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

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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

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[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.

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.

that this be evident in any records of competence. If the analyst is competent to perform a test method, then the test method designation and version should be recorded not just the technique, that is, D2622 – 16 instead of Sulfur by WDXRF. Also, if a test method is comprised of more than one procedure or has multiple options, then records should be clear as to which of these procedures or options was assessed.

5.4 Assessment of competence should include a review to establish that an analyst has received training. In cases where training records are not accessible, this review may not be possible.

5.5 A lack of documented evidence in support of an analyst's competency to perform a test method should initiate the establishment of competence.

5.6 In cases where a test method has been revised, an evaluation should be performed to determine if re-assessment for analyst competence is necessary. In cases where revisions to test methods are not technical in nature and do not impact the outcome of the result, then a re-assessment of analyst competence is likely not necessary. The decision and rationale to not re-assess for minor revisions should be documented. In cases where the revision does not impact how the test is performed, analysts only need to be made aware that there was a revision and not necessarily what the revisions were.

5.7 Re-assessment frequency may vary for test methods based on several factors including, but not limited to, how critical the test is to the laboratory or its customers, whether performance of the test has subjective elements. Additionally, if an analyst does not perform the test regularly or has not performed the test in a long while, it may be advisable to perform a re-assessment before the analyst is deemed competent to perform the test method. Criteria for re-assessment should be defined and documented by the laboratory. If records are updated to reflect competence for a more current version of the test method and a reassessment for competence was not performed for reasons covered under 5.6, the frequency for re-assessment should not reset and should remain intact.

5.8 The approaches listed in Section 6 are in order from simple to more rigorous. A more rigorous approach is recommended, particularly with those tests that the laboratory considers to be critical. Laboratories may use a combination of approaches for different test methods.

5.9 Establish criteria for meeting qualification levels of analyst competence prior to performing the assessment.

6. Approaches to Establishing Analyst Competence to Perform a Test Method

6.1 *Written Examination:*

6.1.1 Written examinations evaluate an analyst's knowledge of the test method.

6.1.2 Written examinations should be reviewed and updated as test methods are revised.

6.1.3 The score at which competency is considered satisfactory should be defined and documented.

6.1.4 There should be a sufficient number of questions to establish the analyst's full understanding of the test method.

6.1.5 To assure the integrity of the written examination, randomized selection of questions from a question "bank" should also be considered.

6.2 *Analyst Interview:*

6.2.1 Questions and answers asked of the analyst should be documented.

6.2.2 The assessor should be technically competent to perform such an assessment and there should be a record to support the assessor's competence.

6.2.3 Cautions should be taken so that the assessor does not "lead" the analyst to the desired answers.

6.3 *Analysis of Reference Material:*

6.3.1 This approach involves having an analyst perform testing on a material with an ARV or SEV. There may be cases where the ARV or SEV is not yet known at the time of the assessment (for example, Exchange Sample) and thus may be obtained later so that the assessment may be concluded.

6.3.1.1 Exchange samples circulated as part of an interlaboratory exchange program, or round robin, may be used as reference material. For an exchange sample to be usable the standard deviation of the interlaboratory exchange program shall not be statistically greater than the reproducibility standard deviation for the test method. An F-test should be applied to test acceptability.

6.3.1.2 If a previously tested exchange sample is used for the assessment, cautions should be taken as the properties may have changed over time.

6.3.1.3 Testing a QC material with an established SEV is a viable and perhaps preferred approach to testing a PTP sample or a Certified Reference Material.

NOTE 1—A QC material may be preferred as it generally less costly and provides precision statistics for the laboratory's actual capability.

6.3.2 In order to guard against the analyst taking steps or precautions that they would not normally take in the course of testing any other routine sample, it is highly recommended that this be a "blind" sample (that is, the analyst is not aware that their results are part of an assessment of their competence).

6.3.3 The acceptance criteria for whether obtained results are satisfactory should be defined and documented.

6.3.4 Aside from or in addition to assessing accuracy, a laboratory may wish to have an analyst analyze a sample multiple times so that precision may be assessed as a means for establishing competence. In cases where a sample with an ARV is difficult to obtain, this may be the only viable approach to take in certain situations.

6.3.5 If the properties or outcomes of the test require a subjective assessment, consistent, accurate outcomes should be subject to a particularly rigorous assessment of competence. Assessment of several "blind" samples, comparison of results to other competent analysts, or other means to verify precision and accuracy of results are encouraged.

6.3.6 In cases where a portion of the test is subjective and the subjective determination is being made on a material that may be retained/preserved while still maintaining its physical properties (for example, a Copper Strip [D130] or Heater Tube Deposit Rating [D3241]), the material may be maintained for the purpose of assessment of the subjective portion of the

performance of a test. In such cases, it is assumed that the ARV would be the consensus value.

6.4 *Test Method Assessment:*

6.4.1 The Test Method Assessment is a multi-step process involving the checking of records, equipment, observation of the analyst, and assessment of results against SEVs or ARVs. The Test Method Assessment is recommended for those tests which are considered critical to the laboratory.

6.4.2 An example of a form that may be utilized to record the Test Method Assessment is provided in Appendix X3. Another way of documenting the Test Method Assessment is to print out the Test Method and make notations on the printed version of the test method itself. Test method specific assessment checklists may be utilized, but these may be difficult to maintain given how frequently test methods are revised.

6.4.3 Some laboratories may approach the assessment in two phases, one phase to assess areas that are general and not specifically related to an individual analyst's technique (for example, whether the equipment specifications conform to test method requirements), and a second phase to witness the analyst's technique specifically. In such cases, these two phases do not need to be performed simultaneously, but it is recommended that the amount of time which elapses between the two phases does not exceed one month.

6.4.4 The first step of the assessment is to perform the assessment pre-work.

6.4.4.1 Print out the test method and other materials in which the assessment will be conducted against (for example, sections of equipment manuals, test method SOPs, etc.) and annotate or highlight specific sections that will be reviewed or witnessed during the assessment process.

6.4.4.2 Possible areas of assessment and their descriptions are listed in Table 2.

6.4.5 Once the pre-work is completed, the assessment may be performed. The assessment may include a variety of techniques including the review of records, interviewing of staff and observation of the analyst performing the test on a reference material.

6.4.6 The observation portion of the assessment should be done in a comprehensive manner without undue influence.

6.4.7 When providing the sample to be tested to the analyst being observed, provide sufficient information about the sample to complete the test.

6.4.8 During the witnessing part of the assessment, it is recommended that the assessor communicate any areas of nonconformance or concern to the analyst during the witnessing process and record them, even if they were corrected during the assessment.

6.4.9 Nonconformities and concerns should be evaluated by the assessor to determine whether re-training is necessary.

6.4.10 When the witnessing is complete, evaluate the test results to determine if they meet acceptance criteria.

6.5 Each of the approaches listed above has limitations which are provided in Table 3.

TABLE 2 Possible Assessment Areas for Test Method Assessment

Assessment Area	Assessment Area Description
Training & Competence	Any analysts being witnessed should have records to demonstrate that they have been trained (see 5.4).
Application of Scope	Analyst should be aware of the scope limitations of the test method.
Apparatus / Equipment Specs	Apparatus and Equipment should be in conformance with any test method specifications and where practical, this should be verified.
Equipment Set Up / Preparation / Operation	Apparatus and Equipment should be in conformance with any test method specifications and where practical, this should be verified.
Equipment Calibration, Verification and Maintenance	The equipment should be calibrated, verified and maintained in conformance with test method and instrument manufacturer requirements as well as organizational procedures and instructions, and should be current.
Standards, Reagents, Materials	Standards, reagents and materials should meet test method requirements and be suitable for use (e.g., standardization is accurate and current, stored properly, in good condition, etc.).
Sample Handling / Preparation	Samples should be handled and prepared in accordance with test method requirements or other standards referenced within the test method (e.g., heating time and temperatures, precautions to minimize vapor loss, etc.).
Procedure Adherence / Technique	When observing the analyst perform the test, the analyst should conform to each step of the test method procedure EXACTLY, even if the analyst or assessor feels that deviations would not have an impact on accuracy or precision of test results.
Recording of Raw Data	Raw data should be recorded neatly, accurately and unambiguously.
Calculations and Rounding	Calculations and rounding should be performed correctly.
QA/QC Protocols	Quality Assurance and Quality Control should be done in accordance with test method and any organizational requirements. Assessing this may include the review of QC Charts or other records.
Results Review & Traceability	Once testing is completed, results should be reviewed according to organizational requirements and all data should be traceable to the analyst, the date the testing was performed and the sample which was tested.
Clean Up	Once testing is completed, the analyst should clean up the affected area.
Health, Safety and Environmental (HSE) Aspects	Equipment and area should be free of any unacceptable HSE concerns, and the analyst should exhibit appropriate behavior such as wearing of Personal Protective Equipment (PPE).

7. Keywords

7.1 analyst competence; proficiency test program; test method assessment

TABLE 3 Limitation of Each Analyst Competency Approach

Approach	Limitation
Written Examination	Does not validate the actual execution of the analysis.
Analyst Interview	Prone to personal bias.
Analysis of Reference Material	Only checks the end result and does not consider the conformance with the test method.
Test Method Assessment	Multi-step process which takes time and resources.

APPENDIXES

(Nonmandatory Information)

X1. EXAMPLE OF COMPETENCE LEVELS

X1.1 Three Level Example of Analyst Competence

Level 1 (L1) – In Training	Level 2 (L2) – Fully Competent	Level 3 (L3) – Qualified Trainer
Analyst has a fundamental understanding of the subject matter but should only apply this knowledge under supervision by someone having a L2 level of competence on the subject.	Analyst has a full grasp of the subject matter and has demonstrated the ability to apply his/her knowledge. Supervision should not be necessary.	Analyst has a full understanding of the subject matter and can confidently train others provided they have the necessary communication skills.