U. S. CBD Manufacturers Association, Inc.

Post Office Box 550829, Jacksonville, Florida 32255-0829
905-555-9999 Info@USCBDMA.org
Dr. Dewey E. Painter, Sr., Ph.D. President
"From the farm to the user products certified to the highest standards"

U.S. CBD Manufacturers Association

Production and Process Compliance Guide

For
Laboratory Certification Program Guidelines

USCBD Standards of Excellence

Encompassing the holistic process from farm to customer

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Part One: Information

1. A**lphabetical list of terms and their definitions as applicable to this guide are limited to those relative to understanding their use as stated herein.** Check your dictionary for common vocabulary terms.

Adulteration refers to a food that may be considered adulterated if it contains "any poisonous or deleterious substance which may render it injurious to health, or if any valuable constituent.

Batch or Lot, and Batch Lot Numbers refer to a specific quantity of hemp that is uniform, that is intended to meet specifications for identity, purity, strength, and composition, and that is produced during a specified period of time according to a single manufacturing record.

Biomass - the amount of living matter in a given habitat, expressed either as the weight of organisms per unit area or as the volume of organisms per unit volume of habitat.

Component - any substance intended for use in the manufacture of hemp, including those that may not appear in the finished batch of the hemp.

Hemp - Cannabis plant varieties and any part of that plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration (THC) of not more than 0.3 percent on a dry weight basis. Industrial hemp is Hemp.

In-process material - any material that is compounded, blended, ground, extracted, sifted, sterilized, derived by chemical reaction, or processed in any way for use in the manufacture of the hemp product.

Microorganism - yeasts, molds, bacteria, viruses, toxins, and other similar microscopic organisms which may or may not have a health or sanitary concern.

Physical plant or facility - all or any part of a building or facility used for or in connection with manufacturing, processing, packaging, labeling, or storage of hemp products or ingredients.

Processor - maker of transformative change to the hemp plant or product following harvest.

Quality - determination that the hemp product meets the established specifications for identity, purity, strength, and composition, and limits on contaminants, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration and contamination.

Quality Management Systems - planned and systematic operations or procedures for ensuring the quality of a hemp product. It also refers to any person, persons, or group, within or outside the organization, designated as responsible for quality control operations.

Representative sample - a sample with an adequate number of units that are intended to ensure that the sample accurately portrays the material being sampled.

Reserve sample - a representative sample of product that is held for a designated period of time.

Sanitize - adequately treat cleaned equipment, containers, utensils, etc. by a process that is effective in destroying microorganisms of public health concern.

2. About the U. S. CBD Manufacturers Association

a. The CBD Seal of Distinction

Offered by the US CBD Manufacturers Association (USCBDMA)

The seal is administered by an independent clean-room, ISO/IEC 17025 certified laboratory that tests for heavy metal, pesticides and herbicides, bacteria and fungus, residential solvents, and foreign matter. The products are also be tested for purity (must be at least 99% CBD), tested for 90 percent accurate concentration claim (mg of CBD oil per ml), and tested that all products have <.03% THC. The tested tolerance for CBD content as stated on the package label is 10% under/over. USCBDMA requires its member companies to list and verify the state and closest township of all products' supply, and requires all producers to submit to unannounced walk-in inspections.

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b. Superior standards for members who earn the right to use the CBD Seal of Distinction. Members agree to the following:

1.. Product has no THC. This is critically important, as even small amounts of THC could be very harmful.

2.. CBD is all natural, non-GMO, and all of our hemp is American grown.

3. CBD has the highest level of independent testing. Our tests are carried out in one of the largest independent labs in US. This lab is one of two ISO/IEC 17025 certified laboratories in the world. Their tests, as established by the CBD Seal Of Distinction, must show no pesticides, no herbicides, no heavy metals, no solvents, no foreign matter, no bacteria, and no fungus. To be certified members products must test 99 percent or more pure.

4. CBD recommends to Association Members their brands provides a scannable QR code on each bottle that allows the consumer to see the independent testing for purity and analysis of our CBD oil for each lot number.

5. USCBDMA is the only association provides up-to-date research posted on its website as it becomes available.

6. USCBDMA members are required that their products are produced in FDA-compliant clean room facilities that have earned the Good Manufacturing Practices (GMP) certification that is awarded to companies with pharmaceutical production standards.

7. USCBDMA requires label accurately states the concentration of CBD in milligrams per bottle, verified by testing.

8. USCBDMA, because of its high standards to earl the "Seal of Distinction" the exact same CBD product that is sold for human consumption is safe for animals. . Our animals deserve no less.

3. About CBD

Legal CBD Oil must meet rigid standards to conform to both Federal and States laws.

The term CBD oil refers to the extracted cannabidiol (CBD) molecules from hemp plants, which is then infused into oil, for many purposes. Pure CBD oil must not contain more than .08% Tetrahydrocannabinol (THC), the known psychoactive component in marijuana.

Is CBD something that will get me high? No, CBD oil will not get you high. The psychoactive parts of marijuana come from the THC molecules, which are not plentiful in hemp plants. Furthermore, any remaining THC must be purged out during the extraction processes, to ensure that it meets federal, and state regulations.

How does CBD oil work? The effect of CBD starts when a person ingests CBD oil whether by mouth, inhalation methods or topical applications. Once in the bloodstream, cannabinoids find their way into the endocannabinoid system. CBD molecules naturally interact with receptors found in systems and cells throughout the body. This interaction occurs in specific receptors called CB1, and CB2. Through this systematic interaction that CBD oil can treat pain, inflammation, anxiety, depression, hunger problems, and significantly reduce seizures in Epilepsy patients.

Is Hemp Legal? Until recently, CBD oil was illegal under federal law. It was classified alongside regular marijuana as a schedule 1 drug. This classification meant that CBD oil, which was proving to have many health & wellness benefits, was deemed with having NO medical benefits and therefore, illegal federally. This changed when President Trump signed the 2018 Farm Bill into law, which broadly legalized industrial hemp products such as CBD oil, providing it meets some criteria:

a. CBD oil must contain less than .03% THC per volume.
b. The cannabidiol (CBD) content must be over 10%.

4. Procedures and introduction: This guide will provide detailed instructions for each phase of growing, processing and manufacture of the CBD products which USCBDMA will approve for the licensed use of its **Seal of Distinction**

a. What are the markers of quality for CBD? USCBDMA has set the highest standards:

(1) American-grown: Quality problems with foreign-grown hemp, particularly from China, make this a priority. Supporting new opportunities for American farmers appeals to conscious consumers.

(2) Laboratory tested: Testing for pesticide residues, heavy metals, THC, microbial contamination and stated CBD content

5. Product handling specifications: Contamination and quality control are essential to maintain the quality of the materials used for CBD growing, processing, manufacture and distribution. In order to comply with Federal and State regulations USCBDMA has produced this guide.

a. Product handling specifications are included in the appropriate PART of this guide and at the minimum will include the following:

(1) Procedure Guide
(2) Sampling Guide
(3) Crop standards and Grower adherence
(4) Pre-Harvest sampling and handling
(5) Post-Harvest sampling and handling
(6) Management and control of samples at each phase of the growing and manufacturing

6. Documentation requirements for all processes from farm to consumer: To ensure quality control and decrease the possibility of contamination, specific analytical documentation must begin with the grower and follow the product through the sampling, handling and processing to development of the product.

7. Development, maintenance and inspection of facilities and grounds. Quality control begins with the land used by the grower, its location in relationship to other fields that might cross-contaminate the crop and therefore diminish its value and use for CDB processing. The equipment used for harvest, transport and stowage of the CBD requires careful handling and cleaning to ensure the harvested crops are not compromised. Every step of the process from planting by the grower, harvesting, transporting, sampling and management control of the bulk product requires excellent quality control and frequent inspection.

8. USCBDM Guidelines for Personnel Management and Employee Training. Because CBD must be quality controlled at all times it is imperative that all employees involved in every step of the process from grower to consumer must have adequate training. Each section

of this guide will provide suggested minimums of training for the employees handling the products and the mangers or supervisors overseeing the development.

9. Safety Standards: Safety is paramount in every operation and should be reminded by posted displays and by periodical safety briefings related to the individual steps of CBD production. This guide will provide some safety guidelines and suggestions.

Part Seven: Quality Control

1. INTRODUCTION

The USCBDMA quality control program and approved laboratory serves one of the most important functions in CBD production and control. A significant portion of the USCBDMA standards pertain to the quality control laboratory and product testing of bulk and final products. This inspection guide supplements other inspectional information contained in other certification agency inspectional guidance documents requiring preapproval inspections (such as organic, non-GMO, etc.), and contains general instructions to conduct product-specific laboratory inspection audits to measure compliance with the applications and USCBDMA requirements. This includes all laboratories used for in-process and finished product testing.

2. OBJECTIVE

The specific objective will be spelled out prior to the inspection. The laboratory inspection addresses all issues to ensure highest quality, and the inspection may encompass a comprehensive evaluation of the laboratory's compliance with USCBDMA standards. As a minimum, each selected quality control laboratory should receive a comprehensive USCBDMA evaluation every two years. In general, these inspections may include

a. The specific methodology which will be used to test a new product.
b. A complete assessment of laboratory's conformance with USCBDMA standards.
c. A specific aspect of laboratory operations

3. INSPECTION PREPARATION

USCBDMA Inspection Guides are based on the team inspection approach and our inspection of a laboratory is consistent with this concept. As part of our effort to achieve uniformity and consistency in laboratory inspections, we expect that complex, highly technical and specialized testing equipment, procedures and data manipulations, as well as scientific laboratory operations will be evaluated by an experienced laboratory analyst with specialized knowledge in such matters.

District management makes the final decision regarding the assignment of personnel to inspections. Nevertheless, we expect investigators, analysts and others to work as teams and to advise management when additional expertise is required to complete a meaningful inspection.

Team members participating in a pre-approval inspection must be familiar with USCBDMA Compliance Program and Pre-Approval Inspections. Team members should meet, if possible, prior to the inspection to discuss the approach to the inspection, to define the roles of the team members, and to establish goals for completion of the assignment. Responsibilities for development of all reports should also be established prior to the inspection.

USCBDMA Quality Control reserves the right of inspection "in the case where" there has been no response to inquiry letters or when the response is judged inadequate.

4. INSPECTION APPROACH

A. General

In addition to the general approach utilized in a CBD approved USCBDMA inspection, the inspection of a laboratory requires observations of the laboratory in operation and of raw laboratory data to evaluate compliance with USCBDMA and to specifically carry out the commitments in an application. When conducting a comprehensive inspection of a laboratory, all aspects of the laboratory operations will be evaluated.

Laboratory records and logs represent a vital source of information that allows a complete overview of the technical ability of the staff and of overall quality control procedures. SOPs should be complete and adequate and the operations of the laboratories should conform to the written procedures. Specifications and analytical procedures should be suitable and, as applicable, in conformance with application commitments and compendial requirements.

Evaluate raw laboratory data, laboratory procedures and methods, laboratory equipment, including maintenance and calibration, and methods validation data to determine the overall quality of the laboratory operation and the ability to comply with USCBDMA regulations. Examine chromatographs and spectra for evidence of impurities, poor technique, or lack of instrument calibration.

Most manufacturers use systems that provide for the investigation of laboratory test failures. These are generally recorded in some type of log. Ask to see results of analyses for lots of product that have failed to meet specifications and review the analysis of lots that have been

retested, rejected, or reworked. Evaluate the decision to release lots of product when the laboratory results indicate that the lot failed to meet specifications and determine who released them.

B. Pre-Approval

Documents relating to the formulation of the product, extraction and isolation of the bulk CBD substance, product specifications, analysis of the product, and others are examined during the review process in headquarters. However, these reviews and evaluations depend on accurate and authentic data that truly represents the product.

Pre-approval inspections are designed to determine if the data submitted in an application are authentic and accurate and if the procedures listed in the application were actually used to produce the data contained in the application. Additionally, they are designed to confirm that plants (including the quality control laboratory) are in compliance with USCBDMA regulations.

The analytical sections of CDB applications usually contain only test results and the methods used to obtain them. Sponsors are not required to file all the test data because such action would require voluminous submissions and would often result in filing redundant information. Sponsors may deliberately or unintentionally select and report data showing that a CDB is safe and effective and deserves to be approved. The inspection team must decide if there is valid and scientific justification for the failure to report data which demonstrates the product failed to meet its predetermined specifications.

Coordination between headquarters and the field is essential for a complete review of the application and the plant. Experienced investigators and analysts may contact the review chemist (with appropriate supervisory concurrence) when questions concerning specifications and standards arise.

Inspections should compare the results of analyses submitted with results of analysis of other batches that may have been produced. Evaluate the methods and note any exceptions to the procedures or equipment actually used from those listed in the application and confirm that it is the same method listed in the application. The analyst is expected to evaluate raw laboratory data for tests performed on the test batches and to compare this raw data to the data filed in the application.

5. FAILURE (OUT-OF-SPECIFICATION) LABORATORY RESULTS

Evaluate the company's system to investigate laboratory test failures. These investigations represent a key issue in deciding whether a product may be released or rejected and form the basis for retesting, and resampling. OOS results fall into three categories:

a. Laboratory error
b. Non-process-related or operator error
c. Process-related or manufacturing process error

A. LABORATORY ERRORS

Laboratory errors occur when analysts make mistakes in following the method of analysis, use incorrect standards, and/or simply miscalculate the data. Laboratory errors must be determined through a failure investigation to identify the cause of the OOS. Once the nature of the OOS result has been identified it can be classified into one of the three categories above. The inquiry may vary with the object under investigation.

B. LABORATORY INVESTIGATIONS

The exact cause of analyst error or mistake can be difficult to determine specifically, and it is unrealistic to expect that analyst error will always be determined and documented. Nevertheless, a laboratory investigation consists of more than a retest. The inability to identify an error's cause with confidence affects retesting procedures, not the investigation inquiry required for the initial OOS result.

The firm's analyst should follow a written procedure, checking off each step as it is completed during the analytical procedure. We expect laboratory test data to be recorded directly in notebooks; use of scrap paper and loose paper must be avoided. These commonsense measures enhance the accuracy and integrity of data.

Review and evaluate the laboratory SOP for product failure investigations. Specific procedures must be followed when single and multiple OOS results are investigated. For the single OOS result the investigation should include the following steps and these inquiries must be conducted before there is a retest of the sample:

a. The analyst conducting the test should report the OOS result to the supervisor

b. The analyst and the supervisor should conduct an informal laboratory investigation which addresses the following areas:

(1) Discuss the testing procedure

(2) Discuss the calculation

(3) Examine the instruments

(4) Review the notebooks containing the OOS result

An alternative means to invalidate an initial OOS result, provided the failure investigation proves inconclusive, is the "outlier" test. However, specific restrictions must be placed on the use of this test.

(1) Firms cannot frequently reject results on this basis.

(2) The USP standards govern its use in specific cases only.

(3) The test cannot be used for chemical testing results. An initial content uniformity test that was OOS is followed by a passing retest. The initial OOS result was claimed the result of analyst error based on a statistical evaluation of the data. The use of an outlier test is inappropriate in this case.

(1) It is never appropriate to utilize outlier tests for a statistically based test, i.e., content uniformity and dissolution.

(2) Determine if the firm uses an outlier test and evaluate the SOP.

(3) Determine that a full-scale inquiry has been made for multiple OOS results. This inquiry involves quality control and quality assurance personnel in addition to laboratory workers to identify exact process or non-process related errors.

When the laboratory investigation is inconclusive (reason for the error is not identified) the firm:

(1) Cannot conduct 2 retests and base release on average of three tests

(2) Cannot use outlier test in chemical tests

(3) Cannot use a re-sample to assume a sampling or preparation error

(4) Can conduct a retest of different materials from the same sample when a retest is considered appropriate

C. FORMAL INVESTIGATIONS

Formal investigations extending beyond the laboratory must follow an outline with particular attention to corrective action. The company must:

(1) State the reason for the investigation

(2) Provide summation of the process sequences that may have caused the problem

(3) Outline corrective actions necessary to save the batch and prevent similar recurrence

(4) List other batches and products possibly affected, the results of investigation of these batches and products, and any corrective action. Specifically {1} examine other batches of product made by the errant employee or machine and {2} examine other products produced by the errant process or operation

(5) Preserve the comments and signatures of all production and quality control personnel who conducted the investigation and approved any reprocessed material after additional testing

1. Quality Control personnel and evaluation control and record keeping

a. Collaborative Quality Assurance Review

A qualified QAI [Quality Assurance Inspector] accompanies at the grower, processor, manufacturing and distribution during an inspection to evaluate the quality of the process, the capabilities of the process and whether a valid inspection using the appropriate inspection protocol was accomplished. The QAI serves both as an assessment of the use of the inspection protocol, either 'within Standards" or "Outside Standards," to enhance the quality and shills utilized in conducting QA inspections.

b. Limited Quality Assurance Review

A qualified QAI performs on-site follow on review to determine the validity of prior and present inspections and work performance in collaboration with operations to either accept or reject the inspection. Following the review, the overall performance is rated "Within Standards" or "Outside Standards."

c. Quality Control Inspection Review

A qualified QAI works in collaboration within the operations to perform a full inspection on-site as a follow-on review of prior inspections submitted prior QAI inspectors, to identify any inconsistencies with the inspection protocol and determine the validity of prior inspections. Following the QAI review the results will be analyzed by two independent QAI and either accept or reject the submitted inspection.

d. Full Inspection

A QAI Supervisor inspects, in collaboration with on-site and supporting QAI's perform a full inspection to sustain organizational goals, priorities and initiatives in support of USCBDMA's Strategic Goal to meet the need for quality produced products. QAI Supervisors perform special inspections in instances such as resolution of issues substantive interest to the

USCBDMA; response to emerging issues for critical product use; and sensitive inquiries from appropriate managers, members or state and local governmental officials and concerned citizens

2. Quality Control Laboratory selection and processing product specifications, testing and quality specifications and Analysis

1. RAW MATERIAL TESTING

Some inspections include the coverage of the manufacturer of the CBD substance. The safety and efficacy of the finished form is largely dependent on the purity and quality of the bulk active CBD substance. Examine the raw data reflecting the analysis of the CDB substance including purity tests, charts, etc.

Check the impurity profiles of the CBD used in the bio-batch and clinical production batches to determine if it is the same as that being used to manufacture full scale production batches. Determine if the manufacturer has a program to audit the certificate of analysis of the CBD, and, if so, check the results of these tests. Report findings where there is substantial difference in impurity profiles and other test results.

Some older methods may not be capable of detecting impurities to the levels necessary for control of the manufacturing process, and newer methods have been developed to test these products. Such methods must be validated to ensure that they are adequate for analytical purposes in the control and validation of the CBD manufacturing process. The CDB substance manufacturer must have complete knowledge of the manufacturing process and the potential impurities that may appear in the CBD substance. These impurities cannot be detected without a suitable method and one that has been validated.

Physical properties tests often require the use of unique equipment and protocols. These tests may not be reproducible in other laboratories, therefore, on site evaluation is essential.

2. IN-PROCESS CONTROLS AND SPECIFICATIONS

Evaluate the test results from in-process tests performed in the production areas or laboratory for conformance with established sampling and testing protocols, analytical methods, and specifications. For example, evaluate the tests for weight variation and percent CBD content. These tests may be performed every fifteen or thirty minutes during bottling, tableting or encapsulating procedures. All testing must comply with USCBDMA standards.

The CBD application may contain some of the in-process testing plan, including methods and specifications. The inspection must confirm that the in-process tests were done, as described in the plan, and ascertain that the results were within specifications. The laboratory work for the lengthier tests should also be reviewed.

The methods used for in-process testing may differ from those used for release testing. Usually, whether the methods are the same or different, the specifications may be tighter for the in-process tests. A product must meet acceptable Federal Established Standards and would be tested using those specifications. . Some of the tests done may differ from those done at release.

Expect to see consistent in-process test results within batches and between batches of the same formulation/process (including development or exhibit batches). If this is not the case, expect to see scientific data to justify the variation.

3. STABILITY

A stability-indicating method must be used to test the samples of the batch. If there are no stability-indicating assay additional assay procedures such as TLC should be used to supplement the general assay method. Evidence that the method is stability indicating must be presented, even for compendial methods.

Manufacturers may be required to accelerate or force degradation of a product to demonstrate that the test is stability indicating. This information may also be obtained from the supplier of the CDB substance. Validation would then be relatively straightforward, with the typical parameters listed in the USP on validation of compendial methods addressed as applicable.

Evaluate the manufacturer's validation report for their stability testing. Again, review the raw laboratory data and the results of testing at the various stations to determine if the data actually reported matches the data found in on site records.

Evaluate the raw data used to generate the data filed documenting that the method is stability indicating and the level of impurities.

4. LABORATORY MANAGEMENT

Overall management of the laboratory work, its staff, and the evaluation of the results of analysis are important elements in the evaluation of a control laboratory. Span of supervisory control, personnel qualifications, turnover of analysts, and scope of the laboratory's responsibility are

important issues to examine when determining the quality of overall management and supervision of work. Individually or collectively, these factors are the basis for an objection only when they are shown to result in inadequate performance of responsibilities required by the USCBDMA.

Review laboratory logs for the sequence of analysis and the sequence of manufacturing dates. Examine laboratory records and logs for vital information about the technical competence of the staff and the quality control procedures used in the laboratory.

Observe analysts performing the operations described in the application. There is no substitute for actually seeing the work performed and noting whether good technique is used. You should not stand over the analysts but watch from a distance and evaluate their actions.

Sometimes the company's employees have insufficient training or time to recognize situations that require further investigation and explanation. Instead they accept unexplained peaks in chromatograms with no effort to identify them. They may accept stability test results showing an apparent increase in the assay of the CDB with the passage of time with no apparent question about the result.

Good manufacturing practice standards require an active training program and the documented evaluation of the training of analysts.

The authority to delete files and override computer systems should be thoroughly examined. Evaluate the history of changes to programs used for calculations. Certain changes may require management to re-examine the data for products already released.

5. CODE OF CONDDUCT

The USCBDMA Code of Conduct requires every inspector to maintain professional conduct, demeanor, appearance and attire at all times prior to, during, and after an inspection, and in all interactions with residents, inspection participants, property representatives, and any other individual with whom the inspector comes in contact. Non-exclusive examples of conduct required and prohibited by the Code of Conduct are described below.

Inspectors must:

- Display the USCBDMA-issued photo identification card throughout the entire inspection;
- Comply with reasonable requests from project representatives during the inspection;

- Defer all questions from project representatives the product to the proper firm representative accompanying the inspector; and
- Defer all questions from third parties about the inspection or the results to the proper firm representative.

Inspectors must not:

- Express opinions or comment about the nature or condition of the products or firm representatives;
- Attend an inspection, or participate in an inspection in any capacity, that is being conducted by another USCBDMA certified QAI inspector while providing independent consulting services of any kind on behalf of the property owner or representative;
- Include in attendance or participation during a USCBDMA inspection any unauthorized person, including family, friends, or USCBDMA certified/decertified inspectors;
- Use any facility on a property, property owner's office, housing agency office, or field office to conduct personal business;
- Use profanity or other offensive language prior to, during or after an inspection;
- Engage in fraudulent activities, such as, but not limited to, falsifying an inspection;
- Conduct an inspection under the influence of alcohol or drugs;
- Smoke anywhere on a property;
- Threaten, verbally or in writing, residents, inspection participants, property representatives or any other individual with whom the inspector comes in contact;
- Carry a firearm or weapon of any kind, or any other object that could be construed as a weapon, on a property;
- Commit theft or intentional damage to property;
- Cancel an inspection due to a QA review;
- Threaten or engage in violence against any person while conducting an inspection; and
- Engage in sexual misconduct or any other type of unwanted conduct.

All inspectors must comply with the Code of Conduct. Failure to do so may result in issuance of a Letter of Warning, issuance of one or more Performance Deficiencies (PDs), suspension, or decertification as a USCBDMA QAI inspector. An inspector may also be suspended pending completion of an investigation into possible violations of the Code of Conduct.

6. QUALITY ASSURANCE AND QUALITY CONTROL PLAN

In order to assist providers in completing their Quality Assurance and Quality Control (QA/QC) Plan, the following guidelines are provided, which indicates the minimum information that should be included.

These Guidelines are divided into three sections:

a. Field Sampling
b. Lab Analysis
c. Reporting Requirements

It is recognized that there may be different interpretations as to what is covered by "Quality Assurance/Control" due to the fact that USCBDMA uses select commercial laboratories. For our purposes, "Quality Assurance" and "Quality Control" refer to the following:

1. Collaborative Quality Assurance Inspection:

a. Collaborative Quality Assurance [CQA] inspector accompanies a certified contract inspector if requested by the client, during an inspection to evaluate the quality of the inspection, the capabilities of the individual contracted inspector, and whether the inspector conducted a valid inspection using the appropriate inspection protocol. The CQA serves both as an assessment of the inspector's use of the inspection protocol, either 'Within Standard" or "Outside Standard", and an opportunity for the inspector to enhance his or her skills through the feedback provided by the CQA inspector.

2. Limited Quality Assurance Inspection:

a. A Limited Quality Assurance [LQA] inspector performs an on-site follow-on review after a certified contract inspector has completed an inspection, to determine the validity of the original inspection and work in collaboration with the client operations to either accept or reject the inspection. Following the LQA's review, the certified contract inspector's overall performance is rated either "Within Standard" or "Outside Standard."

3. Quality Control Inspection:
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a. The QCI works in collaboration with client operations to perform a full inspection on-site as a follow on review of certain inspections submitted by a Collaborative Quality Assurance [CQA[Inspector to identify any inconsistencies with the inspection protocol and determine the validity of the original inspection. Following the QCI review, the client operations will analyze the two inspections and either accept or reject the contractor's inspection.

4. Full Inspection:

a. QA inspectors inspect client field, processing plant, warehouses, distribution and such other areas as appropriate to sustain organizational goals, priorities, and initiatives in support of USCBDMA Strategic Goal to meet the quality for superior products. QA inspectors perform special inspections in instances such as problem resolution of issues of substantive interest to the USCBDMA and/or the client; response to emerging issues in other official offices for critical problem use; and sensitive inquiries from senior level departmental managers, local, state or federal governmental offices, USCBDMA, and concerned citizens.

Quality Control: is the use of established procedures to achieve standards of measurement for the three Regular components of quality: precision, accuracy and reliability.

Field Sampling Guideline:

a. Sample Collection Location

A QA/QC plan must identify the locations of all sampling stations and the markers used to identify the product. If the Surveillance Network Program (SNP) of the product does not specify sampling locations, locations should be chosen with help from an Inspector.

Landmarks identify sampling stations in the fields, while signpost positioning usually marks selected section sample stations. Stations should be used repeatedly, with the same personnel and techniques to reduce operational error.

b. Sampling Equipment

The Plan must include a detailed section on the equipment used for sampling, the rationale behind the choices of equipment, and descriptions of how the equipment is maintained and calibrated. Equipment and bottles should be selected so that they do not contaminate or otherwise alter the concentrations of parameters of interest.

Sampling devices, sample bottles and transportation devices should be constructed of non-metallic material. Most samples are now collected in containers constructed of high-density polyethylene plastic.

c. Sampling Methods

This Section will include details on methods for sample collection and the equipment that is to be used for each station.

In the fields and in batches regular sample bottles are used the majority of the time The sample or the sample bottle is usually lowered to mid depth and washed three times before collecting the sample. Approximately 2% of the sample container capacity should remain to provide for not compressing the samples.

This section should also describe how often field and bulk and replicate samples will be collected. Field blanks are samples that are to be treated in exactly the same manner as the other samples. Bulk samples should therefore be taken to the laboratory field and handled and preserved as part of the sample program. They indicate when a sample may be contaminated and are indicative of general sample integrity. Replicate samples (duplicates and triplicates) are two or three samples

collected from the same station at the same time. They help to ensure sample precision at the laboratory.

d. Sample Handling

(1) Preservation

After collection, most samples must be preserved in order to prevent chemical or biochemical changes to the sample. The QA/QC plan must describe how samples from each station are to be preserved.
Preservation is generally done careful sealing of the samples to avoid contamination. The QA/QC plan should contain more detailed information on the concentrations and amount of any preservatives that may be used.

(2) Sample Identification

The plan should include a description of the system used to identify samples. The system must provide positive sample identification and ensure that the identification is maintained. It is advisable to keep a logbook of samples that have already been delivered. The identification can be maintained by marking the sample container itself or a label, with a water resistant, non-smear felt pen. The information should be clear to persons uninvolved in the sampling and may include such details as company name, sample area, QAI control number, time and date.

(3) Transportation

The section on transportation will describe how sample integrity will be ensured from the time of collection to completion of delivery. Delivery to the lab should be done as soon as possible after the samples have been collected.

Usually, samples are sealed and stored upright in a box with other samples to provide a snug, immobile storage space during transfer. Any samples that require refrigeration for preservation should be kept cool during transport.

e. Lab Analysis

Because certain clients of USCBDMA use Class “A” Laboratories, this section of the Guidelines is divided accordingly.

(1) Lab Accreditation: The USCBDMA will identify in the plan the name of the commercial laboratory that will be conducting the analyses. A letter must be provided from the commercial lab indicating that they are accredited to conduct analyses on each of the required sampling parameters. Ideally, the lab should be accredited and should provide a certificate stating parameters for which they are accredited.

(2) Detection Limits: Detection limits for the commercial lab should be identified for all parameters and should be reported when any SNP data is submitted.

(3) Methodology: Descriptions should be included for any methods of analysis used that are not outlined in "Standard Methods for the Examination of Water and Wastewater".

(4) For Overall Analytical Methods, Precision and Accuracy:

A. The plan must describe how the Laboratory will ensure precision and accuracy in their analytical methods. This includes what action will be taken if any sample results are found to be outside the appropriate ranges.

B. All analyses should be conducted in accordance with methods prescribed in the current requirements of the USCBDMA "Standard Methods for the Examination of CBD" or by other approved methods. In addition, the lab should analyze standard reference material for each parameter measured. For each parameter (group) to be measured, a complete description of the sampling procedure must be documented and adhered to.

C. If any sample results are outside the appropriate QA/QC ranges, attempts should be made to correct the problem and the sample shall be immediately re-analyzed. If any analysis indicates a violation of a products condition, an Inspector shall be notified of the violation, any corrective action taken, and the results of retests.

(5) Accuracy Requirements: The plan should document how the Laboratory will go about ensuring accuracy in the laboratory. Accuracy is the measurement of how closely a value approximates a standard, or true value. The Laboratory should identify the frequency at which certified or reference standards will be analyzed during each sampling period.

(6) Precision Requirements: Precision is a measure of the closeness or repeatability of a set of values. This section will describe how and when replicate samples are taken to ensure lab precision. It is recommended that the Laboratory take triplicates at one SNP station during each sampling period. If daily sampling is required at only one station, a duplicate sample should be taken each time, with a triplicate sample taken once a week.

(7) Methodology: Descriptions should be included of any methods of analysis that are not taken from "USCBDMA Standard Methods for the Examination of Help CBD Products." Standard methods should be referenced.

(8) Reporting Requirements: USCBDMA approved laboratories shall outline the number of results from replicate samples that will be included with each required SNP report. It is recommended that two duplicate sets be collected per month at an assigned SNP site, with one set being sent to a commercial lab while the other is to be analyzed by the lab. Analytical results from both labs should be submitted with each required SNP report. This would serve as an external check for the lab. Any results from a commercial lab should be presented on the lab's letterhead.

7. Educate workers about the importance of in-process inspections: Assurance of manufacturing capacity

The Supplier shall ensure manufacturing capacity sufficient to manufacture products for the Purchaser. Work environment must be maintained in an orderly, tidy, clean and disciplined manner to avoid unexpected trouble and make abnormalities transparent in the work environment.

Part Nine: Membership Requirements and Benefits

Introduction:

USCBDMA Defines the Standard of Excellence

Founded in 2019, the USCBDMA is an Association for CBD Quality is the only organization dedicated to certifying all aspects of CBD quality from the field to professionals, defining the standard of excellence for the profession, and equipping professionals and organizations across the continuum of CBD growing, processing, manufacturing, distribution and sales to meet these standards.

USCBDMA offers extensive educational programming, networking opportunities, and career resources to help our members meet the challenges they face and demonstrate their value.

USCBDMA members are quality professionals who are an indispensable part of the CBD industry, and USCBDMA is committed to you and your success at all levels, from new quality specialist to experienced executive.

Our Mission
To prepare a coordinated, competent workforce to lead and advance CBD quality from grower to consumer use.
Our Vision
The USCBDMA recognizes the quality profession as valued and essential.
Our Strategic Goal Areas
Certification and Recertification
The CBD quality profession is strengthened by certification and recertification programs which are based on industry standards of certifying bodies.
Education
USCBDMA is the primary source for CBD quality education for the CBD quality professional to advance the profession.
Essential Competencies
USCBDMA defines the body of knowledge and competencies for the CBD quality profession.
Recognition of the Profession
Individuals working in health products quality identify themselves as members of the profession and employers recognize the profession.
Learn More About Us

- Download our bylaws.
- Meet our leadership.
- Meet our industry supporters.
- Learn about opportunities to support, advertise, or exhibit with USCBDMA.
- Provide membership benefits through collective bartering for the benefit of all.

Corporate Membership provides your employees with access to information in key areas such as product and service quality, software quality and reliability, tools and techniques in all industries and solutions to maximize revenue and customer satisfaction.

- Professional development tools and member-only pricing on training, books, certification and more.
- Access to the exclusive members-only content of USCBDMA.org.
- Subscriptions to USCBDMA *Connections Quarterly* e-newsletter
- Electronic access to USCBDMA publications including *Quality Progress*
- Monthly updates from USCBCMA, The Insider Newsletter, and Member Gift

Membership requirements of the Association

1. OUTLINE FOR THE USCBDMA MEMBERSHIP APPLICATION Membership in USCBDMA as specified by the Policy and Procedures or other competent authorities, and to other organizations, institutions, and individuals interested in the objectives and purposes of the Association.

2. These purposes and objectives are:

- To promote intercultural understanding and friendship through the activities of Members and Corporate Members.
- To broaden the dimensions of education of all Members involved in the USCBDMA in the interest of a total program of education;
- To advance the professional growth and welfare of individuals belonging to the Association
- To facilitate communication and cooperative action between and among all Members;
- To cooperate with other organizations and individuals pursuing the same objectives as USCBDMA.

3. Membership There shall be two categories of membership: Regular and Affiliate.

a. Regular Members shall be those which meet all membership standards of the USCBDMA and have successfully operated for a minimum of three consecutive years.

b. Affiliate Members shall be those which meet the same membership standards as regular members and which are demonstratively international or internationally minded in style and substance. Affiliate Members shall have access to professional learning events and student conferences according to procedures established by the Board of Directors but shall not be entitled to other USCBDMA services and shall not have voting privileges. (Regular and Affiliate membership shall be reviewed every three years.

c. Approval Process: The Board of Directors will take action on membership applications at the regularly scheduled meetings of the Board in November and in April. The Board may delay its decision if additional information is warranted. The person or corporation requesting

membership will pay all costs incurred in the application process. All application materials should be sent via digital application upload available on the USCBDMA website. The final completed application will be distributed to the Executive Director of USCBDMA. A non-refundable U.S. $250.00 application fee is required to process this application.

d. Annual Membership Fee Schedule

(1) New Applicants a U.S. $250 non-refundable application fee is required to process this application. Please do not send the annual membership fee with this application.

(2) The membership fee will be payable in full (see fee schedule below) as soon as the applicant has been accepted by the Board of Directors. Outline for Membership Application

(3) Membership Fees for Regular and Affiliate Members

A. Regular Members Individual $200.00 Annual Fee
B. Corporate Members [based on number of employees]
0-50: $700.00 Annual Fee
51-100: $1,080.00 Annual Fee
101-200: $2,160.00 Annual Fee
201 or more: $5,950.00 Annual Fee
C. Affiliate Members: $450.00 Annual Fee

Membership Training

Train your team with the leader in CBD/HEMP quality competencies

Are you looking to:

- Develop key competencies for your CBD quality team?
- Orient new and future quality professionals?
- Prepare the frontline to deliver quality?
- Support CBD system executive leaders in making quality a growth strategy?

USCBDMA offers education and training solutions for all levels and types of CBD quality professionals live and online

Develop CBD/HEMP Quality Professionals

USCBDMA has defined the industry-standard competencies for novice, proficient and advanced practitioners of CBD processing quality and provides the industry-standard quality certification. Prepare your team for the certification exam with USCBDMA's QAI Prep which offers convenience and access live and on demand.

Orient New and Future CBD/HEMP Quality Professionals USCBDMA's HQ Principles: An interactive, online certificate program that provides an introduction to quality and safety fundamentals, methodologies, and concepts on industry-standard competencies. It is the first step in understanding quality and the professional competencies to achieve it.

Prepare the Frontline to Deliver Quality

More and more CBD production disciplines and specialties are increasing quality and safety training for their own professionals to improve outcomes. USCBDMA's Concepts in CBD Quality & Safety for Frontline Staff is a one-hour interactive learning module that prepares frontline staff to support organization-wide improvement initiatives, and is essential for achieving success in quality-driven CBD processing to support new goals for value. It will help the frontline understand their role in quality, and identify how their role can specifically affect quality and safety across the system to meet new expectations that all CBD systems are facing in achieving sustainable, affordable person-centric care.

Support CBD System Executive Leaders

USCBDMA offers education, training and research-driven insights on quality-driven growth strategies that are specifically designed for CBD executives. **USCBDMA's National CBD Quality Summit** is an executive symposium on the advantages of quality as a business strategy in the transition to healthcare value.

Executives looking for more resources on quality as a business and growth strategy should visit the Quality-Driven Initiatives developed by USCBDMA.

USCBDMA helps CBD/HEMP production systems build their quality workforce through its **Career Center** which offers the profiles of healthcare quality professionals and links to qualified candidates. Executives looking to build their healthcare quality teams can learn more by contacting USCBDMA.

Benefits for Members:

1. FOR THE MERCHANT PROCESSING: Merchant Processing with no purchase or lease of equipment and all use fees charged to the customer and not the merchant. We have an agreement with "For the Merchant" [FTM] card processors which is available to all members of the USCBDMA. Based on the new financial laws passed recently this is a revolutionary product for our members to use. In the past you paid the processing company fees up to 3.5% and other fees for each charge processed. With the FTM system you can now take any card, including American Express, and that fee is paid by the customer at time of purchase. To apply for this service contact FTM Agent **David Williams** at Email Address **dpwashore@gmail.com**, or call him at **904-599-0522**. The FTM agent for our Membership Benefit Program will assist you to increase your cash flow and reduce your expenses.

2. MORE COMING SOON