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.

Designation: D8428 – 21

Standard Guide for Establishing Analyst Competence to Perform a Test Method[1]

This standard is issued under the fixed designation D8428; 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 general guidance on assessing the competence of an analyst to perform a specific test method for a specific product or set of products (for example, light distillates). It also provides guidance on some of the possible approaches that may be taken to perform the assessment.

1.2 This guide is intended for the establishment of competence for the entire performance of a test method (that is, sample preparation, instrument set up, preparation of standards and reagents, performance of the test method, calculations, etc.) or the establishment of competence may be limited to a specific aspect in the performance of a test method (for example, sample preparation).

1.3 The establishment of analyst competence should only be performed if the laboratory itself is capable of performing the test in strict conformance with the test method (that is, has the equipment, standards and reagents, materials, etc. which meet test method requirements).

1.4 This guide does not cover training of an analyst, other than a review of training records to indicate the analyst has been trained.

1.5 This guide does not cover the establishment of general technical competence of an analyst.

1.6 *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 limitations prior to use.*

1.7 *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:*[2]

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

D6792 Practice for Quality Management Systems in Petroleum Products, Liquid Fuels, and Lubricants Testing Laboratories

D7372 Guide for Analysis and Interpretation of Proficiency Test Program Results

E456 Terminology Relating to Quality and Statistics

2.2 *ISO Standards:*[3]

ISO Guide 30 Reference materials - Selected terms and definitions

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

ISO 17034 General Requirements for the Competence of Reference Material Producers

ANSI/ISO/ASQ Q9000 Quality Management System Standards

2.3 *Other Standards:*

AASHTO R-18 Standard Recommended Practice for Establishing and Implementing a Quality Management System for Construction Materials Testing Laboratories[4]

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

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

Current edition approved Dec. 1, 2021. Published January 2022. DOI: 10.1520/D8428-21.

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

[3] Available from International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, https://www.iso.org.

[4] Available from American Association of State Highway and Transportation Officials (AASHTO), 444 N. Capitol St., NW, Suite 249, Washington, DC 20001, http://www.transportation.org.

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experimental work under the auspices of a scientific or engineering group. **E456**

3.1.2 *calibration standard, n*—a material with a certified value for a relevant property, issued by or traceable to a national organization such as NIST or whose production was ISO 17034 accredited, and whose properties are known with sufficient accuracy to permit its use to evaluate the same property of another sample.

3.1.3 *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. **D6792**

3.1.4 *proficiency testing, n*—determination of a laboratory's testing capability by evaluating its test results in interlaboratory exchange testing or crosscheck programs. **D6792**

3.1.5 *proficiency test program (PTP), n*—statistical quality assurance activities that enable laboratories to assess their performance in conducting test methods within their own laboratory when their data are compared against other laboratories that participate in the same program cycle using the same test method. **D7372**

3.1.6 *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**

3.1.7 *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. **D6792**

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

3.1.8 *site expected value (SEV), n*—for a QC sample this is an estimate of the theoretical limiting value towards which the average of results collected from a single in-statistical-control measurement system under site precision conditions tends as the number of results approaches infinity. **D6299**

3.1.9 *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 which may comprise multiple instruments, 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**

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *analyst competence, n*—verified demonstration of appropriate knowledge and skills to perform a test according to test method requirements without direct oversight.

3.3 *Acronyms:*

3.3.1 *NIST*—National Institute of Standards and Technology

4. Significance and Use

4.1 Analyst Competence is one of the largest influencing factors in whether a test method performed in a laboratory yields accurate and precise test results and thus is an important aspect in managing a laboratory.

4.2 Some Regulations, International Management System Standards, such as ISO 9001, ISO 17025, AASHTO R-18, etc., and Quality Management Systems may require the establishment of analyst competence. This guide aims to provide general guidance in some of the possible approaches that may be taken to fulfill such requirements.

5. General Recommendations

5.1 It is recommended that the process for establishment of analyst competence be documented within the organization's Quality Management System. Documentation may include, but is not limited to, coverage of the following areas listed in Table 1.

5.2 The assessment process should consider factors beyond the actual performance of a test method such as knowledge of the significance and use of the test, knowledge of equipment operation and basic troubleshooting.

5.3 Records should be clear as to what the analyst is being deemed competent to perform. If the establishment of competence is limited to only a particular aspect of the performance of a test method such as sample preparation, it is recommended

TABLE 1 Documentation Elements

Element	Description
Approaches for the Establishment of Competence	Explanation of the approaches taken for the establishment of competence, which may vary dependent on several factors including whether the test is regulated, accredited or has a high level of commercial importance.
Assessor Qualifications	In cases where the establishment of competence involves an assessor, the qualifications of the assessor should be defined, even if the qualifications are general (e.g., a specific level of education, certain number of years of relevant experience, etc.).
Timing and Frequency	The timing and frequency for establishing competence, including re-establishment of competence should be defined (e.g., at what point should the competence be established and for how long is it valid).
Handling of Deficiencies	Actions to be taken to correct analyst and laboratory deficiencies which are detected during the establishment of competence and next steps once the deficiencies have been corrected.
Declaration of Competence and Levels of Competence	In cases where a laboratory wishes to declare or establish various levels of competence, these should be defined. An example is provided in Appendix X1.
Record Keeping	How records generated through the process of establishing competence are managed including retention. An example of a record to document the establishment of competence is provided in Appendix X2.