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## Steps to Set Up and Operate a Biodiesel Laboratory

1. Outside of the physical costs of the laboratory itself, the equipment necessary to make approximately 20 different analyses can cost several hundred thousand dollars. Based on your specific objectives, needs, planned staffing, and available funds, determine how independent your company wants to be. **Here are some of the primary considerations:**
  - If an analytical chemist is not planned to be hired to staff the laboratory then you should consider purchasing automated rather than manual analytical instruments. Automated instruments are more expensive but require less skill to operate and they eliminate errors that can occur with manual analyses. **We will help you decide the best instruments to purchase.**
  - If you do not have several hundred thousand dollars to invest in laboratory instrumentation, then consider initially purchasing only those needed for analysis of every batch and put off purchasing those needed for periodic analysis. The latter tests can be sent out for analysis to external laboratories until and if you decide later to conduct those analyses in your own laboratory. **We will show you how to do this.**
2. Locate and purchase equipment for ASTM\* D 6751 analysis. **We will help as follows:**
  - You will need the required ASTM methods – we will help you obtain those that you need based on your decisions determined from #1 above.
  - You will need analytical instruments that will produce data meeting ASTM requirements and that are consistent with your decisions from #1 above.
  - You will need chemical reagents, gases, and laboratory supplies used with the analyses that you decide to conduct within your own laboratory. We will find sources of these for you to order.
  - You will need to prepare calibration standards for many of the analytical instruments. We will prepare initial calibration standards for you and show you how to do this.
  - You will need to pass fire and safety codes and comply with laboratory waste disposal requirements (e.g., waste acids, flammable solvents, reagents, etc.). We will help you find a qualified laboratory safety specialist to provide a lab inspection.

\* ASTM is the acronym for “ASTM International” (originally known as the American Society for Testing and Materials and formed over a century ago – see [www.ASTM.org](http://www.ASTM.org)) for details.

3. Install and test all analytical instruments. **We will help you with the following requirements:**
  - Establish background sensitivity limits using equipment blanks and analytical blanks.
  - Calibrate each analytical instrument using calibration standards prepared in #2 above.
  - Establish precision and accuracy measurements using analytical standards made from the standard reference materials at multiple concentrations. These must meet precision and accuracy requirements of the ASTM methods obtained in #2 above.
  
4. Write a “Methods Manual” for **each and every** analytical test. **We will write the Methods Manuals for you.**
  - Methods manuals are prepared specifically for your laboratory’s tests. Each is dependent on (1) ASTM method requirements, (2) your Instrument Manual’s instructions, and (3) the National Biodiesel Board’s (**NBB**) BQ-9000 requirements.
  
  - Thus, each Methods Manual is customized for your needs but, to save time and expense, they are written using a copyright protected format developed by Dr. Keith.
  
  - These Methods Manuals also are one of the key requirements necessary to qualify for the BQ-9000 Quality Management Program (for details see [www.bq-9000.org/](http://www.bq-9000.org/)). Thus, writing Methods Manuals to comply with BQ-9000 format and requirements saves time and money because this is only done once for each analytical test procedure. These are controlled documents: signed with numbered, restricted access.
  
5. Establish and write QA/QC\* procedures for all analyses to NBB QC-9000 specifications. **We will write all of the documents and prepare all of the forms for you.**
  - You will need a Quality Management System Document (with operational requirements, document control, management, internal audits, data retention, etc.).
  - You will need Standard Operating Procedures (SOPs) for each method.
  - You will need a Quality Assurance (QA) Manual (BQ-9000 “Quality Manual”)
  - You will need to record and document Quality Control (QC) data for each method
  - You will need to establish quarterly external QA test results from an approved independent laboratory. We will find one for you to approve.
  - You will need to have QC sample archiving procedures. We will write them for you.
  - You will need to develop Certificate of Analysis (COA) for each production lot. We will develop these for you to use for both your laboratory and external laboratories.

\* **QA/QC** is the acronym for “Quality Assurance” and “Quality Control.” **Quality Assurance** is the company’s documented program that ensures the systematic monitoring and evaluation of the various aspects of biodiesel production and analysis standards of quality are being met. **Quality Control** is a system for verifying and maintaining a desired level of quality in the biodiesel produced through laboratory analysis of the product using accepted methods on specified schedules using proper equipment, continued inspection, and corrective action as required.

6. Register the biodiesel produced with EPA using Form 3520-12. **Your company has to do this but we will help you with the process.**
  - You need to include test results from representative samples to demonstrate compliance with ASTM D 6751 – we will prepare the data for you to submit.
  - You need to sign agreement with National Biodiesel Board (NBB) and certify to EPA that product meets NBB emissions and health effects testing data and that NBB has been paid for use of their data. Your company has to do this.
  - You need to complete and submit EPA forms 3520-20A and 3520-20B1 – we will help you complete and submit these forms.
  
7. Register as a NBB QC-9000 Accredited Producer. **Your company has to register but we will write the documents for you and help you to conduct audits and training.**
  - You need to write a Quality Policy document – we will write this document for you.
  - You need to write Quality Systems Procedures manual (operating procedures, specifications, etc.) – we will write this manual for you.
  - You need to conduct internal audits – we will show you how to do these audits.
  - You need to schedule an external audit – we will help you to schedule this audit.
  - You need to prepare a training program meeting – we will prepare the training program meeting and conduct the training meeting for you.