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## 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~~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~~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~~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~~Practice.

NOTE 1—ISO/IEC 17025 has been considered when elaborating this ~~practice~~. ~~It is to be noted that at the time of approval of this practice ISO/IEC 17025 was under revision.~~ Practice. Several, but not all, statements of this ~~practice~~Practice are consistent with ISO/IEC 17025:1999; ISO 17025:2005.

NOTE 2—This ~~practice~~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 Referenced Standards:

**NCSL RP-1 Establishment and Adjustment of Calibration Intervals<sup>2</sup>**

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

### 3. Terminology

#### 3.1 Definitions:

3.1.1 *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.

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

3.1.3 *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.”

3.1.4 *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 Quality System meeting the requirements of this ~~practice~~Practice.

3.1.5 *external qualification exam*—~~a~~ qualification exam Qualification Exam meeting the requirements of **8.3.56.2.3.6** and administered by an ~~independent proctor~~ Independent Proctor. In addition, an ~~external qualification exam~~ External Qualification Exam must be: (1) approved with regard to content and format by a ~~qualification exam provider~~ 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~~ Independent Proctor.

<sup>1</sup> This ~~practice~~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>2</sup> NCSL International, Wilderness Place, Suite 107, Boulder, Colorado 80301-5404

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

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

3.1.7 *internal qualification exam*—a ~~qualification exam~~ Qualification Exam meeting the requirements of ~~8:3.56.2.3.4~~ and administered by the AETB.

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

3.1.9 *performance data*—data ~~generated, or collected, or both generated and/or collected~~ by the AETB indicating conformance with customer and regulatory requirements and with the requirements of this ~~practice~~ Practice. Such data ~~includes~~ 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.

3.1.10 *performance issue*—a ~~performance issue (or quality system~~ 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~~ Quality Manual or a required component of the manual is absent.

3.1.11 *proficiency test*—a means of evaluating an AETB's performance relative to a given set of criteria.

3.1.11.1 *Discussion*—

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

3.1.12 *qualification credentials*—evidence that the ~~qualified individual~~ Qualified Individual meets the requirements of ~~8:3.26.2.3.2~~ and that clearly states the scope of the ~~qualification~~ Qualification (for example, a certificate from a ~~qualification exam provider~~ Qualification Exam Provider).

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

3.1.14 *qualification exam provider*—a recognized association of AETBs who oversees, maintains, ~~or approves, or a combination the three the~~ and/or approves the format and content of ~~qualification exams~~ Qualification Exams meeting the requirements of this ~~practice~~ Practice. A ~~qualification exam provider~~ Qualification Exam Provider also develops policies and procedures for the administration of the ~~exams~~ Exams and issues ~~qualification credentials~~ Qualification Credentials.

3.1.15 *qualified individual*—an individual who meets the requirements specified in ~~8:3.26.2.3.2~~ of this ~~practice~~ Practice.

#### 4. Significance and Use

4.1 This ~~practice~~ Practice establishes general criteria for a ~~quality system~~ Quality System that, when followed, helps ensure consistently acceptable data quality from an AETB. The relevant criteria contained in this ~~practice~~ Practice shall be addressed in the AETB's ~~quality manual~~ Quality Manual, which shall contain or refer to additional specific criteria and requirements where relevant and necessary. The ~~quality manual~~ 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~~ 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~~ 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~~ Practice to insure data of acceptable quality are produced.

4.2 This ~~practice~~ 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~~ Practice is performance-based; that is, it focuses on the actual performance (~~that is, (i.e.,~~ 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~~ 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 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.

5.2 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.

5.3 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 when appropriate, regulatory authorities.

5.1 The AETB shall: *Organization:*

~~5.1.1 Have~~ The AETB shall have in place a system to collect and document performance data from all relevant sources, 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 Provide its employees with the resources and authority to initiate corrective actions and to verify and document their effectiveness.~~ 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 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.~~ 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.

~~5.4.4 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.~~

~~5.4.5 Be organized so that confidence in its independence of judgment and integrity is maintained at all times.~~

~~5.4.6 Be organized so that staff members are aware of both the extent and limitations of their responsibilities.~~

~~5.4.7 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 individuals may supervise a test.~~

~~5.4.8 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 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.~~ 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 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.~~

~~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.~~

~~5.4.10 Have a qualified individual on-site for each test project who is qualified for each test method performed.~~

5.4.11 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.

5.4.12 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. Sections 5.2.2.1 and 5.2.2.2 do not establish new requirements. Data quality objectives may be defined in the testing method (e.g., bias < 5%, leak rate  $\pm 0.6.5$  in. H<sub>2</sub>O, conversion efficiency > 6.30%) or may be defined by regulation or by the client.)

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 in **Appendix X1** of this Practice. 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. The Quality System documents shall be maintained current under the responsibility of the Quality Manager.

### 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, as well as drawings, software, specifications, instructions and manuals. These procedures shall be sufficient to preclude the use of invalid and/or obsolete documents.

5.3.2 Quality system documents generated by the AETB shall be uniquely identified. Such identification shall include the date of issue and/or revision 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:

[RESERVED]

### 5.5 Subcontracting:

5.5.1 When an AETB subcontracts work whether because of unforeseen reasons (e.g. workload, need for further expertise or temporary incapacity) or on a continuing basis (e.g. 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. Procedures shall exist for the purchase, reception and storage of reagents and laboratory consumable materials relevant for the tests and calibrations.

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.

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]

5.8 Complaints:

[RESERVED]

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/or calibration work, 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 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) an evaluation of the significance of the nonconforming work is made;

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

(d) where necessary, the client is notified and work is halted or 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 5.5.3 of this Practice shall be followed.

5.10 Improvement:

[RESERVED]

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 8—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. 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]

5.13 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/or calibration 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:

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 9—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 undertaken.

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

NOTE 11—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 12—AETBs are encouraged to seek a periodic, independent, external assessment of conformity to this Practice. Because air emission testing is a field intensive activity, a thorough assessment may consist solely of a field audit (rather than a “home base” audit) if adequate documentation is available in the field.

### 5.15 Management Reviews:

[RESERVED]

## **6. Document Control**

**6.1 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, or calibration methods, or a combination of thereof, as well as drawings, software, specifications, instructions and manuals. These procedures shall be sufficient to preclude the use of invalid, or obsolete documents, or both.

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

6.3 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:

6.4 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.

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

## 7. Quality System, Audit, and Review

7.1 *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:

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

7.1.2 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:

7.2 *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:

7.2.1 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:

7.2.2 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) should always be a part of any test program. Sections 7.2.1 and 7.2.2 do not establish new requirements. Data quality objectives may be defined in the testing method (for example, bias <5 %, leak rate  $\pm 0.10$  in. H<sub>2</sub>O, conversion efficiency >90 %) or may be defined by regulation or by the client).

7.3 *Quality Manual*—The quality system shall be documented in a quality manual and supporting quality system documentation. The manual shall address all topics covered in the outline provided in **Appendix X1** of this practice. 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. The quality system documents shall be maintained current under the responsibility of the quality manager:

### 7.4 Audits:

7.4.1 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 8**—Nothing in this section should be inferred to require or allow a breach of client confidentiality:

### 7.4.2 Internal Audit Procedure:

7.4.2.1 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:

7.4.2.2 Deficiencies identified from internal audits must be linked to specific performance issues:

7.4.2.3 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 undertaken:

7.4.3 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:

7.4.4 The AETB shall collect performance data. Results of this data, along with any AETB comments, shall be accessible to clients, potential clients, and regulatory authorities. The AETB shall inform clients that this data is available for review:

**NOTE 9**—Nothing in this section should be inferred to require or allow a breach of client confidentiality:

**NOTE 10**—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 7.4.4:

NOTE 11—AETBs are encouraged to seek a periodic, independent, external assessment of conformity to this practice. To help assure consistency between various external assessment and accrediting bodies, use of such bodies recognized by the National Cooperation for Laboratory Accreditation (NACLA) is strongly encouraged. Because air emission testing is a field intensive activity, a thorough assessment may consist solely of a field audit (rather than a “home base” audit) if adequate documentation is available in the field.

## 6. Personnel Technical Requirements

### 6.1 General:

The AETB management shall ensure the competence of all who operate specific equipment, perform tests, or calibrations, or both, evaluate results, and sign test reports and calibration certificates. When using staff undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, qualification, training, experience, examination, or demonstrated skills, or a combination thereof, as required. [RESERVED]

NOTE 12—The personnel responsible for the opinions and interpretation included in test reports should, in addition to appropriate qualification, training, experience and satisfactory knowledge of the test methods carried out, also have understanding of the processes tested and the significance of any deviations occurring in test data.

8.2 The management of the AETB shall formulate requirements with respect to the education, training and skills of the AETB personnel. The AETB shall have a policy and procedures for identifying training needs and providing training to personnel. The AETB shall also have procedures to evaluate the effectiveness of such training. The training program shall be relevant to the present and anticipated tasks of the AETB.

### 6.2 ~~The Qualified Individual:~~ Personnel:

6.2.1 ~~The AETB shall provide qualified individuals to oversee and supervise test projects. The AETB must provide a least one qualified individual on-site at all times during a test project who is qualified in the methods employed for that test project.~~ management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates. When using staff undergoing training, appropriate supervision shall be provided. Personnel performing specific tasks shall be qualified on the basis of appropriate education, qualification, training, experience, examination, and/or demonstrated skills, as required.

NOTE 13—The personnel responsible for the opinions and interpretation included in test reports should, in addition to appropriate qualification, training, experience and satisfactory knowledge of the test methods carried out, also have understanding of the processes tested and the significance of any deviations occurring in test data.

6.2.2 ~~To be deemed a qualified individual under this practice, an individual shall:~~ The management of the AETB shall formulate requirements with respect to the education, training and skills of the AETB personnel. The AETB shall have a policy and procedures for identifying training needs and providing training to personnel. The AETB shall also have procedures to evaluate the effectiveness of such training. The training program shall be relevant to the present and anticipated tasks of the AETB.

8.3.2.1 Meet the experience requirements of 8.3.4.

8.3.2.2 Pass a qualification exam meeting the requirements of 8.3.5.

8.3.2.3 Sign a statement, to be kept on file with the AETB, agreeing that all test projects conducted under his/her supervision will conform to the AETB’s quality manual and to this practice in all respects.

8.3.3 A qualified individual must re-take and pass a qualification exam at least once every five years to retain their status as a qualified individual.

8.3.4 At a minimum, an individual seeking qualification shall meet the following experience requirements prior to taking the qualification exam:

8.3.4.1 Participation in at least ten tests that employ the method(s) for which they are seeking qualification, or

8.3.4.2 Completion of at least one year of general air emissions testing experience. Such experience should include, where applicable:

- (a) instrument calibration;
- (b) equipment preparation and packing;
- (c) field set up;
- (d) equipment operation and data recording;
- (e) sample recovery, handling, and custody;
- (f) sample analysis;
- (g) data reduction including relevant calculations;
- (h) quality control, and
- (i) reporting.

### 6.2.3 Each qualification exam shall: ~~The Qualified Individual:~~

6.2.3.1 Define clearly the scope of knowledge and experience it is designed to evaluate. This shall include the method or methods covered. ~~The AETB shall provide Qualified Individuals to oversee and supervise test projects. The AETB must provide a least one Qualified Individual on-site at all times during a test project who is qualified in the Methods employed for that test project.~~

6.2.3.2 Be sufficiently rigorous to assess not only knowledge of the applicable method(s) as written but also degree of field experience. ~~To be deemed a Qualified Individual under this Practice an individual shall:~~

- (a) Meet the experience requirements of 6.2.3.4.
- (b) Pass a Qualification Exam meeting the requirements of 6.2.3.4.
- (c) Sign a statement, to be kept on file with the AETB, agreeing that all test projects conducted under his/her supervision will conform to the AETB's Quality Manual and to this Practice in all respects.

6.2.3.3 A Qualified Individual must re-take and pass a Qualification Exam at least once every five years to retain their status as a Qualified Individual.

6.2.3.4 At a minimum, an individual seeking Qualification shall meet the following experience requirements prior to taking the Qualification Exam.

- (1) Participation in at least ten tests that employ the Method(s) for which they are seeking qualification, or
- (2) Completion of at least one year of general air emissions testing. Such experience should include, where applicable:
  - (a) Instrument calibration
  - (b) Equipment Preparation and Packing
  - (c) Field set up
  - (d) Equipment operation and data recording
  - (e) Sample recovery, handling, and custody
  - (f) Sample analysis
  - (g) Data Reduction including relevant calculations
  - (h) Quality Control
  - (i) Reporting

6.2.3.5 Consist of questions covering (where relevant): Each Qualification Exam shall:

- (1) Define clearly the scope of knowledge and experience it is designed to evaluate. This shall include the Method or Methods covered.
- (2) Be sufficiently rigorous to assess not only knowledge of the methods as written, applicable Method(s) as written but also degree of field experience.

(3) limitations of the methods, Consist of questions covering (where relevant):

(c) potential field conditions that may affect results;

- (a) Knowledge of the Methods as written
- (b) Limitations of the Methods
- (c) Potential field conditions that may affect results
- (d) Any special considerations needed for low-level measurements
- (e) Shipping and packing considerations
- (f) Sources of uncertainty associated with Methods
- (g) Knowledge of proper operation and calibration of equipment
- (d) any special considerations needed for low-level measurements;
- (e) shipping and packing considerations;
- (f) sources of uncertainty associated with methods; and
- (g) knowledge of proper operation and calibration of equipment.

6.2.3.6 External Qualification Exams shall be used if available. An individual that has been qualified with an Internal Qualification Exam, shall re-qualify with an External Qualification Exam within three years of the initial availability of the External Exam or when taking the re-test required in 6.2.3.3, whichever is sooner.

6.2.3.7 The Qualification Credentials of each Qualified Individual shall be available for inspection at the test site.

NOTE 14—Qualification testing, by itself, does not ensure quality data. It remains the responsibility of the AETB to ensure that all personnel, equipment, and other resources deployed on any testing project are appropriate to the specific circumstances and conditions of that project and that the total requirements of this Practice are followed at all times. Also, having a Qualified Individual on-site should not relieve the regulatory authority from their established observation and oversight role.

6.2.4 External qualification exams shall be used if available. An individual that has been qualified with an Internal qualification exam, shall re-qualify with an external qualification exam within three years of the initial availability of the external exam or when taking the re-test required in—The management of the AETB shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports, to give opinions and interpretations and to operate particular types of equipment. The AETB shall maintain records of the relevant authorizations(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization and/or competence 8.3.3, whichever is sooner, confirmed.

NOTE 15—The term “contracted personnel” includes only personnel not directly employed by the AETB but under the direct supervision of the AETB. It is not necessary to maintain records for personnel employed by and supervised by outside contractors or sub-contractors.

6.2.5 The qualification credentials of each qualified individual shall be available for inspection at the test site. AETB shall use personnel who are employed by, or under contract to, the AETB. Where contracted and additional technical and key support personnel are used, the AETB shall ensure that such personnel are supervised (see 6.2.3.1) and competent and that they work in accordance with the AETB's Quality System.

6.2.6 The AETB shall maintain current job descriptions for managerial, technical and key support personnel involved in tests and/or calibrations.

NOTE 16—Qualification testing, by itself, does not ensure quality data. It remains the responsibility of the AETB to ensure that all personnel, equipment, and other resources deployed on any testing project are appropriate to the specific circumstances and conditions of that project and that the total requirements of this practice are followed at all times. Also, having a qualified individual on-site should not relieve the regulatory authority from their established observation and oversight role. Job descriptions are dependent on a company’s operational model and for that reason can be defined in many ways. A company should consider identifying key functions within its operations and writing job descriptions that convey the duties, responsibilities, authorities, and expertise (i.e., experience, education, and or training) of an individual performing the required function. Job descriptions need not be linked to specific individuals, but may be developed for categories of jobs performed (i.e. crew leader, technician, etc).

6.3 The management of the AETB shall authorize specific personnel to perform particular types of sampling, test, or calibration, or both, to issue test reports, to give opinions and interpretations and to operate particular types of equipment. The AETB shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel. This information shall be readily available and shall include the date on which authorization, or competence, or both is confirmed.*Accommodation and Environmental Conditions:*

6.3.1 The AETB shall ensure, to the extent practical, that environmental conditions do not invalidate the results or adversely affect the required quality of any measurement. Environmental conditions that can affect the results of tests and calibrations shall be documented.

NOTE 17—In many cases, the environmental conditions under which an air emission test takes place are not under the control of the AETB. It is the responsibility of the AETB to inform the client or regulatory authority of the possible effects of environmental conditions on data quality. The decision to abort or delay a test due to environmental conditions rests with the client or regulatory authority unless the conditions pose a safety threat to personnel performing the test, in which case, the AETB shall have the authority to abort or delay the test.

6.3.2 To the extent practical, concurrent activities that are incompatible with the collection or analysis of quality data shall be avoided. Measures shall be taken to avoid cross-contamination.

6.3.3 Access to and use of areas affecting the quality of the tests and/or calibrations shall be controlled. The AETB shall determine the extent of control based on the particular circumstances and requirements of the test project.

6.3.4 Measures shall be taken to ensure good housekeeping in all locations where testing or analysis activities are conducted. Special procedures shall be prepared where necessary.

NOTE 14—The term “contracted personnel” includes only personnel not directly employed by the AETB but under the direct supervision of the AETB. It is not necessary to maintain records for personnel employed by and supervised by outside contractors or sub-contractors.

6.4 The AETB shall use personnel who are employed by, or under contract to, the AETB. Where contracted and additional technical and key support personnel are used, the AETB shall ensure that such personnel are supervised (see 8.3.1) and competent and that they work in accordance with the AETB’s quality system.*Test Methods:*

6.4.1 The AETB shall use appropriate methods and procedures for all testing performed. These include sampling, analysis, handling, transport, storage and preparation of items to be tested and/or calibrated, and, where appropriate an estimation of the measurement uncertainty as well as statistical techniques for analysis of test data.

6.4.2 Methods for air emission testing performed for compliance purposes are currently defined by applicable regulations. Alternatives or deviations from these methods shall be detailed in the test protocol and/or the test report along with any authorizations for the alternatives or deviations.

6.4.3 A site specific test plan (protocol) shall be used for each test project. All procedures and activities specified in the test plan shall meet the requirements of this Practice and shall, at a minimum, address the following points:

- (a) Objectives and summary of test program
- (b) Description of the source, operating conditions and process to be tested
- (c) Description of the test matrix
- (d) Sampling locations
- (e) Test methods to be used, number of runs to be performed, and sampling duration of each run
- (f) Process data to be collected
- (g) QC procedures and audits (including applicable field blanks)
- (h) Reporting format, reporting units and other requirements
- (i) Plant entry and safety requirements
- (j) Responsibilities of test personnel
- (k) Tentative test schedule

NOTE 18—The use of field blanks for quality control is strongly encouraged.

6.4.4 The test plan shall be the primary source of information on testing and quality procedures for the test project. It, along with the AETB’s Quality Manual, is the document against which an assessor shall perform any required on-site assessment. The contents of this plan shall be communicated to all personnel participating in the test project prior to the start of the project. Deviation from test plan shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the client or any relevant regulatory authority (as appropriate).