BQ-9000 Quality Management System
Laboratory Requirements

Revision B
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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 Marketer 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. The requirements are both site and methodology specific.

2 REFERENCES[1]

2.1 Normative References

The following references contain provisions which, through reference herein, constitute provisions of these requirements. All referenced documents are subject to revision, and all those applying these requirements are required to obtain and 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)

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

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

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

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

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

3 DEFINITIONS

For use in this text, the following terms and definitions apply. It has been found to be helpful for organizations to define in-house terms and definitions used within their quality assurance programs, but it is not a requirement.

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. The organization shall notify and document their notification to the NBAC when these quality system changes have been made.

4.1 Quality Manual

The quality program shall be documented in a quality manual, which meets the requirements herein. 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 means to establish the document status; such as a form 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 controlled 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. This requirement does not supersede any federal, state, or other requirement (regulatory or otherwise) for further retention of records.

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, should 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 actions shall be referenced and obtainable through internal audit records.

5.3 Quality Management Review

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

a) results of Internal Quality System Audits;

b) customer feedback, including a review of customer complaints;

c) quality control;

d) calibration and maintenance;

e) status of preventive and corrective actions, along with discussions of root causes and effectiveness of implementations;

f) follow-up actions from previous management reviews;

g) changes that could affect the quality management system;

h) discussions to optimize procedures and work instructions;

i) 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 and documented 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 access to the current product specifications and each 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 12).

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 12).[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 and document such review.

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 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, active participation in an interlaboratory proficiency testing program, 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 REMEDIATION ELEMENTS

Corrective and Preventive Actions shall be managed through the use of documented procedures. Records shall be maintained for corrective and preventive actions. Within these procedures, these forms shall have documented timeline requirements for their completion, review and verification.

For Corrective Actions, the procedure shall require the clear statement of the nonconformity; assignments of responsibility for definition and completion of the corrective action; identification of root cause; identification of the corrective action(s) that are intended to prevent recurrence of the nonconformity and verification of the effectiveness of the action, at an appropriate interval following

[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.

the implementation of the corrective action. Corrective actions shall not be closed until verification of effectiveness activities have been completed and recorded. Records of corrective actions shall be documented using a form that supports the above required processes.

For Preventive Actions, the procedure shall require the clear statement of the condition that could result in a nonconformity (either related to product quality or processes of the Quality Management System); assignments of responsibility for the definition and completion of the preventive action and the identification of the preventive action(s) that are intended to prevent the occurrence of the nonconformity. Records of preventive actions shall be documented via memos and /or the use of forms implemented for corrective actions.

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;
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;
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 investigations shall be communicated to the customer as soon as practical and shall be included within the discussions during the Quality Management Review meetings.

14 TRAINING

Laboratory management shall ensure that all staff performing testing or interpreting data, or both, are appropriately trained. Laboratory training shall 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, a signed BQF-1 form without additional supporting documentation and a copy of the BQ-9000 certificate is all that is required to be retained.

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.

Part B Policy Regulations

1.0 CERTIFICATION PROCESS

1.1 Initial Certification

The initial certification process is described in the NBAC BQ-9000 Application Package document. The date that the NBAC Commission approves the BQ-9000 certification for an applicant becomes the anniversary date of their certification. Approximately one year from their certification anniversary date, an on-site Surveillance Audit will be held. Approximately two years from their certification anniversary date a second Surveillance Audit will be held. At the end of three years, the organizations BQ-9000 certification expires. If the organization wishes to continue in the BQ-9000 certification program, they must reapply and complete a re-certification audit before their certification expiration date.

1.2 Surveillance Audit

The Surveillance Audit is a one day on-site audit where the Auditor reviews the program elements of the BQ-9000 organization. This audit is to verify that the BQ-9000 certified organization continues to comply with the requirements of the BQ-9000 program including any changes in the Program Requirements since the last audit.
A second Surveillance Audit is required within two years from their original certification date.

1.3 Re-Certification Renewal

At 3 years from the original certification date, an organizations BQ-9000 certification expires. The organization may request to continue in the program and must go through a Recertification Audit. A Recertification Audit is a one and one half day audit similar to the initial Certification Audit in that the auditor looks at all elements of the organizations quality system.

See section 1.4 for pre-audit requirements and section 1.5 for post-audit requirements and a description on how the audit information is processed by the Commission.

An Auditor is assigned to perform a certification (or recertification) audit and the following two surveillance audits as well as any interim follow-up audits. When the organization is up for its next recertification audit, a new auditor may be assigned to get a second perspective on the organizations performance of its quality system. However, an organization may request the same auditor for a second cycle of 3 years only once following hteir initial certification.

At least 6 months prior to the expiration of the BQ-9000 certification, the NBAC will provide the certified organization a notice that its certification is about to expire. The notice will be accompanied by a renewal application. The NBAC must receive the renewal application and the current version of the organization's quality manual at least 4 months before the certification has expired. The recertification audit is scheduled to allow the organization to process any nonconformances, and allows NBAC time to review the audit and approve recertification before the organization's current certificate expires. The same cycle of Surveillance Audits will then follow the recertification.

A copy of the Recertification Application Form is in the Appendix at the end of this section.

1.4 Pre-audit Requirements: Surveillance and Recertification Audits

Prior to a scheduled Surveillance Audit or Recertification Audit, the BQ-9000 organization shall:

1) Have completed their annual Internal Audit and have generated an Audit Report.

2) Sometime after this Internal Audit, the QMR should have held a Management Review Meeting to discuss how the organization is performing under their quality system and to discuss the status of any nonconformances from their Internal Audit.
3) A copy of the Internal Audit and the most recent two Management Review Meeting minutes must be forwarded to the NBAC Auditor prior to the upcoming Surveillance or Re-certification Audit.

1.5 Post-audit Requirements: Surveillance and Recertification Audits

Prior to the close of the audit, the Auditor will produce a written audit report, noting any nonconformances, deficiencies and areas of concern. The report will be submitted to the organization's quality management team at the close of the audit for the organization's review and comment.

At the time of the closing meeting, if the QMR or a member of the organization's quality management team believes that a cited nonconformance is the result of different interpretations of a program element, and cannot settle the issue with the Auditor, the QMR can take the following path: Within five days of the closing meeting, contact the NBAC Program Manager at the National Biodiesel Board office and provide written information concerning the interpretation of the specific program element(s) and the organization's position on the nonconformance. The Program Manager will meet with the NBAC Chairman and one or more NBAC Commissioners to review the program requirements and may discuss with the Auditor, their interpretation of the requirement. This NBAC group will make a determination of the correct interpretation and will normally inform the organization of their decision within ten days of the receipt of the information from that organization.

The organization is required to submit an action plan to the Auditor within 30 days of the audit date describing how the organization will address each of the identified nonconformances. The organization must submit a Corrective Action form and at a minimum must supply the following information to the Auditor:

- The nonconformance stated
- The root cause of the nonconformance
- The action plan to address the nonconformance
- The person responsible for executing the action plan
- The expected time to complete the corrective action
- An approval signature of the QMR or responsible management person who is approving this specific action plan

In the Appendix is a sample letter that may be sent out to BQ-9000 organizations prior to an upcoming Surveillance Audit or Recertification Audit that discusses these requirements.

If the organization satisfactorily completes their corrective actions on their nonconformances within 30 days of their just completed audit date, the organization is not required to submit their action plans.

Evidence that corrective actions have addressed the nonconformances can usually be mailed or emailed to the Auditor. Under unusual circumstances a follow-up visit may be required to confirm the corrective action of a specific nonconformance.

All nonconformances are expected to be closed within 60 days of the audit date. The Commission recognizes that there may be a specific nonconformance that cannot be closed within

60 days; and this will be acceptable if the Auditor is informed of such when the organization issues it action plans. An Auditor may reject one or more of the organization's action plans if the plan(s) does not fully address the nonconformance(s). The organization must then revise and resubmit this action plan to the Auditor.

If an organization cannot reach an agreement with the Auditor on an action plan for a specific nonconformance and has submitted at least two action plans to remedy the nonconformance, the organization's QMR or designated representative can take the following path: Within five days of the rejection of a second submitted action plan for a nonconformance, contact the NBAC Program Manager at the National Biodiesel Board office and provide written information concerning the validity of the proposed action plan(s) for this nonconformance. The Program Manager will meet with the NBAC Chairman and one or more NBAC Commissioners to review the submitted action plan(s) as it relates to the cited nonconformance, and may discuss with the Auditor, their position on the proposed action plan(s). This NBAC group will make a determination on the proposed action plan(s) and will normally inform the organization of their decision within ten days of the receipt of the information from that organization.

If the organization delays closing their nonconformances beyond the 60 days (except in the circumstance noted in the above paragraph) requiring further Auditor attention, the organization may be charged $150 per hour for the extra time that the Auditor had to spend on the audit.

If after 60 days from the audit date, the Auditor has not received any communication pertaining to the action plans or corrective actions for this audit, the organization will receive a warning letter from the National Biodiesel Accreditation Commission stating that the organizations nonconformance must be completed within the next 30 days or their certification will be suspended – if this is a surveillance audit; or their request for recertification will be denied – if this is a re-certification audit.

The section **Ranking Program Elements**, describes how the Auditor evaluates the organization's execution of each program element in determining conformance to the requirements.

When the auditor has verified that all nonconformances have been closed through corrective action, a final audit report will be submitted to the NBAC.

The organization may submit written comments on this final report by submitting them to the Commission chair up to one week after receiving the final audit report from the Auditor. The Commission normally holds monthly meetings and tries to respond to Auditor's reports and recommendations within 30 days.

Upon receipt of the Audit Report the Commission will set a meeting to vote on certification status of the organization. The Commission may request to have the Auditor present telephonically during its review to answer questions about the audit report. After dismissing the Auditor, the Commission will perform a final review the Audit Report and any written comments. The Commission can then proceed with one of the following actions:

- Based on a satisfactory Certification or Recertification Audit Report, vote to approve certification or recertification.
- Based on the review of a satisfactory Surveillance Audit Report, allow certification to continue.
- Based on the need for additional facts, vote to postpone the certification status decision and require additional information.

- Based on the determination that the organization needs significant improvement in the execution of their quality system, vote to postpone certification status and require a follow-up audit. This follow-up audit will take place after the organization has had an opportunity to improve their quality system performance. A vote on the certification status will then take place after the results from the follow-up audit have been reviewed.
- Based on the determination that the organization's performance was unsatisfactory, vote to suspend the organization's certification. A follow-up audit is recommended. The Commission can then vote on reconsideration of the suspension based on the results of the follow-up audit.
- Based on the determination that the organization's performance was poor, vote to revoke the organization's certification.

If the Commission determines additional facts are necessary, the Commission may postpone the determination for no longer than sixty (60) days. If not, the Commission shall proceed to determination. The determination will be accomplished by a vote of the commission, with each commissioner having one vote. A majority of the commissioners must vote affirmatively on the certification request for certification to be granted. If certification is not granted, the basis for the denial, identifying all material deficiencies, will be sent to the applicant in writing.

If a follow-up audit is required, the audit fee and travel expenses shall be paid by the organization.

If the organization believes that they have received an adverse decision from the NBAC Commission, the organization may use the Reconsideration or Appeal process to address their concerns. The details for Reconsideration and Appeal are found in the section **Reconsideration and Appeal Process for NBAC Decisions**.

1.6 Audit Scheduling

Under most circumstances, the two Surveillance Audits and the next Recertification Audit shall be scheduled as noted above. Any interim follow-up audit between these required audits shall not change the due dates of the Surveillance and Recertification Audits.

Normally at the close of a Surveillance Audit or Recertification Audit, the next audit should be scheduled. This is required even if the next audit is a Recertification Audit and the Auditor might be changed. In such a case, the Auditor will report to NBAC when the Recert Audit is scheduled. If a new Auditor is assigned, and cannot accommodate that specific date, the new Auditor will contact the organization and establish a mutual audit date.

1.7 Audit Fee Structure

See the BQ-9000 website for details on the fee structure for each type of audit.

2.0 Ranking Program Requirements

The NBAC Commission has established a ranking of each required program element specified in the BQ-9000 Quality Management System Producer Requirements manual. The ranking system is integral to identifying deficiencies in quality management systems. Each element is identified as Critical, Major or Minor. A Critical element is essential to the successful operation of the organizations quality system. A Critical program element not being executed by an organization is a significant indicator that the organization is not focused on the BQ-9000 quality system requirements. Examples would be lack of an internal audit or insufficient quality management review meetings. A Major program element not being executed is a significant indicator that

activities like data gathering and record keeping is not happening, and thus there are no evidence that the organization is meeting specific program requirements. Examples would be not completing Product Loadout forms, or not properly testing product or not training personnel who run ASTM tests. A Minor program element is important in that it supports Major or Critical program requirements. An example would be the requirement to review customer satisfaction at a Quality Management Review Meeting.

During the BQ-9000 audit, the Auditor will look at each required program element and determine whether the element is being executed satisfactorily, is being executed less than satisfactorily or is missing all together. The number and ranking of each deficiency identified in an audit will assist the NBAC Commissioners when they evaluate BQ-9000 certifications.

3.0 Certification Suspension and Revocation

3.1 Suspending BQ-9000 Producer, BQ-9000 Marketer or BQ-9000 Laboratory Status

NBAC may suspend BQ-9000 Producer, Marketer or Laboratory status and remove a company's name from the list of BQ-9000 companies at www.bq9000.org for any of the following reasons:

1. Failure to follow the approved quality management system, policies, or procedures resulting in a major nonconformance without implementing corrective action;
2. Denying access to an operation's facilities and records to the BQ-9000 auditors within the scope of the requested certification;
3. Failure to pay NBAC required fees;
4. Failure to respond to NBAC corrective actions in the timeframe provided; or
5. A production facilities falls under the suspension criteria in Policy 5.0 Idled Production Plants.

NBAC will notify the organization in writing of the suspension and the actions required to regain BQ-9000 status, including a deadline for the specified actions. Once suspended, entities will have 180 days to remedy the reasons for suspension with a reassessment audit. If the suspended entity does not respond to the NBAC's initial notification of suspension within thirty (30) days, the entity's BQ-9000 status will be revoked. Information provided will not include specific remedies to violations.

If an organization's actions or lack of actions do not meet the criteria described above, the NBAC may issue a Warning Letter to an organization that their continued certification is in jeopardy. The organization shall receive a recommendation to initiate some action such as hiring a consultant to help them better develop their program or to better execute their program, perform some internal training, and/or scheduling an interim follow-up audit that could demonstrate their improved performance under their quality system.

3.2 Reinstatement of Suspended BQ-9000 Certification

BQ-9000 status for companies will remain suspended for reasons 1, 2 and 4 above until an on-site audit verifies that effective corrective action has been taken. Final decisions on the suitability of corrective action and the company's eligibility for reinstatement are at the discretion of the NBAC.

BQ-9000 status for companies suspended for failure to pay fees will be reinstated when all outstanding fees and interest have been paid in full.

BQ-9000 status for companies suspended due to an idled production plant may be reinstated after the plant begins production and specific quality system requirements are met as defined in section **7.0 Idle Production Plants**.

3.3 Revoking BQ-9000 Certification

NBAC may revoke BQ-9000 status and remove an organization's name from the list of approved organizations at www.bq9000.org for any of the following reasons:

1. Repeated failure to maintain its system in conformance with the requirements of this directive and the approved quality system;
2. Failure of a suspended operation to meet conditions for reinstatement within the required timeframe;
3. Failure to respond to NBAC in given timeframe;
4. Willful violation of Federal or State regulations relevant to BQ-9000 standards;
5. Deliberate misrepresentation of the products or services distributed under a BQ-9000 system;
6. Fraudulent use of BQ-9000 Logo in advertising and promotional material; or
7. A production facilities falls under the revocation criteria in Policy 5.0 Idled Production Plants.

NBAC will notify organizations in writing of the revocation. Companies whose approval has been revoked may reapply for BQ-9000 certification after a period of one year.

Organizations may request Reconsideration or Appeal of an adverse decision by the NBAC. See section **Reconsideration and Appeal of NBAC Decisions**.

3.4 License Use of BQ-9000 Logo

The NBAC's License Agreement with an organization is coextensive with their BQ-9000 certification per NBAC License Agreement, section 3. Thus when an organization's certification is suspended or revoked, the organization must remove the BQ-9000 logo from the organization's materials and cease to use it. An organizations continued use of the BQ-9000 logo beyond the suspension or revocation date will be actionable as unlawful infringement of intellectual property. The organization's name will be removed from the List of BQ-9000 Producers or Marketers or Laboratories on the NBAC website, but no other steps will be taken by the Commission to publicize this step.

4.0 Reconsideration and Appeal of NBAC Decisions

4.1 Reconsideration of Adverse Decision

An applicant denied certification has thirty (30) days after the Commission's adverse decision in which to submit a written request for reconsideration of a denied certification or other adverse decision to the National Biodiesel Accreditation Commission. The Commission will grant Reconsideration if it believes there is a genuine issue of fact material to the decision it made. The reconsideration request must identify the elements of the audit report or other basis for the Commission decision alleged to be inaccurate or otherwise erroneous. The applicant may attach written evidence of the alleged inaccuracy or error. Before acting on Reconsideration, the

Commission reserves the right to submit to the applicant additional questions in writing or to direct further investigation by its staff or auditor, and to consider also the evidence so acquired.

The question upon Reconsideration shall be exactly the same question as upon original consideration: Shall the Application be approved? The vote required shall be the same as upon original consideration: A majority of the Commissioners in office. In its vote upon Reconsideration, the Commission shall, weighing the evidence before it, act upon the basis of the evidence presented. The Commission's decision shall contain findings of fact and conclusions based thereon.

4.2 Appealing NBAC Rulings

A party aggrieved by a decision of the Commission upon Reconsideration may appeal that decision to an Appeal Board if within twenty (20) calendar days of the decision upon Reconsideration the party writes a letter to the Commission stating the grounds for appeal, requesting a hearing, and enclosing a fee of $2,000 to offset the Commission's miscellaneous costs incurred in the Appeal.

Upon request of such letter, the Commission shall appoint an independent Appeal Board of three industry experts: Preferably, one from academia, one from government, and one from private industry.

The Commission shall forward to each Appeal Board member the entire record of the matter appealed. The record on appeal shall consist of: All documents in the possession of the Commission with respect to Appellant at time of Reconsideration. The Appeal Board's decision shall be based solely on the record; no additional evidence shall be considered.

The Appeal Board shall:
- Within five days of appointment, elect a Chair;
- Within ten days of appointment, receive and thoroughly review the record;
- Invite the Appellant to submit any further written argument, to be received no later than fourteen (14) days after appointment;
- Thoroughly review any written argument submitted;
- Schedule a telephonic hearing on the appeal, to be conducted no later than thirty (30) days after appointment.

At the oral argument session, the Commission shall be represented by its Chair or its counsel. The appellant may appear in person or be represented by counsel. Each party may make an oral statement of no longer than ten minutes. There shall be no further evidence introduced; however each party shall, during oral argument, respond fully and faithfully to questions from the Appeal Board. There shall be no direct or cross-examination by the parties.

After all questions from the Appeal Board have been answered, the Board shall dismiss the parties and reach a decision. The Board may affirm the Commission decision, reverse the Commission decision, or remand to the Commission for further action in accord with the Board's decision. The Board shall reverse or remand it if it determines that the decision of the Commission was not supported by substantial evidence in the record before the Commission when reviewed as a whole. The Board shall affirm it if it determines that the decision of the Commission was supported by substantial evidence in the record before the Commission when viewed as a whole. The Appeal Board Chair shall write the decision and send it to both parties. The written decision of the Appeal Board shall be final.

5. 0 BQ-9000 Producer Provisional Status

5.1 Background

When an organization becomes certified as a BQ-9000 Producer, the certification applies only to that specific facility. As the Producer becomes more established, they may want to have other production facilities owned by the parent organization to become BQ-9000 certified. The following information provides guidance on how these facilities can become certified.

A BQ-9000 Producer shall not imply or represent that an additional production facility owned by the Producer falls under an existing BQ-9000 certification. Nor shall the Producer imply or represent that any other production facility has met the BQ-9000 requirements unless the Producer has received BQ-9000 Producer certification for that particular site.

The NBAC recognizes that an existing BQ-9000 Producer's successful implementation of their quality management system demonstrates commitment to the BQ-9000 program and an understanding of the challenges of producing product from multiple production plants. The NBAC has created a Producer Provisional designation to expedite the recognition of additional production facilities that the organization wants to become BQ-9000 certified.

In the normal BQ-9000 certification process a biodiesel production facility must operate for six months under their quality management system before they can be audited by NBAC to seek full BQ-9000 certification. This allows for sufficient time for the production facility personnel to become ingrained in the program elements of the BQ-9000 Producer requirements, generate production and test data, and allows sufficient time for the QMR to gain experience in managing their quality management system. When an organization wants its other biodiesel production facilities to become BQ-9000 certified, the organization implements its existing BQ-9000 Producer quality management system into these other production facilities. This allows these other facilities to qualify under the BQ-9000 Producer Provisional Status and can be recognized as a BQ-9000 production facility and can use the BQ-9000 logo before completing the six months operational requirements and its certification audit.

5.2 Eligibility Requirements

a) If the BQ-9000 Producer has operated under the BQ-9000 program long enough to satisfactorily complete one Surveillance Audit, the corporation may seek Producer Provisional Status for an additional facility or facilities.
b) If more than one new facility is seeking Provisional Status, each facility is handled separately.
c) Under normal circumstances Producer Provisional Status is granted for a period not to exceed twelve months. After six months, this production facility must have a satisfactory certification audit for full certification. Otherwise the facility loses its Provisional Status and may no longer use the BQ-9000 logo for this facility.

5.3 Producer Provisional Status Prerequisites

There are a certain number of prerequisites that must be completed before NBAC can award Provisional Status. These prerequisites should take approximately three months.
A corporation requesting provisional certification for an additional production facility shall complete the following steps:

1. The BQ-9000 Producer shall submit a written request to the NBAC requesting permission to pursue Provisional BQ-9000 Producer status for a specific facility;
2. Submit a completed application, and the appropriate Provisional Status fees;

3. The new Producer organization shall submit copies to NBAC of any documented work instructions or procedures that are specific to this new Producer organization that are not currently in the parent Producer's quality manual;
4. Complete full specification testing as required in Section 8 of the BQ-9000 Producer Program Requirements;
5. The initial, appointed QMR shall be from the parent organization for a minimum of 6 months;
6. Conduct at least one internal audit. The internal audit shall be completed under the supervision of the internal auditor or QMR either of which is from the existing BQ-9000 certified facility;
7. Hold at least one quality management review meeting led by the QMR from the existing BQ-9000 certified facility;
8. Submit the data from the full spec testing, a copy of the internal audit report and a copy of the Management Review Meeting to the NBAC appointed auditor for verification.

After verification that the prerequisites have been met, NBAC auditor shall make a recommendation to the National Biodiesel Accreditation Commission on the facility's request for Provisional Status. The NBAC shall then vote on awarding Producer Provisional Status to the specified facility.

While the new Producer organization is operating under the Provisional Status, it must operate under its parent's quality manual. If the new Producer plans to operate under its own quality manual, the organization can develop its own manual during this time. The new Producer's quality manual must be submitted to the NBAC Auditor so the Auditor can perform a Desk Audit of the new manual prior to the organization's certification audit. The new Producer cannot operate under its new quality manual until it has been approved by the NBAC Auditor.

5.4 Provisional Status Fee

The fee for an organization seeking Producer Provisional Status is identical to the Application Fee of any organization seeking BQ-9000 Producer Certification.

5.5 Steps to Full BQ-9000 Producer Certification

1. The facility must operate under their quality management system for a minimum of six months after receiving Provisional Status;
2. During the time in which the new Producer organization is operating under the Provisional Status, the Producer's quality system shall be managed by the personnel involved in managing the quality management system of the parent BQ-9000 certified Producer.
3. The facility must complete a satisfactory On-Site registration audit by the NBAC appointed auditor;
4. Resolve all nonconformances identified during the registration audit;

After all nonconformances have been successfully closed out, the NBAC auditor shall issue an Audit Report to the National Biodiesel Accreditation Commission on the facility's request for full BQ-9000 Producer certification. The NBAC shall then vote on awarding the organization full BQ-9000 Producer certification.

5.6 Audit Cycles

1. The audit dates of the existing BQ-9000 Producer do not change with the addition of the new BQ-9000 Producer.
2. The audit scheduling of the new BQ-9000 Producer is totally independent of the audit dates of the existing BQ-9000 Producer. The new BQ-9000 Producer is treated as an independent organization and its audit scheduling is based on when the new Producer achieves full BQ-9000 Producer certification.

6.0 BQ-9000 Producer Seeking BQ-9000 Marketer Certification

6.1 Requirements
If a BQ-9000 Producer wishes to exceed the volumes specified in section 12.0 of Part A, Producer Requirements, on Producers Purchasing Biodiesel, or if the Producer wishes to sell blends lower than B99, the Producer must seek BQ-9000 Marketer certification.

6.2 Seeking Marketer Certification
The process for a BQ-9000 Producer to become a BQ-9000 Marketer is no different than any other marketer wanting to become BQ-9000 certified. An application must be filed, fees paid, a marketing quality manual must be developed based on the BQ-9000 Marketer Requirements manual, and audits executed in the same manner as for BQ-9000 Producer certification.

6.3 BQ-9000 Producers Who Have Received Their BQ-9000 Marketer Designation
BQ-9000 Producers who have received their BQ-9000 Marketer certification but:

- have not marketed or distributed B99 or B100 purchased from a third party supplier or;
- have not sold biodiesel blends of B98 or lower;

have one year from the date of their BQ-9000 Marketer certification to perform these activities under their BQ-9000 Marketer quality management system. If no BQ-9000 Marketer activity has been recorded during this year, then the company shall forfeit their BQ-9000 Marketer Status.

7.0 BQ-9000 Producer Idled Production Plants

7.1 Background
BQ-9000 certification is granted for a period of three years and may be renewed. However, a company undergoes annual surveillance audits to verify that they are maintaining and using their quality management system. The National Biodiesel Accreditation Commission (NBAC) expects that BQ-9000 companies are continuously operating within the scope of their quality management system.

Nevertheless, a BQ-9000 Producer may choose to shut down or idle their plant for an extended period of time due to any number of factors like poor economic conditions, major plant retooling or labor issues. The questions that arise from this temporary change in operating status are “How does a plant shutdown or idling affect a company’s BQ-9000 status?” and “Are there any requirements for restarting the production facility?”

Plant shutdowns may affect plant staffing, quality management system maintenance and employee familiarity with the system. As a result, the effectiveness of the company’s quality management system may be impacted. Therefore, the Commission has outlined the following quality management system restarting verification requirements for a production facility after a shutdown. These requirements are based upon the shutdown category classification.

7.2 Definitions
Category I Shutdown: The facility is not producing biodiesel for 60 days but the quality management system is still being followed and maintained and the quality management representative (QMR), biodiesel plant manager, and possibly the lead operator all retain their positions.

Category II Shutdown: The facility is not producing biodiesel and either the quality management system is not being followed and maintained, or the entity has been under Category I for greater than 180 days. The QMR and the plant manager are still part of the organization but are on other assignments.

Category III Shutdown: The facility is not producing biodiesel and the quality management system is not being followed and maintained. The QMR and/or plant manager are no longer part of the biodiesel operations.

7.3 Guidance

Category I Shutdown:

A company enters Category I Shutdown for less than **180** days but greater than 60 days shall complete the following requirements.

- During the shutdown period the company shall maintain product and tank testing requirements outlined in the quality management system;
- After the 90th day they shall test stored product for all critical parameters prior to shipment;
- Prior to startup the company shall hold an abbreviated Quality Management Review Meeting to focus on startup issues such as refresher training, sampling and testing. All affected personnel shall have had refresher training;
- If the organization has been in a Category 1 Shutdown for at least ninety days, within sixty days after startup the company shall hold an internal audit to verify the effectiveness of the quality system;
- A full quality management review meeting shall then be held within 30 days after the internal audit;
- NBAC shall receive notification of this classification.

No on-site NBAC Audit is required at the time of start-up and the company's BQ-9000 status is maintained. Future Surveillance audits shall be scheduled within a year from the subsequent external audit.

After **180** days of no producing activity, the company enters Category II Shutdown.

Category II Shutdown:

- BQ-9000 status is suspended;
  For entities interested in eventual recertification, the following must be adhered to:
- Prior to shipping stored product from their tanks, the biodiesel shall be sampled and tested for all critical parameters which are identified in the Part A section on Program Requirements;
- The first production lot produced at startup shall receive full Biodiesel ASTM D6751 testing (except Cetane number) and must meet the specifications.
- Prior to startup they shall hold a Quality Management Review Meeting to focus on the startup issues such as refresher training, sampling and testing. All affected personnel shall have had refresher training;
- Within sixty days after startup the company shall hold an internal audit to verify the effectiveness of the quality system;
- Another quality management review meeting shall be held within 30 days after the internal audit;
- An external audit shall be scheduled and occur within 6 months of startup;
- NBAC shall receive notification of this classification.

The next Surveillance Audit shall be scheduled within a year from the date of this new external audit.

Category III Shutdown:

- BQ-9000 status is revoked. (refer to section 3.3)

8.0 Change of Ownership and Acquisitions

8.1 Background

As the biodiesel industry expands, it is possible that biodiesel companies will acquire other biodiesel facilities (producer, marketer, or laboratory). This policy provides guidelines to ensure that the ownership changes are properly accounted for when it involves an organization with a BQ-9000 certification.

8.2 Ownership Changes and Acquisition Scenarios

There are three common scenarios that involve ownership change or acquisition.

- The BQ-9000 organization is purchased by another BQ-9000 organization.
- The BQ-9000 organization is purchased by an organization that does not have a BQ-9000 certification.
- The BQ-9000 organization purchases a non BQ-9000 organization and wants it to become BQ-9000 certified.

A BQ-9000 organization involved in an ownership change must meet requirements outlined as follows to maintain BQ-9000 certification.

In the first scenario, if the acquired BQ-9000 organization will maintain its identity and wants to maintain its BQ-9000 certification, the acquiring organization must inform the NBAC Program Manager in writing of this request. If either entity is a member of the National Biodiesel Board they must also complete the Name Change or Company Merger Notification form and submit it to the Chief Operating Officer of the NBB, and must submit the Name Change Fee to the NBAC. Should this be the case, both entities will exist under their respective BQ-9000 certifications, and from a BQ-9000 perspective, they will be treated as separate and independent entities for audit scheduling.

In the second scenario, if the acquiring entity is not a BQ-9000 organization, and the entity being acquired is BQ-9000 certified, there are two possible cases: one where the existing BQ-9000 quality system is maintained and one where it is not.

If the entity being acquired retains its original quality management system and the quality management team will remain (or remain for a sufficient time) to train a new quality management team, the certification is maintained under the following provisions. The acquiring entity must inform the BQ-9000 Program Manager in writing that the acquired BQ-9000 organization's quality system and quality management team will continue. If the acquired entity is a member of the National Biodiesel Board they must also complete the Name Change or Company Merger Notification form and submit it to the Chief Operating Officer of the NBB, and must submit the Name Change Fee to the NBAC.

If the non-BQ9000 organization does not adsorb the BQ-9000 organization's quality system and its quality management team, then the acquired BQ-9000 organization is no longer considered BQ-9000 certified.

In the third scenario, the organization being acquired may achieve BQ9000 certification via the process described in the NBAC BQ-9000 Application Package. The acquired entity may be eligible for expedited recognition as a BQ-9000 certified organization under the Provisional Status process.

This is outlined in the Policies on Producer Provisional Status and Marketer Provisional Status. There is not yet a provisional policy for Laboratories.

8.3 Fees and Payments

The additional number of audits and audit costs when mergers occur are described in the BQ-9000 website under Program Costs.

Appendix Part C — PRE-AUDIT LETTER

Date: (*90 days from audit due date*)

Dear (*Client*),

Our records show that you are scheduled for a BQ-9000 (*Producer, Marketer, Laboratory*) (*Surveillance, Recertification*) Audit with our BQ-9000 Auditor (*Auditor Name*) on (*Audit Date*). The BQ-9000 program requirements specify that you must complete an internal audit within the last 12 months of your upcoming audit date; and you must also complete at least two management review meetings in this same time frame, with one of the two management review meetings sometime after your internal audit. We are requesting that you email a copy of your most recent internal audit report and a copy of the two most recent management review meeting notes to our auditor at least two weeks prior to the audit date. If you have any problems with this audit date or with these pre-audit requirements please contact your auditor immediately or contact Desiree Hale (DHale@biodiesel.org) , at the National Biodiesel Board.

If during this (*Surveillance, Recertification*) Audit, the BQ-9000 Auditor determines there are one or more non-conformances, these will be reviewed with your Quality Team at the Audit Closing meeting. Within 30 days after the audit date, you are required to submit to the Auditor an action plan for each nonconformance identified.

If one or more corrective action plans are rejected by the Auditor as being insufficient to address the nonconformance, the Auditor will request that these action plans be revised.

Within 60 days of the audit date, the Auditor will expect all corrective action plans to be completed; and the Auditor must receive emailed or mailed evidence of these corrections. If there are delays in closing all non-conformances that requires the Auditor having to spend time beyond the 60 day limit, you will be charged a fee of $150 per hour by the Auditor to review late corrective actions. The Commission recognizes that there may be a specific nonconformance that cannot be completed within 60 days. We will take this into consideration if this is communicated to the Auditor at the time you submit your 30 day corrective action plans to the Auditor.

If after 60 days, the Auditor has received no communications from you pertaining to your action plans or corrective actions, you will receive a warning letter from the National Biodiesel Accreditation Commission stating that you must complete these requirements within the next 30 days or your (*certification will be suspended* – if a surveillance audit, or *request for recertification will be denied* – if a recertification audit).

When all corrective actions have been satisfactorily closed, the Auditor will write a report to the NBAC Commissioner describing the audit. The Commissioners will review the report and vote on your certification. If the Commissioners find that the number and significance of all non-conformances is a concern, they may vote to delay a certification decision until a follow-up audit is held after you have had the time to improve your quality management system.

We hope you realize that an effective internal audit, good management review meetings and an attention to detail should lead to a smooth trouble free audit.

Sincerely,

Program Chair
National Biodiesel Accreditation Commission

Cc: Desiree Hale, (*Auditor*)

BQ-9000 RE-CERTIFICATION FORM

Company Name:

_____

Mailing
Address: _____

_____

_____

Is your facility a subsidiary of another company?

☐ Yes ☐ No

If "Yes" please identify the parent organization:

_____

Mailing
Address: _____

_____

_____

_____

Contact
Person: _____

E-mail: _____

Telephone: _____ Fax: _____

Recertification sought (circle as applicable):

BQ-9000 Producer
BQ-9000 Marketer
BQ-9000 Lab

For Marketers, please indicate the location of facilities or sites where the BQ-9000 program applies. Include the physical address:

_____

_____

_____

_____

Please submit a complete copy of your current Quality Manual and all related documents, which describe your Quality System.

Re-certification forms are to be submitted to:

National Biodiesel Accreditation Commission
P.O. Box 104898
Jefferson City, Missouri 65110-4898
(573) 635-3893
Desiree Hale at dhale@biodiesel.org

PRE-AUDIT LETTER

Date: (*90 days from audit due date*)

Dear (*Client*),

Our records show that you are scheduled for a BQ-9000 (*Producer, Marketer, Laboratory*) (*Surveillance, Recertification*) Audit with our BQ-9000 Auditor (*Auditor Name*) on (*Audit Date*). The BQ- 9000 program requirements specify that you must complete an internal audit within the last 12 months of your upcoming audit date; and you must also complete at least two management review meetings in this same time frame, with one of the two management review meetings sometime after your internal audit. We are requesting that you email a copy of your most recent internal audit report and a copy of the two most recent management review meeting notes to our auditor at least two weeks prior to the audit date. If you have any problems with this audit date or with these pre-audit requirements please contact your auditor immediately or contact Desiree Hale (DHale@biodiesel.org) , at the National Biodiesel Board.

If during this (*Surveillance, Recertification*) Audit, the BQ-9000 Auditor determines there are one or more nonconformances, these will be reviewed with your Quality Team at the Audit Closing meeting. Within 30 days after the audit date, you are required to submit to the Auditor an action plan for each nonconformance identified. You may use your Corrective Action form or the one found on the BQ-9000 website, www.BQ-9000.org .

If one or more corrective action plans are rejected by the Auditor as being insufficient to address the nonconformance, the Auditor will request that these action plans be revised.

Within 60 days of the audit date, the Auditor will expect all corrective action plans to be completed; and the Auditor must receive emailed or mailed evidence of these corrections. If there are delays in closing all nonconformances that requires the Auditor having to spend time beyond the 60 day limit, you will be charged a fee of $150 per hour by the Auditor to review late corrective actions. The Commission recognizes that there may be a specific nonconformance that cannot be completed within 60 days. We will take this into consideration if this is communicated to the Auditor at the time you submit your 30 day corrective action plans to the Auditor.

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We hope you realize that an effective internal audit, good management review meetings and an attention to detail should lead to a smooth trouble free audit.

Sincerely,

Program Chair
National Biodiesel Accreditation Commission

Cc: Desiree Hale, (*Auditor*)

BQ-9000 RE-CERTIFICATION FORM

Company Name:

_____

Mailing Address: _____

_____

_____

Is your facility a subsidiary of another company?

☐ Yes ☐ No

If "Yes" please identify the parent organization:

_____

Mailing Address: _____

_____

_____

_____

Contact Person: _____

E-mail: _____

Telephone: _____ Fax: _____

Recertification sought (circle as applicable):

BQ-9000 Producer

BQ-9000 Marketer

BQ-9000 Lab

For Marketers, please indicate the location of facilities or sites where the BQ-9000 program applies. Include the physical address:

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Please submit a complete copy of your current Quality Manual and all related documents, which describe your Quality System.

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Desiree Hale at dhale@biodiesel.org