BQ-9000 Quality Management System

Producer Requirements

Revision 6
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This requirements document has been prepared by the National Biodiesel Accreditation Commission, an autonomous committee of the National Biodiesel Board, P.O. Box 104898, Jefferson City, MO 65110-4898, for use in a cooperative and voluntary program for the certification of producers of biodiesel. Compliance with these requirements is a minimum requirement for the certification process. The existence of this document does not in any respect preclude any entity from producing, purchasing, or using products, processes, or procedures not conforming to this standard. This document is subject to periodic review and revision control and users are cautioned to obtain the latest edition.

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1 SCOPE

This document specifies requirements for a quality assurance program where an organization needs to

a) demonstrate its ability to provide product that meets ASTM D6751, Standard Specification for Biodiesel Fuel (B100) Blend Stock for Middle Distillate Fuels

b) address quality assurance through the effective application of the program, including processes for corrective action and the prevention of nonconformity.

The requirements specified herein are applicable to biodiesel producers. The process control requirements are prescriptive, while the remaining clauses are descriptive.

2 TERMS AND 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.

2.1 ***ASTM:*** ASTM International, originally known as the American Society for Testing and Materials (ASTM), was formed over a century ago. ASTM International is one of the largest voluntary standards development organizations in the world. ASTM develops technical standards for materials, products, systems, and services.

2.2 ***Biodiesel:*** A fuel comprised of mono-alkyl esters of long chain fatty acids derived from vegetable oils or animal fats and meeting ASTM D 6751, designated B100.

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

2.4 External Laboratory: A third party laboratory that the biodiesel organization can use to test product samples.

2.5 Internal Laboratory: A laboratory that is operated or managed by the biodiesel organization.

2.6 Marketer: An entity engaged in the business of the distribution and sale of biodiesel and/or biodiesel blends of B2 or greater.

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

2.8 Organization: A producer or marketer of biodiesel or biodiesel blends.

2.9 Producer: An organization involved in the production of B100 through assets under their direct control or through a tolling arrangement. Producers can either sell B100 or biodiesel blends of B99 or higher.

2.10 Production Lot: A biodiesel production lot is a homogeneous production volume of finished biodiesel from one or more sources that is held in a single container where representative samples are taken and analyzed to provide an authentic certificate of analysis (COA) for the specific volume.

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

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

2.13 Tolling Producer: An entity that contracts out all or part of its biodiesel processing capability to another party. In a tolling arrangement the contracting party is providing the feedstock to the Tolling Producer and taking responsibility for the quality of the product produced by the Tolling Producer.

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

3 REFERENCES

3.1 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 apply the most recent editions of the references indicated below.[1]

ASTM D1298, *Standard Test Method for Density, Relative Density (Specific Gravity), or API Gravity of Crude Petroleum and Liquid Petroleum Products by Hydrometer Method.*

ASTM D4052, *Standard Test Method for Density and Relative Density of Liquids by Digital Density Meter*

ASTM D4057, *Standard Practice for Manual Sampling of Petroleum and Petroleum Products.*

ASTM D4176, *Standard Test Method for Free Water and Particulate Contamination in Distillate Fuels (Visual Inspection Procedures)*

ASTM D6751, *Standard Specification for Biodiesel Fuel Blend Stock (B100) for Middle Distillate Fuels.*[2]

Form BQF-1, BQ-9000 External Laboratory Verification

[1] ASTM documents are available from www.astm.org.
[2] Any approved alternative test methods listed in ASTM D 6751 are acceptable for use in this program.

3.2 Informative References

The following reference is included as bibliographic information which may contain material useful in the application of this requirements document. Excerpts from this reference were used in the development of the requirements in this document.

ISO 9001:1994[3], *Quality Management Systems - requirements*

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 Producer Program Requirements into their quality management system within 90 days of the effective date of the latest revision. The organization shall notify 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 including the means to ensure that B100 conforms to ASTM D6751, is appropriately blended and meets any customer specific requirements. 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 operation and the expectations of its customers. The quality policy shall be invoked throughout the biodiesel operation 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.

[3] International Organization for Standardization (ISO). This material is reproduced from ISO 9001:1994 with permission of the American National Standards Institute (ANSI) on behalf of ISO.

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 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 Document. 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.

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) process performance & product conformity

d) status of preventive and corrective actions

e) follow-up actions from previous management reviews

f) changes that could affect the quality management system

g) recommendations for improvement

6 OPERATIONAL ELEMENTS

6.1 Process Changes

A significant process change is one that could materially alter the composition of the product. The QMR shall be responsible for reviewing process changes and determining whether the change is considered significant. A record of significant process changes shall be maintained by the organization.

The following are examples of what could be considered a significant process change:

a) the use of different raw materials,

b) the use of new or modified equipment,

c) refurbishment of existing equipment,

d) change in equipment location,

e) use of equipment that has been inactive for volume production for 30 days or more, or

f) change of catalyst technology

6.2 Toll Production

A producer may have all or part of its production done by a “Tolling Producer” pursuant to a contract at a “tolling” facility. In such cases:

a) The Producer’s application shall specify, and any accreditation granted, shall specify the tolling facility or facilities included.

b) Any tolling facility specified shall meet all applicable BQ-9000 requirements and shall be subject to a full registration audit as if it were a BQ-9000 Producer itself.

c) If a Producer changes tolling facilities, the new tolling facility shall meet all applicable BQ-9000 requirements and have undergone a full registration audit as if it were a BQ-9000 Producer itself.

d) The BQ-9000 Producer shall report to the NBAC of any cessation of production at the Tolling Facility.

6.3 Production Lots (see Appendix A)

The organization shall develop documented procedures for identifying the product through a unique identification of individual product, batches, or lots as defined in Section 2.10. Each separate lot shall be identified in a manner that corresponds to that particular volume of fuel. All production lots shall be tested as described herein. Production lots shall be managed so that once the lot is identified; no other product shall be introduced into the lot without reconfirming that it meets specification.

7 LABORATORIES

7.1 Laboratory Practices

Internal and external laboratories used by the organization shall implement the following practices.

a) Shall have copies of the current ASTM D6751 specification and of the test methods for the test being conducted in the laboratory.

b) Shall have all the required equipment and standards that are required for the testing that is being conducted in the laboratory.

c) Shall calibrate the equipment and standardize reagents at least as frequently as required by the methods for testing product to ASTM D6751 specifications. If there is not a requirement for calibrations, then a lab specific schedule shall be established for each test method used by the laboratory. Calibrations and standardizations shall be documented.

d) Shall have a training program that demonstrates competencies for testing product to ASTM D6751 specifications.

e) At least once every four months, a laboratory shall execute a documented program to verify that their testing results are accurate by sending duplicate samples out to an independent laboratory, purchasing and testing standards, or participating in an ASTM (or equivalent) biodiesel cross check program.

f) Shall determine, collect and monitor appropriate data to demonstrate the effectiveness of the testing performance.

g) Shall maintain records that indicate test results that were produced by an external laboratory.

h) Analytical results shall reference the test method specification.

7.2 Laboratory Auditing Protocol

7.2.1 Internal laboratories

Internal lab audits shall be included as part of the Internal Quality System Audit (see 5.2).

7.2.2 External laboratories

Organizations using external laboratories shall receive from the external laboratory a completed and signed Form BQF-1 with supporting documentation indicating their compliance with the requirements specified in 7.1. This form shall be completed annually by the external laboratory and shall be retained by the organization for a minimum of two years.

8 SAMPLING AND TESTING

Inspection, sampling and testing functions associated with the verification that specified product requirements are being met shall be defined in documented procedures. Such procedures shall include the types of inspection and testing performed and the records established by same. [4]

The procedures for final inspection and testing shall require that all specified inspection and tests have been carried out and that the results meet specified requirements. The procedures for final inspection and testing shall, at a minimum, meet the requirements specified in Section 8. A procedure for control of nonconforming product shall be employed (see 9.1) when a lot fails to pass a required inspection or test.

8.1 Production Lot Tank Homogeneity (See Appendix B)

8.1.1 Non-Mechanically Mixed or Agitated Tanks

Tank homogeneity is established after 5 consecutive production lots utilizing a single feedstock[5] meet the Tank Homogeneity requirements. Tank homogeneity is established by obtaining tank samples at the upper, middle and lower regions of the tank. ASTM D4057, Standard Guide for the Sampling of Petroleum Products, addresses the issues relative to the sampling of biodiesel. All three samples shall conform to the Tank Homogeneity requirements. If homogeneity requirements are met then the upper, middle and lower samples can be combined to form a composite sample for testing purposes. If homogeneity is not evident then action shall be taken to make the tank contents homogeneous so that separate shipments from this production lot are representative of a single COA. After the tank is made homogeneous, new samples shall be collected from the three levels of the tank and retested to verify homogeneity.

Tank Homogeneity Requirements:

Property	Test Method	Limits
Relative Density	ASTM D1298 or ASTM D4052	range 0.006

If a production lot consists of biodiesel made from different (but not pre-blended) feedstocks, where there is a difference in relative density or a cloud point difference of 5 degrees C (of the biodiesel); testing shall be conducted on the biodiesel to determine tank homogeneity. If homogeneity is not evident then action shall be taken to make the tank contents homogeneous so that separate shipments from this production lot are representative of a single COA. After

[4] Organizations should check with their laboratories to determine the optimal volume of fuel needed for testing the product and for acceptable shipping containers and procedures.

[5] Single feedstock could include multiple sources that were preblended before entering the biodiesel production process. Preblending means blending feedstocks prior to the feedstock entering the first step in the production process.

the tank is made homogeneous, new samples shall be collected from the three levels of the tank and retested to verify homogeneity.

8.1.2 Mechanically Mixed or Agitated Tanks

In cases where mechanical tank mixing methods are used, tank homogeneity is established after 5 consecutive production lots meet the Tank Homogeneity requirements. Once established, the producer shall identify the method with which production lot samples will be acquired for testing. If homogeneity cannot be established, then a composite or all levels sample shall be used.

8.2 Sampling

Production lots from non-mechanically mixed or agitate tanks shall be sampled per ASTM D4057, Standard Guide for the Sampling of Petroleum Products to gain a representative sample of the product. Mechanically mixed or agitated tanks shall be sampled per 8.1.2. A portion of which shall be retained for a minimum of 60 days.[6]

8.3 Testing

All production lot samples shall be tested to assure that the customer delivered product shall be free from particulate matter, water, and unreacted material per test procedure, ASTM D4176 *Free Water and Particulate Contamination in Distillate Fuels* (maximum of 2). If the product is out of specification the appropriate corrective action shall be taken including documentation.

Further, each production lot of B100 shall be subjected to full specification testing (see 8.3.1) until there is sufficient confidence that the production process consistently produces product that meets ASTM D6751. The production of a minimum of seven consecutive lots that meet the standard provides such a confidence level. Visual appearance results should be reported on the certificate of analysis along with the appropriate ASTM D6751 results. For cetane number, three consecutive lots that meet the standard establish confidence in the cetane number. Once this has been achieved, all production lots of B100 shall at a minimum be subjected to critical specification testing (see 8.3.2) and monthly testing (see 8.3.3).

If a significant process change occurs (one that could materially alter the composition of the product, see 6.1), full specification testing shall resume until confidence in the production process is re-established. Confidence is re-established with the production of a minimum of three consecutive lots that meet the standard. For cetane number, one lot is needed.

If any of the production lot testing fails to meet specification, the production lot shall be isolated and the procedures for the control of nonconforming product shall apply (see 9.1).

8.3.1 Full Specification Testing

Full specification testing shall include testing to each of the limits defined in ASTM D6751 and the following:

Property	Test Method	Limits
Visual appearance	ASTM D4176 Procedure 2	2 max

[6] Retained samples (“retains”) shall be kept in an environmentally appropriate location to avoid spoilage of the sample for the period of time being retained. In most cases, retention of at least one liter of fuel should be sufficient. If it is anticipated that cetane number will need to be tested from the retained sample, then an additional liter of fuel may be needed.

When test properties are added to ASTM D6751 by ASTM, the organization shall test three consecutive production lots to verify that their product meets the new specification requirement. The organization shall keep a record of this testing.

8.3.2 Critical Specification Testing

Critical specification testing shall include testing performed on the production lot sample (except as noted below) to each of the following limits:

Property	Test Method	Limits
Alcohol Control[7]	Per ASTM D6751	per ASTM D6751
Water and Sediment, volume %	Per ASTM D6751	per ASTM D6751
Cloud point, °C	Per ASTM D6751	per ASTM D6751
Acid number, mg KOH/gm	Per ASTM D6751	per ASTM D6751
Free glycerin, % mass	Per ASTM D6751	per ASTM D6751
Total glycerin, % mass	Per ASTM D6751	per ASTM D6751
Sulfur, ppm	Per EPA requirements	per EPA requirements
Oxidation Stability, hours	Per ASTM D6751	per ASTM D6751
Visual appearance	ASTM D4176 Procedure 2	2 max
Cold Soak Filterability Test, seconds	Per ASTM D6751	per ASTM D6751

At least once every six months, a production lot shall be selected for full specification testing. However, only one cetane number test per year is required.

8.3.3 Alternative Testing of Product for Markets Requiring EN 14214 Specifications

Alternatively, the Critical Specification Testing may be performed under the EN 14214 requirements. In such cases, the methods employed, and specifications used, shall be at least as stringent as those listed within the current version of D6751.

The critical testing for each production lot, at a minimum, shall include:

Property	Test Method	Limits
Methanol Content, % m/m	per EN 14214	per EN 14214
Water Content, mg/kg	per EN 14214	per EN 14214
Total Contamination, mg/kg	per EN 14214	per EN 14214
CFPP, ^{o}C	per EN 14214	per EN 14214
Acid Value, mg KOH/g	per EN 14214	per EN 14214
Free Glycerol, % m/m	per EN 14214	per EN 14214
Total Glycerol, % m/m	per EN 14214	per EN 14214
Sulfur Content, mg/kg	per EN 14214	per EN 14214
Oxidation Stability, hours	per EN 14214	per EN 14214
Monoglycerides, % m/m	per EN 14214	per EN 14214

This testing is not a guarantee of compliance with the full specifications. Additional testing, or confidence, may be necessary. It is expected that full specification testing would be necessary as a condition of the sale of exported product.

[7] In ASTM D6751 Alcohol Control can be met using one of the following tests. 1) Methanol Content using EN14110 with a limit of .2% max by volume or, 2) Flash Point using ASTM D93 with a minimum temperature of 130 Degrees C.

At least once every six months, a production lot sample shall be selected for full specification testing. However, only one Cetane Number test per year is required.

8.3.4 Monthly Specification Testing
Some specifications require monitoring less frequently than every production lot but more frequently than every six months. Specifications that fall into this category shall be tested monthly as part of production lot testing. This includes:

Property	Test Method	Limits
Sodium and Potassium, ppm	Per ASTM D6751 or EN 14214	per ASTM D6751 or EN 14214
Calcium and Magnesium, ppm	Per ASTM D6751 or EN 14214	per ASTM D6751 or EN 14214

8.4 Certificates of Analysis (COA)
A COA shall be generated for each production lot and shall contain a unique lot identification. When full specification testing has been performed on a lot, the COA shall contain a listing of each of the actual results. When critical specification testing has been performed on a lot, the COA shall contain a listing of each of the actual results of the critical testing. The results for the remaining specification parameters shall indicate they were not the results of tests performed on this particular production lot and are based upon the results from the most recent full specification testing.

8.5 Commingling of Production Lots
Once production lots have been tested under the protocols outlined in Sections 8.3 – 8.3.3 and have met the specification limits of the tests conducted they can be commingled with other verified lots.

The cloud point of the commingled products shall be reported as either
1) The highest cloud point of the products being commingled or
2) The measured cloud point of a representative blend

The oxidation stability shall be reported as either
1) The lowest oxidation stability hours of the products being commingled or
2) The measured oxidation stability of a representative blend

The cold soak filterability shall be stated as either
1) Meeting the higher of the 360 or 200 second filterability time limits of the products being commingled or
2) The measured cold soak filterability of a representative blend

8.6 B100 Storage Tank Inactivity (See Appendix C)
If a biodiesel storage tank (containing a unique lot) has no activity for 30 days, product shall not be shipped from the storage tank until an outlet sample is taken and tested for water and sediment per ASTM D6751, and for Oxidation Stability per ASTM D6751. If any of the production lot testing fails to meet specification, the production lot shall be isolated and the procedures for the control of nonconforming product shall apply (see 9.1).

9 REMEDIATION ELEMENTS

9.1 Nonconforming Product

The organization shall develop documented procedures that will ensure that product is prevented from unintended use or shipment if it is found to be nonconforming. Controls shall be defined that provide for identification, documentation, evaluation, segregation (when practical), disposition of nonconforming product, and for notification to the functions concerned. Personnel with the authority to review and "sign-off" on the disposition of nonconforming product shall be identified. The review of nonconforming product shall be conducted according to the documented procedures. The disposition of nonconforming product may be categorized as:

a) reprocessed to meet specification

b) re-classified to another application, or

c) rejected or destroyed.

If product is reprocessed, it shall be re-inspected to assure it meets specification. The re-inspection shall be documented.

9.2 Corrective and Preventive Action Procedures

Corrective and Preventive Actions shall be managed through the use of documented procedures. Records shall be maintained for corrective and preventive actions. Corrective actions shall be issued in response to product quality nonconformities (including both internally identified and customer complaints related to product quality) and identified nonconformities related to processes of the Quality Management System (including internal and external audits).

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, at an appropriate interval following the implementation of the corrective action, of the 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.

10 FUEL BLENDING

10.1 Fuel Blending

During the process of creating a biodiesel blend (B99 or higher), the blending operation shall be monitored to assure adequate mixing of the products in the correct proportions. This includes measuring and recording the volumes and blend levels as verified through bills of lading, meter printouts or other auditable records of both the biodiesel and diesel fuel, which comprise the blend. These records shall be kept for a period of two years.

11 PRODUCT LOADOUT

11.1 Truck, Railcar and Vessels Standards

The quality program shall provide cleanliness specification standards that address material and chemical compatibility issues, inspections and cleanliness for trucks, railcars and vessels used for distributing biodiesel in a BQ-9000 Producer's supplied trucks, railcars and vessels. All trucks, railcars and vessels shall be drained and inspected prior to loading if the previous load contained a product that would contaminate the biodiesel (e.g., gasoline, ethanol, methanol, lube oils, raw vegetable oil or animal fats). This would include dyed products and products in excess of 15 ppm sulfur when the biodiesel is destined for ULSD applications.

Agreements and/or contracts with transport companies shall state, explicitly or by reference, the cleanliness standards that shall be complied with before hauling biodiesel. The producer shall periodically verify that the transport companies are meeting the cleanliness specifications.

Appendix A
(informative)
Producer Process Flow
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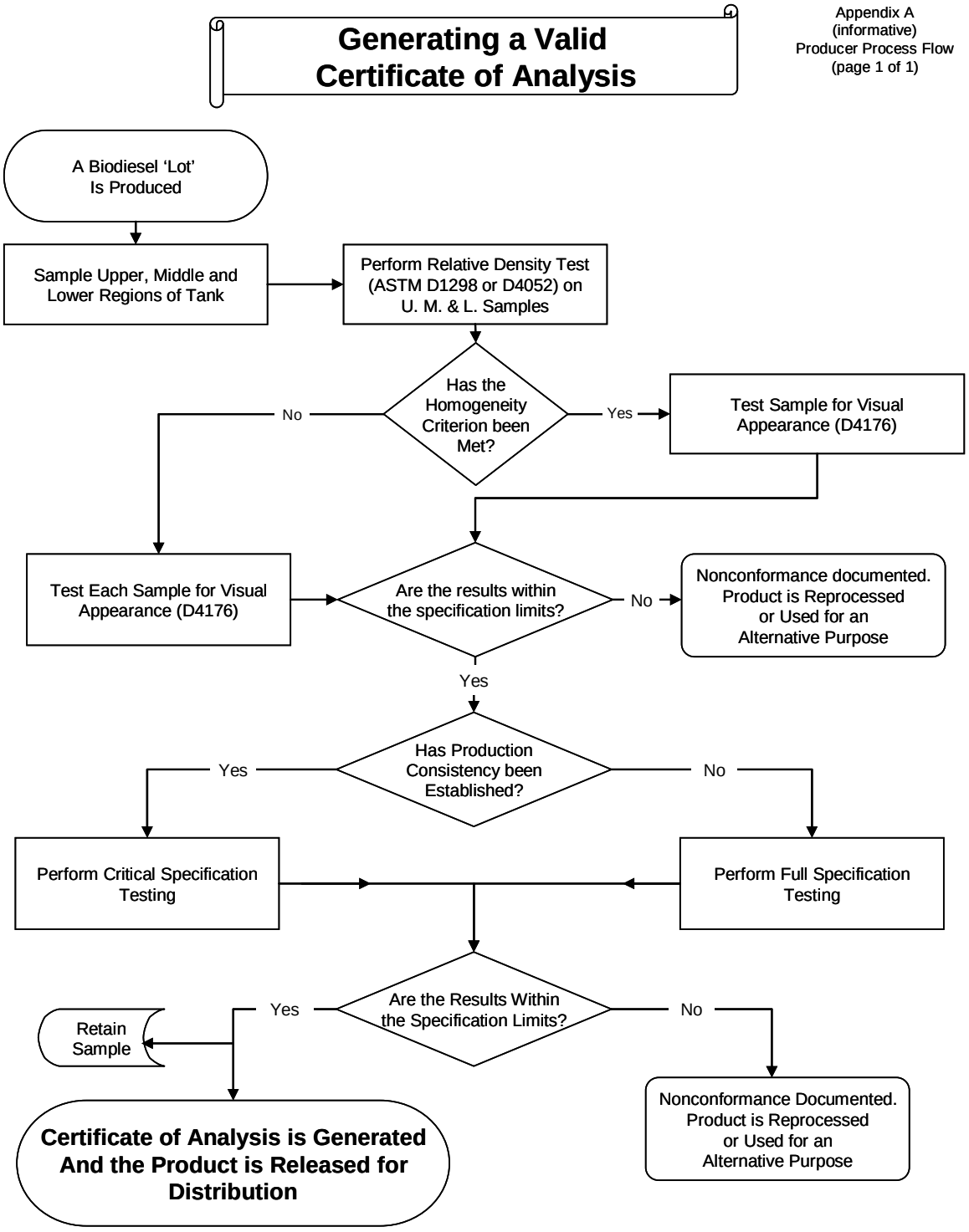

Appendix B
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Producer Process Flow
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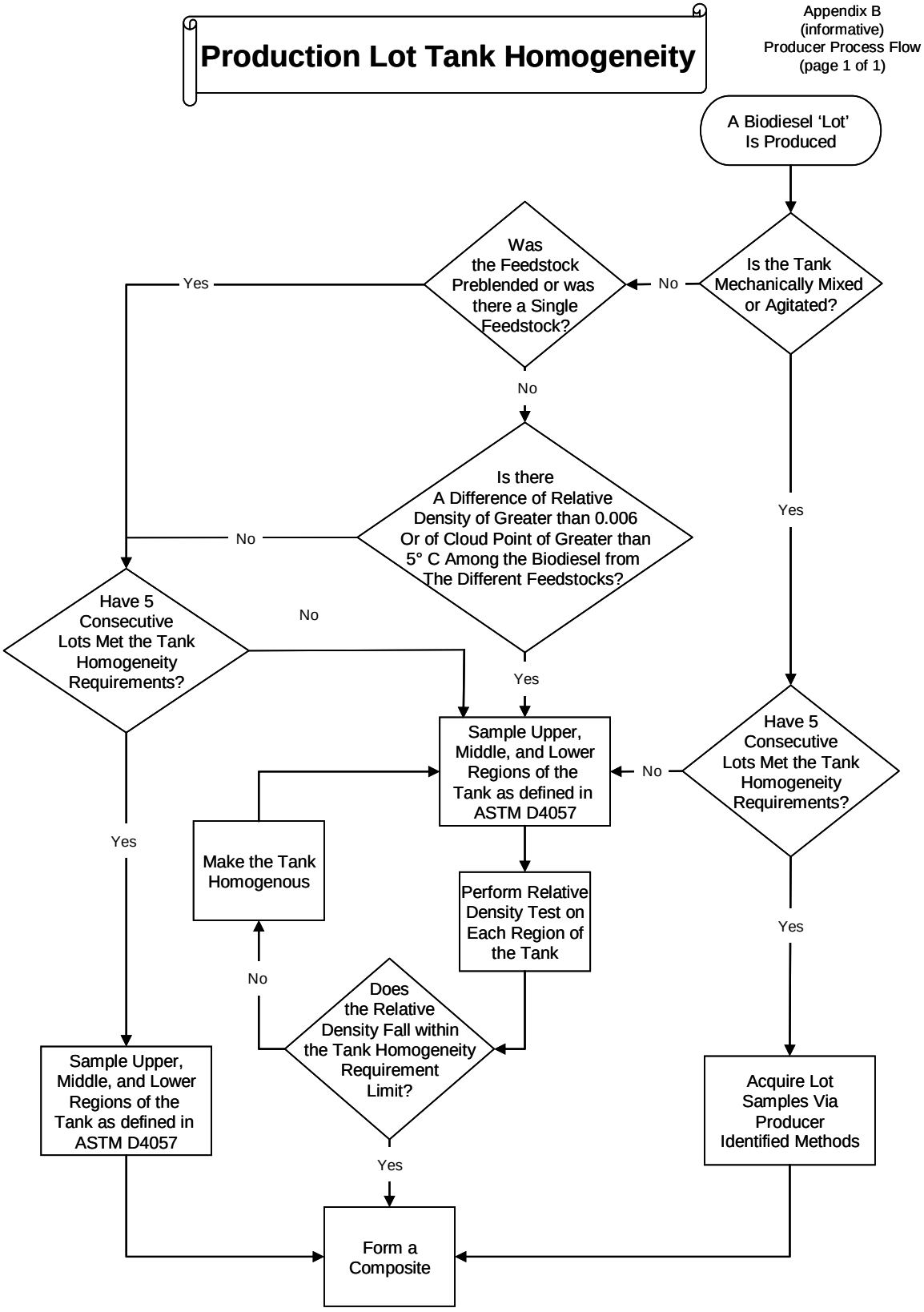

Maintaining the Validity of a Certificate of Analysis

Appendix C
(informative)
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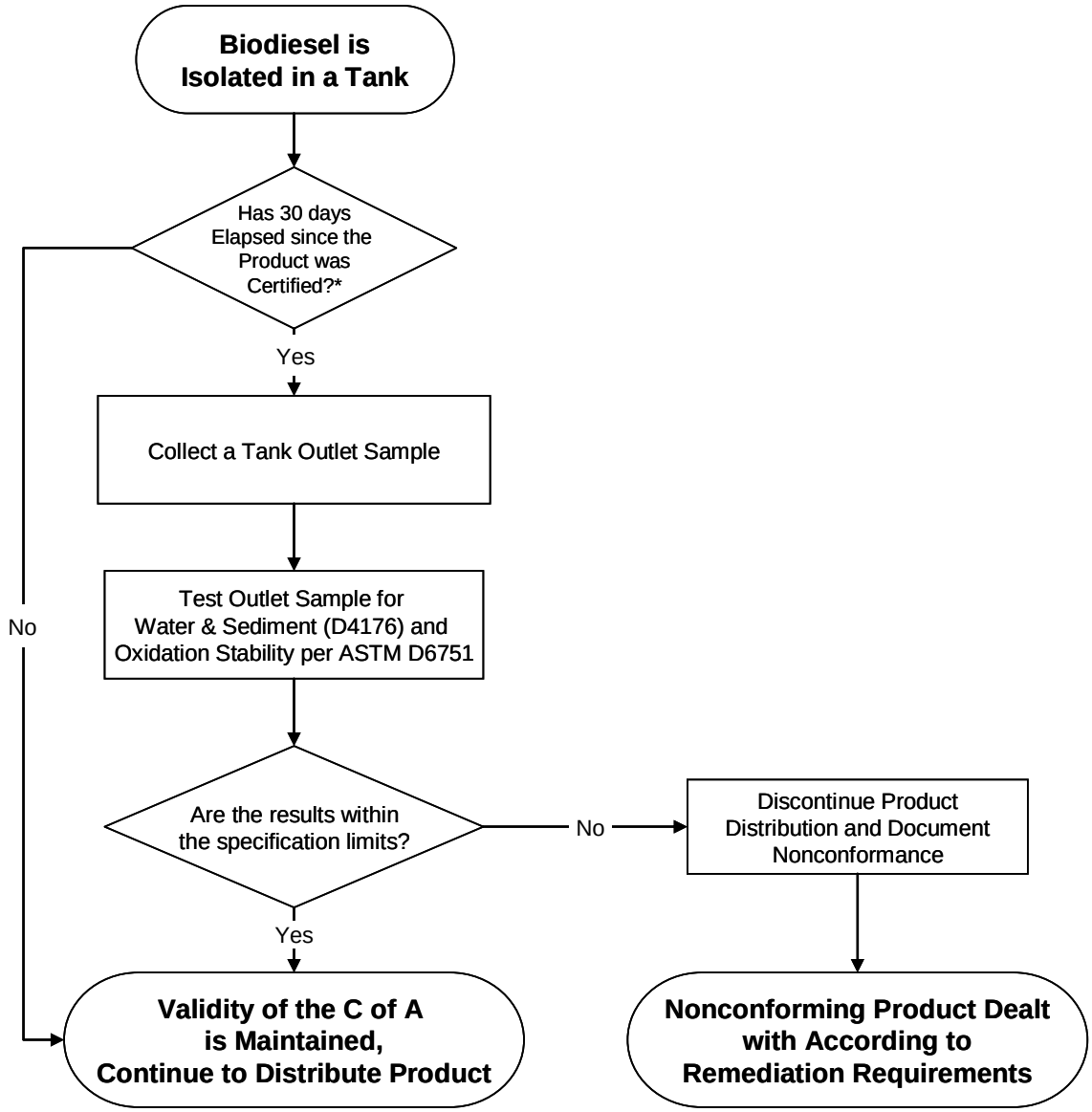

*Under specific storage conditions it may be prudent to conduct more frequent product inspections.