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Standard Practice for Competence of Air Emission Testing Bodies¹

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1. Scope

1.1 This practice specifies the general requirements for 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 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. Several, but not all, statements of this practice are consistent with ISO/IEC 17025:1999.

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 Referenced Standards:

NCSL RP-1 Establishment and Adjustment of Calibration Intervals²

ISO/IEC 17025 General Requirements for the Competence of Testing and Calibration Laboratories³

3. Terminology

3.1 Definitions:

¹ This practice is under the jurisdiction of ASTM Committee D22 on Sampling and Analysis of Atmospheres and is the direct responsibility of Subcommittee D22.03 on Ambient Atmospheres and Source Emissions.

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² NCSL International, Wilderness Place, Suite 107, Boulder, Colorado 80301-5404

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

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*—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.

3.1.5 *external qualification exam*—a qualification exam meeting the requirements of 8.3.5 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.

3.1.6 *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 rules established by the qualification exam provider.

3.1.7 *internal qualification exam*—a qualification exam meeting the requirements of 8.3.5 and administered by the AETB.

3.1.8 *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).

3.1.9 *performance data*—data generated, or collected, or both by the AETB indicating conformance with customer and regulatory requirements and with the requirements of this

practice. Such data includes 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 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.

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 meets the requirements of 8.3.2 and that clearly states the scope of the qualification (for example, a certificate from a 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 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.

3.1.15 *qualified individual*—an individual who meets the requirements specified in 8.3.2 of this practice

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 (that is, 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 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.

5.4 The AETB shall:

5.4.1 Have in place a system to collect and document performance data from all relevant sources.

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

5.4.3 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.

5.4.4 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.

5.4.9 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.

5.4.10 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.

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 ± 0.10 in. H₂O, 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.

8. Personnel

8.1 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.

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.

8.3 *The Qualified Individual:*

8.3.1 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.

8.3.2 To be deemed a qualified individual under this practice, an individual shall:

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.

8.3.5 Each qualification exam shall:

8.3.5.1 Define clearly the scope of knowledge and experience it is designed to evaluate. This shall include the method or methods covered.

8.3.5.2 Be sufficiently rigorous to assess not only knowledge of the applicable method(s) as written but also degree of field experience.

8.3.5.3 Consist of questions covering (where relevant):

- (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, and
- (g) knowledge of proper operation and calibration of equipment.

8.3.6 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 8.3.3, whichever is sooner.

8.3.7 The qualification credentials of each qualified individual shall be available for inspection at the test site.

NOTE 13—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.

8.4 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.

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.

8.5 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.

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

NOTE 15—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 (that is, 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 (that is, crew leader, technician, and so forth).

9. Accommodation and Environment

9.1 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 16—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 has the authority to abort or delay the test.

9.2 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.

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

9.4 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.

10. Equipment and Reference Materials

10.1 The AETB shall have access to all items of sampling, measurement and test equipment required for the correct performance of the tests, or calibrations, or both (including sampling, preparation of test, or calibration items, or both,

processing and analysis of test, or calibration data, or both). In those cases where the AETB needs to use equipment outside its permanent control, it shall ensure that the requirements of this practice are met.

10.2 Equipment and its software used for testing, calibration and sampling shall be capable of achieving the required accuracy and shall comply with specifications relevant to the tests, or calibrations, or both concerned.

10.3 Calibration programs shall be established for key quantities or values of the instruments where these properties have a significant effect on the results. Before being placed into service, equipment (including that used for sampling) shall be calibrated or checked to establish that it meets the AETB’s specification requirements and complies with the relevant standard specifications. The AETB shall confirm or establish a new calibration at an interval established by relevant regulations. If relevant regulations do not specify calibration interval, the AETB shall establish a calibration interval sufficient to ensure the equipment continually meets specification.

NOTE 17—The NCSL standard RP-1 is suggested as a reference to establish calibration intervals.

10.4 The AETB shall take precautions so that malfunctioning or inoperative equipment is not used in a test project.

10.5 Where applicable, all equipment under the control of the AETB and requiring calibration shall be labeled, coded or otherwise identified to indicate the status of calibration, including the date when last calibrated and the date or expiration criteria when recalibration is due.

10.6 Equipment shall be operated by trained and authorized personnel. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals provided by the manufacturer of the equipment) shall be readily available for use by the appropriate AETB personnel.

10.7 Records shall be maintained of each item of equipment and its software significant to the tests, or calibration, or both performed. The records shall include at least the following:

10.7.1 Identity of the item,

10.7.2 Manufacture’s information, model and serial number or other unique ID,

10.7.3 Calibration, repair, and maintenance history,

10.7.4 Instruction manual or reference to its location, and

10.7.5 Current location, if appropriate.

10.8 When rental or loaned equipment is used, relevant records shall be obtained from the equipment provider.

10.9 The AETB shall provide for the safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning and in order to prevent contamination or deterioration.

11. Measurement Traceability and Calibration

11.1 All equipment used for tests, or calibrations, or both, including equipment for subsidiary measurements (for example, for environmental conditions) having a significant effect on the accuracy or validity of the result of the test, calibration or sampling shall be calibrated before being put into service. The AETB shall have an established program and procedure for the calibration of its equipment. Such a program

shall include a schedule of calibration and a method to insure only properly calibrated equipment is used in the test program.

11.2 Reference materials shall, where possible, be traceable to certified reference materials.

11.3 Checks needed to maintain confidence in the calibration status of reference, primary, transfer or working standards and reference materials shall be carried out, as far as technically and economically practicable, in accordance with defined procedures and schedules.

11.4 The AETB shall have procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.

12. Test Methods

12.1 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, or calibrated, or both, and where appropriate, an estimation of the measurement uncertainty as well as statistical techniques for analysis of test data.

12.2 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, or the test report, or both along with any authorizations for the alternatives or deviations.

12.3 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:

12.3.1 Objectives and summary of test program,

12.3.2 Description of the source, operating conditions and process to be tested,

12.3.3 Description of the test matrix,

12.3.4 Sampling locations,

12.3.5 Test methods to be used, number of runs to be performed, and sampling duration of each run,

12.3.6 Process data to be collected,

12.3.7 QC procedures and audits (including applicable field blanks),

12.3.8 Reporting format, reporting units and other requirements,

12.3.9 Plant entry and safety requirements,

12.3.10 Responsibilities of test personnel, and

12.3.11 Tentative test schedule.

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

12.4 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 on-site assessment of conformance to this practice. 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).

NOTE 19—It is recommended that AETBs adopt a standard test plan

format and that this format follow examples provided by regulatory authorities.

12.5 The AETB shall have instructions on the use and operation of all relevant equipment, and on the handling and preparation of items for testing, calibration, or both, where the absence of such instructions could jeopardize the results of tests, or calibration, or both. All instruction, standards, manuals and reference data relevant to the work of the AETB shall be kept up to date and shall be made readily available to personnel.

12.6 The AETB shall use test methods, including methods for sampling, which meet the needs of the client and which are appropriate for the tests it undertakes. Methods established in international, regional or national standards shall be used as practicable. The AETB shall ensure that it uses the latest valid edition of a method unless it is not appropriate or possible to do so. When necessary, the method shall be supplemented with additional details to ensure consistent application. The AETB shall inform the client when the method proposed by the client is considered to be inappropriate or out of date.

12.7 *AETB-developed Methods*—The introduction of test and calibration methods developed by the AETB for its own use shall be a planned activity and shall be assigned to qualified personnel equipped with adequate resources. Plans shall be updated as development proceeds and effective communication amongst all personnel involved shall be ensured.

12.8 *Non-standard Methods*—When it is necessary to use methods not covered by standard methods, these shall be subject to agreement with the client and any relevant regulatory authority and shall include a clear specification of the client's requirements and the purpose of the test program. They shall be described in the test protocol and reported in the same way as standard methods. Any validation data shall be included in the test protocol.

12.9 When it is necessary for an AETB to perform test methods that it has not performed previously, but which are established, published, or validated test methods, the AETB must take appropriate actions to ensure that the applicable requirements of this practice are properly addressed before and during the performance of the new method.

12.10 *Uncertainty*—AETBs shall have and shall apply procedures for estimating the uncertainty of measurement. Conformance with this section may be demonstrated by use of approved test protocols for all tests. When such protocols are used, reference shall be made to published literature, when available, where estimates of uncertainty for test methods may be found.

NOTE 20—In certain cases the nature of the test method may preclude rigorous, metrologically and statistically valid, calculation of uncertainty of measurement. In these cases the AETB should at least attempt to identify all the components of uncertainty and make a reasonable estimation, and should ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation should be based on knowledge of the performance of the method and on the measurement scope and should make use of, for example previous experience and validation data.