



# **BQ-9000 Producer Program Guidebook**

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**BQ-9000 Producer Requirements**  
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# **BQ-9000 Producer Requirements**

## **1.0 SCOPE**

### **1.0 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.

### **GUIDELINES ~ The Intent**

The dictionary defines “scope” as extent of treatment, activity, or influence. It is recommended that each BQ-9000 Producer include a scope section in their quality manual that defines the aspects of their operation covered by the quality management system. The follow items are provided as tips to consider when developing the scope section of the quality manual:

- ◆ The organization’s scope defines what you are doing and the standards you are using to receive the ASTM D6751 biodiesel.
- ◆ The scope should also include the customer base you are serving. If you are blending to B99 or lower you should state the blends you are making and the target markets such as on-road or off-road use etc.
- ◆ The scope should clearly define that you will be in compliance with applicable regulations of the State or Federal laws. If you are in compliance with environmental or other voluntary standards beyond what is required, you may want to reference those.
- ◆ The scope should include your business address or any other business locations or branches that are subject to your quality management system.

## **BQ-9000 Producer Requirements**

### **2.0 TERMS AND DEFINITIONS**

#### **2.0 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 D6751, 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 producer can use to test biodiesel 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.

## **GUIDELINES ~ The Language**

Every business has their own understanding of words or phrases for their work place. This section, along with additional words in the glossary and in the acronym sections, defines many of the words and phrases used in the Biodiesel industry. Remember that Biodiesel production is unique when compared to many other businesses. You may have terms and definitions that need to be explained so that others you deal with can understand your business. These sections are not inclusive.

## **BQ-9000 Producer Requirements**

### **3.0 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.<sup>1</sup>

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<sup>2</sup>

Form BQF-1: BQ-9000 External Laboratory Verification

#### **GUIDELINES ~ Required External Documents**

These documents are your methods and guidelines for testing and tolerance levels for producing B100. Someone in your organization must be responsible for understanding these tests and have the ability to perform (or have an external laboratory perform) them as required. These documents will also become a controlled external document that will be described in element 4.4.

**NOTE:** The Auditor will verify the organization's ability to maintain current versions of the ASTM test methods and specifications and, if needed, other external documents related to the testing.

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<sup>1</sup> ASTM documents are available from: ASTM International, 100 Barr Harbor Drive, West Conshohocken, PA 19428-2959, [www.astm.org](http://www.astm.org)

<sup>2</sup> Any approved alternative test methods listed in ASTM D6751 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 Appendix A.

ISO 9001:1994<sup>3</sup> Quality Management Systems – requirements

### **GUIDELINES ~ Where did BQ-9000 come from?**

The BQ-9000 requirements were initially modeled after the ISO 9001:1994 standards. ISO stands for the International Organization of Standards who establishes quality standards for manufacturing and business applications that are used world-wide. If you would like more information, go to [www.iso.org](http://www.iso.org). You must include the BQ-9000 version you are referencing and any other standard(s) that you may be using to develop your Quality Manual.

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<sup>3</sup> 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. No part of this material may be copied or reproduced in any form, electronic retrieval system or otherwise or made available on the Internet, a public network, by satellite or otherwise without the prior written consent of the American National Standards Institute, 25 West 43rd Street, New York, NY 10036. All ISO documents are available through ANSI's online electronic standards store at <http://webstore.ansi.org>.

## **BQ-9000 Producer Requirements**

### **4.0 DOCUMENTATION REQUIREMENTS**

#### **4.0 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.

#### **GUIDELINES ~ Documenting your quality management system**

Documentation is the written material that describes the various parts of your Quality Management System (QMS) as listed. The documented procedural items listed below are required by this standard. The term “documentation” is used to cover the range of different types of documents that are listed in items a - d. You may find it desirable to develop additional documents that describe parts of your Quality Management System for both your own organization and other parties that you deal with. This guidance document covers the required information for the quality manual. Any additional documentation that you add, beyond what is required, will be included in the audit. You are now structuring a formalized quality management system that will be recognizable by the parties that you deal with.

**Item a):** The quality policy will be covered in element 4.2.

**Item b):** The quality manual will be covered in more detail in element 4.1.

**Item c):** This standard requires you to have certain documented procedures. A *documented procedure* is a procedure which is available in a reproducible form, such as a written statement or section of your quality manual, and which is controlled as indicated in element 4.4. You must ensure that the following are included in documented procedures:

- ◆ 4.3 *Quality System Procedures (this list is not inclusive)*
  - ~ 4.3 *Operational requirements with work instructions*
  - ~ 4.4 *Document Control*
  - ~ 4.5 *Control of records*
  - ~ 5.1 *Quality Management Representative*
  - ~ 5.2 *Internal Quality Audits*
  - ~ 5.3 *Management Reviews*

- ◆ 6.3 *Production Lots*
- ◆ 8.0 *Sampling and Testing*
- ◆ 9.1 *Nonconforming Product*
- ◆ 9.2 *Corrective and Preventative Action*

**NOTE:** These are the only elements where the existence of a *documented procedure* is a specific requirement. A best management practice would be to generate and use documented procedures at any point in your Quality Management System where the absence of that document may cause a non-conformance (either product or system-related).

**Item d):** Records are discussed more in element 4.5. Examples of records that must be on file for at least two years include (*this list is not inclusive*):

- ◆ 5.2 *Internal Audit*
- ◆ 5.3 *Quality management Review*
- ◆ 6.1 *Significant Process Changes*
- ◆ 7.1.c *Calibration of laboratory equipment*
- ◆ 7.1.d *Training in the laboratory*
- ◆ 7.1 g *External Lab test results*
- ◆ 7.2.2 *BQF-1 form*
- ◆ 8.3. *Testing (including Full, Critical, EN 14214, Monthly)*
- ◆ 8.4 *Certificates of Analysis*
- ◆ 8.6 *Storage Tank Inactivity Test Records*
- ◆ 9.1 *Nonconforming Product*
- ◆ 9.2 *Corrective and Preventative Actions*
- ◆ 10.1 *Full Blending*
- ◆ 11.1 *Truck, Railcar and Vessel Standards*
- ◆ *Any record or form that may need a historical view*

**Auditors assigned to conduct document reviews and onsite audits will verify that you have documentation representing all items a – d and that the directives in those items have been completed. An auditor will also verify:**

- ◆ **that you have identified and defined each of the requirements,**
- ◆ **that you have assigned responsibilities for each,**
- ◆ **that you have methods to implement and maintain each, and**
- ◆ **that your methods are effective.**

**Auditor's  
Viewpoint**

## 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.

### GUIDELINES ~ Write down what you do

The quality manual is a key component of your documented quality management system. It represents a comprehensive view of your system and normally provides a “road map” of your system. Very often it will contain brief descriptions of the organization’s processes that satisfy the requirements of the applicable clauses of the BQ-9000 standard.

A lot of your documentation, including your quality manual, can be developed by writing down or formalizing what you already do. You can use the quality manual to provide the overview or road map of your quality management system. You must include in the Quality Manual how you will implement elements listed:

- ◆ 1.0 the scope of your business
- ◆ 2.0 Terms and Definitions
- ◆ 3.0 References
- ◆ 4.0 Documentation Requirements
- ◆ 5.0 Management Responsibility
- ◆ 6.0 Operational Requirements
- ◆ 7.0 Laboratory Management
- ◆ 8.0 Sampling and Testing
- ◆ 9.0 Fuel Blending and Distribution
- ◆ 10.0 Remediation Elements
- ◆ a description of your organization, such as an organizational chart

If any of the listed requirements are not included in the quality manual, it is acceptable for the quality manual to indicate where they may be found. You may also reference external documents provided by others, such as equipment operator manuals and other materials.

A best management practice within the quality manual is to include an explanation of the interaction between the individual processes covered by the quality management system. This may be achieved by means of flow charts, schematic representations, or a cross-reference matrix. If these interactions can be seamless (almost as if they were one and the same), value will be added to the process and the end-user will benefit from the credibility of the system.

You may want to use your quality manual as a marketing tool. If the quality manual is to be shown to outsiders, be careful not to include anything confidential. You are free to choose whichever format for the quality manual you consider most appropriate for your business.

Elements 4.4 and 4.5 indicate that all documents within the Quality Management System must be controlled. This includes the quality manual. The term “controlled” means that you have a system for the writing and approval of documents.

A best management practice is to make use of a matrix or checklist to cross-reference between your quality manual and the requirements in the Standard to ensure you have not missed anything. This will

also serve as a guideline to other people reading your quality manual (e.g. customers, businesses contracting production, or certification/registration bodies).

The point to emphasize is that the quality manual should be a working document and not just a showpiece to impress customers. Whether you write your quality manual or hire a consultant, you should provide the majority of input into its content. You can refer to other examples of quality manuals, but without input from your own staff, it will be difficult to develop a Quality Management System that effectively meets the needs of your organization.



**The auditors will carefully review your quality manual during the “desk audit” to confirm that it includes references to required documented producers. The auditor will determine whether the quality manual is properly controlled, and whether the existence and location of the quality manual has been communicated to the organization. The auditor will use the quality manual as a map and will sample the system to verify that the reference documents and other items are consistent. The auditor will verify that everyone listed as receiving a copy of the quality manual actually has a current controlled copy in their possession.**

## 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.

### **GUIDELINES ~ Establishing your quality policy**

A quality policy should include the 3 c's:

- ◆ commitment to quality
- ◆ context for quality objectives
- ◆ customers' requirements (relating your organization's objectives to them)

Element 4.2 requires you to document a quality policy. Your commitment to quality should describe your overall vision of what quality means to your business and to your customers.

Top management's commitment to quality should be visible, active, and effectively communicated. When the owner or your organization's leader signs the quality policy, it demonstrates top management's commitment and dedication to the Quality Management System. Like the rest of your management system, quality objectives are living documents that will be revised as needed. These objectives can be reviewed during quality management review meetings (element 5.3), and therefore will need to be controlled (element 4.4).

All employees need to understand the quality policy, how it affects them, and their role in the quality management system. Your top management needs to decide how this understanding will be achieved.

Internal communication of the quality policy can be accomplished by a variety of methods, including training, distribution of wallet cards, posting on bulletin boards (office/plant areas), hanging banners, or displaying stickers on hard hats. The version of the quality policy you communicate, regardless of method, must always be consistent with the current version you have published as part of your Quality Management System (normally in your quality manual).

Many organizations are becoming bilingual. If an organization has members who speak English as a second language, the quality policy (and other documented components of the quality management system) must be communicated and implemented by the issuance and control of documents written in their primary language and/or by the use of competent translators.



**Auditors will assess your quality policy by confirming that it includes the required components and that it has been implemented across the organization. Your overall quality policy may be broad, but it *must* also address specific areas of quality that affect your customers and product.**

**Each employee *must* be able to describe the quality policy and its key components. They should be able to briefly discuss how their job supports the quality policy. It is perfectly acceptable for the employee to retrieve their wallet card or look at a posted correct version of the policy during an audit interview.**

**It is important that your quality policy be reviewed as your business or marketing strategies change. It is possible that individual quality specifications may change, while your overall quality objectives remain the same. Your quality policy needs to call attention to these changes and the process for reviewing needed changes *should* be addressed at Management Review meetings.**

### **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.

### **GUIDELINES ~ Documenting what you do**

Documentation includes mandatory written and documented procedures and other work instructions such as specifications, records, etc. Documents are the materials that will guide and communicate the application of your quality management system to your employees. Documents are also controlled (element 4.4).

The important issue is that you and others who work in your business have the information they need to do their jobs. Some common terminology related to documentation is:

- ◆ work practices, work procedures, or work instructions
- ◆ operating practices, operating instructions, or operating procedures
- ◆ production schedules
- ◆ preferred supplier lists (people you buy inputs from)
- ◆ specifications, (ASTM standards)
- ◆ production contract specifications

Many of these terms describe procedures or jobs as you have typically performed them. You are merely formalizing these as part of your general quality management system documents. It would be

helpful to try to look at your production or marketing operation from an outsider's point of view, as one who knows nothing about this type of an operation.

Documentation should indicate, to the extent necessary, who does what, where, when, why, and how. It should not be a wish list of what you would like to happen in your business, but should clearly and accurately reflect what really happens.

You must decide how much detail is needed. This will depend largely on the methods used, the skills needed, the training undertaken and the extent of supervision required. Excessive detail does not necessarily give you more control of the activity and should be avoided. Whenever possible, be brief in your narrative. Training can reduce the need for overly detailed documentation, providing that everyone has the information they need to do their job correctly.

It may be adequate to simply reference existing documentation in the quality procedure manual. For instance, the typical training and certification required for operations can be referenced in your Quality Management System documentation as part of your plan.

Remember, documentation is legitimate in any reproducible form and can vary significantly, ranging from separate formal documents, flowcharts, or technical notes incorporated into a drawing, to a complete instruction manual for equipment. Documentation can also be in pictorial or video form. Visual aids such as graphics, video, or a simple set of pictures can often convey the information more accurately than a lengthy detailed description, and also can serve as effective additions to your documentation for quality management.

**NOTE:** Be aware that Standard Operating Procedures (SOP) and Work Instructions (WI) or checklists are controlled documents. External documents that are used for program procedures are also controlled documents. Control of documents is discussed in *element 4.4*.

Designing the quality management system and the preparing documentation will need to involve everyone who works in your business, to the extent that each can contribute, so that procedural details reflect actual work practices. The more that you involve your employees, the better their understanding and sense of ownership in the quality management system will be.

Be particularly careful when changing employee responsibilities and/or titles within the organization. Changes in responsibilities or job titles that impact the Quality Management System must be updated and reflected consistently throughout all documentation.



**Auditors assigned to conduct procedure reviews will be looking to see that you have documentation representing all procedures (as required by the standard and/or that affect the quality of your product) and that the directives in those items have been completed. An auditor may verify whether:**

- ◆ you have identified and defined each of the processes,
- ◆ you have assigned an individual(s) responsibility for each process,
- ◆ you have identified the linkages between the quality manual, quality procedures and work instruction, and
- ◆ you have implemented effective methods.

#### 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 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.

#### GUIDELINES ~ Providing people with the information they need

Element 4.4 is really about the development and maintenance of your quality management system documents for your own organization’s use. The documents for your system need to be well-written to begin with, but they must also be updated, as necessary, to fit the activities of your business as both your management system and the business evolve.

Document control is making sure that the documents being used are the correct ones. This is important so that management and employees have the correct and current information needed to do the job right the first time. Documentation should be readily available at the work area of the person using the instructions.

The term *document* is used to define the information contained in various media, such as written documents, computer hard disks, diskette, or CD-ROM, video, audiotapes or graphic posters. *Documents* define your quality management system and how your processes of management work. *Records* show that you have actually done something, recorded certain information, or met a particular requirement.

The requirement for control of documents is applicable to both internal and external materials. Internal documents include items such as the quality manual, all Quality System Procedures (QSP’s), Work Instructions (WI’s), quality policy communications, and other forms related to the Quality Management System. All of these internal documents must be published and distributed at the current revision level.

External document control is clearly required for the normative references related to ASTM test methods as identified in element 3.1 at the beginning of this BQ-9000 Standard. The BQ-9000 Standard will most likely be revised in the future, and therefore is also subject to compliance with external document control requirements.

It is the responsibility of the organization to develop and implement processes that ensure current revisions of these externally generated documents are available and utilized. This means that if the revision levels of the normative references or the BQ-9000 standard (or similar external documents in use by the management system) change, the company must realize the change and update what it is using (i.e. internal documents) to define its processes.

The following points of discussion reflect best practices that will support a strong document control system. The document control guidelines and procedures must meet the requirements in a – d of element 4.4.

#### **Adequacy and Approval**

Someone (or a logical combination of several individuals) in your organization needs to determine that your documents are adequate. In other words, do they fit what you do and the way you do it? The person who will be responsible for the review and approval of a document's revisions should be clearly identified for each document. A best management practice is for both the "process owner" and the Quality Management Representative to be identified as the "Reviewers and Approvers" of a document. The approval(s) should be included in a record that is related to the revision and should 'tie' into the issue date of the revision.

#### **Removal of Obsolete Documents**

It is very important that obsolete documents are removed from use. If an old document is saved for some reason it should be properly marked (best practice would be: "Archive – For Reference Only") showing that it is no longer current. Forms and records are considered documents. It is very important that, when a form is revised, all available copies of the form available for use are located and destroyed. It is not unusual (and it is understandable) that employees will make multiple copies of a form they use regularly to save time. If these copies of the form are used after the revision of the form is made, a non-conformance will result.

#### **Document Revision**

Computers readily facilitate document changes and updates. Changes can be made quickly and easily in a computer-based document control system. A best management practice is limiting the ability to revise documents to only a few members of your company (usually by granting them "rights" to edit electronic documents). The balance of the members of your company would have "read-only" rights and would, therefore, be unable to make unauthorized changes to documents. Each person's particular computer access should be defined so that all changes are properly authorized. Another choice is to have password-controlled access linked with the date of approval. If this idea is used, it is very important that the passwords not be shared or written down because that could potentially lead to unauthorized access and changes. Computer changes to any document should update an embedded date/time within the document to indicate when it was last revised. Each version is usually differentiated by the revision date and/or the revision level (usually identified by a letter, beginning with "A" and proceeding through the alphabet). The information that identifies a document's correct version is usually found in the "header" at the top of each page. The header usually includes document title, document number, and other key identifying information. It is important that all document revisions are communicated to any employees affected by the change, and additional training provided, if necessary, to ensure the quality of your products or services is not compromised. It does no good for you to properly revise and update documents in your system if you do not communicate those changes effectively to those in your system that need to know!

The importance of this element cannot be overstated. Imagine the ramifications if a customer complains of an error due to the use of obsolete work instructions, and business is lost because of a non-controlled document.

It is very wise to keep the number of document copies to a minimum and to record the location of each copy so that they may be controlled and replaced when changes are made. A logbook or computer record must show date of changes and distribution of documents by location, brief description of the change and effective date.

**Auditor's  
Viewpoint**

**An auditor will review your document control system and its effective implementation by evaluating the above items. Auditors will look closely to see that you have thought through your document control procedures and have a systematic method to meet these best practices. In quality management systems, document control traditionally accounts for more than half of the noncompliance found during audits.**

**The auditor will review the most current Document Status Form and, randomly, sample documents in your QMS to confirm that the data in the DSF is correct.**

**The auditor will ask members in your plant (all areas) to show how they access the documents they use to do their jobs. This can include both documents and forms. Whether your system is paper-based or electronic, the auditor will observe work areas and check to see that any posted documents or forms in use are at the current revision level.**

**The auditor will also assess how you control external documents, such as ASTM test methods, and what processes you have in place to ensure the most current documents are available and implemented.**

#### **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

#### **GUIDELINES ~ Managing your records**

Records exist in all companies. The records of your quality management system, just as those of your financial system, payroll system, and production system, provide you with information to help you manage your business effectively. Records show that you have actually done something, recorded certain information, or met a particular requirement.

Decisions regarding the retention of records may be as important as the generation of the records themselves. It is important to develop a system that will generate the required records and then retain them in an easily retrievable fashion. At the same time, as records pass their stage of usefulness, they should be identified and disposed of. Only keep what needs to be kept. Records should not be kept just to satisfy an auditor.

The generation and retention of records for your quality management system can be incorporated into other systems such as financial, payroll, and production. Whether your records are paper or electronic, a systematic methodology for storage and retention is important for each set of records. Electronic records should be backed-up on a separate medium. Extremely important paper records require protection from fire and weather damage. A best management practice is to maintain a documented matrix that identifies required records and lists important information about each record.

**Auditor's  
Viewpoint**

**Auditors will be concerned with both your record keeping system(s) and with specific records themselves. The ease of retrieving records can likely be put to the test during an audit. During an audit, you may be required to look for records that are not normally used in the everyday course of business. Many people in your business may be involved in the generation, storage, and retention of records. The auditor will look for evidence that shows how you do this.**

## **BQ-9000 Producer Requirements**

### **5.0 MANAGEMENT RESPONSIBILITIES**

#### **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.

#### **GUIDELINES ~ Who looks after the Quality Management System?**

The Quality Management Representative (QMR) will normally act as the organization's representative to the registration auditor as well as the NBAC office in advance of, during, and following the audit. This will include providing needed materials for the auditor to complete during the desk audit. It will also include coordination of all activities that occur in support of the complete audit process. The QMR will perform the following functions:

- ◆ review and accept, or suggest, changes to) the proposed audit schedule,
- ◆ advise the auditor regarding any safety or other relevant issues applicable to the site,
- ◆ escort the auditor while onsite, to ensure the auditor's safety and to provide access to necessary areas or information needed to complete the audit,
- ◆ coordinate corrective actions taken in response to audit nonconformance.

This element directs you to assign someone the responsibility and authority for the quality management system. In a business the size of most biodiesel production companies, this person will most likely have other duties as well. The importance of the commitment to responsibilities related to the quality management system cannot be underestimated. The success of the system is dependent upon having someone at the management level who takes this responsibility seriously.

If your operation has more than one location operating under one quality management system, there should be only one person assigned with overall responsibility for the system at all locations.

Remember that customer needs are the primary focus of your quality management system. The QMR needs to communicate this to all the employees in the organization. The QMR may not have personal contact with the customers, but must know the customers' needs and ensure that employees are provided with necessary information to meet those needs.

**An auditor will look to see that all items under element 5.1 have been addressed. This will normally include:**

- ◆ **Official appointment of the Quality Management Representative (QMR) and communication of this appointment to the organization by posted memo, distributed email, or inclusion of this responsibility in a Job Description. A record of the "appointment" must be maintained.**
- ◆ **Evidence that the QMR chairs the Quality Management Review meetings. The QMR normally maintains the records of these meetings.**

**Auditor's  
Viewpoint**

- ◆ **Quality Management Review meeting minutes document that the QMR regularly reports on performance metrics of the quality program, including delivery, quality performance, and customer satisfaction .**
- ◆ **Implementation of an effective document control system that ensures all personnel receive the current (most recent) version of the quality manual and supporting documentation.**

## **5.2 INTERNAL QUALITY SYSTEM AUDITS**

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, and 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 increasing 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.

### **GUIDELINES ~ Are you doing what you said you would do and does it work?**

An internal audit is conducted by an external consultant or an internal resource and provides critical information regarding the "health" and effectiveness of the Quality Management System.

The goal of an internal audit is to collect and organize relevant information from a variety of sources and compare it to your QMS objective to confirm that things are being done properly. QMS objectives will be identified in your quality manual, documented procedures, quality plans, monitoring and measuring schedules, and other documents.

Even for a biodiesel business, where familiarity with the day-to-day activities is the norm, a properly conducted audit can be beneficial. You should use internal audits to look at your business objectively and to confirm that the quality management system is helping you achieve quality objectives and comply with accreditation standards.

The audit process should provide evidence, documented or otherwise, that confirms your quality management system is performing as intended. It is not sufficient to simply perform an overview. This will not supply a proper basis or adequate supporting evidence that the quality management system is operating satisfactorily.

#### **How should you conduct the audit?**

Internal audits should be conducted in an organized manner. Random sampling is often used to evaluate the actual effectiveness of the quality management system. This means that a representative portion is examined to determine the overall effectiveness of a specific procedure. For example, records for the testing of a finished fuel might be sampled randomly over a long period of time, or they could be sampled from a single month that was chosen at random.

The audit process should include:

- ◆ planning the audit (e.g. audit schedule, assignment of auditors, scope of audit).
- ◆ reviewing the relevant quality management system documentation.
- ◆ reviewing other relevant information including production reports, failure trends, and customer complaints.
- ◆ conducting the audit by observing the actual work processes, reviewing records, interviewing members, and comparing the responses to the QMS documentation.
- ◆ reporting the results.
- ◆ verifying that corrective actions (**element 10.2**) identified from the previous audit have been effectively implemented.

**How frequently do you need to perform internal audits?**

Internal audits must be scheduled and performed at least annually to assess your operation's quality-related activities against the requirements of the Standard. The following factors should be considered in determining and managing the specifics of audit activities:

- ◆ Are there any complex procedures or processes which would justify individual audits on a more frequent basis?
- ◆ How mature is your quality management system?
- ◆ Have changes occurred in business activity or in customer needs that would require more frequent audits?
- ◆ Are there any processes, procedures, or activities which have a history of problems?
- ◆ In a mature production and marketing environment, one complete audit may be sufficient. In newer or less stable environments a more frequent internal audit requirement might be appropriate.

**Reporting the results of internal audits**

A written report or summary of each internal audit must be developed. The report should describe the audit process, identify any nonconformance items, and provide corrective action plans. The audit record does not need to be complex. If the previous audit recommended or required an action to be taken, the current audit must address how effective the change was. This information must be recorded.

**What use should be made of the results of internal audits?**

The results of internal audits must be included as an input to your management review. Because an internal audit identifies nonconformities and inconsistencies, you will need to develop the necessary corrective actions (element 10.2) and then implement them. You will need to establish an acceptable timeframe for the corrective actions to be implemented, so that continued occurrences of the detected problems can be avoided or minimized. Nonconformities related to product quality must be addressed immediately. The questionable product(s) must be quarantined according to your nonconforming product procedure (element 10.1), with corrective actions initiated (element 10.2). These audits are for your internal use to help you manage and improve your quality management system.

**Who should conduct your internal audits?**

The following is considered additional guidance (best management practice):

- ◆ Auditors should be independent of the work or processes being audited; however, they may be from the same work area or department.
- ◆ Another approach could be to seek the cooperation of another biodiesel plant, biodiesel marketer, consultant, or ISO registered company in which one entity could provide the internal quality audit activity for the other. This may prove attractive if there is a good relationship between the businesses.
- ◆ An internal auditor should have a good understanding of the BQ-9000 standards and be objective in their approach to the process. The organization may develop their own internal audit guidelines or use the auditor checklist. Providing your internal auditor with training in internal auditing procedures may also be appropriate.



**The external auditor will review records of completed internal audits, the audit schedules, and other supporting records as defined in your procedures to confirm:**

- ◆ **that the audits occurred at least once per year (Note that a full cycle of internal audits must be completed and submitted for management review, following system implementation and in advance of the registration audit,**
- ◆ **that the audits cover each element of the system,**
- ◆ **that consideration has been given to the principle: The frequency of the reviews (audits) should be increased when review indicates that increasing frequency would be beneficial”,**
- ◆ **that consideration has been given to the (should) requirement that “audits be performed by persons other than those responsible for the area being audited.” Be prepared to justify auditor selection.**
- ◆ **that “review” results were presented to personnel responsible for the reviewed area,**
- ◆ **that cited (issued) nonconformities result in corrective actions that resolve the problem in a timely manner as defined in the written procedures.**

**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

## **GUIDELINES ~ Is your quality management system working?**

The quality management system should be reviewed on a regular basis. Reviews are required every six months but can be conducted more often if top management requests it, or if problems are found with the system. When changes are planned or being implemented, more frequent review periods may be beneficial. In biodiesel production or marketing operations, the initiation of new contracts or new customers into the business may result in the need for a review.

A consistent approach should be taken for both the review methods and the frequency of review. Input for the meeting should include items a) through g) above. Additional considerations are:

- ◆ relevance of the quality policy and objectives to current needs.
- ◆ how the quality management system is working and whether objectives are being met.

All individual problems and nonconformance issues should be dealt with as they occur. Waiting for management review could cause both internal and external problems. The management review process is intended to verify whether the same problems re-occur. If there are critical continuing problems, this may signal a system breakdown and may indicate the need for an unscheduled management review of the system. Changes may be indicated for corrective action and customer satisfaction.

It is easy to be consumed by everyday activities and problems. Sometimes, management needs to look for “big picture” trends in the industry to effectively determine which actions to take next. Is the Quality Management System:

- ◆ suitable – Does it still fit its purpose?
- ◆ adequate – Is it still sufficient?
- ◆ effective – Does it still achieve the desired results?

The Quality Management Review is an opportunity to analyze the QMS data and information collected since the previous meeting. Trends may be identified that indicate changes are needed. Other considerations are:

- ◆ training needs
- ◆ supplier problems
- ◆ equipment needs and maintenance
- ◆ the work environment and infrastructure

This review will help to identify the issues that are totally within your scope of control and those governed by outside influences. The answers to the above questions can also help you further improve or enhance quality, strategic, and business plans already in place. Your Quality Management System is an important part of the overall guidance structure for your business. Each component of your overall business system should be evaluated at each management review meeting to review progress, clarify current status, and determine future needs.

Some problems will be identified that may be completely eliminated by your corrective actions while others will require continuous monitoring. Improvements that eliminate problems present an opportunity to review the nature and level of inspection controls. Do you need more or less inspections? Are there new methods of inspection or testing that can take you to higher levels of

quality? Is your old process still needed or can you save time and money by modifying it or adopting other methods? This is the basis and true benefit of the principle of continuous improvement.

On the other hand, if the rate of complaints, discounts, or rejections continues or increases in an area, it should be documented, along with the suggested actions that will be implemented, to improve conditions or resolve problems.

**NOTE: The method used for your management review can be tailored to your business practices or management style and will normally consist of formal face-to-face meetings with an agenda, minutes, and formally identified action points (preferred).**

It is important that adequate time be allowed for all parties involved to provide input. This should be quality, uninterrupted time. Records shall be kept that address all points discussed in the review, together with any action to be taken, and specific target dates designated. Records must reflect the required inputs (a-g) as well as other items brought to the table for consideration. Since follow-up actions from previous meetings are a required input (e), the output of the meeting (i.e. minutes or records) must clearly define the “who, what, when” of actions defined at the meeting.

The records may be in any form that suits your business style. A written record such as minutes or reports should be a part of your permanent records. All people affected by these reviews should be included in communications.



**An audit of the Quality Management Review could be fairly extensive. Your management review indicates your commitment to not only the development of a quality management system, but also to maintaining a system that continually improves. Changes in business and customer needs are commonplace in the biodiesel industry. These changes will almost always influence the effectiveness of a Quality Management System. The adjustments may be large or small, but the recognition of these changes during the management reviews will be important to auditors. The auditor will certainly:**

- ◆ **examine the records of the management review to confirm that all of the required inputs were included in the meeting.**
- ◆ **verify that outputs of the meeting include any defined actions with clear designation of responsibility.**
- ◆ **look to see if the quality management representative chaired the meeting.**
- ◆ **confirm that the meetings have occurred at least once every six months and more frequently if the management system documentation requires.**
- ◆ **confirm that the meeting is attended by appropriate representation of top management and department managers.**

**The auditor may also interview top management with a particular focus on the results (and perceived benefits) of management reviews.**

## **BQ-9000 Producer Requirements**

### **6.0 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.

#### **GUIDELINES ~ Changes to your system**

Your organization should define criteria for a “significant process change” that will trigger full specification testing. Your employees should have no question as to when it is necessary to resume testing.

Along with items a – f, your company should make a list of the process changes that would be labeled as significant. Record of those changes must be on file.

**Auditors will be reviewing the company’s list of process changes and the records that would support the actions taken. Personnel may be asked what they understand about process changes and what actions are needed.**



#### **6.2 TOLL PRODUCTION**

A producer may have all or part of its production done by a “Tolling Producer” pursuant to 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 standards and **shall** be subject to a full NBAC audit as if it were a BQ-9000 Producer itself.

- c) If a BQ-9000 Producer changes tolling facilities, the new tolling facility **shall** meet all applicable BQ-9000 standards and have undergone a full NBAC audit as if it were a BQ-9000 Producer itself.
- d) The BQ-9000 Producer **shall** report to NBAC of any cessation of production at the Tolling Facility.

**GUIDELINES ~ Are you getting the same product from somewhere else?**

It is acceptable for a BQ-9000 Producer to receive and, ultimately, ship fuel from a toll producer. The toll producer must, per a contract with the BQ-9000 organization agree to all of the above conditions (6.2 a-d).

It is important that you develop some type of formal system to check that “Tolling” services are delivered or performed as expected. This can include on-site observations by company personnel, representation by a properly trained and contracted observer (during loading and unloading processes), including the toll producer in the internal audit schedule, providing specific work instructions to be implemented by the toller, and maintaining the records of the output as evidence that these procedures had been followed.

Regardless of the strategies used to check tolling services, it will still be necessary to check (sample and test) the product upon delivery to your location. The Toll Facility should understand what these arrangements are and how and when this activity will take place. The important point here is that the Toll facility needs to follow the same BQ-9000 requirements and audits as you would.

The following are explanations of items a-d in the standard for tolling facilities. These items must be explained and carried out by the BQ-9000 Producer or marketer having toll production done.

**Item a:** In the application for BQ-9000 registration, the original producer needs to list the name, address, phone, contact person of any “toll” facility or facilities.

**Item b,c:** The Toll Facility must operate based on the same quality management system that meets all the requirements of the BQ-9000 Producer Standards. This arrangement does not reduce the need for monitoring and measuring the delivered product. (In fact, it might increase it significantly.) The sampling and testing of delivered products will depend directly upon your quality control system. The Toll Facility shall be subject to a full NBAC audit as if it were a BQ-9000 Producer. This includes registration, surveillance, and renewals.

**Item d:** The tolling facility needs to notify the NBAC if their services have been dropped or changed as soon as notice has been given. This will keep the accreditation in the original company’s name and prevent the toll facilities from being certified in your name through misrepresentation. They would have to reapply under a different company as a toll facility or obtain their own accreditation.



**The auditor must be made aware, in advance of the registration audit, of any tolling contracts and relationships. The tolling location must be included in the registration audit. The tolling facility must be able to withstand the scrutiny of the audit in the same manner as an organization applying for its own producer accreditation.**

**The auditor will want to review the current contracts you have with the tolling facility. The auditor will also want to confirm the information provided to the NBAC related to the tolling facility. The auditor will also ask to review the records**

**of internal audits of the tolling facility that have been completed by the tolling organization. Nonconformance, generated by the internal audit process of a tolling facility must result in corrective actions with responsibility for acceptance of the corrective action resting with the registered organization.**

### **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.

### **GUIDELINES ~ Keeping track of your product**

You need to determine exactly what will be needed to satisfy both internal and external needs for identification and tracking processes. The lot number must be located on the COA. (see element 8.4) After you determine what methods best suit your needs, they must be fully documented in your plan so that everybody understands and can apply these methods. Responsibilities need to be assigned so that the record keeping is completed.



**The auditor will check that a documented procedure has been created and implemented to satisfy the stated requirements of element 7.1. The auditor will also evaluate the effectiveness of the implementation of that procedure by sampling during the audit. This can include interviews of personnel who work in the plant, in receiving, purchasing, and quality assurance. The auditor will also observe the handling of product in the plant and storage area, including retained samples which must be traceable to the tank or vessel they represent.**

## **BQ-9000 Producer Requirements**

### **7.0 LABORATORIES**

#### **7.1 LABORATORIES**

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 D 6751 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 D 6751 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.

#### **GUIDELINES ~ Management of the Laboratory**

This element deals with one of the most important parts of your quality management system. It provides you information and confidence that you are doing things right. This element will touch all the production employees in one way or another. To meet this element, people working in or with the laboratory should have a complete understanding of BQ-9000.

Laboratory personal must:

- a) Must have current copies of the ASTM specifications and testing methods. Elements 4.4 and 4.5 address how they must maintain and control all internal and external documents (and records.)
- b) Laboratory equipment that is required for the ASTM procedures must be in place. Equipment that is not used for ASTM should be identified and marked as such. If your organization is using equipment or methods that exceeds ASTM standards, reference to or approval should be done prior to any internal or external audit and identified as such for the operator and auditor.
- c) All laboratory equipment and standardized reagents used for conducting ASTM testing must be calibrated according to ASTM standards. When the requirement is not present, you must set up your own schedule. Check with the laboratory equipment supplier for recommendations. Documentation must be done of the calibration and frequency of calibration on each piece of equipment used for any ASTM test.

- d) All personnel that are using laboratory equipment for testing for ASTM D6751 standards will need to have a training program. This program should have some method of validating competency of the employee and re-validation as determined by common practices for laboratory personal. Evidence through a certificate that states name, date and what they are competent in should be a part of your records.
- e) Every four months the laboratory must follow its own documented program to validate the laboratory results with an approved external laboratory. Care must be taken to use an approved laboratory. You must have a completed Form BQF-1 from the external lab for conformation and keep this as a record. It may be wise to visit lab, if practical, to review their procedures to make sure they are compatible with your methods and personal. If you will be using the ASTM Cross Check Program to validate laboratory results, monitor the schedules to be sure your participation will meet the “every four month” requirement.
- f) Methods for collection and use of “appropriate” data will need to be determined. Statistical process control, spread sheets, or charts can be used to maintain data. You may also want to use this data in quality management review meetings to show effectiveness.
- g) As with all other records required by your QMS, records related to laboratory practices must be kept (according to element 4.5) for at least 2 years.
- h) Test results must be analyzed and referenced to the specific test, and cross- referenced to the ASTM test method. This may be done in various ways, such as simple spreadsheets, statistical process control methods, word documents, or other forms. The auditor will look for evidence of analysis.

Note that External Laboratories are no longer required (by the BQ-9000 requirement documents) to retain samples. You may, however, determine that you wish to include that in your conversations and negotiations as you select one or more external laboratories to support your biodiesel operations.



**An auditor may spend a good portion of their time in the laboratory area. They will review items a – h, and spend time interviewing and observing personnel. The auditor will review training records and methods used by the laboratory staff to analyze its test results and data. The auditor will review BQF-1 form(s) and interview appropriate external lab personnel to verify their understanding of testing requirements, equipment operation and calibration, and retains.**

## **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 6.4. This form **shall** be completed annually by the external laboratory and **shall** be retained by the organization for a minimum of two years.

## **GUIDELINES ~ Laboratory Audits**

The organization laboratory will require an internal audit by personnel who understand the laboratory yet maintain an impartial view of the lab. Impartiality is critical to performing an objective laboratory audit. Having confidence to issue CAR's and PAR's (element 9.2) for the laboratory will help

strengthen the lab and reassure your customers that the biodiesel is being tested properly. Laboratory personnel will need to understand element 9.1 fully in regard to nonconforming products.

BQF-1 forms must be available to complete and keep as records (element 4.5). External laboratories must be reviewed annually to make sure they are performing to your standards as well as those of ASTM. Biodiesel marketers should require enough objective evidence regarding the external laboratory's compliance with section 6.4 requirements to be confident that the external laboratory is actually doing the things they have committed to on BQF-1.



**Auditors will review records of the internal and previous external audits for the lab. They will be looking at CAR and PAR to evaluate your ability to find problems and take action to address them. They will interview laboratory staff and internal auditors assigned to the lab.**

**Auditors will also check that you are monitoring the external labs to ensure they complete the BQF-1 forms annually and according to correct procedures.**

## **BQ-9000 Producer Requirements**

### **8.0 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.<sup>4</sup>

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.

#### **GUIDELINES ~ When you measure and report the result of your process**

Element 8 specifically addresses the requirements related to the testing of final product. This must be done by the use of documented test processes which are specifically based on the “normative references” in element 3.1 of the BQ-9000 Standard.

The organization must create and implement documented procedures that define the use of current versions of the normative references (ASTM test methods). It is the responsibility of the organization to develop and implement systems that will assure that the utilized procedures governed by ASTM or other standards are current. The documented procedures must identify the records that will support the testing process. The procedures must clearly state that the results of the testing shall meet the specified criteria which are clearly defined in the normative references.

The organization may arrange to have the testing conducted internally by its own employees using test equipment and other materials provided by itself, or externally by a competent third-party laboratory. The relationship with an external laboratory must be clearly defined in a contract in which the organization requires the laboratory to conduct the required (current normative references) tests, at a specified cost, in a timely manner. The laboratory must be required to issue a Certificate of Analysis (C.O.A.) and forward it to the organization (element 7.3). A best management practice would be for the laboratory to email a “PDF” file of the test results to the organization.

The testing of “in-process” materials is not governed by the standard. Good manufacturing practices would normally require that the organization monitor its process in a way that assures the process is behaving in a controlled manner, and also that it will yield a finished product which satisfies the required testing.

Whenever a nonconforming material is identified, while either “in-process” or as a finished good, that material must be prevented from unintended use or shipment. Please refer to the discussion in element 9.1.

Have a conversation with your laboratory experts (internal and/or external) to determine the optimal volume of fuel needed for testing as mentioned in “footnote 4.” Considerations should include the type of tests to be conducted, the nature of customer requirements related to testing, and DOT requirements for the shipment of the materials.

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<sup>4</sup> 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.



The auditor will look to see that the required documented procedures have been created and that the organization manages the process to stay current. Test procedures must be current and reflect the current revision of the normative references (ASTM and other methods.)

Regardless of who does the testing, the auditor will want to sample and review records to compare the output results from the testing to the defined, acceptable criteria in the normative references.

The auditor will carefully examine the records to see if any nonconforming conditions have been identified as a result of the tests. If this is found to be the case, the auditor will continue to follow this issue to determine whether nonconforming material processes were implemented, that the material was properly segregated, and its disposition identified.

## 8.1 Production Lot Tank Homogeneity

### 8.1.1 Non Mechanically Mixed or Agitated Tanks

Tank homogeneity is established after 5 consecutive production lots utilizing a single feedstock<sup>5</sup> meet the Tank Homogeneity requirement. 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 homogenous 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 tanks and retested to verify the 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 homogenous so that separate shipments from this production lot are representative of a single COA. After the tank is made homogenous, 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.

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<sup>5</sup> 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.

## **GUIDELINES ~ Tank Homogeneity**

The organization must be able to show that this requirement (ASTM D4057) regarding tank homogeneity has been satisfied for each production or storage tank where samples are drawn for testing. The current version of the ASTM must be in place (element 4.4) to make sure the testing is done properly.

Records of the sampling and testing that satisfies the tank homogeneity requirements, for both production and storage tank, must be maintained and easily accessible to provide evidence that these activities were completed. An important best management practice would be to demonstrate that operators know how to perform this sampling and testing. Testing must be performed using consistent methods between operators and shifts.



**The auditor will be looking for evidence that testing was completed the correct number of times and that the operator applied the most current test method.**

## **8.2 SAMPLING**

Production lots from non mechanically mixed or agitate tanks shall be samples 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.<sup>6</sup>

## **GUIDELINES ~ Retaining samples and keeping them in good condition**

Your organization has already set the procedure in 8.1 regarding both production and storage tank homogeneity. The next step is to retain the samples for a minimum of 60 days in virtually the same condition as when you took the sample. Per the standard, the “retains” shall be kept in an “environmentally appropriate location”.

Your organization will need to define what an “environmentally appropriate location” is, and how you will maintain samples for 60 days and ensure that a sample is not destroyed before its minimum time. Each retained sample must be labeled (lot, date, tank, and operator) so that, via related records, the sample and test results are traceable to the original production batches. Refer to production lots in 6.3.



**An auditor will sample production and laboratory records, and crosscheck samples and dates in the retain area to make sure that retains are available per the requirement. They will verify that retains are stored properly, labels are legible, and the storage area for retains is environmentally appropriate.**

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<sup>6</sup> 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.

### 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 un-reacted 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 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 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 may 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).

### GUIDELINES ~ Testing

All production lot samples must be tested to ASTM D4176 standards. Corrective action must take place immediately to keep any nonconforming product from being shipped.

Documentation must be maintained for the product to help locate problems and determine why product did not meet specifications. Review procedure element 9.2.

Full specification testing, which is specifically addressed in element 8.3.1, is necessary until the requirements identified in the second paragraph are met. Once these requirements are satisfied, critical specification testing element 8.3.2.1 is acceptable. If a significant process change occurs, full specification testing must be resumed until confidence in the process is confirmed by (at least) three consecutive acceptable test results.

To review normal triggers for full specification testing, see element 6.1.



**Auditors will check to make sure you have a current version of work instructions and documents (internal and external) for the operator to refer to for your testing procedure. Auditor will be looking for evidence of significant process changes and will confirm that you resumed full specification testing. They may check to see whether your nonconforming product procedures include potential reactions to this type of condition.**

**If the organization is using the critical specification testing scheme, the auditor will verify the evidence of that requirement.**

### 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 (outlet sample)

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.

### GUIDELINES ~ Full Testing

This element is a work instruction that coincides with ASTM D6751 (element 8.3). Both training and current ASTM documents must be available to personnel who perform the testing. (element 6.4 d)



**Auditors will be looking for evidence that external documents (ASTM) are controlled and that personnel performing the testing are properly trained. They will review records for legibility and accessibility.**

**The auditor will sample test results reports and Certificates Of Analysis (COA's) to confirm that all of the required tests are being conducted for full specification test conditions.**

### 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 <sup>7</sup>	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
Stability, hr	Per ASTM D6751	per ASTM D6751
Visual appearance	ASTM D4176 Procedure 2	2 max (outlet sample)
Cold Soak Filtration 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.

<sup>7</sup> 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.

**GUIDELINES ~ Critical Specification Testing**

This element must be followed as written. Your organization must have procedures in place for testing as specified in element 8.3. Only qualified personnel can perform testing (element 7.1.d). Records of testing and frequency must be maintained. It may be appropriate to utilize an electronic monthly calendar to remind key staff that critical specification testing is due.



**Auditors will verify that documents are controlled and that tests are performed at the prescribed frequency and testing limits. Personnel records of training received will also be verified. Records of an annual cetane number test will be sampled. Records will be sampled to confirm that a production lot has been selected for full specification testing at least once every six months.**

**8.3.3 Alternative Testing of Product for Markets Requiring EN 14214**

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:

<b>Property</b>	<b>Test Method</b>	<b>Limits</b>
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, °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.

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.

**GUIDELINES ~ Alternative testing to EN 14214 Specifications**

Your organization must have procedures in place for testing to the EN 14214 specifications if you implement these tests. Only qualified personnel can perform EN 14214 testing (see element 7.1.d). Records of testing and frequency must be maintained. If your company is shipping the finished and tested biodiesel to export markets, be sure to document testing performed and that it is in agreement with any contractual or other requirements of your customer.



**Auditors will verify that documents are controlled and that tests are performed at the prescribed frequency and testing limits. Personnel records of training related to EN 14214 testing will also be verified. Records of an annual cetane number test will be sampled. Records will be sampled to confirm that a production lot has been selected for full specification testing at least once every six months.**

**The auditor may also sample purchase documentation and contracts to be sure that you are following agreed upon testing protocols.**

### 8.3.4 MONTHLY SPECIFICATION TESTING

Some specifications require monitoring less frequently than every production lot but more frequently than every six months. Specification 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 D 6751 or EN 14214	per ASTM D6751 or EN 14214

#### GUIDELINES ~ Monthly Specification testing

This standard must be followed as written. Your organization must have procedures in place for testing as in element 6.3. Only qualified personnel can perform testing (element 6.4.d). Record of the testing and frequency must be maintained. It may be appropriate to use an electronic monthly calendar to remind key staff that critical specification testing is due.



**Auditors will be checking for evidence of controlled documents, frequency of tests, and testing limits. Personnel records of training received will be verified.**

**The auditor will sample to confirm that the organization has completed the required monthly specification testing.**

### 8.4 CERTIFICATES OF ANALYSIS (COA)

A COA **shall** be generated for each production lot and **shall** contain 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 reduced 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.

#### GUIDELINES ~ Required External Documents

The organization must make sure that all production lots have a Certification of Analysis (COA) related to them. The COA is usually an electronic document which can be printed or transmitted by e-mail attachment. PDF files are preferred so they can not be edited. A copy of an approved COA, attached to a shipping (released) tank, is often used to indicate that the product in the tank has been tested, approved, and released for shipment. The approved lot number can be printed on the shipping document

and then checked and initialed during shipment activities by the personnel loading the product. This will serve as evidence of a final check that the product is released. This is an excellent example of mistake-proofing.

You will need to define what “typical” is from previous results and be able to use that same method of calculation on each of those “typical” results. They are usually the average of previous test results.

See “Appendix A” for an example of a flow chart for developing a COA. The appendix information is intended for use as a guidance example only. You will need to develop your own COA for your facility.



**Auditors will review COA records for both pending and previous shipments. The auditor may also sample results on COA's to confirm that the results met the defined requirements, and that the use of the word “typical” was appropriate on critical test COA's. The auditor may also confirm the accuracy of any data transferred from an external laboratory report to your COA record.**

## **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 seconds filterability time limits of the products being commingled or
- 2) The measured cold soak filterability of a representative blend

### **GUIDELINES ~ Commingling of Production Lots**

Your documented procedures must indicate how you will report the cloud point of commingled product. This could be either or both of the above methods. Remember that fuel quality must be verified to required specifications prior to commingling.

If you will measure the cloud point of a representative blend, a procedure must be in place for the blending process. Remember to perform the homogeneity test initially to ensure that the blending process is yielding representative and homogeneous samples. Records of the testing that yields this data must be retained for a minimum of two years.

It is recommended that the blended sample be tested per ASTM D4176 (maximum of 2) and that the sample be retained for a minimum of 60 days.

**Auditor's  
Viewpoint**

The auditor will check your procedure to confirm whether you have selected to use one or both (1 and 2) methods to report commingled cloud point. The auditor will then verify that you have reported commingled cloud point per your procedures. Did you generate representative samples per a verified (homogeneous) procedure? Were all measure values for cloud point within specification?

## **8.6 B100 STORAGE TANK INACTIVITY (See Appendix B)**

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 Oxidative 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).

### **GUIDELINES ~ Tank Inactivity**

You will need to specify the meaning of “no activity” for a Biodiesel storage tank after thirty days. If a tank has “no activity” you must retest for ASTM D4176 and D664, with acceptable results, before any shipments are made from that tank. Until satisfactory testing is completed, you will need to have a procedure in place to make the tank unavailable for shipment by tagging it as a nonconforming product (element 9.1).

**Auditor's  
Viewpoint**

The auditor verifies your procedures for determining whether biodiesel in storage for 30 days or more is inactive. The auditor will confirm that testing is done according to this requirement. Auditor may take the opportunity to review nonconforming product procedures to verify that personnel understand specific procedures for addressing inactive product. Records will be sampled to identify any 30-day periods between shipments from the storage tank, whether appropriate tests were conducted, and whether acceptable results were received before a subsequent shipment occurred.

## **BQ-9000 Producer Requirements**

### **9.0 REMEDIATION ELEMENTS**

#### **9.1 NONCONFORMING PRODUCT**

The organization shall develop documented procedures to ensure that product is prevented from unintended use or shipment if found to be nonconforming. Controls shall be defined that provide for identification, documentation, evaluation, segregation (when practical), disposition of any 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 non-motor vehicle fuel application
- c) “rejected” or destroyed.

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

#### **GUIDELINES ~ Sorting out product problems**

In the course of business, problems will occur and you will need to solve them. BQ-9000 requires you to develop documented methods for identifying product nonconformity and taking appropriate action when nonconformance is found. It will be necessary to keep nonconforming product separate from acceptable products.

It is strongly suggested that you generate records when nonconforming products are identified. When nonconformities are found *after delivery or use has started*, appropriate action should also include informing all those affected in the supply chain.

Although the standard does not clearly state that raw materials and materials in-process (MIP) are included, it is clearly a best, and strongly recommended, practice that all of the nonconforming procedures apply to these items as well. The methods and techniques you use for controlling and recording nonconformities should be appropriate for your organization. While the use of formal nonconformity reports or customer complaint forms may be necessary for large companies with a large customer base, a small business can achieve the same level of control by simpler and less bureaucratic means. For instance, when customer complaints on nonconformities are infrequent; the entire history of a complaint, its investigation, and the corrective action taken (including follow-up actions to check the effectiveness of implementation) can be recorded in a single correspondence file. The standard does require that the responsibility and authority for determining the disposition be clearly identified. This issue is normally documented in the Quality Manual, Procedures, or Work Instruction.

Element 9.1 requires that controls shall be defined in a documented procedure that provides for identification, documentation, evaluation, segregation, disposition of nonconforming product, and for notification to the parties concerned. These points will be discussed briefly below:

### **Identification**

Nonconforming product must be clearly identified, including its status, as soon as it is known. This is usually accomplished with a “Red Tag” containing relevant information such as date, lot number, product identification, location, and name of the individual who determined the product was nonconforming. The “Red Tag” serves to communicate the status of the material as being “not fit for further use” without disposition (see below).

### **Documentation**

A documented procedure is required by the BQ-9000 standard. This is most effectively completed by issuing both a Quality System Producer (QSP) and a Work Instruction (WI) that define the procedure(s) related to the management of nonconforming materials. Documentation also includes the generation and maintenance of records. Records are the organization’s evidence that a required process has occurred. It is a best management practice to initiate a record that will be used to track the material as it is evaluated for disposition.

### **Evaluation**

The evaluation of a nonconforming material is the process that identifies material as being out of specification. In a quality management system, Quality System Procedures (element 4.3) and Inspection and Testing Functions (element 6.3) are the most common internal methods for identifying problems with your product. Customer complaints (nonconformity claims) are the most common external indications, which will enable you to target where attention is needed.

### **Segregation**

Since the whole purpose of the BQ-9000 standard is to ensure that only good (conforming) product is shipped by producers and marketers, it is difficult to imagine situations where segregation is not absolutely required. Segregation means that unintended use is prevented. Unintended use applies to shipment, mixing nonconforming product with finished product that is within specifications, or the further use in the process of manufacturing (if related to Raw materials or MIP). This can be accomplished by separation or physically moving material to a special tank or container, or by locking out valves of the material from normal production materials. The nonconforming material must be identified in that container as unavailable for shipment.

### **Disposition**

When a nonconforming product/service is detected, options that must be selected from the requirements are:

- a) **Reprocessed to meet specification:** The organization may choose (depending on evaluation results and other business, technical reasons) to perform additional or repeat processes to achieve specification. The product must continue to be treated (all requirements) as nonconforming until further testing identifies it as meeting specification. It is an absolute that the reprocessed material must be re-inspected to assure it meets specification!
- b) **Re-classified to another specification** for which it is suitable. (Be very careful when doing so). Keep records of any such disposition, including the communication from any customer accepting the product, with clear indication of the alternative intended use.
- c) **Rejecting or Destroying the Product (Material):** This is the least attractive choice. Considering the energy or financial value of the off-spec fuel, this will be a very unlikely direction. Please remember to follow all appropriate regulations regarding the disposition of the material when rejecting or destroying product.

Your Quality Management Representative (element 5.1) or some other person with the necessary authority, has to decide which of these options will be applicable to each instance of a nonconforming product and authorize the disposition. This person must be clearly identified (by title) in your documented procedure.

Records should be kept of any decision made, approval given by the customer, and any rework requested with its corresponding monitoring and measurements.

The absolute best way to react to a nonconforming material or situation of any kind is to initiate a corrective action. This activity is discussed in element 9.2 and should (when completed effectively) address the root cause of the nonconformity and support actions to prevent recurrence.



**Auditors will interview members in the plant, warehouse, and offices to confirm awareness of this documented procedure as well as effective implementation. Auditor will look for signatures and make sure they are authorized personnel, as stated in your procedure. Auditors will evaluate the effectiveness of your nonconformance procedures according to how well you responded when a nonconformance was first identified from either an internal or external source. Auditors will also verify that successful retesting followed the reprocessing of a nonconforming product.**

## **9.2 CORRECTIVE & PREVENTATIVE 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 action's effectiveness at an appropriate interval following the implementation of the corrective action. Corrective actions **shall** not be closed until verification of effectiveness activities has 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.

### **GUIDELINES ~ Correcting the causes of problems**

Both corrective and preventive actions can be seen as steps in a quality improvement cycle. The need for corrective action can arise when nonconformity from internal sources occurs (product, service or quality management system), or from external sources (customer complaints, product rejection or problems encountered with a supplier).

The Standard requires that a written (documented) procedure is used to manage corrective actions. The Corrective Actions Report (CAR) can document that a problem has been discovered and record subsequent actions taken. Best practices and principles related to corrective actions are as follows:

**Anyone can initiate a CAR**

The initiation of a corrective action in a healthy quality management system is a very positive thing because it begins the process of fixing the problem. Every member of the team that works within the quality system has their own area of specialization, and they each have an opportunity (actually a responsibility) to make improvements. When a CAR is initiated, often with the aid and encouragement of a supervisor, the company is presented with an opportunity to improve. Continuous improvement should be the goal of every business.

**CAR's are not an offensive 'weapon'**

No one should consider a CAR, even if it identifies a problem in their area of responsibility, as a personal offense of their abilities. CAR's are never initiated against a person or a department, rather they are written against the "system" or process. The initial quality management system is often imperfect due to lack of time, experience, or other resources during the development phase. Its purpose is to identify and provide opportunities for improving your processes, your products, and ultimately, your business. The use of corrective actions is a very important improvement activity. It seeks to eliminate the root causes and subsequent effects of problems that could negatively impact:

- ◆ your business results
- ◆ your products, services, processes, quality management system, or customer satisfaction

**Root Cause**

The key to a successful corrective action is the identification of the root cause of the problem. As you search for a cause, don't be tempted to stop at the first answer you uncover. Work as a team to question your findings further until you believe all probable causes have been identified. You can do this by asking who, what, when, where, why, and how. This is one method to help you identify the root cause, but many other resources are available to coach and assist you. The automotive industry uses a process known as "8D." Use internet search engines, speak with a quality consultant, ask customers, read books, or do whatever you can to improve this area of your system. Effective implementation of your QMS will help significantly.

**Nonconformance > Corrective Action**

It is required that you generate a CAR whenever you identify a nonconformance internally or receive a customer complaint. Do this even if the complaint is service-related as opposed to issues with product chemistry. The discipline and nature of the process will drive you to eliminate the root cause and thus, fix the problem. The result is quality products and service for your customer.

Preventive action differs from corrective action in that it addresses potential issues before they happen. A corrective action responds to problems after they have occurred. Preventive actions can easily fit into the same process and record format as the corrective action. The need for corrective action could be indicated by as the following factors:

- ◆ customer complaints
- ◆ product rejections
- ◆ problems with suppliers
- ◆ nonconformities

- ◆ rework or repairs
- ◆ internal and external audit reports (element 5.2).

You must record your corrective action activities on the form that has been created for this process and set a time limit for their completion. You must follow-up on the actions to verify that they have yielded acceptable results. You must document this verification in a CAR record before it is “closed”.

You may need to change the quality manual, documented procedures, and any other relevant documentation as a result of changes that you implement. Modifications to your documentation must comply with the provisions of element 4.3. If a document is revised as a result of a corrective action, the individuals that use that procedure need to receive communication (and training) regarding the change. Communication and implementation of procedural changes is vital to receiving maximum benefit from the CAR results. It is not beneficial to identify the root cause, make the necessary changes to procedures, and then continue to follow “the old way.”

It is important that you make adequate resources available to ensure that required corrective action activities can be carried out.

**NOTE: You do need to ensure that the effects of corrective action(s) taken in one area do not cause adverse effects in another area of your organization.**

### **GUIDELINES ~ Preventative action is finding the problems before they happen**

Preventive action is an important improvement activity that helps prevent the occurrence of potential problems that could have a negative effect on your business results, products, processes, quality management system, or customer satisfaction.

A documented procedure describing how you implement and carry out preventive action (PAR) activities must be established.

You need to identify data sources that will enable you to monitor trends in performance, so that you can be proactive in addressing potential problems before they become a nonconformance issue.

Examples of data sources include:

- ◆ statistical process control results
- ◆ manufacturers’ recommended machinery service limits
- ◆ monitoring capacity usage
- ◆ monitoring machine usage of capacity
- ◆ tardiness and absentee rates among staff
- ◆ service reports
- ◆ customer or market survey results
- ◆ sales trends

If analysis of the data verifies that potential problems exist, preventive actions should be developed and implemented in order to resolve the problems.

Preventive action activities must:

- ◆ be recorded either on a CAR/PAR form or by some other method
- ◆ have a time-limit set for their completion

As a result of preventive action, the quality manual, documented procedures, and any other relevant documentation might need to be changed. Documentation changes must be recorded and made in accordance with the provisions of element 4.3.

Examples of the application of preventive action include:

- ◆ planned preventive maintenance
- ◆ alarms, indicators
- ◆ mistake-proofing techniques

It is important that top management provides adequate resources to ensure the above preventive action activities are implemented.

The implementation of preventive actions should be carefully planned to ensure that effects of preventive action taken in one area do not cause adverse effects in another area of the organization.

**NOTE:** An example of a combined CAR and PAR Form can be found on the next page of this guidance document. A CAR Form must be used to document corrective actions. A form such as the attached may also be used to document PAR's. Preventive actions may also be documented in a other formats such as emails, memos to file, etc.



The auditor will verify that a documented procedure exists to satisfy the stated requirements for this element as defined in the BQ-9000 Standard. The auditor will ask any personnel he speaks with to confirm their awareness of the corrective action and preventative action processes, as well as procedures for initiating a CAR or PAR. The auditor will examine records of the various situations that resulted, or should have resulted, in CAR's or PAR's (see above list). The auditor will examine records of internal audits and attempt to track CAR and PAR output from the audit process to the CAR or PAR system.

The auditor will also closely examine records of the process. Inadequate corrective actions are considered to be warning flags of an ineffective system. Auditor confidence in your system can be improved with evidence that you have performed root cause analysis. The auditor will research to verify that resulting "actions" such as modification of procedures, addition of a preventive maintenance, or provision of training have been taken. The auditor will also confirm that you have verified effectiveness of the corrective or preventative action before closure.

## Corrective and Preventive Action Request (CPAR) Form

**Corrective Action**  **or** **Preventive Action**  # \_\_\_\_\_  
(Quality Assigns)

**SECTION 1** (Initiator or Quality Department Designee completes)

Request as a result of: Nonconforming Product <input type="checkbox"/> Internal Audit <input type="checkbox"/> Customer Advisory <input type="checkbox"/> Management Concern <input type="checkbox"/> External Audit <input type="checkbox"/> Other: _____
Problem Description or attach report: _____ _____ _____
Signature: _____ Date: _____

**SECTION 2** (Quality designee or Other \_\_\_\_\_ completes) Signature: \_\_\_\_\_

Owner: _____ Date Assigned: _____ Investigation Due Date: _____
---

**SECTION 3** (Owner completes and returns to Quality designee for review prior to Due Date)

Identify Root Cause: _____ _____ _____
--

Interim Corrective Actions: (include containment activities) _____ _____ _____
--

Permanent Corrective Actions to prevent reoccurrence (indicate documents to be revised): _____ _____ _____
--

<b>ASSESS CHANGES TO:      SIMILAR PROCESSES <input type="checkbox"/> CONTROL PLAN <input type="checkbox"/></b>
All Corrective Actions COMPLETED: <input type="checkbox"/> Yes <input type="checkbox"/> No, Committed Due Date: _____ (may attach supporting data)                      Signature: _____

**SECTION 4** (Quality Designee or Other \_\_\_\_\_ completes): Signature: \_\_\_\_\_

Corrective Action Approved: <input type="checkbox"/> Yes <input type="checkbox"/> No recommendations:		
Owner: _____	Date Assigned: _____	Date Action Due: _____

**SECTION 5** (Assigned Owner completes and returns to Quality)

Corrective Action Effective: <input type="checkbox"/> Yes <input type="checkbox"/> No      Signature: _____      Date: _____
Explain (may attach supporting data): _____ _____

**SECTION 6** (Quality Designee or Other \_\_\_\_\_ completes) Signature: \_\_\_\_\_

Reviewed / Approved for closure: <input type="checkbox"/> Yes <input type="checkbox"/> No, New CPAR#: _____	Date: _____
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## **BQ-9000 Producer Requirements**

### **10.0 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.

#### **GUIDELINES ~ Blending the fuel**

Your organization must have a method for creating the biodiesel blend with the correct proportions. The organization can verify the fuel was blended correctly by a number of different methods. A best management practice would be to verify, at some frequency, the accuracy of your measurement equipment. Scale or meters should be calibrated by a competent third party. Records of any calibration activities should be maintained, either by an outside service or by your organization. Be sure to keep the blending records for two years as a control document (element 4.5).

If the vessels that are carrying blended fuel can not be dedicated to Biodiesel service, a procedure should be in place as in element 11.1 for tank drainage and cleaning.

**Auditors will look for evidence that your organization has an established method to validate the blending of Biodiesel. Records of fuel blending will be sampled by an auditor to confirm that the process was monitored and effective.**

**Auditor's  
Viewpoint**

## **BQ-9000 Producer Requirements**

### **11.0 PRODUCT LOAD OUT**

#### **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 supplier 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 15ppm 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.

#### **GUIDELINES ~ Protecting the Biodiesel in transit**

The organization will need to define cleanliness specification standards and chemical compatibility issues to be met when biodiesel is transported in their trucks, railcars and vessels or transportation that is arranged for (and paid for) by the organization. These specification standards must be communicated to the transport companies via agreements and/or contracts – and the BQ-9000 Producer must have records of this communication. As with other records related to the BQ-9000 Quality Management System, these records must be retained for a minimum of two years.

The cleanliness specification standards and chemical compatibility concerns must include consideration of potential contamination from raw materials common to the biodiesel production such as feedstocks, methanol, catalysts, as well as other fuels such as gasoline and diesel that does not meet ULSD specifications. A process must exist to verify the previous load contents and require the draining and inspection of the vessel prior to loading the biodiesel. A standard process would be to require the vessel to be washed and have the driver present a copy of the (dated) wash ticket to the biodiesel load out facility prior to the start of product loading.

The periodic verification that the transport companies are meeting specifications can be determined by the BQ-9000 Producer. It is critical that this requirement be addressed in a manner that addresses the potential risk of contamination. A best practice would be to randomly (but at some minimum frequency) select transactions where a visual inspection occurs. The periodic verification process must be documented in a work instruction or be implemented as part of an electronic system that ensures it occurs at the desired frequency. Records of these verification inspections must be retained for a minimum of two years.

In cases where the customer of the BQ-9000 Producer arranges for the transportation of the biodiesel, no inspection is required; however, it is strongly advised that the Producer do the following, whenever practical and possible:

1. Communicate (directly to their customer) the cleanliness specification standards and chemical compatibility issues to be met when biodiesel is transported – and why it is so important to the quality of biodiesel (and everyone's businesses) that the biodiesel not become contaminated.

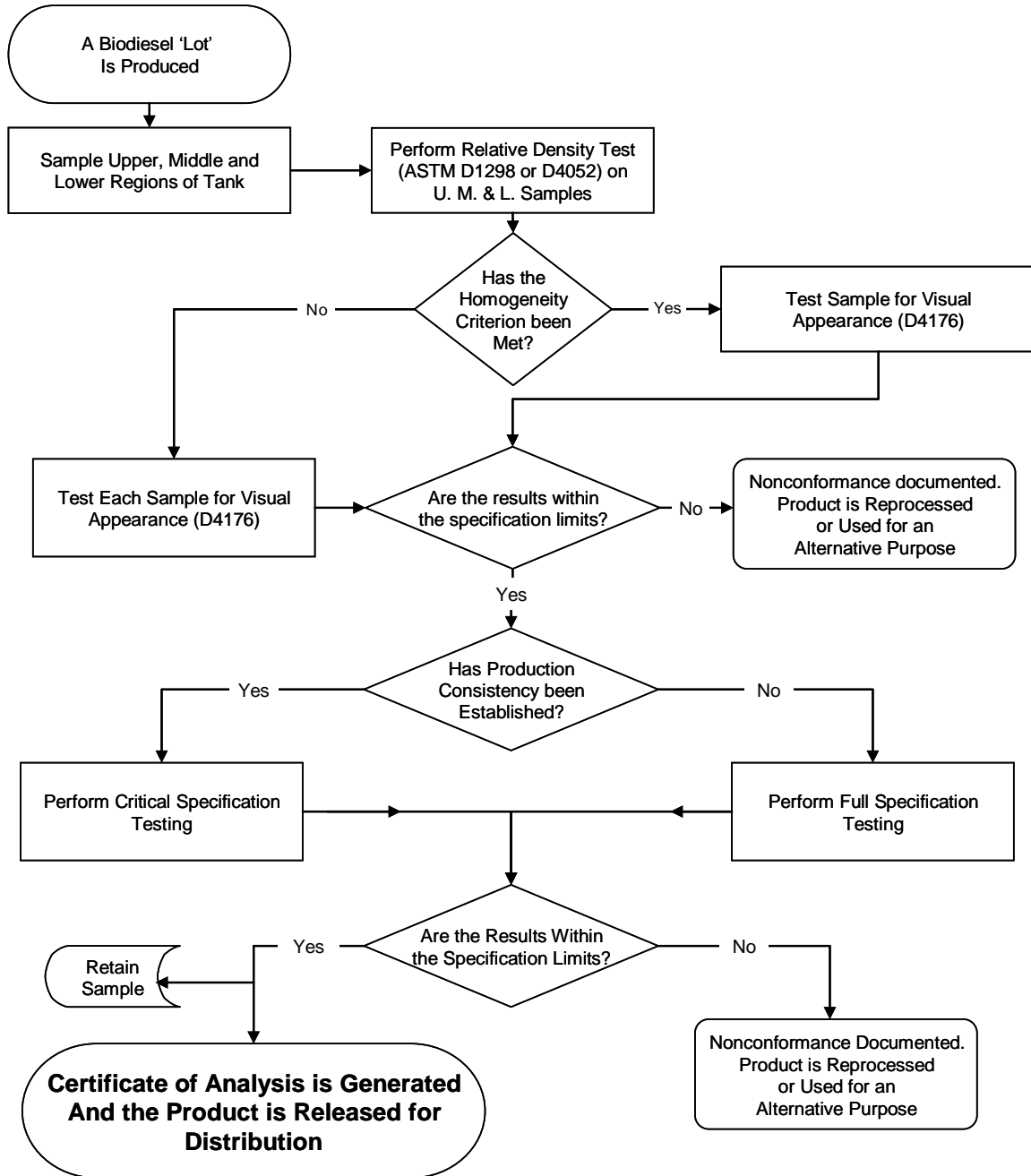
2. Inspect trucks, railcars and vessels provided by their customers for the transportation of biodiesel in order to verify that the containers are satisfactorily clean for the hauling of the biodiesel. If any concerns are noted, the marketer should be contacted and advised. At that point, it is the decision of the customer as to whether to arrange for alternative transportation. In any case, the inspection, the results of the communication to the customer should be documented in records that are maintained by the Producer.

**Auditor's  
Viewpoint**

**Auditors will look for how the organization handles the cleanliness standards of trucks, railcars and vessels before loading.**

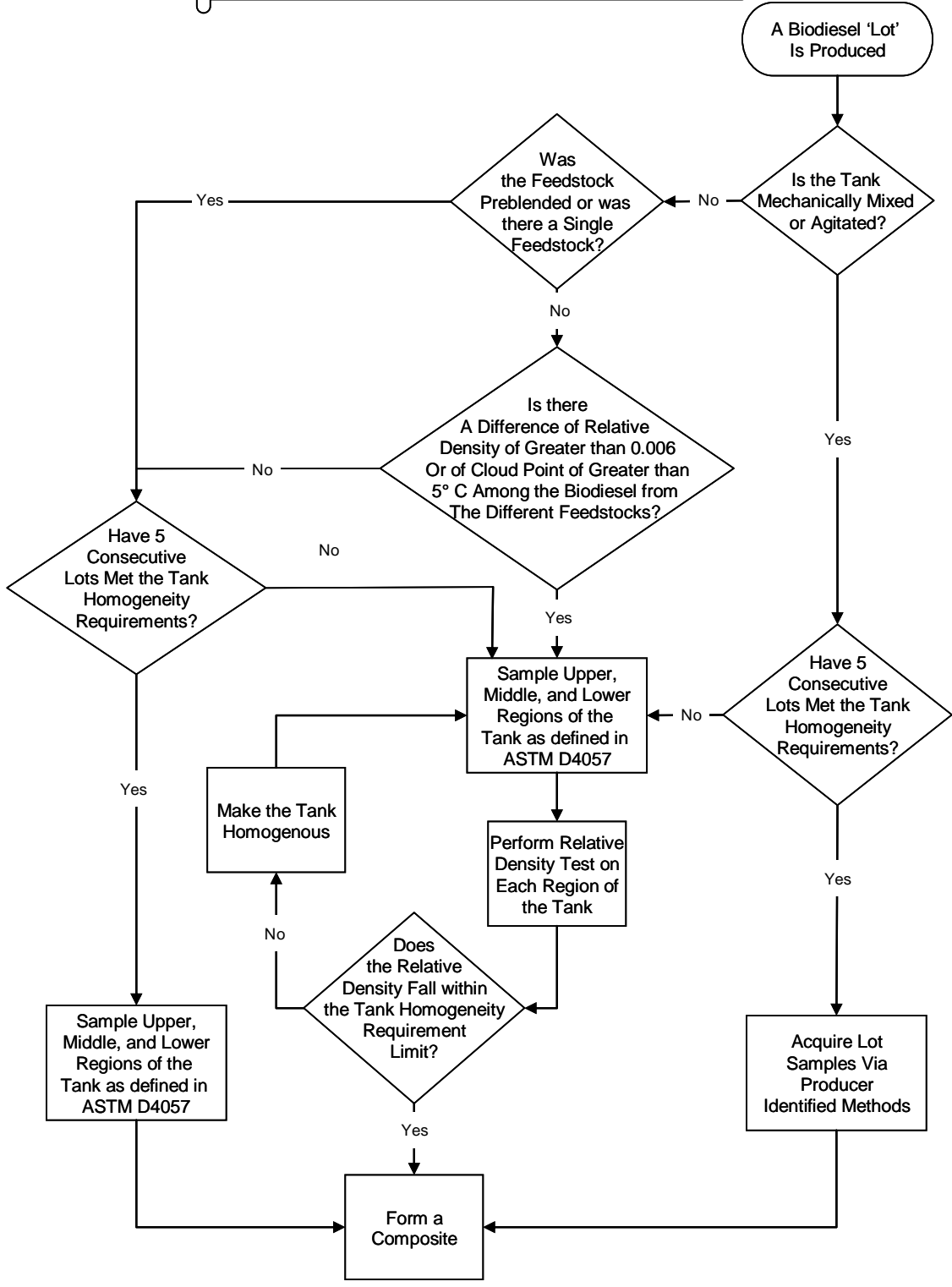
**On transactions where the Producer arranges for the transportation, the auditor will sample to confirm the existence of agreements and/or contracts that state explicitly or by reference the required cleanliness and compatibility standards. The auditor will review procedures in place as well as the resulting records of the periodic verifications that their arranged transportation meets the cleanliness standards. The auditor will confirm that all of the records related to this element (including the agreements and/or contracts, verifications, etc) are maintained for at least two years. The auditor may observe the process and interview load out personal.**

## Generating a Valid Certificate of Analysis

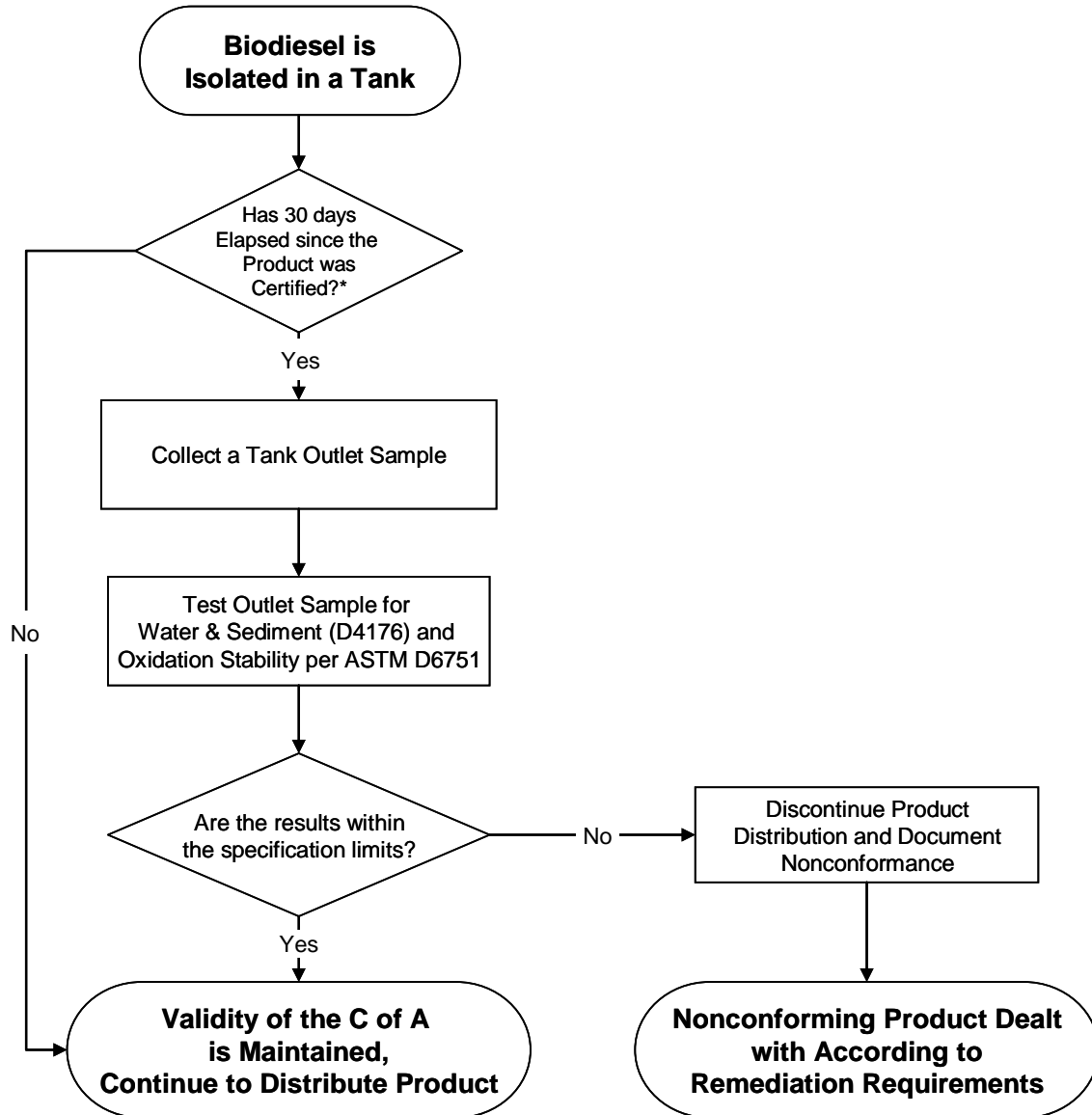


# Production Lot Tank Homogeneity

Appendix B  
(informative)  
Producer Process Flow  
(page 1 of 1)



## Maintaining the Validity of a Certificate of Analysis



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

