# TABLE OF CONTENTS

1  GLOSSARY ................................................................................................................................. 2

2  GROWERS ................................................................................................................................. 8

  2.1  Registration / Application / Notification ............................................................................. 9

      2.1.1  Registration / Application Guidance .............................................................................. 9

      2.1.2  Notification of Changes to the Licensor by the Licensee .............................................. 9

      2.1.3  Notification of Theft or Loss ......................................................................................... 9

  2.2  Personnel Guidance .......................................................................................................... 10

      2.2.1  Sanitation Measures for Personnel .................................................................................. 10

      2.2.2  Personnel and Employee Safety Measures ..................................................................... 10

      2.2.3  Training Records ........................................................................................................ 10

  2.3  Sampling and Handling Hemp for Analysis ...................................................................... 11

      2.3.1  Introduction .................................................................................................................. 11

      2.3.2  Sampling Timeline and Grower Responsibilities ........................................................... 11

      2.3.3  Pre-Harvest Sampling Procedure .................................................................................. 11

      2.3.4  Handling Procedures of Pre-Harvest Samples ............................................................... 12

      2.3.5  Post-Harvest Sampling Procedures .............................................................................. 12

      2.3.6  Handling Procedures of Post-Harvest Samples ............................................................ 13

  2.4  Contaminant Testing and Hemp Cannabinoid Quantification ........................................ 14

      2.4.1  Potency / Strength Cannabinoid Quantification in Pre-Harvested Material ................. 14

      2.4.2  Purity & Contaminants .................................................................................................. 14

  2.5  Storage and Transportation .............................................................................................. 17

  2.6  Import / Export ................................................................................................................... 18

      2.6.1  USDA & the Importation of Hemp Seeds and Hemp Plants for Planting ................... 18

      2.6.2  Export ........................................................................................................................... 19

  2.7  State Seed Laws and Truth in Labeling ........................................................................... 21

  2.8  Record Retention ................................................................................................................ 22

  2.9  Prohibitions ....................................................................................................................... 23

  2.10  Overview of Best Farm Management Practices Checklist ........................................... 24

  2.11  Overview of Facility & Security Checklist ..................................................................... 25

3  PROCESSORS/MANUFACTURERS .......................................................................................... 27

  3.1  Hemp Processing or Handling Registration / Application / Notification ....................... 28

      3.1.1  Registration / Application Guidance .............................................................................. 28

      3.1.2  Notification of Changes to the Licensor by the Licensee .............................................. 28

  3.2  Additional Registration Requirements .............................................................................. 29
3.2.1 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ................................................................. 29

3.3 Personnel Guidance ........................................................................................................ 30

3.4 Employee Training ......................................................................................................... 31

3.5 Physical Plant and Grounds .......................................................................................... 33

3.6 Overview of Facility & Security Checklist ...................................................................... 34

3.7 Quality Management Systems ....................................................................................... 35

3.7.1 Establishment of Specifications .................................................................................. 35

3.7.2 Guidance for Quality Management Systems Personnel ............................................. 36

3.7.3 Guidance Requirements for In-House and Independent, Third-Party Hemp Laboratory Operations ........................................................................................................ 36

3.8 Supplier Qualification & Specifications ........................................................................ 38

3.9 Sampling and Handling Hemp for THC & Cannabinoid Analysis .................................. 39

3.10 Contaminant Testing and Hemp Cannabinoid Quantification ...................................... 40

3.10.1 Potency / Strength Cannabinoid Quantification ....................................................... 40

3.10.2 Purity & Contaminants ............................................................................................. 40

3.11 Equipment and Utensils .............................................................................................. 42

3.12 Production and Process Control .................................................................................. 43

3.13 Production and Process Control Systems Master Manufacturing Record ................. 44

3.14 Packaging and Labeling .............................................................................................. 45

3.14.1 Labeling Practices ..................................................................................................... 45

3.14.2 Appropriate Nutrition Facts and Supplement Facts Panels ..................................... 46

3.14.3 Guidance for Packaging and Labeling Operations .................................................. 46

3.14.4 Quality Control Procedures for Packaging and Labeling ........................................ 47

3.15 Holding and Distributing .............................................................................................. 48

3.16 Quality Control Operations Related to Product Complaints, Adverse Events and Recalls ...................................................................................................................... 49

3.17 Import / Export ............................................................................................................ 51

3.17.1 The Agriculture Improvement Act of 2018 (“2018 Farm Bill”) .................................. 51

3.17.2 Additional Import Requirements & Guidance .......................................................... 51

3.17.3 Export ....................................................................................................................... 52

3.18 Record Retention .......................................................................................................... 54

3.19 Prohibitions .................................................................................................................. 55

4 BRAND OWNERS ............................................................................................................ 57

4.1 Hemp Specific Registration / Application / Notification .............................................. 58
GUIDANCE PROCEDURES GLOSSARY
1 GLOSSARY

The following definitions and interpretations apply to these terms when used in these U.S. Hemp Authority™ Certification Program Guidance Procedures.

* * *

**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 has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is. In the event the substance is not an added substance, such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.

**Authority having jurisdiction** usually means the state, but it could be FDA, FTC, USDA, EPA, tribal government, county or city.

**Batch** means a specific quantity of a hemp product 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 during the same cycle of manufacture.

**Batch number, or lot number** means any distinctive group of letters, or numbers, or any combination of them, from which the complete history of the processing, packaging, labeling, and/or storage of a batch or lot of hemp product can be determined.

**Bioengineered** has the same definition as found in 7 CFR Part 66.

**Brand owner** means a company that owns a hemp product brand, but does not grow or process hemp, or manufacture a hemp product. The brand owner is responsible for the compliance of the finished hemp product to current Good Manufacturing Practices (cGMP) as produced through co-manufacturers or qualified suppliers.

**Broad Spectrum** is the total extract of the hemp floral material present in the finished hemp product that contains at least two cannabinoids derived from hemp and a minimum of one terpene.

**Cannabidiol (CBD)** is a crystalline, nonintoxicating cannabinoid (C_{21}H_{30}O_{2}) found in the genus Cannabis.

**Cannabinolic acid (CBDA)** is the acid precursor to cannabidiol (CBD).

**Cannabinoids** means a group of 21-carbon compounds present in the genus Cannabis. Cannabinoids includes their analogs and transformation products.

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1 U.S. Food & Drug Administration.
3 U.S. Department of Agriculture.
4 U.S. Environmental Protection Agency.
**Cannabimimetic phytochemical** means any substance not derived from the genus *Cannabis* with similar pharmacological effects to those of the genus *Cannabis* in that it acts directly or indirectly on cannabinoid receptors in the body.

**Certified seed** means seed for which a certificate or any other instrument has been issued by an agency authorized under the laws of a state, tribal government, federal government, territory, or province to certify seed and which has standards and procedures approved by the United States Secretary of Agriculture to ensure the genetic purity and identity of the seed certified.


**Component** means any substance used in the manufacture of a hemp product, including those that may not appear in the finished batch of the hemp product. This includes, but is not limited to, processing aids, solvents, and water used for cleaning.

**Delta-9- tetrahydrocannabinol (THC)** means the same as tetrahydrocannabinol (THC).

**Full Spectrum** is the total extract of the hemp flower and leaves, including THC and other cannabinoids, terpenes, omegas and plant matter. Full spectrum retains the natural profile as seen in nature with THC present at its natural levels without tampering or mitigation.

**Genetically engineered** means produced from an organism or organisms in which the genetic material has been changed through the application of:

a. Vector-based recombinant deoxyribonucleic acid (DNA) or ribonucleic acid (RNA) techniques; direct introduction of DNA or RNA into cells, protoplasts, or organelles; or other in vitro nucleic acid techniques;

b. Methods of fusing cells or protoplasts beyond the taxonomic family that overcome natural physiological, reproductive barriers; and

c. Does not include techniques used in traditional breeding and selection, such as selective breeding and hybridization.

**Genetically engineered ingredient** means an ingredient in dietary supplements or as an additive to food and beverages that is derived from or produced by a genetically engineered organism regardless of whether the ingredient contains detectable DNA or protein from a genetically engineered organism.

**Genetically modified organism (GMO)** is a term used in the common vernacular that often relates to bioengineering and/or genetic engineering. These Guidance Procedures instead use the terms “bioengineered” and “genetically engineered,” which are the precise terms and definitions used by government authorities and by many non-profit organizations that offer guidance on these issues.

**Good Agricultural Practices (GAP)** are a collection of principles to apply for on-farm production and post-production processes, resulting in safe and healthy food and non-food agricultural products, while taking into account economic, social and environmental sustainability – per the Food and Agricultural Organization of the United Nations (FAO). Note that no GAP program specific to hemp has been developed by the U.S. Department of Agriculture to date.

**Good Hygiene Practices (GHP)** cover the minimum sanitary and hygiene practices for food processors to ensure that food is safe and suitable for human consumption. It is a required foundation to implement other food safety management initiatives, such as cGMP.
(current) **Good Manufacturing Practice (cGMP)** means a system for ensuring that products are consistently produced and controlled according to quality standards. cGMP for food and dietary supplements are regulated by the FDA within the Code of Federal Regulations (CFR). The FDA provides for voluntary GMPs for cosmetics.

**Growth medium** means soil, or the solid, liquid or semi-solid substance used to support the growth of the plant.

**Guidance Procedures** means these U.S. Hemp Authority™ Certification Program Guidance Procedures.

**Hemp** means plant varieties of the genus *Cannabis* 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, that is defined in U.S. federal law as having a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

**Hemp country of origin (HCO)** means the country where the hemp was grown prior to being used in processing, manufacturing or finished hemp products. HCO labeling is required for U.S. Hemp Authority™ Certification.

**Hemp cultivation** means the growing and cultivation of hemp plants.

**Hemp product** means a product manufactured or produced with hemp or containing or comprised of hemp.

**Industrial hemp** means hemp.

**Ingredient** means any substance that is used in the manufacture of a hemp product and that is intended to be present in the finished batch of the hemp product.

**In-process material** means any material that is processed in any way for use in the manufacture of the hemp product and has not yet been packaged or approved for sale.

**Isolate** is the confined molecule and most pure form of the cannabinoid such as CBD.

**Lot** means a batch, or a specific identified portion of a batch, or, in the case of a hemp product produced by continuous process, a specific identified amount produced in a specified unit of time or quantity in a manner that is uniform and that is intended to meet specifications for identity, purity, strength, and composition.

**Microorganisms** means yeasts, molds, bacteria, viruses, protozoa and other microscopic organisms having public health or sanitary concern. This definition includes species that:

a. May have public health significance;

b. May cause a component or hemp product to decompose;

c. Indicate that the component or hemp product is contaminated with filth; or

d. Otherwise may cause the component or hemp product to be adulterated.

**Must** is used herein to state a requirement. “Shall” means the same as must.
Personal Protective Equipment (PPE) means protective clothing, helmets, goggles, or other garments or equipment designed to protect the wearer's body from injury or infection. The hazards addressed by protective equipment include physical, electrical, heat, chemicals, biohazards, and airborne particulate matter.

Pest means any objectionable insect or other animal including but not limited to birds, rodents, flies, mites, and larvae.

Physical plant or facility means 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.

Phytocannabinoid means any cannabinoid that is naturally derived from the genus Cannabis.

Phytosanitary Certificate means a certificate issued by a governing body certifying that the plants, plant product or other regulated articles described herein have been inspected and/or tested according to appropriate official procedures and are considered to be free from the quarantine pests, specified by the importing contracting party and to conform with the current phytosanitary requirements of the importing contracting party including those for regulated non-quarantine pests.

Plot means a contiguous area in a field, greenhouse, or indoor growing structure containing the same variety or strain of hemp throughout the area.

ppm means parts per million.

ppb means parts per billion.

Post-harvest sample means a sample, batch or lot number taken from the harvested hemp material from a particular plot’s harvest. The entire plot’s harvest must be in the same form (e.g., intact-plant, flowers, ground materials, etc.), representative of the plot, and not mixed with non-hemp materials or hemp materials from another plot.

Pre-harvest sample means a composite, representative portion from plants in a hemp plot collected in accordance with the procedures as defined by the state or tribal government providing authority.

Preventative Controls Qualified Individual (PCQI) means a qualified individual who has successfully completed training in the development and application of risk-based preventive controls at least equivalent to that received under a standardized curriculum recognized as adequate by FDA or be otherwise qualified through job experience.

Processing means making a transformative change to the hemp plant or product following harvest; converting an agricultural commodity into a marketable form.

Product complaint means any communication that contains any allegation, written, electronic, or oral, expressing concern, for any reason, with the quality of a hemp product, that could be related to current good manufacturing practice. Examples of product complaints are: Foul odor, off taste, illness or injury, disintegration time, color variation, tablet size or size variation, under-filled container, foreign material in a hemp product container, improper packaging, mislabeling, or hemp products that are superpotent, subpotent, or contain the wrong ingredient, or contain other contaminants (e.g., bacteria, pesticide, mycotoxin, glass, lead).
Quality means 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.

Quality Management Systems (QMS) means a planned and systematic operation or procedure for ensuring the quality of a hemp product. Quality Management Systems means the same as Quality Control (QC).

Quality Management Systems personnel means any person, persons, or group, within or outside the organization, designated to be responsible for quality control operations. Quality Management Systems personnel means the same as quality assurance (QA) and quality control (QC) personnel.

Representative sample means a sample that consists of an adequate number of units that are drawn based on rational criteria, such as random sampling, and that are intended to ensure that the sample accurately portrays the material being sampled.

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

Sample means a sufficient amount of material that is statistically representative of the population from which it is taken. A sample may be a particular plant part, including inflorescence (flower), leaf, stalk or seed, or it may be a processed product (oil, extract, powder, etc.).

Sanitize means to adequately treat cleaned equipment, containers, utensils, etc. or any other cleaned contact surface by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other microorganisms, but without adversely affecting the product or its safety for the consumer.

Seed source means the origin of the seed or propagules as determined by the state or tribal government providing authority.

Synthetic cannabinoid means a cannabinoid that is (1) produced in a laboratory, whether from chemicals or from biological agents including but not limited to yeast and algae; and (2) not derived from the genus \textit{Cannabis}. This includes biosynthetic cannabinoids.

Tetrahydrocannabinol (THC) is an intoxicating crystalline compound found in the genus \textit{Cannabis}. U.S. federal law mandates that hemp plants may only contain trace amounts of THC (not greater than 0.3% on a dry weight basis).

Tetrahydrocannabinolic acid (THCA) is the acid precursor to tetrahydrocannabinol (THC).
GROWERS
2 GROWERS

PLEASE NOTE: On October 31, 2019, the U.S. Department of Agriculture published in the Federal Register its Interim Final Rule for the U.S. Domestic Hemp Production Program. It also released guidelines for testing and sampling hemp. All of the documents related to this rulemaking process are available at https://www.ams.usda.gov/rules-regulations/hemp/rulemaking-documents.

A sixty-day public comment period commenced upon the Rule’s publication. The USDA indicates that the 2020 growing season will operate under this interim regulatory structure, with the Final Rule being issued no earlier than the 2021 growing season. However, the testing and sampling guidelines may be adjusted during the Interim Final Rule period without the need to formally amend the Interim Final Rule.

The Guidance Procedures in this Growers Section 2 have been released during this period of transition. Accordingly, the U.S. Hemp Authority™, in consultation with the USDA and state regulatory agencies, will amend these Guidance Procedures once there is more clarity on their final status prior to the 2020 growing season, to reconcile them with USDA regulations and guidelines.
2.1 REGISTRATION / APPLICATION / NOTIFICATION

Prior to the hemp grower planting any seed, a license or agreement with the state, tribal government or USDA must be obtained. The following information is typical of what is required to make the application before a license will be issued: (Each state or tribal government may have different regulations – refer to application.)

2.1.1 Registration / Application Guidance

a. Name of the person or corporation to whom the license or authorization is to be issued
b. Address of the farm or place including county and township or legal description
c. The number of acres
d. Global Positioning System coordinates
e. Intended purpose of hemp, e.g., foods, dietary supplements, fiber production, etc.
f. In the case of a plant breeder, the variety of hemp that may be cultivated; and
   i. Any conditions that are necessary to minimize security, public health or safety hazards related to the licensed or authorized activities
   ii. Specify if the hemp is for food or non-food purposes

2.1.2 Notification of Changes to the Licensor by the Licensee

Every licensee shall notify the state, tribal government, or USDA (as applicable) of any changes to the information provided on the application, within 15 days after the change (unless otherwise required by the state or tribal government), including:

a. Corporate name or ownership, or officers, and the replacement of an officer, or director
b. Any change to the address of the licensee
c. The replacement of an individual referred to as a licensee
d. Any change in the mailing address of the licensee
e. Any change in the ownership of the land used to cultivate hemp
f. Any change from the approved cultivar being sown or, in the case of a plant breeder, to the variety of hemp being sown, including any genetic engineering

Any such changes shall also be communicated by the licensee to the U.S. Hemp Authority within 15 days after the change.

2.1.3 Notification of Theft or Loss

Refer to the authority having jurisdiction regarding any requirements to report loss or theft of hemp (including seeds and propagules).
2.2 PERSONNEL GUIDANCE

Qualified employees who grow, manufacture, package, or label hemp shall be qualified to do so, and those responsible for quality control or performing any quality control operations must have the education, training, or experience to perform the assigned functions.

Supervisors shall be qualified by education, training, or experience to supervise.

2.2.1 Sanitation Measures for Personnel

Contamination prevention and hygienic measures shall be taken to exclude from any operations any person who might be a source of contamination.

Such measures shall include the following:

a. Instructing employees to notify their supervisor if there is a possibility that they have an illness, infection, open lesion, or any other abnormal source of contamination for potential removal from operations
b. Wearing outer garments in a manner that protects against the contamination
c. Maintaining adequate personal cleanliness
d. Washing hands thoroughly, and sanitizing if necessary, in a hand-washing facility
e. Removing or covering all unsecured jewelry and other objects that might fall into components, hemp, equipment, or packaging
f. Using gloves when appropriate
g. Wearing, where appropriate, hair nets, caps, beard covers, shoes, PPE, etc.

2.2.2 Personnel and Employee Safety Measures

Personnel and employee safety measures shall include the following:

a. Appropriate and adequate first aid equipment
b. Adequate bathrooms and changing rooms
c. Appropriate OSHA warnings, labels, and training
d. Appropriate personal protective equipment and training
e. Appropriate farm equipment training
f. Appropriate safety training. Such training should track federal guidance, to include compliance with the Occupational Safety and Health Act and 26 CFR §§ 1910 (general) and 1928 (agriculture).

2.2.3 Training Records

Records shall be maintained of all training provided to employees for the performance of all assigned functions for five (5) years, or longer if required by the authority having jurisdiction.
2.3 SAMPLING AND HANDLING HEMP FOR ANALYSIS

2.3.1 Introduction

The USDA filed its Interim Final Rule on October 31, 2019 which included a “Sampling guidelines for hemp growing facilities” document and a “Testing guidelines for Identifying Delta-9 Tetrahydrocannabinol (THC) Concentration in Hemp” document. These sampling and testing guidelines may be adjusted during the Interim Final Rule period without the need to formally amend the Interim Final Rule; and the U.S. Hemp Authority™, in consultation with the USDA and state regulatory agencies, will amend these Guidance Procedures once there is more clarity on their final status prior to the 2020 growing season, to reconcile them with USDA regulations and guidelines.

While this is an Interim Final Rule and these sampling and testing guidelines are not necessarily set in stone, it is advised to err of the side of caution and follow the sampling and testing guidelines provided by the USDA as well as the authority having jurisdiction for any cannabinoid analysis sampling and handling regulations or guidance applicable to your license. The USDA guidelines for sampling and testing can be found at:


The sections directly below outline the cannabinoid analysis sampling and handling regulations largely based on regulations in the Commonwealth of Kentucky.

2.3.2 Sampling Timeline and Grower Responsibilities

a. The grower shall refer to the authority having jurisdiction to determine a timeline.

b. During the sampling, the grower or an authorized representative shall be present at the growing site.

c. Harvested hemp shall not be moved beyond the processor, nor commingled, nor extracted, until test results are complete.

2.3.3 Pre-Harvest Sampling Procedure

a. Adequate personal protective equipment shall be used.

b. Proper equipment shall be used to prevent cross contamination.

c. The material selected for pre-harvest sampling will be determined by the grower. Cuttings will be collected to make one representative sample.

d. Refer to the authority having jurisdiction to determine adequate number of samples and proper locations. In the absence of jurisdictional requirements, the following guidance is given:

   i. Clip the top 12 inches of hemp plant’s primary stem, including female floral material.
   ii. Take cuttings from at least five (5) hemp plants within the plot.
   iii. Place the complete sample in a clean paper bag.
   iv. Seal the bag by folding over the top once and staple the bag shut.
   v. A separate sample must be taken from each non-contiguous plot of a given variety.
vi. A separate sample must be taken for each variety.
vii. Samples shall be secured in a paper bag (to allow for air-drying during transport).
viii. Label the sample container with a sample ID.

2.3.4 Handling Procedures of Pre-Harvest Samples

a. Samples will be taken for drying and storage.
b. Samples should be arranged in a single layer for drying.
c. Drying oven will be used when possible.
d. Samples in the oven will be left in the labeled sample bag.
e. If selected for testing, the entire sample will be sent to a testing lab for analysis.
f. It is suggested for samples to be shipped in a vacuum sealed plastic bag, packed into the shipping container with bubble wrap or packing peanuts.

2.3.5 Post-Harvest Sampling Procedures

a. Refer to the authority having jurisdiction to determine adequate number of samples and proper locations. In the absence of jurisdictional requirements, the following guidance is given.
b. Adequate personal protective equipment shall be used.
c. Proper equipment shall be used to prevent cross contamination.
d. The plot selected for sampling shall be designated by the pre-harvest sample results. The material selected for post-harvest sampling from this plot will be determined by the grower. All post-harvest samples of hemp shall be taken from the designated harvested plot materials in the form (intact-plant, flowers, ground materials, etc.) in which the material will be sent to the processor.
e. Grower must inventory the entire harvest to determine the form in which it exists and follow the protocol as appropriate in parts (A), (B), or (C) directly below:
   i. If, upon inventory, the grower determines that the entire harvest is not in a homogenous form (intact-plant, flowers, ground materials, etc.), it must be determined to take additional samples or other course of action or take the pre-harvest results.
   ii. For intact-plant post-harvest samples:
      A. Ensure that the entire harvest is accounted for.
      B. Clip the top 12 inches of hemp plant, primary stem, including female floral material. If sampling dried flower still on the plant, take equal parts top, middle, and bottom and then homogenize this into a representative sample.
      C. Take cuttings from at least five (5) non-adjacent hemp plants within the harvest’s storage/drying area.
      D. Place the complete sample in a paper bag.
      E. Seal the paper bag by folding over top once and stapling to keep closed.
F. Complete sampling procedures in parts (D) and (E) in this Section 2.3.5 (e)(ii).

iii. For ground plant material post-harvest samples:
   A. Ensure that the entire harvest is accounted for and in the same form (i.e., all harvested material whether whole plant or floral material only must be ground with no intact plants or whole flowers remaining from that harvest).
   B. Sample material from bag or container.
   C. Sample from a minimum of four (4) locations within the containers from a given harvest.
   D. Place the complete sample in a plastic sample container.
   E. Seal the plastic sample container.
   F. Complete sampling procedures in parts (D) and (E) directly above.

iv. For post-harvest samples in other forms (e.g., trimmed floral material, or floral material and stems, etc.):
   A. Ensure that the entire harvest is accounted for and in the same form (i.e., all harvested material must be uniform).
   B. Collect a randomized sample of an appropriate amount of plant material by volume.
   C. Place the complete sample in a paper bag or plastic container and seal the container, as appropriate.
   D. Complete sampling procedures in parts (D) and (E) in this Section 2.3.5(e)(ii).

v. A separate sample must be taken for each plot designated for post-harvest sampling.

vi. Samples shall be labeled and prepared for transport to the lab.

vii. Label the sample container with a sample ID.

2.3.6 Handling Procedures of Post-Harvest Samples

a. Fifty percent (50%) of the collected, homogenized sample will be sent to the testing lab for analysis. The grower shall retain the remaining fifty percent (50%) as a reserve sample for a period of six (6) months after the crop has been sold in order to validate results and/or prove inaccuracies.

b. Hemp crops generated from certified seed will incur post-harvest testing of at least five percent (5%) of growing plots per variety, per seed source.

c. Hemp crops from planting materials other than certified seed will incur post-harvest testing of at least fifty percent (50%) of growing plots per variety, per seed source.

d. 100% of post-harvest samples will be tested.

e. All plots will be tested with a representative sample.
2.4 CONTAMINANT TESTING AND HEMP CANNABINOID QUANTIFICATION

2.4.1 Potency / Strength Cannabinoid Quantification in Pre-Harvested Material

Refer to the authority having jurisdiction for any cannabinoid quantification analysis regulations or guidance applicable to your license. In the absence of such cannabinoid quantification analysis regulations or guidance by the authority having jurisdiction, use these Guidance Procedures which are based on references found in the American Herbal Pharmacopeia (AHP) Cannabis monograph and the American Herbal Products Association (AHPA) Guidance Policies.

Ensure that methods measuring cannabinoids are fit for purpose. Laboratories should adopt analytical methods that meet SMPR 2017.002 (attached in Appendix) approved by Cannabis stakeholders with AOAC.5

a. Farmers must quantify the THC level and any other cannabinoid required by the authority having jurisdiction.

b. List all target plant parts of hemp to be tested (flower, leaf, stalk, seed).

c. Laboratories and their relevant methods must be ISO 17025 accredited unless such accreditation conflicts with laboratories mandated by the authority having jurisdiction.

Cannabinoid potency/strength methods must be able to determine the concentration of target cannabinoids to effectively distinguish Cannabis as either legal hemp or marijuana. Specifically, methods must be accurate and precise at concentrations that bracket 0.3% THC. Laboratories should consider utilizing analytical methods which have achieved AOAC International First Action Status or Final Action Status (when available) or use such methods for internal verification or validation purposes.

Growers shall refer to the authority having jurisdiction for regulations regarding the disposal of non-compliant material.

2.4.2 Purity & Contaminants

Hemp is a phytoremediator, meaning it absorbs contaminants in the soil including, among others, heavy metals and pesticides. Farms producing hemp for products intended for human consumption, including cosmetics, are subject to federal regulations, and may be subject to state or tribal regulations, regarding good agricultural practices and harmful substances and contaminants.

Different techniques are used for farming, including conventional, organic, and regenerative. Your soil with suitable macronutrients and free of excessive heavy metals and pesticide, fungicide or insecticide residues should be used for producing hemp for products intended for human consumption, including cosmetics.

Note that equipment used to sow, harvest and transport hemp must be thoroughly cleaned to prevent contamination.

5 AOAC International (formerly Association of Analytical Chemists); SMPR is standard method performance requirements.
Refer to the authority having jurisdiction for any contaminant analysis regulations or guidance applicable to your license. In the absence of such contaminant analysis regulations or guidance by the authority having jurisdiction, use these Guidance Procedures which are based on references found in the American Herbal Pharmacopoeia (AHP) Cannabis Monograph, the American Herbal Products Association (AHPA) Guidance Policies, and the U.S. Food and Drug Administration (FDA) Pesticide Analytical Manual (PAM).  

a. **Soil Testing**

i. **Required Contaminant Testing.** U.S. Hemp Authority™ Guidance Procedures require that the soil tests directly below be performed prior to planting. Ensure that methods measuring purity and contaminants are fit for purpose. Limits for the following soil contaminants are listed in the following references:

   **Soil:** International Plant Nutrition Institute’s Grid Soil Testing, found at:
   

   **Heavy Metals:** USDA’s Heavy Metal Soil Contamination Note, found at:
   

   **Pesticides:** American Herbal Pharmacopoeia Cannabis Monograph, “Standards of Identity, Analysis and Quality Control” or AOAC Official Method 2007.1, “Pesticide Residues in Food” found at:
   

   Note: AHPA guidance does not include the stricter limits for lead consumption required in the state of California under Proposition 65. Also note that most pesticide testing panels do not include glyphosate; thus, if glyphosate testing is desired, that request must generally be specifically and separately made to the lab.

ii. **Suggested Micro and Macro Nutrient Testing.** Soil testing is a critical diagnostic tool for determining the nutrient needs of plants as well as for environmental assessments. Some soils are intrinsically deficient in plant nutrients, while others once had sufficient levels of nutrients in the past, but removal with crop harvest has reduced or exhausted the reserves. Soil testing is also useful to identify application rates of waste materials containing nutrients or other elements that could be harmful to the environment. Farmers should test soil for micro and macro nutrients to determine nutrient needs.

iii. Sampling should only be conducted with a stainless-steel probe, as galvanized can produce false positives in the analysis.

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6 The FDA is responsible under the Federal Food, Drug, and Cosmetic Act for enforcing tolerances established by the Environmental Protection Agency (EPA) for amounts of pesticide residues that may legally remain on food.
b. **Harvested Plant Material Testing**

   i. **Required Harvested Plant Material Testing.** U.S. Hemp Authority™ Guidance Procedures require that the tests directly below be performed on harvested plant material. Ensure that methods measuring cannabinoid quantification, purity and contaminants are fit for purpose. Limits for the following harvested plant material cannabinoid quantification and contaminants are listed in the following references:

   **Cannabinoid Quantification:** See Section 2.4.1 of these Guidance Procedures above regarding fit for purpose testing / AOAC* SMPR\(^7\) 2017.002 (attached as Appendix 1)

   **Heavy Metals, Pesticides, Microbiology and Mycotoxins:** These limits are listed in the American Herbal Pharmacopoeia *Cannabis* Monograph, “Standards of Identity, Analysis and Quality Control” and the following AHPA Guidance Documents:

   "Microbiology & Mycotoxins,” found at:


   “Guidance on Heavy Metals,” found at:


   **Notes:**

   a. AOAC SMPR 2017.002 has been approved by *Cannabis* stakeholders with AOAC and the method has been validated specifically for quantification of cannabinoids in dried plant material

   b. AHPA guidance does not include the stricter limits for lead consumption required in the state of California under Proposition 65. Also note that most pesticide testing panels do not include glyphosate; thus, if glyphosate testing is desired, that request must generally be specifically and separately made to the lab

   c. Microbiology limits are based on products consumed orally

   ii. **Suggested Harvest Plant Material Testing**

   Extraction processes should remediate the mycotoxin presence in the extracted material. The grower shall establish the microbiological and mycotoxin levels taking into consideration the intended consumer use of the finished product. For guidance, please see AHPA Guidance Document, “Microbiology & Mycotoxins,” found at:


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\(^7\) SMPR is Standard Method Performance Requirements.
2.5 Storage and Transportation

a. Storage of hemp shall be properly labeled to indicate a hold or available for release.

b. Storage of hemp shall be under appropriate conditions of temperature, humidity, and light so that the identity, purity, strength, and composition of the components and hemp are not affected.

c. Storage of hemp shall be properly labeled at all times to prevent adulteration, contamination and unintended comingling.

d. Storage of in-process material shall be held under appropriate conditions of temperature, humidity, and light.

e. Storage of packaging and labels shall be under conditions adequate to prevent the packaging and labels from being adversely affected.

f. Storage of packaging and labels shall be under conditions adequate to prevent adulteration of the hemp.

g. Transportation of hemp shall be under conditions that will protect the hemp against contamination and deterioration.

h. Transportation of hemp shall be under conditions that will protect the hemp against adulteration.

i. Labeling and storage of hemp shall at a minimum include information representative of variety, field and harvest date.
2.6 IMPORT / EXPORT

2.6.1 USDA & the Importation of Hemp Seeds and Hemp Plants for Planting

The passing of the Agriculture Improvement Act of 2018 ("2018 Farm Bill") removed hemp and hemp seeds from the Drug Enforcement Administration's ("DEA") schedule of Controlled Substances. Additionally, hemp stalk and hemp fiber and non-viable seed products have never been controlled substances in the United States. The 2018 Farm Bill action removed the entire hemp plant, its derivatives, and its seeds from DEA authority for parts and products containing THC levels not greater than 0.3 percent. Therefore, the DEA no longer has authority to require hemp seed permits for import purposes.

A person may only import hemp seed or hemp plants that are of an approved cultivar in the authority having jurisdiction where the hemp seed or hemp plant is to be sold or planted.

The U.S. Department of Agriculture (USDA) regulates the importation of all seeds for planting to ensure safe agricultural trade. USDA guidelines for the import of hemp seeds and hemp plants can be found at:


A summary follows:

a. Importation of Hemp Seed and Hemp Plants for Planting from Canada

i. Hemp seeds for planting may be imported into the United States from Canada if accompanied by either:

A. A phytosanitary certification from Canada's national plant protection organization (NPPO) to verify the origin of the seed and confirm that no plant pests are detected; or

B. A Federal Seed Analysis Certificate (SAC, PPQ Form 925) for hemp seeds harvested from plants grown in Canada.

ii. Hemp plants for planting may be imported into the United States from Canada if accompanied by a phytosanitary certificate from Canada's NPPO to verify the origin of the plant and to confirm that no plant pests are detected.

b. Importation of Hemp Seed and Hemp Plants for Planting from Countries other than Canada

i. Hemp seed for planting may be imported into the United States from countries other than Canada if accompanied by a phytosanitary certificate from the exporting country's NPPO to verify the origin of the seed and confirm that no plant pests are detected. Hemp seed shipments will be inspected upon arrival at the first port of entry by U.S. Customs and Border Protection (CBP) to ensure they meet APHIS\(^8\) regulations, including certification

\(^8\) U.S. Department of Agriculture Animal & Plant Health Inspection Service.
and freedom from plant pests.

ii. Hemp plants may be imported into the United States from countries other than Canada if accompanied by both:
   A. A phytosanitary certificate from the exporting country’s NPPO to verify the origin of the plant and to confirm no plant pests are detected; and
   B. An Application for Permit to Import Plants or Plant Products.

2.6.2 Export

As with importation, certain countries still consider hemp seeds and/or hemp plants and certain hemp derivatives/products to be controlled substances, and certain states and tribal governments may require specific authorization or licensing for exporting these items. Additionally, there is still confusion among government agencies and border / law enforcement as to the legal status of hemp. It is critical to procure proper legal and/or experienced professional service advice concerning any U.S. authorization, licensing, or documentation requirements for export, as well as the laws and regulations of the destination country.

a. An exporter who applies for a permit to export hemp plants, hemp seed, viable grain, raw hemp (non-seed), raw hemp materials or derivatives as may be necessary per the authority having jurisdiction and/or receiving country may be required to, and if so shall, submit the following information to the proper authority having jurisdiction:
   i. the name, mailing address and export number of the holder of the permit;
   ii. the permit number and the number of any license, if required, that authorizes the export;
   iii. the name of the consignee and their address in the country of importation;
   iv. country of origin;
   v. address of the port of exit from USA;
   vi. each mode of transportation used and the countries of transit and transshipment;
   vii. indicate whether seed, viable grain, raw hemp materials or derivatives are being exported and the quantity of each form exported;
   viii. the variety of hemp from which the hemp seed, viable grain, raw hemp materials or derivatives were harvested or, in the case of germplasm, its name or number;
   ix. the type of packaging for each form exported;
   x. the concentration of THC, expressed as a percentage concentration, in the flowering heads and leaves of the variety of hemp from which the seed, viable grain, raw hemp materials or derivatives were harvested;
   xi. a statement certifying that the package and the contents do not contravene any known requirement of the laws of the country from which the hemp seed, viable grain, raw hemp materials or derivatives originated, were imported, or any country of transit or transshipment;
   xii. the effective date of the permit; and
   xiii. the date of the expiration of the permit (if applicable).
b. An application, if required, shall be signed by the applicant or, in the case of a corporation, cooperative, or partnership, one of its officers, directors, or partners, as the case may be, and indicate that all information submitted in support of the application is correct and complete to the best of his or her knowledge.

c. A person who is authorized to export hemp seed, viable grain, raw hemp materials or derivatives as may be necessary shall ensure that a copy of the export permit is attached to the shipment of the hemp seed, viable grain, raw hemp materials or derivatives.

**PLEASE NOTE:** All imports and exports must meet the sanitary and phytosanitary requirements of USDA APHIS and possibly the country of origin or receipt.
2.7 STATE SEED LAWS AND TRUTH IN LABELING

State seed laws and regulations provide a system of checks and balances to ensure growers receive the expected product. These laws require accurate labeling and purity standards for all seeds in commerce and prohibit the importation and movement of adulterated or misbranded seeds. All 50 states have seed laws that govern the intrastate movement and sale of seed. These laws are basically "truth-in-labeling" laws designed to provide consumers with important information relating to product quality and identity. Growers should also be aware that interstate commerce of seed involves the Federal Seed Act, acting in coordination with the state seed laws. It is imperative that consumers get the quality and type of seed they desire, and that the seed will grow and produce their expected result. Existing state and federal laws are in place for that protection.
2.8 RECORD RETENTION

Growers/licensee shall keep records, electronically or in hard copy, that contain the following information for at least five (5) years after obtained, or longer if required by the authority having jurisdiction. Such information shall include but is not limited to the below. Refer to the authority having jurisdiction for any additional record retention requirements:

a. Record(s) of the authorization or licensing for hemp cultivation
b. Source and quantity of the imported or purchased hemp seed (imported or purchased or grown), and dates thereof and all accompanying documentation
c. Name and address and country of origin of the entity or person from whom the hemp seed was purchased, and, if licensed, the licensee name, license number, and issuer of the license
d. If propagated from a source other than seed, such as clones or seedlings, quantity and form in which the propagules are imported or purchased, dates thereof and all accompanying documentation
e. Name and address and country of origin of the entity or person from whom the propagules were purchased, and, if licensed, the licensee name, licensee number and issuer of the license
f. Variety of hemp planted
g. Germination certificate
h. Site history
i. Curing and drying records
j. Quantity and each form of hemp sold
k. Date of planting and harvest
l. Date of each pesticide, herbicide, fungicide and fertilizer application, if any
m. Destination of the hemp that is sold, name and address of the purchaser and, if applicable, the country to which it is exported
n. Date that each shipment of hemp is sent or received
   i. Name of the carrier
   ii. Results of any testing
   iii. Quantity shipped or received
o. Name of the person to whom the hemp was sold and, if applicable the licensee name and license number
p. Results of all testing
q. Disposition of any non-compliant hemp, including date(s) of disposition, method, individuals who performed the disposition, and evidence of disposition
r. Employee training records
2.9 PROHIBITIONS

Products with synthetic cannabinoids, biosynthetic cannabinoids, cannabimimetic phytochemicals in lieu of hemp-derived cannabinoids, bioengineered hemp, and or genetically engineered hemp are not eligible for U.S. Hemp Authority™ Certification. Only products containing cannabinoids derived from the hemp plant are eligible for U.S. Hemp Authority™ Certification.
2.10 OVERVIEW OF BEST FARM MANAGEMENT PRACTICES CHECKLIST

Although not mandatory under the U.S. Hemp Authority Certification Program, the following key best practices are recommended:

- Has the grower made contact with all local, state and regional federal law enforcement to make them aware of the grower’s operation and provided them with a copy of the grower’s license or authorization to cultivate hemp? (NOTE: this may be required by the authority having jurisdiction)
- Are you using the best soil available?
- Have you soil tested for macro and micro nutrients?
- Are you collecting data to determine nutrient needs to target desired yield per acre according to soil test?
- Are you using animal manure as a source of nutrients?
- If using animal manure as a source of nutrients, do you have testing results showing nutrient content and heavy metal levels?
- Have you used the appropriate growth medium for intended purposes?
- Did you use hemp seed and propagules suitable for your location?
- Do you have a water quality report or history?
- Have you consulted with your hemp seed and propagules source the optimum planting date and plant population per acre?
- Do you have adequate labor and equipment to harvest the plant?
- Do you have sufficient and proper drying facilities available?
- Do you have sufficient and proper storage facilities available?
- Do you have sufficient and adequate transportation equipment available?
2.11 OVERVIEW OF FACILITY & SECURITY CHECKLIST

There are many aspects of facility and security management to consider on the farm, some of which are not applicable to all farms. The U.S. Hemp Authority™ provides its independent, third-party auditors with a comprehensive checklist intended to account for a broad range of farms. Not every item is required for every farm. However, to the extent equipment exists, it must be in working order; and to the extent programs exist, they must be in written form and consistently followed and documented as necessary.
3 PROCESSORS/MANUFACTURERS

PLEASE NOTE: Hemp processors and manufacturers subject to FDA regulation must comply with the Federal Food, Drug and Cosmetic Act -- as amended by the Food Safety and Modernization Act -- as a baseline in addition to the requirements outlined by these Guidance Procedures. The requirements listed below in Guidance Procedures Processors/Manufacturers Section 3 serve as both an inexhaustive guide to complying with federal regulation, as well as supplemental requirements imposed by the U.S. Hemp Authority™ Certification Program.

Federal regulations that merit compliance include:

- 21 CFR §§ 101.1-101.108, 190.6—Food Labeling (including Dietary Supplements)
- 21 CFR §§ 111.1-111.610—Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements
- 21 CFR §§ 117.1-117.475—Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- 21 CFR §§ 701.1-701.30—Cosmetics Labeling
- 21 CFR §§ 740.1-740.19—Cosmetic Product Warning Statements

The FDA provides comprehensive information on Current Good Manufacturing Practices (CGMP) for foods and supplements on their website at this link:


The FDA provides guidance for the industry on Cosmetic Good Manufacturing Practices at this link:


Signature: _____________________________           Date: ________________________
Printed Name: __________________________   Company/Location: _______________________

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Disclaimer: The U.S. Hemp Authority™ is a tax-exempt organization, organized under section 501(c)(6) of the Internal Revenue Code, is legally independent of all other hemp organizations and companies, and is neither a governmental body nor a regulatory agency.
3.1 **HEMP PROCESSING OR HANDLING REGISTRATION / APPLICATION / NOTIFICATION**

Prior to the hemp processor/manufacturer processing any hemp seed or hemp product, a license, authorization, or agreement with the state or tribal government must be obtained where required by state or tribal government regulation. The following information is typical of that required to make the application before a license or registration will be issued: (Each state or tribal government may have different regulations – refer to application)

### 3.1.1 Registration / Application Guidance

- **a.** Applicant’s contact information, including a copy of current driver’s license for applicant and each proposed signing authority
- **b.** Full names of each individual who will be primarily responsible for the processing or handling of the applicant's hemp material
- **c.** Research plan, including the estimated quantity of hemp material to be processed annually
- **d.** Address of each location and GPS coordinates of each building or site where hemp will be stored, processed or handled
- **e.** Map(s) depicting each site where hemp will be processed, or stored, and designating entrances and specific points where GPS coordinates were taken
- **f.** Seed/propagule acquisition plan, including a list of proposed affiliated growers
- **g.** Material acquisition plan, including a list of proposed affiliated growers
- **h.** Marketing plan, including the type of products to be marketed and to whom
- **i.** Consent to all statements in the Acknowledgments Section in the Processor/Handler Application
- **j.** Quality Management Systems

### 3.1.2 Notification of Changes to the Licensor by the Licensee

Every licensee shall notify the state or tribal government of any changes to the information provided on the application, within 15 days after the change, including:

- **a.** Corporate name or ownership or officers and the replacement of an officer, or director
- **b.** Any change to the address to the licensee
- **c.** The replacement of an individual referred to as a licensee
- **d.** Any change in the mailing address of the licensee
- **e.** Any change in the ownership of the land used to cultivate hemp
- **f.** Any change to the approved cultivar being sown or, in the case of a plant breeder to the variety of hemp being sown

Any such changes shall also be communicated by the licensee to the U.S. Hemp Authority within 15 days after the change.
3.2 Additional Registration Requirements

Registration requirements are not limited to what may be required for hemp processing or hemp manufacturing. The authority having jurisdiction may require additional registration, permit or licensing based on the type of product being produced.

3.2.1 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Federal Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies. To carry out certain provisions of the Bioterrorism Act, FDA established regulations requiring that:

a. Food facilities register with FDA, and
b. FDA be given advance notice on shipments of imported food.

Unless exempted by law, compliance with the Bioterrorism Act which requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA, and such registration is required for U.S. Hemp Authority™ Certification.
3.3 PERSONNEL GUIDANCE

Qualified employees who manufacture, package, or label hemp shall be qualified to do so and those responsible for quality control or performing any quality control operations, must have the education, training, or experience to perform the assigned functions.

Supervisors shall be qualified by education, training, or experience to supervise.

Contamination prevention and hygienic measures shall be taken to exclude from any operations any person who might be a source of contamination.

Such measures shall include the following:

a. Excluding personnel from working in any operations that may have, an illness, infection, open lesion, or any other abnormal source of contamination

b. Instructing employees to notify their supervisor if there is a possibility that they have a health condition described above

c. Wearing outer garments in a manner that protects against the contamination

d. Maintaining adequate personal cleanliness

e. Washing hands thoroughly, and sanitizing if necessary, in a hand-washing facility

f. Removing or covering all unsecured jewelry and other objects that might fall into components, hemp, equipment, or packaging

g. Using gloves when appropriate

h. Wearing, where appropriate, hair nets, caps, beard covers, shoes, PPE, etc.

Personnel and employee safety measures shall include the following:

a. Appropriate and adequate first aid equipment

b. Adequate bathrooms and changing rooms

c. Appropriate OSHA warnings, labels, and training

d. Appropriate training and personal protective equipment
3.4 EMPLOYEE TRAINING

a. Quality Assurance (QA) or Training Manager shall ensure all personnel receive adequate training to complete assigned responsibilities safely and effectively prior to beginning the work.

b. All staff receive training upon hiring. Such training should track federal guidance, to include compliance with the Occupational Safety and Health Act and 26 CFR § 1910 (general).

c. Ongoing training related to job and current Good Manufacturing Practices (cGMP) requirements are conducted no less frequently than a yearly basis. All personnel are trained to follow Standard Operating Procedures (SOP) relevant to the tasks assigned to them.

d. The training program ensures all staff are trained or notified on the following, as required by job or regulatory requirements:
   i. Company policies and procedures
   ii. Emergency procedures
   iii. Hazardous materials
   iv. Hygiene and food-handling safety
   v. Industry policies and standards
   vi. Labeling and packaging
   vii. Product quality
   viii. Product testing
   ix. Regulatory inspections
   x. U.S. Hemp Authority™ Guidance Procedures
   xi. Recordkeeping
   xii. Sanitation and cleaning procedures
   xiii. Security
   xiv. Sexual harassment
   xv. Specific job training as required
   xvi. Violations and enforcement
   xvii. Worker health and safety

e. Training may be conducted internally, or by external parties, trade associations or consultants

f. Key personnel responsible for managing and supervising manufacture, quality assurance and quality control shall have the managerial and professional or technical skills and experience to assume responsibility for ensuring that products consistently meet standards and specifications.
   i. Job descriptions and organizational charts are used to establish areas of responsibility and are available to personnel.
   ii. The responsibilities placed on any one person should not be so extensive as to compromise the effective execution of assigned duties in relation to cGMP.
   iii. Personnel in responsible positions should have adequate authority to perform their duties.
iv. QA shall reinforce training effectiveness through testing comprehension, observing behaviors in the workplace, and providing timely feedback.

v. Personnel with less than the required qualifications or experience should be provided with a training program designed to make up deficiencies.

vi. Personnel should be presented work instructions in the appropriate language and be expected to complete forms, documents, and all applicable paperwork correctly and accurately.

vii. General Precautions for Training: Personnel shall not be permitted to sign or initial a document unless they have been trained in the task associated with the signature and in the significance of the signature.

viii. Personnel working in areas where contamination is a hazard, e.g. clean areas or areas where highly active, toxic, infectious or sensitizing materials are handled, should be given specific training.

ix. Visitors or untrained personnel shall not be permitted into production, storage or Quality Control (QC) areas without direct supervision.

x. Casual or contract personnel (including cleaners) should also receive appropriate induction training in cGMP.

g. Records retention: training records shall be retained for at least five (5) years, or longer if required by the authority having jurisdiction.
3.5 **Physical Plant and Grounds**

- Facilities shall provide adequate space for the equipment and materials necessary for normal operations as well as maintenance, cleaning, and sanitizing operations and to prevent contamination.

- Facilities used in the processing, packaging, labeling, or holding of hemp shall be adequate in size, construction, and design. Equipment that controls temperature and humidity as well as fans and other air-blowing equipment used shall be adequate for the size of the facility.

- Aisles or working spaces between equipment and walls shall be adequate to permit all persons to perform their duties.

- Adequate light shall be available in all areas as needed.

- Facilities shall be maintained to protect against contamination of components.

- Facilities shall be maintained in a state of repair sufficient to prevent hemp or products contamination.

- Facilities shall have adequate bathrooms and changing rooms.

- Facilities shall have a sanitary/cleaning plan.

- Cleaning compounds, sanitizing agents, pesticides, and other toxic materials must be free from microorganisms and be safe and adequate under the conditions of use.

- Pest control includes not allowing animals or pests in any area of the facilities except guard or working dogs.

- Insecticides, fumigants, fungicides, herbicides, or rodenticides shall be used with care and in the intended manner.

- Water supply needs to meet EPA drinking water standards, be safe and sanitary, at suitable temperatures, and under pressure as needed for appropriate use.

- Plumbing in the facility shall be of an adequate size and design and be adequately installed and maintained to satisfy operational needs.

- All drainage shall be adequate for operations and to prevent contamination of hemp products or components, including the use of backflow prevention.

- Sewage disposal shall be adequate for operational needs and bathrooms.

- Hand-washing facilities shall be available and designed to ensure that an employee’s hands are not a source of contamination of hemp products.

- Trash disposal shall be adequate to minimize odors, the attraction of pests, or becoming a source of contamination.

- Grounds shall be maintained to protect against contamination of components.

- Ground maintenance includes:
  - Properly storing equipment, removing litter and waste, and cutting weeds or grass so that it does not attract pests, harbor pests, or provide pests a place for breeding
  - Maintaining roads, yards, and parking lots to prevent contamination of hemp products
  - Adequately operating waste treatment and disposal
3.6 OVERVIEW OF FACILITY & SECURITY CHECKLIST

There are many aspects of facility and security management to consider, some of which are not applicable to all facilities. The U.S. Hemp Authority™ provides its independent, third-party auditors with a comprehensive checklist intended to account for a broad range of facilities. Not every item is required for every facility. However, to the extent equipment exists, it must be in working order; and to the extent programs exist, they must be in written form and consistently followed and documented as necessary.
3.7 **QUALITY MANAGEMENT SYSTEMS**

Quality management systems (QMS) must be developed and implemented for manufacturing, packaging, labeling, and holding operations.

Quality management systems based on food safety programs such as HACCP may be used to complement internal quality programs required for the U.S. Hemp Authority™ Certification Program. Personnel with sufficient expertise in food safety and preventive controls, having undergone Preventative Controls Qualified Individual (PCQI) training required under the Food Safety Modernization Act (FSMA), are required to administer food safety programs.

### 3.7.1 Establishment of Specifications

Specifications must be established for:

a. Any point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the hemp product.

b. For each component used in the manufacture of a hemp product
   
   i. Component specifications as follows:
      
      A. Identity specification;
      
      B. Specifications that are necessary to ensure purity, strength and composition of limits on those types of contamination that may adulterate or may lead to the adulteration of the finished batch of the hemp product to ensure the quality of the hemp product.

c. For the in-process production:
   
   i. In-process specifications for any point, step, or stage in the master manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the hemp products;
   
   ii. Relevant and valid documentation for meeting the in-process specifications, in combination with meeting component specifications, will help ensure that the specifications are met for the identity, purity, strength, and composition of the hemp products and for limits on those types of contamination that may adulterate, or may lead to adulteration of the finished batch of the hemp product;
   
   iii. Quality control personnel must review and approve the documentation of the U.S. Hemp Authority™ Certification Program.

d. Specifications must be established for hemp product labels (label specifications) and for packaging that may come in contact or quality of the hemp product.

e. Each hemp product manufactured must have established product specifications for the identity, purity, strength, and composition of the finished batch of the hemp product, and for limits on those types of contamination that may adulterate, or that may lead to adulteration of, the finished batch of the hemp product to ensure the quality of the hemp product.

f. Products received from a supplier for packaging or labeling as a hemp product (and for distribution rather than for return to the supplier), must have specifications to provide sufficient assurance that the product received is adequately identified and is consistent with your purchase order.
g. Specifications must be established for the packaging and labeling of the finished hemp products, including specifications that ensure the use of the specified packaging and the specified label.

h. Written procedures must be established for Quality Management Systems, including written procedures for conducting a material review and making a disposition decision, and for approving or rejecting any reprocessing.

3.7.2 Guidance for Quality Management Systems Personnel

Quality management systems personnel must ensure that the manufacturing, packaging, labeling, and holding operations ensure the quality of the hemp product and that the hemp product is packaged and labeled as specified in the master manufacturing record. Quality management personnel must perform operations that include:

a. Approving or rejecting all processes, specifications, written procedures, controls, tests, and examinations, and deviations from or modifications to them, that may affect the identity, purity, strength, or composition of a hemp product;

b. Reviewing and approving the documentation setting forth the basis for qualification of any supplier;

c. Reviewing and approving the documentation setting forth the basis as to why meeting in-process specifications, in combination with meeting component specifications, will help ensure that the identity, purity, strength, and composition are met.

3.7.3 Guidance Requirements for In-House and Independent, Third-Party Hemp Laboratory Operations

Hemp in-house and independent, third-party laboratory operations shall establish and follow written procedures for laboratory operations, including written procedures for the tests and examinations to be conducted to determine whether specifications are met.

Adequate laboratory facilities shall be available to perform whatever testing and examinations are necessary to determine whether:

a. Components used meet specifications

b. In-process specifications are met as specified in the master manufacturing record

c. All laboratory control processes must be reviewed and approved by quality control personnel, including the following:

   i. Use of criteria for establishing appropriate specifications

   ii. Use of sampling plans for obtaining representative samples

      A. Components, packaging, and labels

      B. In-process materials

      C. Product received for packaging or labeling

         I. Use of criteria for selecting appropriate fit for purpose testing methods

         II. Use of criteria for selecting standard reference materials used in performing analytical testing
III. Use of test methods and examinations in accordance with established criteria

d. The following requirements apply to laboratory methods for testing and examination:

i. Verification that the laboratory examination and testing methodologies are fit for purpose and use ISO 17025-certified\(^9\) methods when available

ii. Identify and use the appropriate scientifically valid and fit for purpose method for each established specification for which testing or examination is required to determine whether the specification is met

iii. Identify and use the appropriate reference materials that have been produced and certified under ISO 17034 requirements. Reference materials must be accompanied with a certificate of analysis that lists the certified purity of the material. Preferably, materials are certified by an independent, third-party laboratory using highly precise methods such as Nuclear Magnetic Resonance (NMR)

\(^9\) International Organization for Standardization.
3.8 **Supplier Qualification & Specifications**

a. Management or your Quality Management System (QMS) personnel shall assess suppliers of starting materials (where possible by direct audit) and assign, where appropriate “approved supplier” or “certified supplier” status. Suppliers are evaluated based on level of risk.

b. Material should not be granted “approved supplier” status except in relation to materials in sealed containers bearing the manufacturers’ original label and batch, lot or equivalent number.

c. Management or your QMS personnel shall evaluate suppliers of materials, equipment, consumables and services which affect the quality of materials and their measurement.

d. Management or your QMS personnel shall maintain records of supplier evaluations and list those approved.

e. Specifications for materials shall be reviewed and discussed with suppliers on a periodic basis. All aspects of the production and control of materials, in addition to handling, labeling, and packaging requirements, as well as complaints and rejection procedures, are reviewed and approved by both manufacturer and the supplier.

f. Suppliers are responsible for the following:

   i. Meeting product specifications with valid tests and verifications for materials

   ii. Ensuring the integrity of product and packaging

   iii. Ensuring all documentation establishes traceability from raw materials to customer delivery, including orders, delivery notes, product labels, specifications and test results

   g. Material specifications include, where applicable:

   i. Standard product name to be used in production documents, and compendia name if applicable

   ii. Supplier’s product code and trade names

   iii. Supplier’s name and address

   iv. A unique reference code for the material specification and approval date

   v. Tests and limits for identity, purity, physical and chemical characteristics, microbiological standards (where appropriate) and assay or potency

   vi. Details of, or reference to, the test methods to be used by the manufacturer

   vii. Approved or certified supplier(s) of the material

   viii. Type of packaging, storage conditions and precautions

   ix. Physical appearance and characteristics

   x. Precautions or reference to appropriate parts of a standard procedure

   xi. Period during which approval will remain valid (e.g. review frequency or date)
3.9 **SAMPLING AND HANDLING HEMP FOR THC & CANNABINOID ANALYSIS**

For sampling and handling hemp products for THC and cannabinoid analysis, processors and manufacturers shall utilize, at a minimum, the following requirements:

a. The samples must be representative.

b. With regard to variability of starting materials, the confidence intervals and the level of necessary precision, the number of containers from which samples are taken as well as the amount of material sampled must be based on statistical criteria.

c. The sampling plan must take into account the past quality history of the supplier.

d. The sample quantity must be sufficient in size to perform analysis and to keep reserve samples.

e. The processor/manufacturer is required to develop an approach that guarantees a high level of certainty that each container contains exactly the material indicated on the label.
3.10 CONTAMINANT TESTING AND HEMP CANNABINOID QUANTIFICATION

3.10.1 Potency / Strength Cannabinoid Quantification

Refer to the authority having jurisdiction for any cannabinoid quantification analysis regulations or guidance applicable to your license. In the absence of such cannabinoid quantification analysis regulations or guidance by the authority having jurisdiction, use these Guidance Procedures which are based on references found in the American Herbal Pharmacopeia (AHP) Cannabis monograph, the American Herbal Products Association (AHPA) Guidance Policies, and methods available through AOAC.\(^{10}\)

To ensure that methods measuring cannabinoids are fit for purpose, laboratories should adopt analytical methods that meet SMPR 2017.002 (attached in Appendix) approved by Cannabis stakeholders with AOAC.

a. Processors/Manufacturers must quantify THC level and any other cannabinoid required by the authority having jurisdiction. In addition, testing for levels of all cannabinoids present in the finished product is required for proper labeling.

b. List all target plant parts of hemp (flower, leaf, stalk, seed) and oils/extracts.

c. Third-party laboratories and their relevant methods must be ISO 17025 accredited unless such accreditation conflicts with laboratories mandated by the authority having jurisdiction.

Cannabinoid potency methods must be able to determine the concentration of target cannabinoids to effectively distinguish Cannabis as either legal hemp or marijuana. Specifically, methods must be accurate and precise at concentrations that bracket 0.3% THC.

Processors and manufacturers shall refer to the authority having jurisdiction for regulations regarding the disposal of non-compliant material.

3.10.2 Purity & Contaminants

Hemp is a phytoremediator, meaning it absorbs contaminants in the soil including, among others, heavy metals and pesticides. Hemp products intended for human consumption, including cosmetics, are subject to federal regulations, and may be subject to and state or tribal regulations regarding harmful substances and contaminants.

Various extraction methods can lead to different levels of contaminants. Refer to the authority having jurisdiction for any contaminant analysis regulations or guidance applicable to your license. In the absence of such contaminant analysis regulations or guidance by the authority having jurisdiction, use these Guidance Procedures which are based on references found in the American Herbal Pharmacopeia (AHP) Cannabis monograph, the American Herbal Products Association (AHPA) Guidance Policies, the U.S. Food and Drug Administration (FDA) Pesticide Analytical Manual (PAM),\(^{11}\) and methods available through AOAC. Refer to these documents and AOAC for fit for purpose methods.

\(^{10}\) AOAC International (formerly Association of Analytical Chemists); SMPR is standard method performance requirements.

\(^{11}\) The FDA is responsible under the Federal Food, Drug, and Cosmetic Act for enforcing tolerances established by the Environmental Protection Agency (EPA) for amounts of pesticide residues that may legally remain on food.
Heavy Metals, Pesticides, Solvents, Microbiology and Mycotoxins: These limits are listed in the American Herbal Pharmacopoeia Cannabis Monograph, “Standards of Identity, Analysis and Quality Control” and the following AHPA Guidance Documents:

“Microbiology & Mycotoxins,” found at:


“Guidance on Heavy Metals,” found at:


Pesticides: Limits for foods are listed in AOAC Official Method 2007.1, “Pesticide Residues in Foods,” found at:


Residual Solvents: These limits are listed in U.S. Pharmacopeia (USP) 30, Section 467, “Residual Solvents,” found at:


Notes:

a. AHPA guidance does not include the stricter limits for lead consumption required in the state of California under Proposition 65. Also note that most pesticide testing panels do not include glyphosate; thus, if glyphosate testing is desired, that request must generally be specifically and separately made to the lab.

b. Microbiology limits are based on products consumed orally.
3.11 **Equipment and Utensils**

a. Equipment and utensils shall be designed and built so that use will not result in contaminations.

b. Equipment and multi-use utensils shall be designed, and built, to be suitable for their intended use and able to be adequately cleaned and properly maintained.

c. Equipment shall be installed and maintained to facilitate cleaning the equipment, utensils, and all adjacent spaces.

d. Equipment shall be maintained to protect hemp from contaminants.

e. Equipment shall have a certificate of Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ).

f. Freezer, refrigerator, and other cold storage equipment shall have a working thermometer.

g. Compressed air or other gases shall be used and be treated in such a way that the hemp product or contact surface is not contaminated.

h. Instruments and controls used in processing, manufacturing, packaging or labeling or testing hemp products shall be calibrated as necessary to assure accuracy.

i. Automated, or electronic equipment used to process, manufacture, package, label, or hold hemp products shall be designed to ensure that hemp product specifications are consistently met.

j. Equipment shall be properly calibrated according to the manufacturer’s specifications.

k. Automated, mechanical, and electronic equipment (including software for a computer-controlled process) shall be used and operated by trained personnel for proper use.

l. Utensils intended for one-time use, (e.g. paper cups, and paper towels, etc.) shall be stored in appropriate containers and disposed of to prevent contamination.

Cleaning materials shall be approved and properly labeled for intended use and safe under their conditions of use.
3.12 PRODUCTION AND PROCESS CONTROL

a. Production and in-process control system shall be designed to ensure that the hemp is manufactured, packaged, labeled, and held in a manner that will ensure the quality of the hemp and that the hemp is packaged and labeled as specified in the manufacturing record.

b. Specifications shall be made for any part of the manufacturing process where control is necessary, and limits are set to ensure the quality and consistency of the hemp products.

c. In-process production shall have established in-process specifications for any part in the manufacturing record where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the hemp products and, as necessary, for limits on those types of contamination that may adulterate or may lead to adulteration of the finished batch of the hemp product.

d. Production documentation shall be made for meeting the in-process specifications.

e. Quality control personnel shall review and approve the in-process documentation.

f. Product definitions and specifications shall be established for all hemp products for identity, purity, strength, and composition of the hemp product.

g. Product specifications shall also include the packaging and labeling requirement of the finished packaged and labeled hemp.

h. Labeling operations procedures shall be made for packaging hemp products.

i. Quality Management Systems in the manufacturing, packaging, labeling, and holding of hemp products shall ensure the quality of the hemp product is as specified in the manufacturing record.

j. Quality control procedures shall include:
   i. Verify the identity of any component that is to be used in the production or processing of the hemp products.
   ii. Maintain documentation of verification.
   iii. Monitor each in-process part of the process where control is necessary to ensure the quality of the hemp products.
   iv. For each batch or lot of finished hemp products, a sample shall be taken to verify, if necessary, that the batch meets its product specifications.
3.13 PRODUCTION AND PROCESS CONTROL SYSTEMS MASTER MANUFACTURING RECORD

a. A written master manufacturing record must be produced for each unique formulation of a hemp product that is manufactured, and for each batch size, to ensure transparency and uniformity in the finished batch from batch to batch.

b. The master manufacturing record:
   i. Provides transparency of supply chain data;
   ii. Identifies specifications for the points, steps, or stages in the manufacturing process where control is necessary to ensure the quality and labeled as specified in the master manufacturing record; and
   iii. Establishes controls and procedures to ensure that each batch of product that is manufactured meets the specifications identified in accordance with Guidance Procedures.

c. The master manufacturing record must include:
   i. Transparency of supply chain data including but not limited to grower information as well as raw material and finished product test results for purity, contaminants, and cannabinoid quantification;
   ii. The name of the product to be manufactured and the strength, concentration, weight, or measure of each hemp product for each batch size;
   iii. A complete list of components to be used;
   iv. An accurate statement of the weight or measure of each component to be used;
   v. The identity and weight or measure of each hemp product ingredient that will be declared on the label and the identity of each ingredient that will be declared on the ingredients list of the hemp product;
   vi. A description of packaging and a representative label, or a cross-reference to the physical location of the actual or representative label; and
   vii. Written instructions, including the following:

A. Specifications for each point, step, or stage in the manufacturing process where control is necessary to ensure the quality of the hemp product and that the hemp product is packaged and labeled as specified in the master manufacturing record;

B. Procedures for sampling and a cross-reference to procedures for tests or examinations; and

C. Specific actions necessary to perform and verify points, steps, or stages in the manufacturing process where control is necessary to ensure the quality of the hemp product and that the hemp product is packaged and labeled as specified in the master manufacturing record.
3.14 Packaging and Labeling

Packaging and Labeling products received, but not processed, shall have a control system to examine each container to determine that the appropriate product was received, content labeled, and that the container had no damage, contamination or deterioration of the components.

3.14.1 Labeling Practices

a. All products labeled for consumer use shall be labeled according to applicable parts of Title 21 to the Code of Federal Regulations for foods and dietary supplements, the Food Drug & Cosmetic Act for cosmetics as applicable, as well as any additional state or tribal government requirements. Dietary supplements shall also comply with guidelines promulgated by the Federal Trade Commission as found in the agency’s “Dietary Supplements: An Advertising Guide for the Industry,” found at:


b. All finished hemp products derived from hemp not grown in the United States shall be labeled with the hemp country or countries of origin as defined herein, and consistent with 19 CFR Part 134. All finished hemp products derived from hemp grown in the United States may be labeled with a statement such as “produced from hemp grown in the U.S.” The hemp country of origin statement must be conspicuous and must appear in close proximity to the name and address of the firm responsible for manufacturing or distributing the product and be at least comparable in size of lettering. Country abbreviations are not acceptable. All labeling and marketing must be legible and clearly identifiable.

c. Use of the terms “broad spectrum,” “full spectrum,” and “isolate” on labels shall be consistent with the definitions of these terms in Section 1 of these Guidance Procedures. Any use of isolate as an ingredient in an ingestible product shall be included in the ingredients list.

d. All claims must be truthful and not misleading.

e. All ingredients added to the product must be declared, consistent with the FDA’s guidance, found at:


f. Bioengineered food must be labeled consistent with the requirements of 7 CFR Part 66.

g. Genetically engineered ingredients in dietary supplements and additives to foods and beverages, must be labeled consistent with the labeling policies found in the Food and Drug Administration’s “Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants,” Docket Number: FDA-2000-D-0075. Adherence to the FDA Guidance is mandatory for labeling of ingredients derived from genetically engineered organisms that may not contain detectable DNA.

h. Hemp products packaged for retail sale should have a “best by date” on the package.

i. No products may have labels or marketing that claim to diagnose, treat, prevent or cure any disease.
j. All dietary supplements and cosmetics intended to support the structure or function of the body must include a disclaimer such as: “This product is not intended to diagnose, treat, cure or prevent any disease.”

k. All products containing measurable amounts of cannabinoids should include proper warnings and cautions, such as the following:
   i. This product should be used with caution when driving motor vehicles or operating heavy machinery.
   ii. Use this product under the guidance of a physician if you have a medical condition, are pregnant or lactating.
   iii. Keep out of the reach of children.
   iv. This product meets federal requirements for hemp products; however, consumption may be flagged by some drug tests.
   v. Use with caution if subject to urinalysis.

3.14.2 Appropriate Nutrition Facts and Supplement Facts Panels

a. Nutrition Facts panels must be included on food and beverage products and supplement fact panels must be included on dietary supplement products.

b. Food and beverage nutrition fact panels should follow FDA guidelines that are outlined in the FDA Food Labeling Guide, found at:

c. Supplement fact panels should follow FDA guidelines that are outlined in the FDA’s Dietary Supplement Guide, found at:

d. Cosmetics should be labeled consistent with the FDA’s Cosmetic Labeling Guide, found at:
   https://www.fda.gov/media/88234/download

3.14.3 Guidance for Packaging and Labeling Operations

a. Packaging and labeling operations shall be such that the condition of the packaging will ensure the quality of the hemp products and shall be compliant with all applicable food packaging and contact regulations and requirements.

b. Issuance and use of packaging and labels shall be controlled and recorded.

c. Packaging and labels for each lot or batch of hemp product shall be documented to determine whether the packaging and labels conform to the manufacturing record.

d. Packaged and labeled hemp products shall be documented through distribution.

e. Packaging, labeling, and other related operations shall ensure that the quality of the hemp products are packaged and labeled as specified in the manufacturing record, including the following:
   i. Cleaning and sanitizing all filling and packaging equipment, as appropriate.
ii. Protecting hemp products from contamination, including airborne contamination.

iii. Using sanitary handling procedures.

iv. Establishing physical or spatial separation of packaging and label operations from operations on other components.

v. Identifying containers that are set aside and held in unlabeled condition.

vi. Assigning a batch or lot number to each lot of packaged and labeled hemp product from a finished batch.

f. Representative samples of each batch of the packaged and labeled hemp product shall be kept to determine whether the product meets specifications.

g. Suitably disposing of labels and packaging which are obsolete or incorrect to ensure that they are not used in any future packaging and label operations.

h. Records shall be kept of the written procedures for packaging and labeling operations.

i. Quality management personnel shall approve the hemp products for final distribution/sale.

### 3.14.4 Quality Control Procedures for Packaging and Labeling

Quality control procedures for packaging and labeling shall include:

a. Determine whether the received product meets the product specification.

b. Approval of the components for use in the packaging and labeling of a hemp product.

c. Identifying each unique lot within each shipment of components received so that it can be tracked through the packaging, labeling, marketing, and distribution processes.

d. Storage of the components shall be under conditions that will protect against contamination and deterioration.

e. Collection of a representative sample of each lot of product.

f. Hold packaging material and labels under conditions that will protect against contamination and deterioration.
3.15 HOLDING AND DISTRIBUTING

a. Holding of hemp and hemp products shall be properly labeled at all times to prevent contamination and unintended commingling.

b. Holding of hemp and hemp products shall be properly labeled to indicate a hold or available for release.

c. Holding of in-process material shall be identified under conditions that prevent mix-ups, contamination, and deterioration.

d. Holding of in-process material shall be held under appropriate conditions of temperature, humidity, and light.

e. Holding of packaging and labels shall be made under conditions adequate to prevent the packaging and labels from being adversely affected.

f. Holding of packaging and labels shall be under conditions adequate to prevent adulteration of product.

g. Distribution of hemp

h. Products shall be under conditions that will protect the products against contamination, deterioration, and adulteration.

i. Holding of hemp shall be in under appropriate conditions of temperature, humidity, and light so that the identity, purity, strength, and composition of the components and hemp are maintained.
3.16 Quality Control Operations Related to Product Complaints, Adverse Events and Recalls

Quality control operations for product complaints, adverse events, and recalls must include reviewing and approving decisions about whether to investigate a product complaint and reviewing and approving the findings, and follow-up action of any investigation performed.

The following records must be kept:

a. Written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision and written procedures for approving or rejecting any reprocessing.

b. Written documentation, at the time of performance, that quality control personnel performed the review, approval, or rejection requirements by recording the following:
   i. Date that the review, approval, or rejection was performed; and
   ii. Signature of the person performing the review, approval, or rejection.

c. Documentation of any material review and disposition decision and follow-up. Such documentation must be included in the appropriate batch production record and must include:
   i. Identification of the specific deviation or the unanticipated occurrence;
   ii. Description of your investigation into the cause of the deviation from the specification or the unanticipated occurrence;
   iii. Evaluation of whether or not the deviation or unanticipated occurrence has resulted in or could lead to a failure to ensure the quality of the product or a failure to package and label the hemp product as specified in the master manufacturing record;
   iv. Identification of the action(s) taken to correct, and prevent a recurrence of, the deviation or the unanticipated occurrence;
   v. Explanation of what you did with the component, hemp products, packaging, or label;
   vi. A scientifically valid reason for any reprocessing of a product that is rejected or any treatment or in-process adjustment of a component that is rejected; and
   vii. The signature of the individual(s) designated to perform the quality control operation, who conducted the material review and made the disposition decision, and of each qualified individual who provides information relevant to that material review and disposition decision.

d. Product Withdrawal and Recall

The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall:
   i. Identify those responsible for initiating, managing and investigating a product withdrawal or recall;
   ii. Describe the procedures to be implemented by site management;
   iii. Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident; and
iv. Investigation shall be undertaken to determine the cause of a withdrawal, mock recall, or recall and details of investigations and any action taken shall be documented.
3.17 IMPORT / EXPORT

3.17.1 The Agriculture Improvement Act of 2018 ("2018 Farm Bill")

The passing of the Agriculture Improvement Act of 2018 ("2018 Farm Bill") removed hemp and hemp seeds from the Drug Enforcement Administration’s ("DEA") schedule of Controlled Substances. Additionally, hemp stalk and hemp fiber and non-viable seed products have never been controlled substances in the United States. The 2018 Farm Bill action removed the entire hemp plant, its derivatives, and its seeds from DEA authority for parts and products containing THC levels not greater than 0.3 percent. Therefore, the DEA no longer has authority to require hemp seed permits for import purposes. The U.S. Department of Agriculture (USDA) regulates the importation of all seeds and plants for planting to ensure safe agricultural trade. See Section 2.6.1 of these Guidance Procedures for additional information.

3.17.2 Additional Import Requirements & Guidance

As noted above, the 2018 Farm Bill removed hemp and hemp seeds from the DEA’s schedule of Controlled Substances. However, certain countries still consider hemp and/or hemp seeds and certain hemp derivatives / products to be controlled substances, and certain states and tribal governments may require specific authorization, licensing, and/or documentation for importing these items. Additionally, there is still confusion among government agencies and border / law enforcement as to the legal status of hemp. Check with the jurisdiction(s) having authority as to any authorization, licensing, or documentation requirements for import and obtain proper legal or experienced professional service advice if necessary.

a. When viable grain is imported, the importer shall ensure that each shipment is accompanied by a document, issued by the competent authorities.

Production of viable grain meets requirements that:

i. are equivalent to those set out in these Guidance Procedures; and

ii. ensure that the viable grain will not produce a plant containing more than 0.3% total THC in any part of the plant.

b. An importer who applies for a permit to import hemp seed, viable grain, raw hemp (non-seed) materials or derivatives as may be necessary per the authority having jurisdiction and/or exporting country may be required to, and if so shall, submit the following information to the proper authority having jurisdiction:

i. the name, mailing address and importer number of the holder of the permit;

ii. the permit number and the number of any license, if required, that authorizes the importation;

iii. the name of the exporter and their address in the country of export;

iv. country of origin;

v. address of the port of entry into USA;

vi. each mode of transportation used and the countries of transit and transshipment;

vii. indicate whether seed, viable grain, raw hemp materials or derivatives are being imported and the quantity of each form imported;
viii. the variety of industrial hemp from which the seed, viable grain, raw hemp materials or derivatives was harvested or, in the case of germplasm, its name or number;

ix. the type of packaging for each form imported;

x. the concentration of THC, expressed as a percentage w/w, in the flowering heads and leaves of the variety of industrial hemp from which the seed, viable grain, raw hemp materials or derivatives were harvested;

xi. a statement certifying that the package and the contents do not contravene any known requirement of the laws of the country from which the hemp seed, viable grain, raw hemp materials or derivatives originated, were imported, or any country of transit or transshipment;

xii. the effective date of the permit; and

xiii. the date of the expiration of the permit (if applicable).

An import application, if required, shall be signed by the applicant or, in the case of a corporation, cooperative, or partnership, one of its officers, directors, or partners, as the case may be, and indicate that all information submitted in support of the application is correct and complete to the best of his or her knowledge.

c. A person who is authorized to import hemp seed, viable grain, raw hemp materials or derivatives as may be necessary shall ensure that a copy of the import permit is attached to the shipment thereof.

3.17.3 Export

As with importation, certain countries still consider hemp and/or hemp seeds and certain hemp derivatives/products to be controlled substances, and certain states and tribal governments may require specific authorization or licensing for exporting these items. Additionally, there is still confusion among government agencies and border / law enforcement as to the legal status of hemp. It is critical to procure proper legal and/or experienced professional service advice concerning any U.S. authorization, licensing, or documentation requirements for export, as well as the laws and regulations of the destination country.

a. An exporter who applies for a permit to export hemp products as may be necessary per the authority having jurisdiction and/or receiving country may be required to, and if so shall, submit the following information to the proper authority having jurisdiction:

i. the name, mailing address and export number of the holder of the permit;

ii. the permit number and the number of any license, if required, that authorizes the export;

iii. the name of the consignee and their address in the country of importation;

iv. country of origin;

v. address of the port of exit from USA;

vi. each mode of transportation used and the countries of transit and transshipment;

vii. indicate which hemp products are being exported and the quantity of each;

viii. the type of packaging for each hemp product exported;
ix. the concentration of THC, expressed as a percentage by concentration, in the hemp product;

x. a statement certifying that the package and the contents do not contravene any known requirement of the laws of the country from which the hemp originated, was imported, or any country of transit or transshipment;

xi. the effective date of the permit; and

xii. the date of the expiration of the permit (if applicable).

An application, if required, shall be signed by the applicant or, in the case of a corporation, cooperative, or partnership, one of its officers, directors, or partners, as the case may be, and indicate that all information submitted in support of the application is correct and complete to the best of his or her knowledge.

b. A person who is authorized to export hemp products as may be necessary shall ensure that a copy of the export permit is attached to the shipment of the hemp products.

**PLEASE NOTE:** All imports and exports must meet the sanitary and phytosanitary requirements of USDA APHIS\(^\text{12}\) and possibly the country of origin or receipt.

\(^{12}\) U.S. Department of Agriculture Animal & Plant Health Inspection Service.
3.18 RECORD RETENTION

Processor, packagers, and labelers shall keep records, electronically or hard copy, for at least five (5) years after processor operations, or longer if required by the authority having jurisdiction. This shall include but is not limited to:

a. Records of the license or other authorization or registration for hemp processing, manufacturing or handling
b. Source of the hemp, including name and address and the country of origin
c. Quantity and form in which the hemp is purchased and country of origin
d. Grower(s)’ record(s) of the authorization or licensing for hemp cultivation
e. Variety of hemp
f. Hemp country of origin
g. Destination of the hemp products that are sold, date that they are sold, name and address of the purchaser, and the country to which it is exported
h. Date that each shipment of hemp in any form is sent or received
   i. Name of the carrier
   ii. Results of any tests
   iii. Quantity shipped
i. Written procedures of production processes (master manufacturing records, sanitation processes, packaging and labeling, etc.)
j. Product complaints, adverse events and all recall procedures and processes
k. Images of all products and labels
l. Processing records, including the time the operations were performed, the components, packaging, labels, or products used, and the batch and lot number for the finished product
m. Any and all certification documents
n. Records kept shall be originals or true copies, such as photocopies, or other accurate reproductions of the original records, or as electronic records
o. Results of all tests and fit for commerce or fit for transport certifications when required
p. Disposition of any non-compliant hemp material, including date of disposition, method, individuals who performed the disposition
3.19 PROHIBITIONS

Products with synthetic cannabinoids, biosynthetic cannabinoids, cannabimimetic phytochemicals in lieu of hemp-derived cannabinoids, bioengineered hemp, and or genetically engineered hemp are **not eligible** for U.S. Hemp Authority™ Certification. Only products containing cannabinoids derived from the hemp plant are eligible for U.S. Hemp Authority™ Certification.
4 BRAND OWNERS

PLEASE NOTE: Brand owners subject to FDA regulation must comply with the Federal Food, Drug and Cosmetic Act -- as amended by the Food Safety and Modernization Act -- as a baseline in addition to the requirements outlined by these Guidance Procedures. The requirements listed below in Guidance Procedures Brand Owners Section 4 serve as both an inexhaustive guide to complying with federal regulation, as well as supplemental requirements imposed by the U.S. Hemp Authority™ Certification Program.

Federal regulations that merit compliance include:

- 21 CFR §§ 101.1-101.108, 190.6—Food Labeling (including Dietary Supplements)
- 21 CFR §§ 111.1-111.610—Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements
- 21 CFR §§ 117.1-117.475—Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- 21 CFR §§ 701.1-701.30—Cosmetics Labeling
- 21 CFR §§ 740.1-740.19—Cosmetic Product Warning Statements

The FDA provides comprehensive information on Current Good Manufacturing Practices for foods and supplements on their website at this link:


The FDA provides guidance on Cosmetic Good Manufacturing Practices at this link:

4.1 HEMP SPECIFIC REGISTRATION / APPLICATION / NOTIFICATION

Prior to the hemp brand owner handling any finished hemp product, a license or agreement with the state or tribal government must be obtained if required by the authority having jurisdiction. The following information is typical of that required to make the application before a license or other authorization will be issued: (Each state or tribal government may have different regulations – refer to application.)

4.1.1 Registration / Application Guidance

a. Applicant’s contact information, including a copy of current driver’s license for applicant and each proposed signing authority
b. Full names of each individual who will be primarily responsible for oversight of the suppliers or co-manufacturers of the applicant’s finished hemp product(s)
c. Address of each location and GPS coordinates of each building or site where finished hemp products will be packaged, labeled, distributed, held, or used
d. A list of hemp extract and cannabinoid suppliers
e. Marketing plan, including the type of products to be marketed and to whom
f. Consent to all statements in the Acknowledgments Section in the application
g. A Statement of Quality Management Systems

4.1.2 Notification of Changes to the Licensor by the Licensee

Every licensee shall notify the state or tribal government of any changes to the information provided on the application, within 15 days after the change, including:

a. Corporate name or ownership or officers and the replacement of an officer, or director
b. Any change to the address to the licensee
c. The replacement of an individual referred to as a licensee
d. Any change in the mailing address of the licensee

Any such changes shall also be communicated by the licensee to the U.S. Hemp Authority’s independent, third-party auditor within 15 days after the change.
4.2 ADDITIONAL REGISTRATION REQUIREMENTS

Registration requirements are not limited to what may be required for handling finished hemp products. The authority having jurisdiction may require additional registration, permit or licensing based on the type of product being handled.

4.2.1 Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) directs the Federal Food and Drug Administration (FDA), as the food regulatory agency of the Department of Health and Human Services, to take steps to protect the public from a threatened or actual terrorist attack on the U.S. food supply and other food-related emergencies. To carry out certain provisions of the Bioterrorism Act, FDA established regulations requiring that:

a. Food facilities register with FDA, and
b. FDA be given advance notice on shipments of imported food.

Unless exempted by law, compliance with the Bioterrorism Act which requires domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA and such registration is required for U.S. Hemp Authority™ Certification.
4.3 PERSONNEL GUIDANCE

Qualified employees who handle finished hemp products shall be qualified to do so and those responsible for quality control or performing any quality control operations, must have the education, training, or experience to perform the assigned functions.

Supervisors shall be qualified by education, training, or experience to supervise.

Contamination prevention and hygienic measures shall be taken to exclude from any operations any person who might be a source of contamination.

Such measures could include the following:

- Excluding personnel from working in any operations that may have, an illness, infection, open lesion, or any other abnormal source of contamination
- Instructing employees to notify their supervisor if there is a possibility that they have a health condition described above
- Wearing outer garments in a manner that protects against the contamination
- Maintaining adequate personal cleanliness
- Washing hands thoroughly, and sanitizing if necessary, in a hand-washing facility
- Removing or covering all unsecured jewelry and other objects that might fall into equipment, packaging, or finished hemp products
- Using gloves when appropriate
- Wearing, where appropriate, hair nets, caps, beard covers, shoes, PPE, etc.

Personnel and employee safety measures shall include the following:

- Appropriate and adequate first aid equipment
- Adequate bathrooms and changing rooms
- Appropriate OSHA warnings, labels, and training
- Appropriate training and personal protective equipment
4.4 **Employee Training**

a. Quality Assurance (QA) or Training Manager shall ensure all personnel receive adequate training to complete assigned responsibilities safely and effectively prior to beginning the work.

b. All staff receive training upon hiring.

c. Ongoing training related to job and current Good Manufacturing Practices (cGMP) requirements are conducted no less frequently than a yearly basis. All personnel are trained to follow Standard Operating Procedures (SOP) relevant to the tasks assigned to them.

d. The training program ensures all staff are trained or notified on the following, as required by job or regulatory requirements:
   
   i. Company policies and procedures  
   ii. Emergency procedures  
   iii. Hazardous materials  
   iv. Hygiene and food-handling safety  
   v. Industry policies and standards  
   vi. Labeling and packaging  
   vii. Product quality  
   viii. Product testing  
   ix. Regulatory inspections  
   x. Recordkeeping  
   xi. Sanitation and cleaning procedures  
   xii. Security  
   xiii. Sexual harassment  
   xiv. Specific job training as required  
   xv. Violations and enforcement  
   xvi. Worker health and safety  

e. Training may be conducted internally, or by external parties, trade associations or consultants.

f. Key personnel responsible for auditing suppliers and managing quality assurance and quality control shall have the managerial and professional or technical skills and experience to assume responsibility for ensuring that finished hemp products consistently meet standards and specifications. These practices shall include but are not limited to:
   
   i. Job descriptions and organizational charts are used to establish areas of responsibility and are available to personnel.  
   ii. The responsibilities placed on any one person should not be so extensive as to compromise the effective execution of assigned duties in relation to cGMP.  
   iii. Personnel in responsible positions should have adequate authority to perform their duties.
iv. QA shall reinforce training effectiveness through testing comprehension, observing behaviors in the workplace, and providing timely feedback.

v. Personnel with less than the required qualifications or experience should be provided with a training program designed to make up deficiencies.

vi. Personnel should be sufficiently fluent in spoken and written English to respond to training provided in English, accept and implement instructions exactly that are provided in English, and where their duties require it, fill out forms correctly.

vii. General Precautions for Training: Personnel shall not be permitted to sign or initial a document unless they have been trained in the task associated with the signature and in the significance of the signature.

viii. Personnel working in areas where contamination is a hazard, e.g. clean areas or areas where highly active, toxic, infectious or sensitizing materials are handled, should be given specific training.

ix. Visitors or untrained personnel should not be permitted into production, storage or Quality Control (QC) areas without training.

x. Casual or contract personnel (including cleaners) should also receive appropriate induction training in cGMP.

g. Records retention: training records shall be retained for at least five (5) years, or longer if required by the authority having jurisdiction.
4.5 PHYSICAL PLANT AND GROUNDS

a. Plumbing in the facility shall be of an adequate size and design and be adequately installed and maintained to satisfy operational needs.

b. Floor drainage shall be adequate for operations and to prevent contamination of finished hemp products.

c. Sewage disposal shall be adequate for operational needs and bathrooms.

d. Hand-washing facilities shall be available and designed to ensure that an employee’s hands are not a source of contamination of finished hemp products.

e. Trash disposal shall be adequate to minimize odors, the attraction of pests, or becoming a source of contamination.

f. Grounds shall be maintained to protect against contamination of finished hemp products.

g. Facilities used in the packaging, labeling, or holding of finished hemp products shall be adequate in size, construction, and design.

h. Facilities shall provide adequate space for the equipment and materials necessary for normal operations as well as maintenance, cleaning, and sanitizing operations and to prevent contamination.

i. Equipment that controls temperature and humidity as well as fans and other air-blowing equipment used shall be adequate for the size of the facility.

j. Facilities shall be maintained to protect against contamination of finished hemp products.

k. Facilities shall have adequate bathrooms and changing rooms.

l. Facilities shall have a sanitary/cleaning plan.

m. Cleaning compounds, sanitizing agents, pesticides, and other toxic materials must be free from microorganisms and be safe and adequate under the conditions of use.

n. Pest control includes not allowing animals or pests in any area of the facilities except guard or working dogs.

o. Insecticides, fumigants, or rodenticides shall be used with care and in the intended manner.

p. Water supply needs to be safe and sanitary, at suitable temperatures, and under pressure as needed for appropriate use.
4.6 **OVERVIEW OF FACILITY & SECURITY CHECKLIST**

There are many aspects of facility and security management to consider, some of which are not applicable to all facilities. The U.S. Hemp Authority™ provides its independent, third-party auditors with a comprehensive checklist intended to account for a broad range of facilities. Not every item is required for every facility. However, to the extent equipment exists, it must be in working order; and to the extent programs exist, they must be in written form and consistently followed and documented as necessary.
4.7 **Supplier Qualification & Specifications**

a. All finished hemp product suppliers shall have either the U.S. Hemp Authority™ Certified Seal, a U.S. Hemp Authority™ Certificate of Compliance, or a current and valid SQF, BRC, GFSI (or other qualified auditing program) certification that can be and has been verified by our independent, third-party auditor Validus.

- **PLEASE NOTE:** Any change to hemp extract and cannabinoid suppliers shall be communicated to the U.S. Hemp Authority's independent, third-party auditor Validus within 15 days after the change. Validus will additionally perform random confirmation checks with suppliers.

b. Management or your Quality Management System (QMS) personnel must assess (where possible by direct audit) suppliers of finished hemp products, materials, equipment, consumables, and services and assign, where appropriate “approved supplier” or “certified supplier” status. Suppliers are evaluated based on level of risk.

c. QMS personnel shall maintain records of supplier evaluations and list those approved.

d. Specifications and master manufacturing records for finished hemp products shall be reviewed and discussed with suppliers on a periodic basis.

e. Finished hemp product suppliers are responsible for the following:
   1. Meeting product specifications with valid tests and verifications for materials. See Sections 3.9.1 and 3.9.2 of these Guidance Procedures for testing guidance.
   2. Ensuring the integrity of product and packaging
   3. Ensuring all documentation establishes traceability from grower and raw materials to customer delivery, including but not limited to orders, delivery notes, product labels, specifications and test results

f. Material specifications include, where applicable:
   1. Standard product name to be used in production documents, and compendia name if applicable
   2. Supplier's product code and trade names
   3. Supplier's name and address
   4. A unique reference code for the material specification and approval date
   5. Tests and limits for identity, purity, physical and chemical characteristics, microbiological standards (where appropriate) and assay or potency
   6. Approved or certified supplier(s) of the material
   7. Type of packaging, storage conditions and precautions
   8. Physical appearance and characteristics
   9. Precautions or reference to appropriate parts of a standard procedure
   10. Period during which approval will remain valid (e.g. review frequency or date)
4.8 Packaging and Labeling

Packaging and labeling finished hemp products received shall have a control system to examine each container to determine that the appropriate finished hemp product was received, content labeled, and that the container had no damage, contamination or deterioration of the components.

4.8.1 Labeling Practices

a. All products labeled for consumer use shall be labeled according applicable parts of Title 21 to the Code of Federal Regulations for foods and dietary supplements, the Food Drug & Cosmetic Act for cosmetics as applicable, as well as any additional state or tribal government requirements. Dietary supplements shall also comply with guidelines promulgated by the Federal Trade Commission as found in the agency’s “Dietary Supplements: An Advertising Guide for the Industry,” found at: https://www.ftc.gov/system/files/documents/plain-language/bus09-dietary-supplements-advertising-guide-industry.pdf

b. All finished hemp products derived from hemp not grown in the United States shall be labeled with the hemp country or countries of origin as defined herein, and consistent with 19 CFR Part 134. All finished hemp products derived from hemp grown in the United States may be labeled with a statement such as “produced from hemp grown in the U.S.” The hemp country of origin statement must be conspicuous and must appear in close proximity to the name and address of the firm responsible for distributing the finished hemp product and be at least comparable in size of lettering. Country abbreviations are not acceptable. All labeling and marketing must be legible and clearly identifiable.

c. Use of the terms “broad spectrum,” “full spectrum,” and “isolate” on labels shall be consistent with the definitions of these terms in Section 1 of these Guidance Procedures. Any use of isolate as an ingredient in an ingestible product shall be included in the ingredients list.

d. All claims must be truthful and not misleading.

e. All ingredients added to the product must be declared.

f. Bioengineered ingredients must be labeled consistent with the requirements of 7 CFR Part 66.

g. Genetically engineered ingredients in dietary supplements and additives to foods and beverages must be labeled consistent with the labeling policies found in the Food and Drug Administration’s “Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Derived from Genetically Engineered Plants,” Docket Number: FDA-2000-D-0075. Adherence to this FDA Guidance is mandatory for labeling of ingredients derived from genetically engineered organisms that may not contain detectable DNA.

h. Finished hemp products packaged for retail sale should have a “best by” or “expiration” date on the package.

i. No products may have labels or marketing that claim to diagnose, treat, prevent or cure any disease.

j. All dietary supplements intended to support the structure or function of the body must include a disclaimer such as: “This product is not intended to diagnose, treat, cure or prevent any disease.”

k. All products containing measurable amounts of cannabinoids should include proper warnings and cautions, such as the following:

   i. This product should be used with caution when driving motor vehicles or operating heavy machinery.
ii. Use this product under the guidance of a physician if you have a medical condition, are pregnant or lactating.

iii. Keep out of the reach of children.

iv. This product meets federal requirements for hemp products; however, consumption may be flagged by some drug tests.

v. Use with caution if subject to urinalysis.

I. Nutrition Facts panels must be included on food and beverage products and supplement fact panels must be included on dietary supplement products:

   i. Food and beverage nutritional fact panels should follow FDA guidelines that are outlined in the FDA Food Labeling Guide, found at:

   ii. Supplement fact panels should follow FDA guidelines that are outlined in the FDA’s Dietary Supplement Guide, found at:

   iii. Cosmetics should be labeled consistent with the FDA’s Cosmetic Labeling Guide, found at:
     https://www.fda.gov/media/88234/download

4.8.2 Guidance for Packaging and Labeling Operations

   a. Holding of packaging material and labels under conditions that will protect against contamination and deterioration.

   b. Packaging and labeling operations shall be such that the condition of the packaging will ensure the quality of the hemp products and shall be compliant with all applicable food packaging and contact regulations and requirements.

   c. Issuance and use of packaging and labels shall be controlled and recorded.

   d. Packaging and labels for each lot or batch of finished hemp products shall be documented to determine whether the packaging and labels conform to the Standard Operating Procedures (SOP) and specifications.

   e. Representative samples of each batch of the packaged and labeled finished hemp product shall be tested for purity, contaminants and cannabinoid quantification to ensure the product meets those specifications and shall be kept for further testing if necessary, such as for complaints and potential recall.

   f. Suitably dispose of labels and packaging which are obsolete or incorrect to ensure that they are not used in any future packaging and label operations.

   g. Records shall be kept of the written procedures for packaging and labeling operations.

   h. Quality management personnel shall approve the finished hemp products for final distribution/sale.

   i. Packaging, labeling, and other related operations shall ensure that the quality of the finished hemp products are packaged and labeled as specified in the Standard Operating Procedures (SOP) and product specifications, including the following:
Quality Control Procedures for Packaging & Labeling

Quality control procedures for packaging and labeling shall include:

a. Determining whether the received finished hemp product meets the product specification.
b. Approval of the supplies for use in the packaging and labeling of a finished hemp product.
c. Identifying each unique lot within each shipment of finished hemp products received so that it can be tracked through the packaging, labeling, marketing, and distribution processes.
d. Storage of the finished hemp products under conditions that will protect against contamination and deterioration.
e. Collection of a representative sample of each lot of finished hemp product.
4.9 HOLDING AND DISTRIBUTING

a. Holding of finished hemp products shall be under appropriate conditions of temperature, humidity, and light so that the identity, purity, strength, and composition of the finished hemp products are maintained.

b. Holding of finished hemp products shall always be properly labeled to prevent contamination and unintended commingling.

c. Holding of finished hemp products shall be properly labeled to indicate a hold or available for release.

d. Holding of in-process material shall be identified under conditions that prevent mix-ups, contamination, and deterioration.

e. Holding of packaging and labels shall be under conditions adequate to prevent the packaging and labels from being adversely affected.

f. Distribution of finished hemp products shall be under conditions that will protect the products against contamination and deterioration.

g. Distribution of finished hemp products shall ensure that the hemp products are shipped to the intended place and to the intended recipient.
4.10 **QUALITY CONTROL OPERATIONS RELATED TO PRODUCT COMPLAINTS, ADVERSE EVENTS, AND RECALLS**

Quality control operations for product complaints, adverse events, and recalls must include reviewing and approving decisions about whether to investigate a product complaint and reviewing and approving the findings, and follow-up action of any investigation performed.

The following records must be kept:

a. Written procedures for the responsibilities of the quality control operations, including written procedures for conducting a material review and making a disposition decision and written procedures for approving or rejecting any reprocessing request to brand owner’s supplier.

b. Written documentation, at the time of performance, that quality control personnel performed the review, approval, or rejection requirements by recording the following:
   i. Date that the review, approval, or rejection was performed; and
   ii. Signature of the person performing the review, approval, or rejection.

c. Documentation of any material review and disposition decision and follow-up. Such documentation must be included in the appropriate production record:
   i. Identification of the specific deviation or the unanticipated occurrence:
   ii. Description of your investigation into the cause of the deviation from the specification or the unanticipated occurrence;
   iii. Evaluation of whether or not the deviation or unanticipated occurrence has resulted in or could lead to a failure to ensure the quality of the product or a failure to package and label the finished hemp product as specified in the production record;
   iv. Identification of the action(s) taken to correct, and prevent a recurrence of, the deviation or the unanticipated occurrence;
   v. Explanation of what you did with the finished hemp product, packaging, or label; and
   vi. The signature of the individual(s) designated to perform the quality control operation, who conducted the material review and made the disposition decision, and of each qualified individual who provides information relevant to that material review and disposition decision.

d. **Product Withdrawal and Recall.**

The responsibility and methods used to withdraw or recall product shall be documented and implemented. The procedure shall:

   i. Identify those responsible for initiating, managing and investigating a product withdrawal or recall;
   ii. Describe the procedures to be implemented by site management;
   iii. Outline a communication plan to inform customers, consumers, authorities and other essential bodies in a timely manner appropriate to the nature of the incident; and
   iv. Investigation shall be undertaken to determine the cause of a withdrawal, mock recall, or recall and details of investigations and any action taken shall be documented.
4.11 RECORD RETENTION

Brand owners shall keep records, electronically or hard copy, for at least five (5) years after processor operations, if required by the authority having jurisdiction. Such information shall include but is not limited to:

a. Records of the license or other authorization or registration for hemp handling
b. Source of the finished hemp product, name and address and the country of origin
c. Form in which the finished hemp products are received
d. Quantity of each form of finished hemp product received and sold
e. Written Standard Operating Procedures (SOP) and specifications
f. Images of all products and labels
g. Distribution records, including the finished hemp product name, quantity sold, purchaser name and address, batch and lot number for the finished hemp product; and, if from an authority having jurisdiction that requires processing or handling licensure or authorization, a record of such processing or handling license or authorization
h. Any and all certification documents
i. Product complaints, adverse events and all recall procedures and processes
j. Records kept shall be originals or true copies, such as photocopies, or other accurate reproductions of the original records, or as electronic records
k. Results of all tests
l. Disposition of any non-compliant finished hemp products, including date of disposition, method, individuals who performed the disposition, and documented evidence of the disposition

Suggested Record Retention. Request a copy of the manufacturer’s master manufacturing record and any grower(s)’ record(s) of the authorization or licensing for hemp cultivation.
4.12 PROHIBITIONS

Products with synthetic cannabinoids, biosynthetic cannabinoids, cannabimimetic phytochemicals in lieu of hemp-derived cannabinoids, bioengineered hemp, and or genetically engineered hemp are not eligible for U.S. Hemp Authority™ Certification. Only products containing cannabinoids derived from the hemp plant are eligible for U.S. Hemp Authority™ Certification.
AOAC SMPRs® 2017.002

Standard Method Performance Requirements (SMPRs) for Quantitation of Cannabinoids in Dried Plant Materials

Intended Use: Consensus-Based Reference Method

1 Purpose

AOAC SMPRs describe the minimum recommended performance characteristics to be used during the evaluation of a method. The evaluation may be an on-site verification, a single-laboratory validation, or a multi-site collaborative study. SMPRs are written and adopted by AOAC stakeholder panels composed of representatives from the industry, regulatory organizations, contract laboratories, test kit manufacturers, and academic institutions. AOAC SMPRs are used by AOAC expert review panels in their evaluation of validation study data for method being considered for Performance Tested Methods® or AOAC Official Methods of Analysis®, and can be used as acceptance criteria for verification at user laboratories.

2 Applicability

The method will be able to identify and quantify individual cannabinoids (as listed in Tables 1 and 2) in dried plant materials.

3 Analytical Technique

Any analytical technique(s) that measures the analytes of interest and meets the following method performance requirements is/are acceptable.

4 Definitions

Dried plant materials.—Dried whole or milled flower plant material from Cannabis sativa and its hybrids.

Limit of quantitation (LOQ).—The minimum concentration or mass of analyte in a given matrix that can be reported as a quantitative result.

Quantitative method.—Method of analysis which response is the amount of the analyte measured either directly (enumeration in a mass or a volume), or indirectly (color, absorbance, impedance, etc.) in a certain amount of sample.

Repeatability.—Variation arising when all efforts are made to keep conditions constant by using the same instrument and operator and repeating during a short time period. Expressed as the repeatability standard deviation (SD); or % repeatability relative standard deviation (%RSD).

Reproducibility.—The standard deviation or relative standard deviation calculated from among-laboratory data. Expressed as the reproducibility standard deviation (SD), or % reproducibility relative standard deviation (%RSD).

Recovery.—The fraction or percentage of spiked analyte that is recovered when the test sample is analyzed using the entire method.

5 Method Performance Requirements

See Tables 3 and 4.

Table 1. Required cannabinoids

<table>
<thead>
<tr>
<th>Common name</th>
<th>Abbreviation</th>
<th>IUPAC name</th>
<th>CAS No.</th>
<th>Molecular structure</th>
<th>Reference material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannabidiol</td>
<td>CBD</td>
<td>2-[(1R,6R)-6-Isopropenyl-3-methylcyclohex-2-en-1-yl]-5-(\prescript{\circ}{})prenylbenzene-1,3-diol</td>
<td>13056-29-1</td>
<td><img src="image" alt="Molecular structure" /></td>
<td>Restek, Cerilliant, Sigma-Aldrich, API Standards, Echo Pharm, Lipomed AG</td>
</tr>
<tr>
<td>Cannabidiolic acid</td>
<td>CBDA</td>
<td>2,4-Dihydroxy-3-[(1R,6R)-3-methyl-6-prop-1-en-2-ylcyclohex-2-en-1-yl]-6-pentylbenzoic acid</td>
<td>1244-58-2</td>
<td><img src="image" alt="Molecular structure" /></td>
<td>Cerilliant, USP, Restek, Lipomed AG, Echo Pharmaceutical</td>
</tr>
<tr>
<td>Cannabinol</td>
<td>CBN</td>
<td>6,8,9-Trimethyl-3-pentyl-benzo[c]chroomen-1-ol</td>
<td>521-35-7</td>
<td><img src="image" alt="Molecular structure" /></td>
<td>Cerilliant, Restek</td>
</tr>
<tr>
<td>Tetrahydro-cannabinol</td>
<td>THC</td>
<td>(±)-(6aR,10aR)-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chroomen-1-ol</td>
<td>1972-08-3</td>
<td><img src="image" alt="Molecular structure" /></td>
<td>Cerilliant, USP, Echo Pharmaceuticals</td>
</tr>
<tr>
<td>Tetrahydro-cannabinolic acid</td>
<td>THCA</td>
<td>(6aR,10aR)-1-hydroxy-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chroomene-2-carboxylic acid</td>
<td>23978-85-0</td>
<td><img src="image" alt="Molecular structure" /></td>
<td>Cerilliant, USP, Echo Pharmaceuticals</td>
</tr>
</tbody>
</table>
**Table 2. Additional, desirable cannabinoids**

<table>
<thead>
<tr>
<th>Name</th>
<th>Abbreviation</th>
<th>IUPAC name</th>
<th>CAS No.</th>
<th>Molecular structure</th>
<th>Reference material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannabichromene</td>
<td>CBC</td>
<td>2-Methyl-2-(4-methylpent-3-enyl)-7-pentyl-5-chromenol</td>
<td>26675-51-8</td>
<td><img src="image" alt="Cannabichromene" /></td>
<td>Centrillant Sigma Aldrich Echo Pharmaceuticals</td>
</tr>
<tr>
<td>Cannabichromenic acid</td>
<td>CBCA</td>
<td>5-Hydroxy-2-methyl-2-(4-methyl-3-penten-1-yl)-7-pentyl-2H-chromene-6-carboxylic acid</td>
<td>20408-52-0</td>
<td><img src="image" alt="Cannabichromenic acid" /></td>
<td>No reference material</td>
</tr>
<tr>
<td>Cannabidivanic acid</td>
<td>CBDVA</td>
<td>2,4-Dihydroxy-3-[[1R,6R]-3-methyl-6-prop-1-en-2-yloctahex-2-en-1-yl]-6-propybenzoic acid</td>
<td>31932-13-5</td>
<td><img src="image" alt="Cannabidivanic acid" /></td>
<td>Centrillant</td>
</tr>
<tr>
<td>Cannabigerol</td>
<td>CBG</td>
<td>2-[(2E)-3,7-dimethylocta-2,6-dienyl]-5-pentylbenzene-1,3-diol</td>
<td>25554-31-3</td>
<td><img src="image" alt="Cannabigerol" /></td>
<td>Centrillant lipomed AG Echo Pharmaceuticals SPEX Certiprep Tocris (UK)</td>
</tr>
<tr>
<td>Cannabigerolic acid</td>
<td>CBGA</td>
<td>3-[(2E)-3,7-dimethylocta-2,6-dienyl]-2,4-dihydroxy-6-pentylbenzoic acid</td>
<td>25555-57-1</td>
<td><img src="image" alt="Cannabigerolic acid" /></td>
<td>Centrillant Echo Pharmaceuticals SPEX Certiprep</td>
</tr>
<tr>
<td>Cannabidivarin</td>
<td>CBDV</td>
<td>2-[(1S,6S)-3-methyl-6-(prop-1-en-2-yl)cyclohex-2-enyl]-5-propybenzene-1,3-diol</td>
<td>24274-48-4</td>
<td><img src="image" alt="Cannabidivarin" /></td>
<td>Centrillant SPEX Certiprep</td>
</tr>
<tr>
<td>Δ²-Tetrahydro-cannabinol</td>
<td>Δ²THC</td>
<td>6,6,9-Trimethyl-3-pentyl-6a,7,10a-tetrahydrobenzo[c]chromen-1-ol</td>
<td>5957-75-5</td>
<td><img src="image" alt="Δ²-Tetrahydro-cannabinol" /></td>
<td>Centrillant SPEX Certiprep</td>
</tr>
<tr>
<td>Tetrahydro-cannabivarin</td>
<td>THCV</td>
<td>6,6,9-Trimethyl-3-propyl-6a,7,8,10a-tetrahydro-6Hbenzo[c]chromen-1-ol</td>
<td>28172-17-0</td>
<td><img src="image" alt="Tetrahydro-cannabivarin" /></td>
<td>Centrillant USP</td>
</tr>
<tr>
<td>Tetrahydrocannabivarin acid</td>
<td>THCVA</td>
<td>28172-17-0</td>
<td></td>
<td><img src="image" alt="Tetrahydrocannabivarin acid" /></td>
<td>No reference material</td>
</tr>
</tbody>
</table>
6 System Suitability Tests and/or Analytical Quality Control

Suitable methods will include blank check samples, and check standards at the lowest point and midrange point of the analytical range.

7 Reference Material(s)

See Tables 1 and 2 for sources of reference materials.


8 Validation Guidance

Method performance should be demonstrated with homogeneous samples. Inherent variation in the plant may preclude or limit homogeneity for the following reasons: (a) they are resinous; cannabinoids are concentrated in the resin, which can clump during grinding; (b) between-flower variation can be high; grinding multiple flowers can impact the homogeneity; (c) grinding can introduce heat, which will cause degradation of cannabinoidic acids into neutral forms, resulting in less accurate results. Grinding would be the best option for homogeneous samples, but, in some cases, there are issues with clumped resin, highly variable samples, and additional grinding would impact the results and lead to inaccurate data.


Appendix K: Guidelines for Dietary Supplements and Botanicals, Official Methods of Analysis of AOAC INTERNATIONAL (20th Ed.), AOAC INTERNATIONAL, Rockville, MD, USA (http://www.eoma.aoc.org/app_k.pdf)

9 Maximum Time-to-Result

None.