several sources.

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

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

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

3.1.15.1 *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.

3.1.16 *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.

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

[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.

3.1.17 *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.

3.1.18 *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**

3.1.19 *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.

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

3.1.20 *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**

3.1.21 *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**

3.1.22 *risk, n*—effect of uncertainty on objectives. **ISO 31000**

3.1.22.1 *Discussion*—An effect is a deviation from the expected and can be positive, negative, or both, and can address, create, or result in opportunities and threats. **ISO 31000**

3.1.23 *risk appetite, n*—organization's approach to assess and eventually pursue, retain, take, or turn away from risk. **ISO Guide 73**

3.1.24 *risk assessment, n*—overall process of risk identification, risk analysis, and risk evaluation. **ISO Guide 73**

3.1.24.1 *Discussion*—Risk assessments typically utilize an evidence based approach to assist the decision making process when evaluating the impact of risk to the laboratory. The risk should be evaluated in terms of consequence to the business and likelihood of recurrence when no mitigation of the risk is implemented.

3.1.25 *risk management, n*—coordinated activities to direct and control an organization with regard to risk. **ISO 31000**

3.1.26 *risk tolerance, n*—organization's readiness to bear the risk after risk treatment in order to achieve its objectives. **ISO Guide 73**

3.1.26.1 *Discussion*—Risk tolerance can be influenced by legal or regulatory requirements. **ISO Guide 73**

3.1.27 *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**

3.1.28 *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. **D6299**

3.1.29 *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: