BQ-9000 Quality Management System
Laboratory Requirements

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1 SCOPE

This document covers the establishment and maintenance of a quality management system in commercial laboratories engaged in the analysis of biodiesel and biodiesel blends. Laboratories operated by BQ-9000 Producers or Marketers are also eligible to seek this certification. The laboratory quality requirements described herein shall be applied to all test results performed by the laboratory for testing of biodiesel and biodiesel blends.

2 REFERENCES[1]

2.1 Normative References

The following references contain provisions which, through reference herein, constitute provisions of this standard practice. All referenced documents are subject to revision, and all those applying these requirements are required to apply the most recent editions of the references indicated below.

ASTM D975, Standard Specification for Diesel Fuel Oils

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

ASTM D6300, Standard Practice for Determination of Precision and Bias Data for Use in Test Methods for Petroleum Products and Lubricants

ASTM D6751, Standard Specification for Biodiesel Fuel Blend Stock (B100) for Middle Distillate Fuels

ASTM D6792, Standard Practice for Quality System in Petroleum Products and Lubricants Testing Laboratories

ASTM D7467, Standard Specification for Diesel Fuel, Biodiesel Blend (B6 to B20)

EN 14214, Automotive Fuels – Fatty acid methyl esters (FAME) for Diesel Engines – Requirements and test methods

2.2 Informative References

The following references are included as bibliographic information which may contain material useful in the application of this standard practice.

ISO 9001:2008, Quality Management Systems - Requirements

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

ASTM D3244, Standard Practice for Utilization of Test Data to Determine Conformance with Specifications

[1]ASTM documents are available from www.astm.org. ISO documents are available from www.ansi.org.

ASTM D6617, Standard Practice for Laboratory Bias Detection Using Single Test Result from Standard Material

ASTM E29, Standard Practice for Using Significant Digits in Test Data to Determine Conformance with Specifications

3 DEFINITIONS

For use in this text, the following terms and definitions apply.

Note: The word **"shall"** indicates mandatory requirements of this document. The word **"should"** indicates a mandatory requirement with some flexibility allowed in compliance methodology. Those choosing other approaches to satisfy a "should" must be able to show that their approach meets the intent of these requirements.

3.1 ***Biodiesel:*** A fuel comprised of mono-alkyl esters of long chain fatty acids derived from vegetable oils or animal fats and meeting ASTM D6751, designated B100.

3.2 ***Blend:*** A blend of biodiesel with fuel oils in a specified ratio, designated Bxx, where xx is the volume percent of biodiesel.

3.3 NBAC: The National Biodiesel Accreditation Commission is an autonomous committee of the National Biodiesel Board that oversees and directs the BQ-9000 program.

3.4 ***Quality Manual:*** A document that describes the elements of the quality program used to assure that the requirements of this document are met.

3.5 ***Quality Program:*** The organizational structure, responsibilities, procedures, processes and resources necessary to manage quality.

3.6 ***Verification:*** Confirmation by examination and provision of objective evidence that specified requirements have been fulfilled.

4 DOCUMENTATION REQUIREMENTS

The quality management system documentation shall include

a) documented statements of a quality policy

b) a quality manual

c) documented procedures required by the BQ-9000 Program

d) records required by this standard

The organization shall establish and maintain a documented quality management system containing provisions which explicitly or by reference, include the requirements contained in this document. The organization shall implement the newest revision of the BQ-9000 Program Requirements into their quality management system within 90 days after the effective date of the latest revision.

4.1 Quality Manual
The quality program shall be documented in a quality manual. The quality manual shall include or make reference to quality system procedures.

4.2 Quality Policy
A quality policy shall be defined and documented which includes the objectives for and commitment to quality. The quality policy shall be related to the business goals of the biodiesel laboratory and the expectations of its customers. The quality policy shall be invoked throughout the biodiesel laboratory and understood by all levels of personnel.

4.3 Quality System Procedures
Documented Quality System Procedures (QSPs) shall be prepared that describe the process to be employed for determining and documenting how operational quality requirements will be met and be consistent with the requirements herein. Procedures shall make reference to work instructions that define how an activity is performed.

4.4 Document Control
The quality program shall contain provisions for maintaining and controlling BQ-9000 quality program related documents and records. Document Control shall have at least the following:

a) A method of identifying the current document; such as revision letter, a revision date, or an effective date on each page of the document.

b) A document status form(s) that lists all documents in the Quality System, and that defines the current revision of each document as defined in a) above and the effective date of the revision.

c) A distribution list of those in possession of your Quality Manuals.

d) A method for controlling the distribution of new and updated sections of your quality system documents. This should include a mechanism to remind the recipients to destroy the copy of the obsolete documents. This is particularly important where forms are copied in advance of use.

4.5 Control and Retention of Records
Records shall be established and maintained to provide evidence of effective implementation, operation, and compliance of the organization's quality system. Records shall be retained for a minimum of two years. Records shall be legible, identifiable and accessible. The storage of quality records shall be done in a manner that ensures record integrity.

Procedures for retaining records of all original observations, calculations and derived data, calibration records, and final test reports for an appropriate period shall be established. The records for each test shall contain sufficient information to permit verification of the results.

5 MANAGEMENT RESPONSBILITY

5.1 Quality Management Representative

A quality management representative (QMR) shall be appointed and irrespective of other duties, shall chair quality management review meetings, ensure that a quality program is established and that it meets the requirements herein, report on the performance of the quality program and ensure that the most recent version of the quality documents are made available to personnel.

5.2 Internal Quality System Audit

The organization shall develop and implement a system for performing internal quality audits. Internal quality system audits of each element of the quality system shall occur at a minimum of once per year to verify that the organization's operations comply with the requirements stated in its quality management system to determine the effectiveness of the quality program. Audits should be performed by persons other than those responsible for the area being audited. Audit frequency should be increased when audit results indicate that increased frequency would be beneficial. Audit results shall be presented to personnel responsible for the audited area and cited nonconformities shall be resolved in a timely manner as defined in documented procedures. The audit process, nonconformance reports, corrective action plans, and effective corrective action shall be included in internal audit records.

5.3 Quality Management Review

Quality management review meetings shall be held at least once every six months. Records shall be kept of the review meetings. The input to management review meetings should include information on the following:

a) results of Internal Quality System Audits
b) customer feedback
c) quality control
d) calibration and maintenance
e) status of preventive and corrective actions
f) follow-up actions from previous management reviews
g) changes that could affect the quality management system
h) recommendations for improvement

6 SAMPLE MANAGEMENT

The elements of sample management shall include at a minimum:

a) Procedures for unique identification of samples submitted to the laboratory.
b) Procedures for sample handling.
c) Procedures for sample storage and retention. Items to consider when creating these procedures include:
    i) Requirements for shelf life and time-dependent tests that set product stability limits,
    ii) Type of sample containers required to preserve sample integrity,

iii) Control of access to the retained samples to protect their validity and preserve their original integrity,

iv) Storage Conditions,

v) Customer Requirements

d) Procedures for sample disposal in accordance with applicable government regulatory requirements.[2]

7 DATA AND RECORD MANAGEMENT

7.1 Reports of Analysis

The work carried out by a laboratory shall be covered by a certificate or report that accurately and clearly presents the test results and all other relevant information. Items actually included in laboratory reports should be specified by laboratory management through agreements with customers, or both. Procedures for corrections or additions to a test report after issue shall be established. The following items shall be included in laboratory reports:

a) Name and location of the testing laboratory,

b) Unique identification of the report (such as serial number) on each page of the report,

c) Name and address of the customer,

d) Description and identification of the test sample,

e) Date of receipt of the test sample and date(s) of performance of test, as appropriate,

f) Identification of the test specification, method or procedure, and if not the current version, the revision level used,

g) Identification of the tests performed by an outsourced laboratory,

h) Description of the sampling procedure, if samples were taken by the laboratory or its agent,

i) Any deviations, additions to or exclusions from the specified test requirements, and any other information relevant to a specific test,

j) Any other information which might be required by the customer,

k) A signature and job title of person(s) accepting responsibility for the test report and the date of issue.

7.2 Reporting and Rounding the Data

The reporting requirements specified in the test method or procedure shall be used (unless specifically required otherwise by the customer or applicable regulations). If rounding is performed, the rounding protocol of ASTM E29 should be used unless otherwise specified in the method or procedure.

[2] This may be handled through a separate chemical hygiene or waste disposal plan.

8 SPECIFICATIONS AND EQUIPMENT

8.1 Product Specifications
The laboratory shall have copies of the current product specifications and of the test methods for the tests being conducted in the laboratory. These shall be maintained up-to-date and be readily available to the laboratory staff.

8.2 Testing Equipment
The laboratory shall have all the required equipment and standards that are required for the testing that is being conducted in the laboratory.

9 CALIBRATION AND MAINTENANCE

9.1 Calibration and Maintenance Frequency
The laboratory shall calibrate and maintain the equipment and standardize reagents at least as frequently as required by the test methods used. If there is not a calibration requirement then a lab specific schedule shall be established for each test method used by the laboratory. Calibrations and standardizations shall be documented.

9.2 Calibrations Done Outside the Laboratory
The performance of apparatus and equipment used in the laboratory but not calibrated in that laboratory (e.g. pre-calibrated, vendor supplied) should be verified by using a documented, technically valid procedure at periodic intervals.

9.3 Calibration Standards
Calibration standards shall be appropriate for the method. Quantitative calibration standards should be prepared from constituents of known purity. Use the primary calibration standards or certified reference material (CRMs) specified or allowed in the test method. Where appropriate, values for reference materials should be traceable to national or international standard reference materials.

9.4 Out of Calibration Instruments
If an instrument is found to be out of calibration or control, and the situation cannot be immediately addressed, the instrument shall be taken out of operation and tagged as such until the situation is corrected (see Section 11).

9.5 Records of Calibration and Maintenance
Procedures shall be established for the management of instrument calibration records, including the basis for recalibration. Such records shall indicate the instrument calibrated (including a unique instrument identification traceable to a serial number), method or procedure used for calibration, the date of the last calibration, the person performing the calibration, the values obtained during calibration, and the nature and traceability (if applicable) of the calibration standards (that is, certified values associated with specific lot numbers).

Procedures shall be established for the management of instrument maintenance records. Such records shall indicate the instrument maintained, the dates of the last and next maintenance, and the person performing the maintenance. Records may be electronic.

10 QUALITY CONTROL (QC)

10.1 Test Methods Included in Quality Control

The laboratory shall use quality control charts or other quality control practices (for example, like those described in ASTM D6299) for each test method performed within this program by the laboratory.

10.2 Quality Control Testing Frequency

Testing of QC samples shall occur on a regular schedule. Principal factors to be considered for determining the frequency of testing include: (*1*) frequency of use of the analytical measurement system, (*2*) criticality of the parameter being measured and business economics, (*3*) established system stability and precision performance based on historical data, (*4*) regulatory requirements, (*5*) contractual provisions, and (*6*) test method requirements.

10.2.1 For those test methods that don't specify a quality control sampling frequency the recommended frequency for analysis of QC samples is one QC sample out of every ten samples analyzed or one QC sample each day that samples are analyzed, whichever is more frequent.

10.2.2 All persons who routinely operate the system shall participate in generating QC test data. Quality control samples should be treated as regular samples.[3]

10.3 Quality Control Sample and Test Data Evaluation

Quality control samples should be stable and homogeneous materials having physical or chemical properties, or both, representative of the actual samples being analyzed by the test method. This material shall be well-characterized for the analyses of interest, available in sufficient quantities, have concentration values that are within the calibration range of the test method, and reflect the most common values tested by the laboratory. For QC testing that is strictly for monitoring the test method stability and precision, the QC sample expected value is the control chart centerline, established using data obtained under site precision conditions. For regular QC testing that is intended to assess test method bias, reference materials, or certified reference materials with an accepted reference value should be used. The results should be assessed in accordance with ASTM D6299 requirements for check standard testing. For infrequent QC testing for bias assessment, refer to ASTM D6617.[4]

If the QC material is beyond the sample manufacturer's expiration date or if observed to be degrading or changing in physical or chemical characteristic, a replacement QC material shall be prepared for use.[5]

[3] Avoid special treatment of QC samples designed to "get a better result." Special treatment seriously undermines the integrity of precision and bias estimates.
[4] It is not advisable to use the same sample for both a calibrant and a QC sample. It is not advisable to use the same chemical lot number for both a calibrant and a QC sample.
[5] In a customer-supplier quality dispute, it may be beneficial to provide the customer with the laboratory's test results on QC material to demonstrate testing proficiency. ASTM D3244 may be useful.

10.4 Quality Control Charts

QC sample test data should be plotted on a control chart and evaluated to determine if the results obtained are within the method specifications and laboratory-established control limits.[6] The charts used should be appropriate for the testing conditions and statistical objectives. Corrective action should be taken and documented for any analyses that are out-of-control (see Section 11).[7]

10.4.1 The charts should indicate the test method, date when the QC analyses were performed, and who performed them. Test samples should not be analyzed or results for samples should not be reported until the corresponding QC data are assessed and the testing process is verified to be in statistical control.

10.4.2 Adequate training should be given to the analysts to enable them to generate and interpret the charts.

10.4.3 It is suggested that the charts be displayed prominently near the analysis workstation, so that all can view and, if necessary, help in improving the analyses.

10.4.4 Supervisory and technical personnel shall periodically review the QC charts.

10.4.5 The laboratory shall establish written procedures outlining the appropriate interpretation of QC charts and responses to out-of-statistical-control situations observed. When an out-of-statistical-control situation has been identified, remedial action shall be taken before analyzing further samples. In all such cases, run the QC sample and ensure that a satisfactory result can be obtained before analyzing *unknown* samples.

10.4.6 Out-of-control situations may be detected by one or more analyses. In these cases, it may be necessary to retest samples analyzed during the period between the last in-control QC data point and the QC data point that triggered the out-of-statistical-control notice (or event) using retained samples and equipment known to be in control. If the new analysis shows a difference that is statistically different from the original results, and the difference exceeds the established site precision of that test, the laboratory should decide on what further actions are necessary (see Section 12).

10.5 Revision of Control Charts

QC chart revision is covered in detail in ASTM D6299. Control charts shall be revised only when the existing limits are no longer appropriate. As a guideline, revisions may be needed when:

a) Additional information becomes available,

b) The process has improved,

c) A new QC material is initiated and the mean value is different than the previous QC material, or

d) There are major changes to the test procedure.

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[6] Charts such as individual, moving average and moving range, exponentially weighted moving average, or cumulative summation charts may be used as appropriate. Refer to ASTM D6299 for guidance on plotting these charts.

[7] A generic checklist for investigating the root cause of unsatisfactory analytical performance is given in ASTM D6792, Appendix X1.

10.6 Quality Control Materials

The materials analyzed in proficiency testing programs meeting the requirements of ASTM ASTM D6300 may be used as quality control materials. The consensus value is most likely the value closest to the true value of this material; however, the uncertainty attached to this mean value will be dependent on the precision and the total number of the participating laboratories.

The laboratory shall establish procedures for the storage of quality control materials in a manner to ensure their integrity and protection from contamination.

10.7 Quality Control (QC) Testing Records

The laboratory shall have documented procedures for creating and maintaining records for the analysis of QC samples including the basis for the maintenance schedule. The records shall include the sample name and source, the test(s) performed, the assigned values and their uncertainty where applicable, testing frequency and values obtained upon analysis. The receipt date or date put into active quality control use in the laboratory shall be documented, along with the expiration date (if applicable).

11 PROFICIENCY TESTING

Regular participation in interlaboratory proficiency testing programs, where appropriate samples are tested by multiple test facilities using a specified test protocol, shall be integrated into the laboratory's quality control program. Proficiency test programs should be used as appropriate by the laboratory to demonstrate testing proficiency relative to other industry laboratories. At a minimum, the laboratory shall participate in the ASTM Interlaboratory Crosscheck Program on Biodiesel[8] or the Alberta Research Council's International Quality Assurance Exchange Program on Biodiesel[9]. The laboratory shall use proficiency testing programs for each test method, if available, performed by the laboratory.

The laboratory shall evaluate the lab's performance versus the mean values of the proficiency program test results. Participants should plot their deviations from the consensus values established by the proficiency test program averages on a control chart to ascertain if their measurement processes are non-biased. Participation in proficiency testing shall not be considered as a substitute for in-house quality control.

12 CORRECTIVE AND PREVENTIVE ACTION

The need for corrective and preventive action may be indicated by one or more of the following unacceptable situations:

a) Equipment out of calibration,

b) QC or check sample result out of control,

c) Test method performance by the laboratory does not meet performance criteria (for example, precision, bias, and the like) documented in the test method,

[8] Participation in the ASTM Interlaboratory Crosscheck Program on Biodiesel is available by registering with: ASTM International www.astm.org.

[9] Participation in the Alberta Research Council's International Quality Assurance Exchange Program on Biodiesel is available by contacting www.exchange.arc.ab.ca.

d) Outlier or unacceptable trend in an interlaboratory cross-check program,

e) Nonconformance identified in an external or internal audit,

f) Nonconformance identified during review of laboratory data or records,

g) Customer complaint.

12.1 Root Cause

When any of these situations occur, the root cause shall be investigated and identified. Procedures for investigating root cause shall be established.

It is possible that the analytical results are correct, even if they don't meet specifications. Procedures should consider this possibility. See ASTM D6792, Appendix X1 for a checklist for investigating the root cause of unsatisfactory analytical performance.

12.2 Corrective and Preventive Actions

Procedures should also be established for the identification and implementation of appropriate corrective and preventive action so that the situation does not reoccur. This may involve:

a) Training or retraining personnel,

b) Reviewing customer specifications,

c) Reviewing test methods and procedures,

d) Establishing new or revised procedures,

e) Instrument maintenance and repair,

f) Re-preparation of reagents and standards,

g) Recalibration of equipment,

h) Re-analysis of samples, and

i) Additional QC sample analysis.

j) Identifying results that may have been adversely affected,

k) How to handle affected results already reported to a customer,

l) The situation, root cause, and corrective/preventive action taken should be documented promptly. A corrective and preventive action report is a suitable format for documentation.

m) The report should be reviewed and approved by management and then verified for effectiveness of the corrective or preventive action.

13 CUSTOMER COMPLAINTS

A procedure shall exist to follow-up on customer complaints. The result of such investigation should be communicated to the customer as soon as practical.

14 TRAINING

Laboratory management shall ensure that all staff performing testing or interpreting data, or both, are appropriately trained. Laboratory training should cover at a minimum the following areas: test methods, results reporting and data interpretation. Records of training shall be maintained.

15 OUTSOURCING OF TESTS

The laboratory shall maintain records that indicate which test results were produced by an outsourced laboratory.

15.1 Tests Outsourced from a BQ-9000 Laboratory

If a test is outsourced to a BQ-9000 laboratory that includes the outsourced test in their scope of service, then the test results can be used without further laboratory verification.

15.2 Tests Outsourced from a Non BQ-9000 Laboratory

Organizations using outsourced laboratories shall receive from the outsourced laboratory a completed and signed Form BQF-1 with supporting documentation. This form shall be completed annually by the outsourced laboratory and shall be retained by the organization for a minimum of two years.

The material in Appendices A and B is provided for information purposes only.

APPENDIX A
TEST METHOD PRECISION PERFORMANCE ASSESSMENT

A.1 Test Performance Index[10]

The test performance index (TPI) can be used to compare the precision of the laboratory measurements with the published reproducibility of a standard test method. The term TPI is defined as:

$$\text{test performance index (TPI)} = \frac{\text{test method reproducibility}}{\text{site precision}}$$

A.2 Precision Ratio

A precision ratio (PR) is determined for a given published test method so that the appropriate action criteria may be applied for a laboratory's TPI. The PR for a published test method estimates the influence that non-site specific variations has on the published precision. The PR can be calculated by dividing the test method's Reproducibility (R) by the test method's repeatability (r) as shown below:

$$\text{Precision Ratio (PR)} = \frac{\text{Test Method reproducibility (R)}}{\text{Test Method repeatability (r)}}$$

where the ratio of R/r is calculated to the nearest integer (that is, 1, 2, 3, 4, ...).

A test method with PR greater than or equal to 4, for the purpose of this practice, is deemed to exhibit a significant difference between repeatability and reproducibility. For further explanation on why the greater than or equal to 4 criterion was chosen, please see ASTM D6792, Appendix X3.

A.3 Action Based on TPI

A laboratory's TPI may be a function of the sample type being analyzed and variations associated with that laboratory. As general guidelines Table 1 may be used once the TPI of that laboratory and the PR of the published standard test method has been calculated. Similar information to that provided in Table 1 is provided in A.3.1 through A.3.3.

A.3.1 For a published standard test method with a PR less than 4 the following TPI criteria should be applied: *(a)* A TPI greater than 1.2 indicates that the performance is probably satisfactory relative to ASTM published precision, *(b)* A TPI greater than or equal to 0.8 and less than or equal to 1.2 indicated performance may be marginal and the laboratory should consider method review for improvement, *(c)* A TPI less than 0.8 suggests that the method as practiced at this site is not consistent with the ASTM published precision. Either laboratory method performance improvement is required, or ASTM published precision does not reflect achievable precision. Existing interlaboratory exchange performance (if available) should be reviewed to determine if the latter is plausible.

[10] The ASTM International Committee D02 sponsored Inter- laboratory Crosscheck Program employs a test performance index based on the ratio of the published ASTM reproducibility to the Robust Reproducibility calculated from the program data. This index is termed the TPI (Industry) to distinguish from the definition in A.1.

A.3.2 For a published standard test method with a PR greater than or equal to 4 the following TPI criteria should be applied: *(a)* A TPI greater than 2.4 indicates that the performance is probably satisfactory relative to ASTM published precision, *(b)* A TPI greater than or equal to 1.6 and less than or equal to 2.4 indicated performance may be marginal and the laboratory should consider method review for improvement, *(c)* A TPI less than 1.6 suggests that the method as practiced at this site is not consistent with the ASTM published precision. Either laboratory method performance improvement is required, or ASTM published precision does not reflect precision achievable. Existing interlaboratory exchange performance (if available) should be reviewed to determine if the latter is plausible.[11]

A.3.3 A laboratory may choose to set other benchmarks for TPI, keeping in mind that site precision of an adequately performing laboratory cannot, in the long run, exceed the practically achievable reproducibility of the method when PR is less than 4 or approaches repeatability when PR is much greater than 4.

TABLE 1 Guidelines for Action Based on TPI

TPI for Standard Test /Methods with PR<4	TPI for Standard Test Methods with PR≥4	Recommended Quality Improvement Action
>1.2	>2.4	Indicates that the performance is probably satisfactory relative to ASTM published precision.
>0.8 and <1.2	>1.6 and <2.4	Indicates that the performance is probably satisfactory relative to ASTM published precision, however a method review could be necessary to improve its performance.
<0.8	<1.6	This condition suggests that the method as practiced at this site is not consistent with the ASTM published precision. Either laboratory method performance improvement is required, or the ASTM published precision does not reflect precision achievable. Existing interlaboratory exchange performance (if available) should be reviewed to determine if the latter is plausible.

A.4 Precision Review

A laboratory should review their precision obtained for multiple analyses on the same sample. The site precision of the QC samples can be compared with the reproducibility or repeatability given in the standard test methods to indicate how well a laboratory is performing against the industry standards.

A laboratory precision significantly worse than the published test method reproducibility may indicate poor performance. An investigation should be launched to determine the root cause for this performance so that corrective action can be undertaken if necessary. Such a periodic review is a key feature of a laboratory's continuous improvement program.

[11] Experience has shown, for some methods, published reproducibility is not in good agreement with the precision achieved by participants in well-managed crosscheck programs. Users should consider this fact when evaluating laboratory performance using TPI.

APPENDIX B
RELATIONSHIP WITH OTHER QUALITY STANDARDS

Some laboratories in the petrochemicals testing area have been registered to ISO/IEC 17025. There are a number of similarities between the ISO standard and this practice in key areas of managing laboratory quality. A cross-reference between ISO/IEC 17025 and ASTM D6792 can be found in ASTM D6792.

Measurement Uncertainty—For test methods under the jurisdiction of ASTM Committee D02, measurement uncertainty as required in ISO/IEC 17025, as practiced by a laboratory, can be estimated by multiplying 2x the site precision standard deviation as defined in ASTM D6299.

The complexity and empirical nature of the majority of Committee D02 methods preclude the application of rigorous measurement uncertainty algorithms. In many cases, interactions between the test method variables and the measurand cannot be reasonably estimated due to the covariance of the variables that affect the measurand. The site precision approach estimates the combined effects of these variables on the total uncertainty for the measurand.

The methodology of using site precision established using QC materials and control charts to estimate measurement uncertainty assumes that the laboratory is unbiased. This assumption should be validated periodically using check standards. See ASTM D6617 or ASTM D6299 for further guidance.