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Designation: <del>D7036 - 12</del> D7036 - 16

### **Standard Practice for** Competence of Air Emission Testing Bodies<sup>1</sup>

This standard is issued under the fixed designation D7036; 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 ( $\epsilon$ ) indicates an editorial change since the last revision or reapproval.

#### 1. Scope

1.1 This Practice specifies the general requirements for the competence to carry out sampling and analysis for air emissions tests of stationary sources. It covers testing and calibration performed using standard methods, non-standard methods and methods developed by the AETB.

1.2 This Practice is applicable to all bodies engaged in air emission testing regardless of the number of personnel or the scope of testing activities. When an AETB does not undertake one or more of the activities covered by the Practice such as developing test methods, the requirements of those clauses do not apply.

1.3 The notes given provide clarification of text, examples, and guidance. The notes do not contain requirements and do not form an integral part of this Practice.

NOTE 1—ISO/IEC 1702517025:2005 has been considered when elaborating this Practice. Several, but not all, statements of this Practice are consistent with ISOISO/IEC 17025:2005.

NOTE 2-This Practice is a specification for competence. It does not address accreditation or any activities specific to accreditation such as on-site inspections/audits by external assessors or proficiency testing.

#### 2. Referenced Documents

2.1 ASTM Standards:

2.1 ASIM Standards. D1356 Terminology Relating to Sampling and Analysis of Atmospheres NCSL RP-1 Establishment and Adjustment of Calibration Intervals<sup>2</sup>

ISO 17025ISO/IEC 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories<sup>3</sup>

#### 3. Terminology

3.1 For air quality and other terms not defined here in, please refer to ASTM D1356-15 Standard Terminology Relating to Sampling and Analysis of Atmospheres.

3.2 Definitions: Terms Specific to this Standard:

3.2.1 air emission testing—the direct testing of emissions to the atmosphere from stationary sources by sampling, measurement, and analysis including determination of the relative accuracy and QA/QC auditing of continuous monitoring systems. This definition excludes fuel sampling, visible emission evaluations, and daily operation and maintenance of continuous monitoring systems.

3.2.2 air emission testing body (AETB)—a company or other entity that conducts Air Emission Testing.

3.2.3 approved test protocol—a statement, approved by the relevant regulatory authority or other receiving party, of the objectives of a specific test program and the test methods (and deviations) to be used to achieve those objectives. Also referred to as "sampling plan" or "test plan."

3.2.4 competence—for an AETB, competence is the ability to consistently produce acceptable data of known and documented quality. An AETB shall be considered competent if it has in place and continually operates under a Quality System meeting the requirements of this Practice.

3.2.5 contract—any oral or written agreement between an AETB and a customer to provide services to that customer.

<sup>&</sup>lt;sup>1</sup> This Practice is under the jurisdiction of ASTM Committee D22 on Air Quality and is the direct responsibility of Subcommittee D22.03 on Ambient Atmospheres and Source Emissions.

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<sup>&</sup>lt;sup>2</sup> NCSL International, Wilderness Place, Suite 107, Boulder, Colorado 80301-540480301-5404.

<sup>&</sup>lt;sup>3</sup> Available from American National Standards Institute (ANSI), 25 W. 43rd St., 4th Floor, New York, NY 10036.



3.2.6 *external qualification exam*—a Qualification Exam meeting the requirements of 6.2.3.66.2.3.4 and administered by an Independent Proctor. In addition, an External Qualification Exam must be: (1) approved with regard to content and format by a Qualification Exam Provider. This test will be administered in accordance with rules established by the Provider; and (2) administered and scored by an Independent Proctor.

3.2.7 *independent proctor*—a person not employed by or associated with the AETB who oversees the administration of the External Qualification Exam according to the the rules established by the qualification exam provider.

3.2.8 internal qualification exam—a Qualification Exam meeting the requirements of 6.2.3.4 and administered by the AETB.

3.2.9 *known and documented quality*—for the purposes of this Practice, data will be of known and documented quality if collected under a Quality System meeting the requirements of this Practice (including adherence to approved test protocols and deviations).

3.2.10 *performance data*—data generated <u>and/oror</u> collected <u>or both</u> by the AETB indicating conformance with customer and regulatory requirements and with the requirements of this Practice. Such data may include feedback from regulatory agency observers, customers, internal and external audit results, results from participation in proficiency testing programs and any other data that provides direct, objective documentation of the quality of data collected by the body.

3.2.11 *performance issue*—a Performance Issue (or Quality System problem) may be of two types: (1) some aspect of a test program or test data failed to meet expectations; and (2) failure to follow the Quality Manual or a required component of the manual is absent.

<u>3.2.12 preventive action</u>—preventive action is a proactive process to identify opportunities for improvement rather than a reaction to the identification of problems or complaints. Apart from the review of the operational procedures, the preventive action might involve the analysis of data, including trends and risk analysis.

3.2.13 proficiency test-a means of evaluating an AETB's performance relative to a given set of criteria.

3.2.13.1 Discussion-

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A proficiency test, for example, may be a blind determination of a reference sample, comparison of paired sampling trains, or recovery from dynamic spiking.

3.2.14 *qualification credentials*—evidence that the Qualified Individual meets the requirements of  $\frac{6.2.3.26.2.3}{6.2.3}$  and that clearly states the scope of the Qualification (for for example, a certificate from a Qualification Exam Provider).an AETB.

3.2.15 *qualification exam*—a test to evaluate the knowledge of the individual to become qualified.

3.2.16 *qualification exam provider*—a recognized association of AETBs—who oversees, maintains, and/orand approves the format and content of Qualification Exams meeting the requirements of this Practice. A Qualification Exam Provider also develops policies and procedures for the administration of the Exams and issues Qualification Credentials.Exams.

3.2.17 qualified individual—individual (QI)—an individual who meets the requirements specified in 6.2.3.26.2.3 of this Practice.

<u>3.2.18 request</u>—any request of an AETB by a customer for services. A request may be verbal or in writing. (for example, request for proposal).

3.2.19 tender-any formal or informal response to a customer's request by an AETB (for example, proposal).

3.2.20 test method—an externally or internally published procedure for sampling or analysis or both of emissions from stationary sources.

#### 4. Significance and Use

4.1 This Practice establishes general criteria for a Quality System that, when followed, helps ensure consistently acceptable data quality from an AETB. The relevant criteria contained in this Practice shall be addressed in the AETB's Quality Manual, which shall contain or refer to additional specific criteria and requirements where relevant and necessary. The Quality Manual and its implementation (including test protocols, reports, and personnel testing) shall provide the sole basis for determining the conformance of the AETB with this standard.

NOTE 3—This Practice assesses the overall ability of an AETB to deliver data of known and documented quality on a consistent basis regardless of the test method used. There is no requirement to define a scope of testing. It is a requirement of this Practice that prior to performing a test method for the first time, the AETB has in place resources, training, and QA/QC consistent with this Practice to insure data of acceptable quality are produced.

4.2 This Practice is for use by AETBs in developing the quality, administrative, and technical systems that govern their operations. Clients, regulatory authorities, and accreditation bodies may also use it in confirming or recognizing the competency of AETBs.

NOTE 4—This Practice is performance-based; that is, it focuses on the actual performance (i.e., (in other words, consistent generation of data of known and documented quality) of the AETB rather than on an extensive collection of prescriptive criteria that may or may not be relevant to a particular AETB. It also focuses on the education and qualifications of the individual tester.

NOTE 5—There has been an effort in the development of this Practice to keep the paperwork and administrative burdens on affected AETBs to the minimum required for an effective program.

#### 5. Organization and Management

5.1 Organization:

5.1.1 The AETB shall have in place a structure, including a Quality System that enables it to continually monitor and improve its ability to deliver its scope of services. This ability shall be measured by Performance Data.

5.1.2 The organization of the AETB shall be clearly defined including its place in any parent organization, and the relationships between quality management, technical operations, and support services.

5.1.3 It is the responsibility of the AETB to carry out its activities in such a way as to meet the requirements of this Practice, the requirements of local, state and federal laws and regulations, and to meet the needs of the client and regulatory authorities. 5.1.4 The AETB shall:

5.1.4.1 Have in place a system to collect and document Performance Data from all relevant sources.

5.1.4.2 Provide its employees with the resources and authority to initiate corrective actions and to verify and document their effectiveness.

5.1.4.3 Be legally identifiable, that is, it shall meet the applicable legal requirements of the governmental jurisdiction in which it conducts business. It shall be organized and shall operate so that its facilities and resources meet the requirements of this Practice.

5.1.4.4 Be organized so that staff members are not subject to undue pressure or inducement that might inappropriately influence their judgment or results of their work, including quality issues.

5.1.4.5 Be organized so that confidence in its independence of judgment and integrity is maintained at all times.

5.1.4.6 Be organized so that staff members are aware of both the extent and limitations of their responsibilities.

5.1.4.7 Provide adequate supervision of technical staff, including trainees, by persons familiar with relevant methods and procedures, the purpose of the test project, and with assessment of testing results. Only qualified individualsQualified Individuals may supervise a test.

5.1.4.8 Have a Technical Manager or Director (however named) who has overall responsibility for the technical operations of the AETB and has demonstrated competence in air emissions testing activities through education or professional experience, or both.

5.1.4.9 Have a Quality Manager (however named) who has responsibility for the Quality System and its implementation. The quality manager shall have authority and responsibility for ensuring that the requirements of this Practice are implemented and maintained. The quality manager must have direct access to the highest levels of management at which decision are made on policies affecting the AETB.

NOTE 6—The Quality Manager may also be the Technical Manager in AETBs with limited staff. Whenever possible, the quality and technical manager positions should be filled independently.

5.1.4.10 Have a Qualified Individual on-site for each test project who is qualified for each test method performed.

5.1.4.11 Be able to provide documentation or otherwise demonstrate, on request from the persons or organizations evaluating its competence, that it complies with the relevant and appropriate federal, state, and local requirements for conducting testing procedures under its scope, including compliance with this Practice.

5.1.4.12 Be able to provide documentation or otherwise demonstrate, on request from the persons or organizations evaluating its competence, that it complies with applicable local, state, and federal requirements governing health and safety, transportation, shipping and other relevant requirements.

#### 5.2 Management System:

5.2.1 *Quality Policy*—The AETB shall develop and disseminate a quality policy. A quality policy is a formal statement signed by top management that states the commitment by top management and staff to conform to the requirements documented in the Quality Manual and to this Practice.

5.2.1.1 The management of the AETB shall define and document its quality policy, quality objectives, and commitment to quality.

5.2.1.2 The AETB shall ensure that its quality policy includes recognition of the needs and expectations of its customers. The AETB shall also ensure that its quality policy is understood, implemented, and maintained at all levels within the AETB.

5.2.2 *Quality System*—The AETB shall establish, maintain, and operate under a documented Quality System as a means of ensuring that its operations are appropriate to providing air emission testing services and meet the requirements of this Practice.

5.2.2.1 The Quality System shall be designed to ensure the required degree of completeness, representativeness, comparability, and uncertainty (within the limits of uncertainty documented in the test method) needed to meet the data quality objectives of each project undertaken by the AETB.

5.2.2.2 The Quality System and the AETB's conformance to the Quality System shall be documented to the extent necessary to ensure consistent achievement of data quality objectives for projects undertaken by the AETB.

NOTE 7—Data quality objectives (however named) have always been a part of any test program. SectionsSubsections 5.2.2.1 5.2.2.1 and 5.2.2.2 and 5.2.2.2 do not establish new requirements. Data quality objectives may be defined in the testing method (e.g., bias < 5%, (for example, bias <5 %, leak rate  $\pm 0.6.5$  in. HH2O,<sub>2</sub>O, conversion efficiency > 6.30%) or may be defined by regulation or by the client.)

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5.2.3 *Quality Manual*—The Quality System shall be documented in a Quality Manual and supporting Quality System documentation. The manual shall be structured according to the outline provided <u>If an existing</u>, <u>Quality Manual adequately</u> <u>addresses each of these topics in Appendix X1 of this Practice. the standard, it should not need to be rewritten</u>. Portions not relevant to the scope of the AETB's services may be eliminated. This documentation shall be available for use by the AETB staff. <u>staff and for review by clients</u>, regulatory authorities, and accreditation bodies upon request. The Quality System documents shall be maintained current under the responsibility of the Quality Manager.

NOTE 8—The following link provides one option for structuring a Quality Manual, but AETBs will be audited against this standard and should consider addressing the elements of this standard in the AETB's QA Manual in the order in which they are presented in the standard to simplify the process of conducting an audit against this standard. (Link: http://www2.epa.gov/quality/epa-qar-2-epa-requirements-qualitymanagement-plans)

#### 5.3 Document Control:

5.3.1 *General*—The AETB shall establish and maintain procedures to control all documents that form part of its Quality System (internally generated or from external sources), such as regulations, standards, other normative documents, test and/or calibration methods, or calibration methods or both, as well as drawings, software, specifications, instructions and manuals. These procedures shall be sufficient to preclude the use of invalid and/or obsolete documents, or obsolete documents or both.

5.3.2 Quality system documents generated by the AETB shall be uniquely identified. Such identification shall include the date of issue <u>and/oror</u> revision <u>or both</u> identification, page numbering, the total number of pages or a mark to signify the end of the document, and the issuing authority(ies).

5.3.3 Changes to documents shall be reviewed and approved by the same organizational group that performed the original review unless specifically designated otherwise. Personnel conducting the review shall have access to pertinent background information upon which to base their review and approval. Where practicable, the altered or new text shall be identified in the document or the appropriate attachments.

5.3.4 If the AETB's documentation control system allows for the amendment of documents by hand pending the re-issue of the documents, the procedures and authorities for such amendments shall be defined. Amendments shall be clearly marked, initialed and dated. A revised document shall be formally re-issued as soon as practicable.

5.3.5 Procedures shall be established to describe how changes in documents maintained in computerized systems are made and controlled.

# 5.4 Review of Requests, Tenders, and Contracts: Standards.iten.al)

5.4.1 The AETB shall establish and maintain procedures for the review of requests, tenders and contracts. The policies and procedures for these reviews leading to a contract shall ensure that:

(*a*) The requirements, including the methods to be used, are adequately defined, documented and understood by the AETB; (*b*) The AETB has the capability and resources to meet the requirements of the customer;

(c) The appropriate test methods are selected and are capable of meeting the customer's requirements.

Any differences between the request or tender and the contract shall be resolved before any work begins. Each contract shall be acceptable both to the AETB and the customer.

5.4.2 Records of reviews, including any changes, shall be maintained. Records shall also be maintained of pertinent discussions with a customer relating to the customer's requirements or the results of the work during the period of execution of the contract.

5.4.3 The review shall also cover any work that is to be subcontracted by the AETB.

5.4.4 The customer shall be informed of any deviation from the contract prior to or during its execution.

5.4.5 If a contract needs to be amended after work has commenced, the amendment shall be reviewed and any amendments shall be communicated to all affected personnel.

#### 5.5 Subcontracting:

5.5.1 When an AETB subcontracts work <u>it normally performs</u> whether because of unforeseen reasons (e.g. (for example, workload, need for further expertise or temporary incapacity) lack of capacity) or on a continuing basis (e.g. (for example, through permanent subcontracting, agency or franchising arrangements), this work shall be placed with a competent subcontractor. A competent subcontractor is one that, for example, complies with this Practice for the work in question.

5.5.2 The AETB shall advise the client of the arrangement in writing and, when appropriate, gain the approval of the client, preferably in writing.

5.5.3 The AETB is responsible to the client for the subcontractor's work, except in the case where the client or a regulatory authority specifies which subcontractor is to be used.

5.5.4 The AETB shall maintain a register of all subcontractors that it uses and a record of the evidence of compliance with this Practice for the work in question.

#### 5.6 Purchasing of Services and Supplies:

5.6.1 The AETB shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. tests. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.tests.

5.6.2 The AETB shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are not used until they have been inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. These services and supplies used shall comply with specified requirements. Records of actions taken to check compliance shall be maintained.

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5.6.3 Purchasing documents for items affecting the quality of AETB output shall contain data describing the services and supplies ordered. These purchasing documents shall be reviewed and approved for technical content prior to release.

5.7 Service to the Customer:

#### [RESERVED]

5.7.1 The AETB shall be willing to cooperate with customers or their representatives in providing access to the AETB's facilities for the purpose of witnessing the tests performed for that customer provided that the AETB ensures confidentiality to other customers.

5.7.2 The AETB shall seek feedback, both positive and negative, from its customers for example by customer satisfaction surveys or during review of test reports or both. The feedback shall be used and analyzed to improve the Quality System, services provided by the AETB and customer service.

#### 5.8 Complaints:

#### [RESERVED]

5.8.1 The AETB shall have a policy and procedure for the resolution of complaints received from customers or other parities. 5.8.2 Records shall be maintained of all complaints, the investigations undertaken and the corrective actions taken by the AETB.

#### 5.9 Non-conforming Work:

5.9.1 The AETB shall have policies and procedures that shall be implemented when any aspect of its testing and/oror calibration work, work or both, or the results of this work, do not conform to its own procedures or the agreed requirements of the client. The policies and procedures shall ensure that:

(a) the <u>The</u> responsibilities and authorities for the management of nonconforming work are designated and actions (including halting of work and withholding of test reports, as necessary) are defined and taken when nonconforming work is identified;

(b) anAn evaluation of the significance of the nonconforming work is made;

(c) corrective<u>Corrective</u> actions are taken within an appropriate time period, together with any decision about the acceptability of the nonconforming work;

(d) where <u>Where</u> necessary, the client is notified and work is halted or re-done; re-done.

5.9.2 Where the evaluation indicates that the nonconforming work could recur or that there is doubt about the compliance of the AETB's operations with its own policies and procedures, the corrective action procedures given in  $\frac{5.5.35.11}{5.5.35.11}$  of this Practice shall be followed.

## 5.10 *Improvement:* [RESERVED]

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5.10.1 The AETB shall continually improve the effectiveness of its Quality System through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management reviews.

#### 5.11 *Corrective Action:*

5.11.1 *General*—The AETB shall establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the Quality System or technical operations have been identified.

NOTE 9—Causes of non-conforming work may be of two types: (1) Common causes are attributed to random variation in any system and are not correctable through a corrective action process. Common causes are not likely to be repeated. An example may be an experienced field technician forgetting to sign a data sheet. (2) Special causes are the result of some systematic flaw in the Quality System and are thus likely to be repeated. While in some instances a special cause can be identified after a single instance (e.g. (for example, inadequate technician training) sometimes an analysis of performance feedback must be made to determine which quality problems are of a systematic nature. It is these systematic problems that should be addressed by the corrective action procedures in this section.

5.11.2 *Cause Analysis*—The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.

5.11.3 Selection and Implementation of Corrective Actions—Where corrective action is needed, the AETB shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.

5.11.4 Corrective actions shall be to a degree appropriate to the magnitude and the risk of the problem. The AETB shall document and implement any required changes resulting from corrective action investigations.

5.11.5 *Monitoring of Corrective Actions*—The AETB shall monitor the results to ensure that the corrective actions taken have been effective.

5.11.6 Additional Audits—Where the identification of nonconformances or departures casts doubts on the AETB's compliance with its own policies and procedures, or on its compliance with this Practice, the AETB shall ensure that the appropriate areas of activity are audited in accordance with this Practice as soon as possible.



#### 5.12 Preventive Action:

[RESERVED]

5.12.1 Needed improvements and potential sources of nonconformities, either technical or concerning the Quality System, shall be identified. When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities of improvement.

5.12.2 Procedures for preventive actions shall include the initiation of such actions and the application of controls to ensure that they are effective.

5.13 Control of Records:

5.13.1 General:

5.13.1.1 The AETB shall establish and maintain procedures for handling and storage of quality and technical records. Quality records shall include reports from customer and regulatory authority feedback, internal audits and management reviews as well as records of corrective and preventive actions.

5.13.1.2 All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss. Retention times of records shall be established.

5.13.1.3 All records shall be held secure and in confidence.

5.13.1.4 The AETB shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.

5.13.2 Technical Records:

5.13.2.1 The AETB shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period. The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original. The records shall include the identity of personnel responsible for the sampling, performance of each test and/oror calibration or both and checking of results.

5.13.2.2 Other records include but are not limited to quality records, results of internal and external audits, training and qualification records for personnel, performance feedback, gas certifications, and chain of custody records.

5.13.2.3 Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.

5.13.2.4 When mistakes occur in records, each mistake shall be crossed out, not erased, made illegible or deleted, and the correct value entered alongside. All such alterations to records shall be dated and signed or initialed by the person making the correction. In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.

5.14 Internal Audits: iteh aj/catalog/standards/sist/54785ff5-24a3-410d-8b82-e71d36f82bcb/astm-d7036-16

5.14.1 The AETB shall annually conduct internal audits of its activities to verify that its operations continue to conform to the requirements of the Quality System. Such audits shall be carried out by qualified personnel who, whenever practical, are independent of the activity audited.

NOTE 10-Nothing in this section should be inferred to require or allow a breach of client confidentiality.

5.14.2 Internal Audit Procedure:

5.14.2.1 Conformance to this Practice shall be determined in stages as follows:

(*a*) An evaluation of the AETB's Quality Manual to ensure that it addresses all relevant requirements of this Practice and all relevant topics listed in the outline provided in Appendix X1 of this Practice.

(b) A determination of the AETB's conformance to its Quality Manual as indicated by a review of the AETB's Performance Data and subsequent corrective actions.

5.14.2.2 Deficiencies identified from internal audits must be linked to specific Performance Issues.

5.14.2.3 Determination of effective corrective actions undertaken in response to deficiencies is at the discretion of the AETB. The AETB shall document the effectiveness of any corrective actions <u>undertaken.undertaken.</u>

5.14.3 The AETB shall participate in third party Proficiency Testing programs if available and relevant to their scope of work (as determined by organizations requiring use of Proficiency Testing). Results from these programs shall be used to assess the effectiveness of the quality program. Upon failure of any Proficiency Test, the AETB shall initiate corrective action.

5.14.4 The AETB shall collect Performance Data. Results of this data, along with any testing company comments, shall be accessible to clients, potential clients, and regulatory authorities. The AETB shall inform clients that this data is available for review.

Note 11-Nothing in this section should be inferred to require or allow a breach of client confidentiality.

NOTE 12—If a national database for dissemination of AETB performance data becomes available, AETBs are encouraged to make use of this tool to meet the requirements of 5.14.4.

Note 13—AETBs are encouraged to seek a periodic, independent, external assessment of conformity to this Practice. Because air emission testing is