Patient Focused Certification

INDUSTRY PROGRAM GUIDE

A Project of Americans for Safe Access Foundation

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PATIENT FOCUSED CERTIFICATION

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Introduction

Welcome to the Patient Focused Certification (PFC) Program!

Americans for Safe Access Foundation (ASA) has created the Patient Focused Certification (PFC) Program to address issues of quality control and product safety in the cannabis industry to ensure patients (consumers) and their healthcare providers can rely on high-quality medical cannabis products and services. ASA has been advocating for safe and legal access to cannabis for therapeutic use and research on behalf patients for over a decade. Founded in 2002, ASA developed a vision for safe access that includes a legal and regulatory framework that has shaped the medical cannabis industry we see today.

The PFC Program has established guidelines that provide a system of processes, procedures, and documentation to ensure that Cannabis products (hemp, medical cannabis, and cannabis-derived products intended for human consumption) have the strength, composition, purity, and identity they claim to constitute or possess. PFC helps companies that are cultivating, manufacturing, and distributing these products achieve a commitment to quality and product safety. PFC represents the consensus of the world's leading experts on cannabis, hemp and botanical product regulations.

The PFC program addresses quality control and product safety through:

1. Developing and Adopting Industry Standards
2. Industry Training
3. Certification Program

To date, we have:

- Worked with American Herbal Pharmacopoeia (AHP) to release a Cannabis Monograph, which now serves as a guide for identifying the quality, purity, and potency of the cannabis plant internationally;
- Collaborated with the American Herbal Products Association (AHPA) to create the AHPA Cannabis Committee which has developed industry standards in the form of Recommendations for Regulators for Distribution, Cultivation, Analytics, and Manufacturing, Packaging and Labeling;
- Worked with regulators to get AHP and AHPA cannabis standards adopted in over a dozen states and;
- Partnered with American Chemical Society (ACS) divisions of Small Chemical Business(SCHB), Agriculture and Food (AGFD), and Chemical Health & Safety(CH&S) to create a Cannabis Chemistry committee to provide education and training that addresses the needs of laboratories, chemists, and service/equipment providers

Our experienced staff have trained thousands in the medical cannabis industry over the last decade. The PFC training program prepares employees to understand state and local regulations and to meet required safety and operational protocols, while teaching them the basics of cannabis as medicine and common therapeutic uses of cannabis. PFC training is currently licensed by the Department of Public Health in the District of Columbia as a mandatory training for all staff working in the DC medical cannabis program.

PFC offers third-party certification and support services to companies cultivating, manufacturing, analyzing or distributing medical cannabis products and is the nation's only certification program based upon the AHPA and AHP standards. All PFC companies are required to adhere to these rigid quality standards. Certification includes compliance inspections, ongoing monitoring, regulatory updates, staff training and an independent complaint process for consumers.

PFC certified laboratories have each demonstrated that their equipment and instruments are calibrated and maintained properly. Laboratories must also show that they have implemented operating protocols that are followed in accordance with the AHP Monograph and AHPA guidelines, establishing the first standardized testing of medical cannabis and medical cannabis products. Through standardized testing, patients and their medical practitioners can now have confidence that the products utilized not only comply with PFC's high quality and safety standards, but are also properly labeled and standardized to ensure consistency of quality

and effectiveness.

PFC certified companies are awarded the distinctive PFC mark to be displayed on promotional materials, product labeling and packaging to help distinguish products for consumers. PFC is similar to other nationally recognized certification programs including United States Pharmacopoeia (USP), Good Housekeeping, NSF, and International Organization for Standardization (ISO). PFC certification is currently offered as a voluntary certification program in all medical cannabis states for cultivators, manufacturers, dispensaries, and laboratories.

PFC Certification Highlights:

1. offers cannabis businesses a third-party auditing option that ensures compliance with standards required under regulation and best practices;
2. provides your company visibility in all PFC advertising and marketing programs to patients, caregivers, and health care providers;
3. provides a mark that lets consumers, policy makers, regulators, health inspectors, community members and health care providers know that companies are meeting compliance and product safety standard requirements;
4. monitors violations of regulations;
5. provides trainings that include: Legal Issues, Robbery Preparedness, Patient Education, Good Neighbor Policies, Safe Handling Protocols, Working with Patient Populations, Understanding Test Results and Delivery Systems, Adherence to Local Laws and Regulations, and Adherence to AHPA and AHP standards;
6. provides companies with educational materials for patients, caregivers, healthcare providers and regulators that describe the certification program;
7. provides a third-party process to evaluate complaints, allowing you to identify, focus on and resolve legitimate quality and service issues;
8. funds activities that benefit the medical cannabis industry, including education, legal services and research;
9. verifies through independent auditors that state and local rules, as well as AHPA and AHP standards, are followed by companies, ensuring patient safety and product quality, purity, and reliability;
10. offers third-party certification that can help reduce company liability and oversight burden;
11. provides companies and, if required, regulators with annual Audit Reporting;
12. assists your company with regulatory acceptance by verifying the reliability, consistency, and accuracy of your processes;
13. is overseen by a Peer Review Board that has over 300 years of collective expertise in USDA food and product safety protocols; federal regulatory development; medical cannabis research, pharmacology, biochemistry, and industry practices.

II. PFC Benefits and Services

BENEFITS

Government Relations: PFC works at the local and state level to increase awareness of the AHPA standards and the AHP *Cannabis Monograph* with relevant agencies. PFC and AHPA work directly with legislators, regulators and industry trade groups to encourage the adoption of AHPA's *Recommenda-tions to Regulators* and standards outlined in the AHP Cannabis Monograph. As such, regulators in the states of Alaska, Florida, New York, Illinois, Maryland, Nevada, Washington, Oregon, Massachusetts, Minnesota, Hawaii, and Colorado have adopted portions of the AHPA's *Recommenda-tions* and/or the AHP *Cannabis Monograph.*

As the regulatory framework for medical cannabis businesses continues to develop throughout the US, demonstrating adherence to national best-practice standards can help businesses avoid being subjected to the development of onerous state and local regulations that may challenge the ability of small businesses to be

successful. Throughout history, big business, with the support of government, has used unnecessarily narrow or stringent regulations to monopolize marketplaces. Certifying your business with PFC shows regulators and lawmakers that your business has high standards of operation in accordance with other botanical products, discouraging the development of overly restrictive regulations.

Both ASA and AHPA are dedicated to the adoption of mandatory standards for the medical cannabis industry nationally. Your participation in the PFC Program helps to ensure that our outreach to your specific regulators gives your company an advantage.

Be prepared for regulatory inspections: In today's regulated marketplace, failure to meet regulatory compliance can result in the denial of licensure for an applicant. Or, in the case of an established company can result in costly fines, the recall and/or confiscation of products, and suspension or termination of your company's license. As a participant in the PFC program, your company can rest assured that PFC's inspection auditors will identify any and all compliance issues that could jeopardize your company's ability to maintain compliance with local and state regulations. As localities and state regulators adjust and update regulations, PFC staff will ensure that your company is aware of all upcoming regulatory changes.

Reduce company liability: Prior to the adoption of product safety guidelines in the herbal, botanical, and nutraceutical industries product liability lawsuits continually challenged the stability, growth, and future of these companies. As public concern in the US mounted over the increasing number of product liability lawsuits larger agencies such as the FDA entered into the conversation about regulations and pressures rose to restrict herbal, botanical, and nutraceutical products from public availability. However, through the voluntary adoption of rigorous product safety guidelines, the herbal, botanical and nutraceutical industry was able to ease the concerns of both the public and regulatory agencies allowing the industry to stabilize and avoid overly onerous FDA regulations.

Today, the medical cannabis and adult use industry find themselves in a very similar situation. As medical cannabis and adult use laws have been implemented throughout the US, product safety has been an afterthought in many of these laws and rule making processes. By working with PFC to adopt nationally recognized product safety standards, you directly reduce your company's service and product liability. Through proper lot and batch number tracking, health and hygiene protocols, standardized testing, proper labeling, as well as adverse event reporting and recall strategies cannabis businesses who wear the PFC seal of approval raise the bar of product safety to that of the herbal, botanical, and nutraceutical industry in the US.

PFC certification helps your company identify, develop and address product safety protocols before a product safety liability issue can arise. Engaging in the PFC program costs the average company less than 1% of their annual revenue whereas product liability lawsuits often cost companies hundreds of thousands of dollars. Let PFC help your company develop a solid foundation of product safety and avoid costly product liability lawsuits that often irreparably damage businesses or close them all together.

Instill confidence in consumers and health care providers: The PFC seal displayed by cannabis businesses and on cannabis/hemp products provides medical practitioners, patients, and regulators with peace of mind that your company is adhering to regulatory guidelines. The seal also shows that your company is committed to the purity and identity of products being sold, has implemented lot and batch number tracking protocols including an operations product recall plan, and has implemented standardized methods for the cultivation, manufacturing, distribution, and lab testing of those products.

Additionally our outreach programs educate patients, their caregivers, and medical professionals to look for PFC certified products so that they can choose their medicine with confidence, knowing that it was produced in a manner that provides consistent results and protects consumer safety. PFC's advertising and marketing prominently features our certified companies and includes both traditional industry publications and unique channels, such as Complementary and Alternative Medicine outlets.

Have confidence in company compliance: As medical cannabis, adult use, and hemp businesses have emerged in the legal marketplace , state and local lawmakers have created a patchwork of laws and regulations. Almost all companies entering into the PFC program will find that some form of corrective action is necessary to achieve and maintain certification. Let PFC help your company achieve excellence in compliance, Best

Business Practices, quality of care, and product safety.

Due to the ever-changing and expanding nature of medical cannabis regulations and medical cannabis industry innovations, PFC recognizes the need to continually review and adopt new standards and guidelines that reflect regulatory changes. For this reason the PFC Program has been developed as a continually evolving program overseen by a Peer Review Board which along with AHPA and AHP act to oversee the ongoing update of PFC program standards. Depending on the extent of standard updates approved by the PFC Peer Review Board, a PFC auditor may be assigned to the affected certified companies in order to verify that all necessary compliance updates have taken place. Additional staff training may also be required. The addition of program requirements, determination of corrective actions, and need for additional trainings, are all determined by the PFC Peer Review Board.

Complaint hotline, investigation and resolution: PFC operates an independent complaint hotline that provides patients, consumers, and caregivers the means to report a concern, complaint, or adverse event relating to a service or product. If a verified third-party complaint is recorded and it is determined to require an investigation or a large number of complaints are lodged against a specific certified service or product, a review audit may be necessary. PFC will evaluate and respond to all third-party complaints verifying the legitimacy and severity of the complaint, and when necessary, require immediate corrective action. Certified companies are required to respond to complaint inquiries within five (5) business days of notification by an assigned PFC auditor or staff person.

When filing a complaint, a Complaint Investigation Request provided by PFC and available online, must be completed and signed by the complaining party. Complaints will be sent directly to the Program Director, who will track all complaints and investigations. PFC will acknowledge receipt of the complaint, promptly investigate and validate the complaint, and take appropriate actions. PFC shall ensure the proper corrective actions have been implemented and notify the complainant of such actions. The certified company will be advised of the complaint at the appropriate time during the investigation. PFC shall determine, together with the certified company and complainant (and regulators where necessary), if the complaint and resolution should be made public.

When a complaint is made by a company, whether PFC certified or not, the complainant agrees to bear the cost of an investigation if the complaint is not verified. If the complaint is substantiated, the certified company shall be responsible for all costs of the investigation. Regulatory authorities, individual consumers, and licensed health care providers are exempt from bearing the costs of any investigation costs. PFC shall not identify the complainant unless required to do so by law. If a complainant does not sign a Complaint Investigation Request, PFC will consider it an informal complaint and will investigate as needed but has no obligation to investigate or respond.

Services: Patient Focused Certification offers a variety of services designed to calibrate your business for excellence regardless of whether your company is just entering into the marketplace or is already an established provider.

PFC Advisory Services: Not sure if your company is ready to engage in the PFC program? Starting a new business and need guidance on local and state compliance or Best Business Practices? Or, maybe you have an in-house production lab that doesn't qualify for certification but your company could benefit from bringing it up to PFC standards? The Patient Focused Certification staff can help your company answer these questions through the PFC Advisory Services Program. The PFC Advisory Program gives your company access to some of the industry's best technical experts, delivering consistent, personalized service with the highest levels of integrity. To engage in PFC's Advisory Services, simply fill out an application and check the Advisory Service box. Within 5 business days a PFC staff person will contact your company to discuss the breadth of services desired and assign the appropriate staff and/or auditor(s) to assist your company. All PFC Advisory Services are billed at a rate of $150 per hour plus travel expenses.

Pre-licensing Certification: Companies interested in the PFC program but not yet licensed can engage in the PFC program and begin the audit process prior to license approval by providing PFC with a 50% deposit. In this case, the company must be able to show verification that all staff, as identified on the application, have successfully completed the PFC Core Cannabis Training and that the company has successfully completed a document

audit of all proposed SOP's and Employee Manuals by an assigned PFC auditor. As with other document audits conducted for PFC, the assigned PFC auditor will create a detailed audit report for the company outlining any corrective actions necessary for the SOP's to meet the standards of the PFC program as well as local and state regulatory requirements. All corrective actions must be successfully implemented prior to receiving PFC approval from the assigned auditor. PFC will then provide the company with a letter of engagement verifying that the provided documents are of adequate content to show that the company has implementable procedures ensuring compliance with local and state laws, and applicable PFC standards. Upon approval of state licensure, your company is encouraged to complete the PFC required trainings. All companies engaged in pre-licensing certification are required to complete the certification process within 90 days of opening the company for operation.

Industry Certification: Medical cannabis, adult use cannabis and hemp product companies operating within the legal parameters of local and state regulations are encouraged to apply for the PFC certification . Once PFC has received the required 50% deposit, PFC staff will assign an independent auditor to your company and schedule the document and physical audits. PFC staff will also request a full employee list from your company and assist your company in enrolling in the required PFC training courses. Upon the successful completion of the pre-certification audit process, subsequent corrective actions, and required staff trainings PFC staff will issue your company an official certification packet, including directions for the proper branding and use of the PFC seal.

Industry Training: PFC's required staff training program is designed to meet the requirements of state mandated training programs, provide your staff with continuing educational opportunities, and can help your company reduce the cost of developing, implementing and operating in-house medical cannabis training programs.

III. Developing and Adopting Industry Standards: AHPA and AHP

Seed to consumption national quality standards now exist for the medical cannabis industry thanks to the 2011 collaboration of ASA, the American Herbal Products Association (AHPA), and the American Herbal Pharmacopoeia (AHP). This unique collaboration combines the expertise of ASA, the nation's largest medical cannabis patient advocacy organization; AHPA, the principal U.S. trade association and voice of the herbal products industry since 1982; and the AHP, an organization that has developed qualitative and therapeutic monographs on Western herbs since 1994. The result is that patients, healthcare providers, lawmakers, regulators, and medical cannabis businesses now have the tools they need to ensure reliable, high-quality hemp, medical cannabis, and medical cannabis products.

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

Founded in 1982, AHPA is the oldest non-profit organization specializing in service to the herbal industry. All of AHPA's activities are focused on its mission, to promote the responsible commerce of herbal products. These activities are undertaken to maintain and improve market opportunities for companies that sell herbs, herbal and botanical products, and other health-related products, including foods, beverages, dietary supplements, and personal care products, while also ensuring that consumers continue to enjoy informed access to a wide choice of goods. In 2010 AHPA established a Cannabis Committee tasked with the development of national Recommendations to Regulators that address sensible regulatory practices for hemp, cannabis, and cannabis-derived products. As such, the AHPA's Cannabis Committee developed a series of Recommendations to Regulators, or guidelines, in the following four areas:

1. Cultivation and Processing—Intended to establish a basis for oversight of entities that cultivate cannabis in outdoor, greenhouse, and/or indoor facilities, these guidelines address good cultivation practices, pesticide guidance, facility requirements, management of water resources, recordkeeping, product safety recall systems, adverse event recording, and information disclosure. These recommendations also establish best practices and safe handling procedures for operations that provide post-harvest processing of cannabis.
2. Manufacturing, Packaging, Labeling and Holding—Intended to establish a basis for oversight of entities that are engaged in the manufacturing of cannabis and cannabis-derived products, these guidelines are

modeled after federally recognized Good Manufacturing Practices (GMPs) for botanical and nutraceutical products. These recommendations ensure that GMP's are maintained in manufacturing operations by focusing on personnel, physical condition of the plant and surrounding grounds, manufacturing controls, packaging, holding, and labeling controls, cannabis material acquisition, inventory and recordkeeping, complaints, returns, product safety recalls, and adverse event recording.

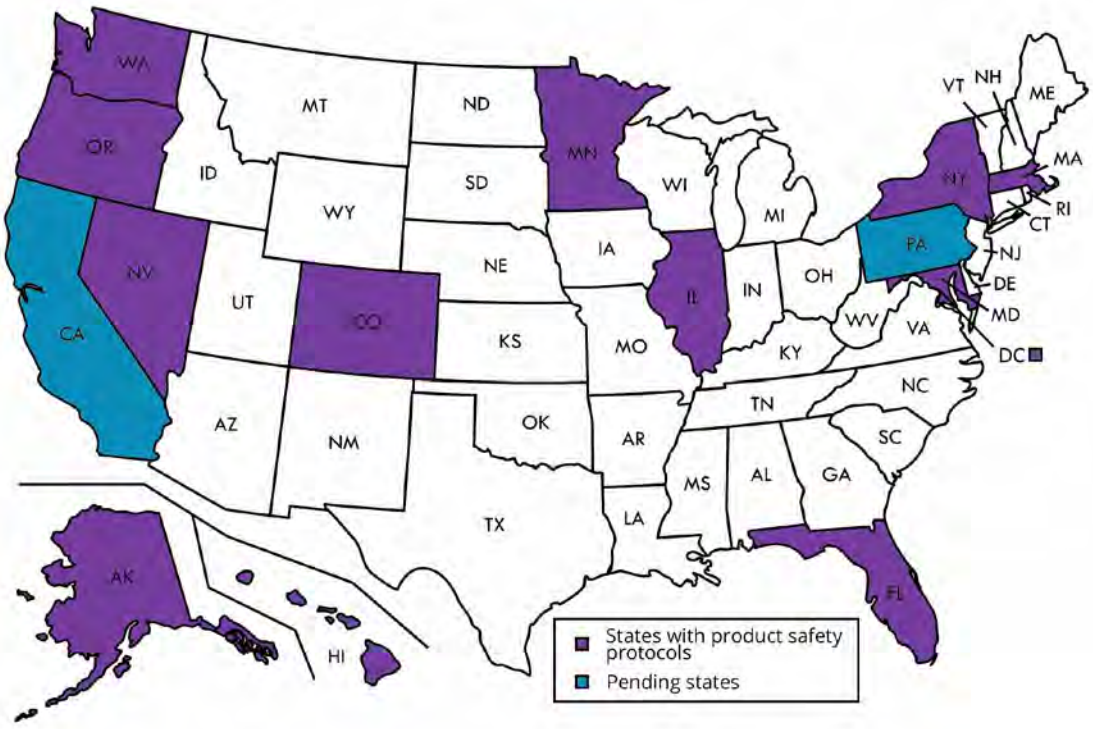
3. Distribution—Intended to establish a basis for oversight of entities that provide cannabis and cannabis-derived products directly to compliant individuals through storefront operations, delivery services, direct-from-garden operations, and growing co-op operations, these guidelines focus on personnel, security, product acquisition, record keeping, customer policies, implementable product safety recall systems, adverse event recording, and other matters that can contribute to best practices in the dispensary setting.

4. Laboratory Analysis—Intended to establish a basis for the oversight of entities performing laboratory analysis of cannabis, cannabis-derived products, and hemp products, these guidelines were developed as a complement to existing good laboratory practices and focus on the personnel, security, sample handling and disposal, data management, personnel safety and hygiene, and reporting activities that may be unique to laboratories analyzing cannabis, cannabis-derived products, and hemp samples. In addition to the AHPA guidelines, PFC certified laboratories are also required to adhere to the standards presented in the AHP Cannabis Monograph.

AMERICAN HERBAL PHARMACOPOEIA®

Established in 1995, the American Herbal Pharmacopoeia (AHP) is a non-profit 501(c)(3) California- based organization with a mission to promote the responsible use of herbal products and herbal medicines. The AHP produces critically reviewed documents called monographs that outline the quality control criteria needed for ensuring the identity, purity, and quality of botanical raw materials.

Each monograph also presents a complete and critical review of the traditional and scientific literature regarding the efficacy and safety of herbal medicines and includes information on specific products such as tinctures and extracts. In 2011, the AHP began the development of a Cannabis Monograph and a Therapeutic Compendium for Cannabis. The first edition of the Cannabis Monograph was released in 2013 and provides scientifically valid standards for companies engaged in laboratory analysis of cannabis, cannabis-derived products



and hemp products with regards to:

1. Ensuring the identity, quality, purity, and potency of cannabis, cannabis-derived and hemp products;
2. Reporting, analytic equipment calibration and method validation;
3. And, ensuring product safety by identifying safe levels of pesticides, metals, and microbial limits.

PFC works at the local and state level to increase awareness and adoption of the AHPA guidelines and the AHP Cannabis Monograph with relevant agencies. PFC and AHPA also works directly with regulators and industry trade groups to coordinate the further development of cannabis industry standards. ASA is dedicated to the adoption of mandatory standards for the cannabis industry nationally. Quality control and product safety standards based on the AHPA guidlines and the AHP *Cannabis Monograph* have been adopted in over a dozen states.

IV. Industry Training

As state medical cannabis laws and regulations continue to evolve, medical cannabis-specific trainings have become increasingly mandated. States such as Arizona, Massachusetts, Nevada, Florida, Illinois, Connecticut, Washington, Maryland, Oregon, and the District of Columbia have mandated comprehensive training for all staff working or volunteering in state-licensed medical cannabis facilities. PFC's required staff training program is designed to meet the requirements of state mandated training programs and can help your company reduce the cost of developing, implementing and operating in-house medical cannabis training programs.

PFC currently holds the first government-issued educational permit from the District of Columbia to provide the required staff trainings for the District's legal medical cannabis providers. Additionally, PFC has been awarded a contract with the State of Maryland to train all compliance inspectors for the State's medical cannabis program.

As a leader in medical cannabis education since 2002, ASA has distributed millions of copies of educational literature to patients, healthcare professionals, researchers, industry labor, regulators, and concerned community members and has conducted thousands of legal and advocacy trainings nationwide.

The PFC required trainings include the Core Cannabis Training, the National Cannabis Standards training(s) and a State Specific Legal and Compliance training. PFC is constantly developing new course material designed to fulfill the requirements of state mandated trainings, while providing ongoing educational opportunities to enrich and meet the continuing educational needs of your company's staff. PFC trainings are available online or are offered in-person by a PFC Certified Instructor.

1. CORE CANNABIS TRAINING (CCT)

This training provides the foundation for PFC required trainings and is a prerequisite for all additional training. All paid and volunteer staff, working at a PFC company, are required to successfully complete the CCT. The CCT courses address the following topics:

- CANNABIS RESEARCH AND CLINICAL DATA: Find out what research is revealing about the therapeutic potential of cannabis, and learn what types of pain, disorders and diseases this plant potentially relieves. Clinical trials and their importance are also covered. Finally, see what groundwork has been laid for future cannabis research.
- THE ENDOCANNABINOID SYSTEM: This module gives a brief history of opioids and cannabinoids, and explains how the endocannabinoid system was discovered. The workings of the endocannabinoid system. This module will also explore the physiological role of endocannabinoids.
- CANNABIS 101: Gain a fundamental understanding of the cannabis plant by learning the varieties of cannabis and their uses, the most common cannabinoids, the effects of cannabis, and the difference between psychoactive and non-psychoactive cannabinoids.
- CANNABIS-BASED MEDICINES: Cannabis-Based Medicines covers the cannabis pharmaceuticals that are

currently available. It also takes a look at cannabis extracts and concentrates and how they might be used. The module concludes with a section on cannabis edibles including a brief discussion about how cannabis might be incorporated into topicals, food and drink.

- QUALITY OF CARE: Targeted at dispensary workers, this module covers customer service, how to identify and handle medical emergencies, and patient education. A discussion of the Patient's Bill of Rights finishes the module.
- KNOW YOUR RIGHTS: This module prepares you for interactions with federal law enforcement (FLE). Know what to do in event of detainment or arrest as well as how to answer questions from FLE. Finally, understand when Miranda warnings apply.
- ROBBERY PREPAREDNESS: Cannabis businesses, like other businesses, are at risk for being robbed . Know what to do should this happen. In this module, learn what operations should be followed during a robbery to keep employees safe . Discover what logistical and security preparations should be taken in advance to decrease the chances of a robbery and what protocols should be in place for staff and customers should they bep resent during a robbery.
- RUNNING A SAFE BUSINESS: Dispensaries, cultivators, and processing centers alike need to take precautions to ensure the safety of their product. Learn how to spot contaminants and maintain safe and sanitary conditions. Security considerations will also be discussed. The module concludes with tips on neighborhood and community relations.

2. NATIONAL STANDARDS COURSES

The National Cannabis Standards Training(s) are designed to educate attendees about the particulars of compliance specific to the AHPA and AHP guidelines. National Cannabis Standards Trainings are available in four cannabis industry disciplines. All paid and volunteer staff working at PFC companies are required to successfully complete the National Standards Course work in the discipline(s) that the staff person will be working in. For example, all staff working in cultivation and/or processing facilities must successfully complete the National Standards Course in Cultivation and Processing.

A. CULTIVATION AND PROCESSING: Based on the AHPA Recommendations to Regulators for Cultivation and Processing operations, this training applies to all types of cultivation operations including outdoor, greenhouse, and indoor cultivation facilities. This training is designed to provide learners with the skills necessary to implement Good Cultivation Practices including pesticide guidance, facility requirements, water resource management, recordkeeping, product safety recall systems, adverse event reporting, and information disclosure. This course also explores best practices and safe handling procedures for operations that provide post-harvest processing of cannabis.

B. MANUFACTURING, PACKAGING, LABELING AND HOLDING: Designed for individuals engaged in the manufacturing of hemp and cannabis-derived products, this training is designed to provide learners with the tools necessary to comply with General Manufacturing Practices including general personnel responsibility and safety, physical condition of the plant and surrounding grounds, manufacturing controls including packaging, holding and labeling controls, cannabis material acquisition, inventory and recordkeeping, fielding and documenting complaint,product returns, product safety recalls, and adverse event reporting.

C. DISTRIBUTION: This comprehensive training is designed to provide participants with the skills necessary to implement Best Management Practices relating to the distribution of cannabis, cannabis-derived products, and hemp-derived products directly to compliant individuals through storefront operations, delivery services, direct-from-garden operations, and growing co-op operations. This training includes information regarding personnel policies, facility security, product acquisition, record keeping, customer policies, implementable product safety recall systems, and adverse event reporting.

D. LABORATORY: Designed for individuals performing laboratory analysis of cannabis, cannabis-derived products, and hemp products, this course has been developed to educate learners on good laboratory practices and focuses on facility security, sample handling and disposal, data management, personnel safety and hygiene, and reporting activities that may be unique to laboratories analyzing cannabis, cannabis- derived products, and hemp product samples.

3. STATE SPECIFIC COMPLIANCE TRAINING

Each State-Specific Compliance Training is designed to give medical cannabis staff a comprehensive foundation of knowledge, ensuring they know the compliance expectations of local and State government and regulatory agencies.

- STATE AND LOCAL LAWS: Medical cannabis facilities are often regulated by both State and local laws. During this training, participants will get to know their local and state medical cannabis laws and how those laws apply to them as medical cannabis facility staff, as well as to the patients they will be serving.
- STATE AND LOCAL REGULATIONS: This training provides a broad regulatory overview, necessary to maintain compliance, in all disciplines of the medical cannabis industry. Because compliance may be subject to both State and local oversight, this training discusses the specifics of both local and State regulatory provisions.

ADDITIONAL STATE REQUIREMENTS

As medical cannabis laws continue to evolve, additional trainings above and beyond the PFC required trainings are sometimes required by law. For this reason, PFC offers a broad array of "enrichment courses" designed to assist medical cannabis businesses in fulfilling all mandatory training requirements. Additionally, where required by law, these trainings will cover the specific aspects of the State and local requirements unique to the operation of that State'smedical cannabis program. These trainings may also be utilized to meet the continuing education requirements of PFC companies engaging in recertification and include, but are not limited to, the following PFC course options.

- PESTICIDE GUIDANCE AND INTEGRATED PEST MANAGEMENT (IPM): This in-person course is recommended for all staff who will be working in cultivation and processing facilities. During this course, students are familiarized with key definitions pertaining to pesticides and learn how to properly read a pesticide label. The course will also explore the importance and function of tolerance thresholds, major chemical families, Restricted Entry Intervals (REI's), and Personal Protective Equipment (PPE's) as well as employee safety and employer responsibilities. The second portion of this course covers the key components to successful IPM.
- SUSTAINABILITY, SANITATION, AND RECORD KEEPING FOR CULTIVATION FACILITIES: This course is recommended for all PFC company staff engaged in cultivation and processing operations . Designed to help cultivators reduce their impact on the environment, this course provides tools for reducing the carbon footprint of cultivation operations as well as the use, recycling and reuse of mediums. In addition, this course discusses appropriate nutrient use, the consequences of mined and imported materials, and the proper storage of chemicals. Water resource use, storage, and reduction techniques are also addressed in this course as well as the proper tracking of materials used during the cultivation process.
- REPRESENTATIVE BATCH and LOT SAMPLING - QA/QC: This course is recommended for of all PFC staff regardless of the discipline(s) they will be employed for. During this course, learners will be provided with an overview of paradigm shifts and global perspective relating to Quality Assurance (QA) and Quality Control (QC). Details on developing and implementing QA/QC systems will be discussed including method validation and General Manufacturing Practices (GMP's) as they relate to QA/QC topics.

(PFC reserves the ability to require additional training, as recommended by the PFC Peer Review Board, to ensure compliance with any changes to the AHPA and AHP guidelines, local and state regulatory updates, and during certification renewal.)

V. Types of Certification Offered

Patient Focused Certification is available to cannabis companies in all states with medical cannabis and/or legal adult use laws in place and is designed to show the quality commitment of cannabis companies engaged in providing patients with hemp, cannabis, and cannabis-derived products. There are several options for certifica-

tion available to companies engaged in the PFC program ranging from single discipline certification to multiple discipline certification options. While all available PFC program certifications verify compliance with local and state laws and regulations, as well as AHPA and AHP guidelines, some areas of certification may require additional trainings and/or additional compliance criteria, such as for companies engaged in manufacturing or laboratory testing operations.

CULTIVATION CERTIFICATION

- Ensures the company is compliant with state and local regulations, including licensing, zoning, and environmental requirements.
- Demonstrates the safety of products used in the cultivation process.
- Verifies that the raw medical cannabis does not contain an unacceptable level of contaminants.
- Verifies adherence to AHPA and AHP quality standards and that procedures are in place for implementable product recall protocols, adverse event reporting, proper storage, and safe handling protocols.
- Determines the hazard, risk, and impact of the products used during the cultivation of medical cannabis, protecting the health and well being of the environment, employees, and patients.
- The Cultivation Certification process includes: comprehensive staff training, a document review, a label review to verify product and marketing claims, a thorough facility inspection, and laboratory testing and a contaminant review to ensure there are no unsafe levels of contaminants.

MANUFACTURING, PACKAGING, LABELING AND HOLDING CERTIFICATION

- Ensures the company is compliant with state and local regulations, licensing, zoning, and applicable environmental requirements.
- Verifies the identity, purity, quality, and quantity of ingredients declared on the product label.
- Demonstrates the product does not contain undeclared ingredients.
- Verifies that the product does not contain an unacceptable level of contaminants.
- Verifies adherence to AHPA and AHP quality standards and procedures, including product recall protocols, adverse event recording, as well as proper packaging, labeling, storage, and handling systems.
- Determines the hazard, risk, and impact of the products used in the medical cannabis manufacturing processes to ensure environmental, employee, and patient safety.

The Manufacturing, Packaging, Labeling, and Holding certification process includes: comprehensive staff training; document review; a label review to verify product identity, formulation, and marketing claims; a formulation review to identify and quantify dietary ingredients declared on the product label; a contaminant review and laboratory testing to ensure there are no unsafe levels of contaminants; and a thorough facility inspection.

DISTRIBUTION CERTIFICATION

- Ensures the company is compliant with state and local regulations, licensing, and zoning requirements.
- Verifies adherence to AHPA and AHP quality standards and procedures, including product recall protocols, adverse event reporting , and proper storage and handling systems
- Determines the hazard, risk, and impact of the processes used in the medical cannabis distribution operation to ensure community, employee, and patient safety.

The Distribution certification process includes: comprehensive staff training, document review, a label review to verify product formulation and marketing claims, and laboratory testing to ensure there are no unsafe levels of contaminants in products provided to patients.

LABORATORY CERTIFICATION

- Ensures the company is compliant with state and local regulations, environmental, licensing, and zoning requirements.
- Demonstrates the laboratory's commitment to accuracy and integrity.
- Verifies adherence to AHPA and AHP quality standards and procedures, including proper calibration, storage, and handling systems.
- Determines the hazard, risk, and impact of the processes used in the medical cannabis laboratory to ensure employee and patient safety.

The Laboratory Testing certification process includes: comprehensive staff training, document review, equipment and standards review, testing verification, and a thorough facility inspection.

MULTIPLE DISCIPLINE CERTIFICATION

For those companies engaged in multiple types of industry operations, PFC offers multiple discipline certifications. This certification opportunity allows companies engaged in a combination of cultivation, manufacturing, and/or distribution to certify all areas with one PFC seal of approval denoting the combination of disciplines and a commitment to product safety for all aspects of their operation. In order to uphold the integrity of PFC independent laboratory testing services and the product safety verification such certified laboratory's offer, PFC does NOT allow laboratory certification to be combined with other disciplined operations receiving PFC certification. If a PFC laboratory operation wishes to certify in a second discipline, then the certified laboratory facility may NOT be used to satisfy the testing requirements of the secondary discipline.

VI. Certification Process

HOW TO BECOME CERTIFIED

PFC offers a confidential and supportive certification process that includes:

1. Application—the PFC process begins when the licensee or licensee applicant provides a completed application to PFC. A confidential review of the business operations is completed to determine appropriate inspections and testing.
2. Quote—using information generated by the Application, PFC staff prepares a price quote and an estimate of time required for completing the certification process
3. Contract—a contract is executed outlining the responsibilities of all parties involved including financial obligations, non-disclosure protections for the applying company, and acceptance of terms.
4. Preliminary Assessment (optional)—available as PFC Advisory Services, PFC staff is available to provide procedures for an upcoming document and physical audit and can work with management to prepare the operations facilities and processes.
5. Documentation Audit—an offsite review of company documentation determines if the company's licensing and processes are sufficient to ensure adherence to standards.
6. Training Audit—verification of the mandatory training of all paid and volunteer employees, including all new hires that occur over the course of the certification year. This audit is ongoing and employees must have successfully completed all PFC required trainings prior to certification approval or renewal.

7. Document and Facility Audit—trained independent PFC field inspectors conduct a confidential PFC standards audit and a facility inspection.
8. Product Testing— PFC tests for pesticides, molds, and contaminants with an independent third-party laboratory when available, necessary, and appropriate for certification or complaint resolution.
9. Initial Scoring and Corrective Recommendations—the licensee receives the results of the PFC audit and is given corrective actions to be remedied as needed.
10. Secondary Audit—as needed
11. Certification—the PFC Review Board will issue the licensee's certification once the PFC auditor verifies any required corrective actions have been remedied and all compliance standards have been met.

HOW TO PREPARE FOR CERTIFICATION

Your company is ready for certification after you've implemented good management practices based on AHPA standards, trained employees to become proficient with processes, and developed a sufficient evidentiary trail of documents that can be assessed. PFC staff can provide applicants with discounted training programs, as well as document preparation and advisory services to help you company prepare for certification. Please contact PFC for additional information on advisory services.

PRELIMINARY ASSESSMENT

In many cases, the company seeking certification may request an optional preliminary assessment of their operations which is offered through PFC's Advisory Services. This gives PFC the opportunity to identify in advance any weaknesses that may exist in the company's management systems. A preliminary assessment gives the company sufficient lead- time to correct deficiencies before audits are conducted and assists PFC in planning for the certification. The scope of the preliminary assessment is determined by the company and may range from a review of documents to a full assessment, including on-site operational observation and assessment. While the preliminary assessment is optional, it is recommended. Ultimately, it may save time and expense by revealing deficiencies that, if corrected before the required audits, can save the expense of follow-up audits before certification can be granted.

DOCUMENTATION AUDIT

A PFC Independent Auditor assigned to the company will retrieve all local and state licensing documents, as well as management system documents and manuals. The assigned PFC auditor will review the documentation to determine whether it meets all requirements of local and state regulations, and the AHPA and AHP standards.

Documentation should include, at a minimum:

1. Standards manual(s) – outlining systems utilized to ensure compliance with state and local law and regulations as well as the AHPA and AHP guidelines
2. Operating procedures – including detailed descriptions on how to perform system functions;
3. Work instructions – defining specific job activities affecting the safety and quality of products and processes; and
4. Quality documentation – documents that demonstrate how quality is managed including records, charts, files, inspection and testing records, assessment results, implementable product recall procedures, adverse event reporting, and any other records of objective evidence.

If the documentation fails to meet standards, the deficiencies will be identified in an audit report, and the licensee is required to take corrective action before certification can be awarded. Once PFC has determined that the documented management systems are satisfactory, a facility audit will be scheduled.

TRAINING AUDIT

A PFC auditor assigned to the company will verify that all paid and volunteer staff has successfully completed the required PFC trainings. Successful completion of PFC required courses is documented by passing the corresponding on-line tests with a score of no less than 80%. All company staff must successfully complete the required trainings prior to receiving certification and all new hires are required to successfully complete the required trainings within 30 days of hire date in order for the company to maintain PFC approved company status.

FACILITY AUDIT

The assigned PFC auditor(s) will complete a thorough on-site assessment of the facility and its operations. An audit agenda will be prepared for the licensee prior to the arrival of the PFC auditor(s) including a daily schedule and any accommodation requests. It is the auditor(s) responsibility to verify whether the management systems of the company meet all of the requirements of applicable standards.

Upon arrival at the facility, the PFC auditor(s) will conduct an introductory meeting followed by a full facility walk-through to observe activities and confirm that the operating procedures outlines in the document audit have been successfully implemented. All PFC auditors reserve the right to obtain samples for the purpose of laboratory testing, conduct private interviews with employees, inspect documents and records, observe work processes, and examine equipment. The objective of the facility audit is to verify technical competency including statements, documented procedures, records, and written policies.

If deficiencies are found during the course of the audit, the PFC auditor(s) will bring the deficiencies to the licensee's attention and record them in the audit report as required or suggested corrective actions, depending on the severity of the deficiency. The audit report will specifically describe, in detail, what deficiency was observed, the related standard or policy to which it relates, and the necessary corrective actions required to remedy the deficiency. PFC audit reports also include a recommended timeline for the company to receive certification. This timeline varies depending on potential corrective actions.

PRODUCT TESTING

PFC provides a wide range of comprehensive medical cannabis product safety testing, where available (services may be limited in some states). PFC's independent laboratory testing services assist certified companies with the establishment of product stewardship by confirming content and purity, identifying problems with contamination, and determining potential for human and environmental exposure risk to ingredients and by-products including potential allergens, residuals, and microbiological adulterants. The PFC program specializes in examining product composition, proper packaging, labeling, and storage protocols that ensure public and patient safety. PFC laboratory testing conducted for certification verification is provided by PFC independent certified labs conforming to AHPA and AHP guidelines, as well as all applicable local and state laws and regulations. Laboratory testing for the purposes of certification verification is limited to necessary testing to meet standards. Where allowed by state law, our independent certified laboratory testing facilities can also provide patients, caregivers, and licensees cannabis analytical services as requested.

EXIT MEETING

Upon completion of the on-site audit, the assigned PFC auditor(s) will conduct an exit meeting. A summary review of the facility audit will be discussed with management or the primary contact person, and regulators as applicable. If deficiencies were recorded, they will be described at this time and included in the final facility audit report. All PFC applicants will be given a reasonable time period to implement any required corrective action(s).

CORRECTIVE ACTION

All companies with identified deficiencies will be given a reasonable timeframe to implement the mandated corrective action. PFC requires that all corrective actions be implemented and approved by the assigned auditor before certification can be granted. The corrective action response must include objective evidence, which shows

the necessary corrective actions have been completed. PFC may require a follow-up on-site facility audit, limited to the area of concern, depending on the nature of the deficiency. Certification cannot be awarded until any and all deficiencies have been adequately corrected.

FINAL REVIEW, REPORT AND APPEAL PROCESS

Within 10 business days of the facility audit (if no deficiencies are found) or upon confirmation of completed corrective actions, PFC will issue a confidential report and certification decision (report will be provided to regulators if necessary). All documentation will be forwarded to PFC's Peer Review Board, and the Executive Committee will review the audit report and checklist prior to issuing a decision on the certification. If the Peer Review Board grants a company certification, they are notified immediately and the appropriate certification materials will be issued.

In the event that an application for PFC certification is denied, an appeal may be submitted within 10 business days of the issuance of the decision. PFC provides an independent Dispute Board that includes at least three members from the PFC Peer Review Board. Each Dispute Board member must have sufficient knowledge and expertise in the discipline to perform a review of materials and reports and issue an impartial decision.

CERTIFICATION

Upon the successful completion of PFC required trainings, audits, and necessary corrective actions the company will become PFC approved and will receive a PFC approved materials package. PFC certification materials include:

1. A certificate bearing the certified company's name, physical address and the PFC's certification logo;
2. PFC certification window decals;
3. Educational and promotional materials for patients, healthcare providers and regulators;
4. PFC website links;
5. A Standards Packet including applicable AHPA guidelines and an AHP Cannabis Monograph;
6. Verification that copies of the approved certification(s) have been sent to regulators and localities, as required by law;
7. Annual audit reports, audit checklists and compliance updates.

Once certification has been granted, the review period begins, and the company may be subject to random and unannounced audits and/or product testing. An annual re-certification process is mandatory. Follow-up audits may require document submissions and/or an on-site visit. Certified companies are required to respond within five (5) business days to any complaint submitted to PFC (by consumers, healthcare providers, stakeholder groups, regulators, etc.) for which a response is determined by the PFC Peer Review Board, to be necessary. PFC will maintain records of complaints on certified companies. Such complaints may trigger unannounced inspections depending on the complaint severity and/or frequency. If for whatever reason certification must be suspended, PFC will notify regulators.

CERTIFICATION PROCESS TIMELINE

The length of time required to complete the certification process depends on several variables including: the discipline(s) and size of facility, number of employees, and complexity of operations. The amount of time it takes a company to achieve readiness for certification depends on the quality of management systems currently in place. PFC provides optional advisory services to identify and resolve documentation and process deficiencies in advance of the audit process.

The speed of the certification process is dependent upon timely and complete responses from the applicant. A typical certification process will follow a timeline similar to the following:

1. Application Submitted

2. Quote Issuance
3. Contract Execution
4. Preliminary Assessment Completion (optional)
5. Documentation Audit – (3-5 business days)
6. Facility Audit/Product Testing (3-5 business days)
7. Corrective Action Period (if necessary) – (5-15 business days)
8. Final Review, Report and Decision – (5-10 business days)

VII. Ongoing Review & Compliance

The assigned PFC auditor and PFC staff will continually monitor certified operations throughout the annual certification period. PFC is committed to working with companies engaged in the PFC Program to achieve excellence by providing ongoing support and monitoring of corrective actions.

In the event of a law or regulation change, or when AHPA or AHP releases updated standards, a review audit may need to be completed. PFC staff will notify certified companies of any updates to rules, regulations, and/or standards and provide an explanation of actions required by the company to comply with said update, including a required timeframe for compliance.

VIII. PFC Program Oversight

The PFC Program is overseen by the PFC Peer Review Board that provides over 300 years of collective expertise in the realms of USDA food and product safety protocols, federal regulatory development, medical cannabis research, medical cannabis industry operations, pharmacology, and biochemistry. The PFC Peer Review Board is tasked with the annual review and update of audit methodologies and program standards, the processing and review of all certification appeals, complaint investigation and resolution, and any and all revocation actions. The review board may be asked to weigh in on a company's corrective actions as determined through either a scheduled or a secondary follow up audit. Expanded PFC Peer Review Board bios can be found at patientfocusedcertification.org.

PFC REVIEW BOARD

Dr. Sunil Aggarwal, M.D., Ph.D., is an Associate Member of the New York Academy of Medicine and a Resident in Physical Medicine and Rehabilitation at NYU's Rusk Institute of Rehabilitation Medicine. As a NYU Graduate Research Fellow, he conducted human studies of medical cannabis use under the first federal Certificates of Confidentiality ever granted.

Todd Dalotto is a cannabis industry consultant, horticultural scientist, public policy advisor, and expert witness specializing in medical cannabis. Todd is the Chair of the Oregon Health Authority's Advisory Committee on Medical Marijuana, chairs the ACMM's Horticulture, Research & Safety Committee, and helped draft the regulations for Oregon's licensed dispensary law.

Don Duncan has served on the Board of Directors of Americans for Safe Access since he co-founded it in 2002. As California Director, he is coordinating the grassroots and grasstops campaign to fully implement the state's medical marijuana laws, respond to federal interference, and build a broader, more powerful coalition for medical marijuana. Don co-founded one of the oldest and most reputable families of medical cannabis dispensing collectives in California, helping to open legal facilities in Berkeley, West Hollywood, and Los Angeles.

Dr. Robert L. Epstein served as Associate Administrator and Chief Operating Officer for the Agricultural Marketing Service, U.S. Department of Agriculture (USDA) from January 2013 until his retirement in June 2013. With over 34 years of service at the USDA Dr. Epstein has held various leadership positions involving food safety, laboratory services, toxicology, residue chemistry, and quality assurance.

Jill Lamoureux has a background in toll road operation and municipal bond finance, and an MBA from the University of Denver. She is a founding member of, and served as the first woman Chair of the National Cannabis Industry Association and has been a leader in Colorado's medical marijuana industry since. Jill developed Patient Focused Certification with Americans for Safe Access and serves as Chair of the PFC Peer Review Board.

Philippe G. Lucas holds a master's degree in the area of Studies in Policy and Practice from the University of Victoria and is co-owner and COO of the Canadian Cannabis Research Institute. Philippe has also served as a co-investigator for Medical Cannabis Standards, Engagement, Evaluation, and Dissemination (SEED) Project, and served on the Victoria City Council from Nov 2008-Nov 2011.

Jahan Marcu, Ph.D. is the Vice-Chair of the Americans for Safe Access Multidisciplinary Scientific Advisory Board and is currently investigating the pharmacology of cannabinoid receptors at Temple University. He received his Ph.D. for studying the structure and function of the CB1 receptor, and the role of the endocannabinoid system in bone.

Michael McGuffin is President of the AHPA and Managing Editor of AHPA's Botanical Safety Handbook, and of Herbs of Commerce, second edition (2000). He serves on the boards of the AHP and United Plant Savers, and on the Advisory Board of the USC School of Pharmacy Regulatory Science Master's Degree Program.

Kristin Nevedal is Director of PFC and chairs the AHPA Cannabis Committee's Cultivation Working Group, assisting in the development of model cultivation regulations and best practices for agency consideration. She is also an instructor at Oaksterdam University, teaching classes on environmental sustainability and Best Management Practices, as well as Co-Founder and Chair of the Emerald Growers Association.

Dr. Michelle Sexton is a naturopathic doctor, herbalist, educator and clinical cannabis researcher. Dr. Sexton completed a postdoctoral fellowship focused on the endogenous cannabinoid signaling system (ECS) in the Departments of Pharmacology and Psychiatry and Behavioral Medicine at the University of Washington. Michelle is also research faculty at Bastyr University research institute and Technical Advisor to the American Herbal Pharmacopoeia.

Steph Sherer is a medical marijuana patient with over 15 years managing non-profit businesses and community organizations including: event planning, consulting, fund development, public relations, and project management. Steph is a powerful advocate, a skilled spokesperson, an energetic initiator of campaigns, and a nationally recognized activist in the global justice movement and a guest lecturer at the University of California, Berkeley and George Washington University, DC.

Tim Smale is the Co-Founder and Executive Director of Remedy Compassion Center in Auburn, Maine and a results-driven leader with over 30 years domestic and international experience with nonprofit and for profit organizations, from small businesses to Fortune 100 companies.

Elan M. Sudberg, CEO of Alkemist Labs, holds a degree in chemistry and has authored numerous journal articles on phytochemistry. He is the instructor of AHPA's Seminar on Microscopic Identification of Popular Botanical Materials, an appointed board of trustees member of AHPA, a board member of AHPA's ERB Foundation, and the former Chair of the Hemp and Medical Marijuana Committee. He serves as a Technical Adviser for the AHP.

Dr. Jim Tozzi worked for five consecutive presidential administrations, including service as the senior career regulatory policy official at the White House Office of Management and Budget. Dr. Tozzi is the father of the Data Quality Act and has been appointed to the Administrative Conference of the US overseeing the federal regulatory process.

IX. PFC Auditor Qualifications

PFC independent auditors have extensive experience in the medical cannabis industry or in auditing similar industry and/or the herbal products industries. All PFC independent auditors are required to successfully complete the PFC trainings and are assigned a mentor to oversee PFC audits until such time as the mentoring auditor can verify the trainees' readiness to audit without mentor oversight. All auditor trainees are required to conduct a minimum of two audits per discipline with his or her mentor before being allowed to audit independently.

All PFC Cultivation and Processing auditors must have five years or more direct experience in the field of medical cannabis cultivation and processing or five years or more direct experience in the field of agricultural inspection and must demonstrate a thorough understanding of the standard operating systems associated with all modalities of cannabis cultivation.

Manufacturing, packaging, labeling, and holding auditors must have five years or more direct experience in the field of medical cannabis manufacturing and are required to be food-safe certified; or have three years or more direct experience in the inspection and auditing of facilities engaged in the manufacturing of food, food products, or botanical and nutraceutical products. In addition, all manufacturing, packaging, labeling, and holding auditors must also demonstrate a fundamental knowledge of any extraction processes used in the medical cannabis industry.

PFC Laboratory auditors must have, at minimum, a degree in biochemistry; or a minimum of five years experience providing laboratory analysis of medical cannabis and medical cannabis-derived products the equivalent experience providing laboratory analysis of other raw botanicals, botanical products, or nutriceutical products.

Dispensary auditors must have, at a minimum, three years of direct experience in managing a medical cannabis distribution facility offering patient services, or the equivalent experience offering patient services and managing a traditional or Complementary Alternative Medicine facility.

X. Fees and Discounts

Each applicant has its own unique characteristics that will determine the cost of certification. Two key elements comprise the cost of certification: size and complexity of the operations. As the size of a company increases so does the number of patients or consumers engaging in the company's services or products. PFC's patient and caregiver education program serves to provide your business with plenty of educational materials designed to help consumers understand the importance of the PFC seal of approval.

All quotes also include the cost of the initial pre-certification audit plus the required compliance audit. As a company grows in size and possibly in complexity of operations so does the amount of time necessary to conduct a thorough audit of the company's operations. For example, a company that dispenses medical cannabis often requires much less time to conduct an audit than a company that cultivates and manufactures medical cannabis. As such these scalable costs are reflected in the PFC quote.

PFC will provide a quote after a complete review of your application. This quote is an estimated cost and will include:

1. Fees for preliminary assessment (optional)
2. Fees for the initial audit plus one unannounced compliance audit and certification review
3. Fees for certification including graphics and promotional literature
4. Fees for ongoing compliance including complain hotline, complaint investigation, and possible certification challenges

PFC is committed to providing your company with a quality certification program that adds value to your business. We are committed to providing the most qualified inspection and audit team at the lowest cost possible. The program's value drivers include:

1. No application fee
2. Discounts for some trade association members, AHPA members, and UFCW contracted businesses.
3. No mandatory preliminary site visit
4. No hidden costs, overtime charges, or penalties for properly noticed schedule changes
5. Reimbursable expenses are charged at cost without mark-ups
6. Advanced off-site preparation is completed by PFC, reducing travel time required
7. Audits include a review of compliance with local and state regulations
8. Press release development by PFC outreach staff
9. ` Advertisement of your participation in all PFC ads

Discount Opportunity: PFC is pleased to offer discounts to members of organizations that have endorsed the PFC program. Endorsing organization discounts can be combined to provide your business with a maximum 15% discount on certification. PFC can also offer group discounts for organizations that want certify 10 members, or more, at a given time. For more information on endorsing organizations please see the website: www.patientfocusedcertification.org

Endorsement Opportunity for Trade Associa-tions and other Accrediting Groups: PFC recognizes the importance of endorsing organizations ongoing work with their members to insure compliance with local and state regulatory guidelines. As such, PFC is pleased to offer discounts to organizations working directly with the PFC program. Once PFC has approved your association's or accrediting group's endorsement , PFC will happily offer all members and companies acknowledged by your group a 5% discount on PFC certification.

XI. About ASA, AHPA and AHP

AmericansFor SafeAccess
Advancing Legal Medical Marijuana Therapeutics and Research

Founded in 2002, Americans for Safe Access (ASA) is the largest organization of patients, medical professionals, scientists and concerned citizens promoting safe and legal access to medical cannabis. ASA's mission is to ensure safe and legal access to cannabis (marijuana) for therapeutic uses and research. ASA works with our grassroots base of over 50,000 members to effect change using public education and direct advocacy at the local, state, and federal level. ASA trains and educates patients, advocates, health care professionals and other stakeholders. ASA also provides direct legal support and uses impact litigation to protect and expand patients' rights.

As patient advocates, ASA has worked to create laws and regulations that foster the rights of patients, and ensure access to safe and legal medical cannabis. Now, through PFC, patients, caregivers, and health care practitioners, as well as state and local regulators, can rely on the PFC seal of approval and know the medical cannabis or cannabis-derived product has been produced in a manner that is not only compliant with local and state laws but also with a commitment to product safety. To learn more about ASA go to: www.americansforsafeaccess.org.

AHPA
AMERICAN HERBAL PRODUCTS ASSOCIATION

The American Herbal Products Association chartered a Cannabis Committee in 2010 to meet the needs its members who cultivate, manufacture, or distribute medical cannabis in the states where its use is allowed by state law, and of companies that market industrial hemp products. AHPA has been the principal U.S. trade association and voice of the herbal products industry since 1982. AHPA promotes the economic health of the herbal products industry and promotes high quality herbal and nutraceutical products. AHPA serves its members by promoting the responsible commerce of products that contain herbs and that are used to enhance health and quality of life. To learn more about AHPA go to: www.ahpa.org.

A H P
American Herbal Pharmacopoeia®

The American Herbal Pharmacopoeia was formed in 1994 to promote the responsible use of herbal products and herbal medicines. AHP is a worldwide network of botanists, chemists, herbalists, medical doctors, pharmacists, pharmacologists, and

other experts in medicinal plants. AHP has published monographs for 28 different botanicals, including Aloe Vera Leaf, American Ginseng Root, and Echinacea. The organization expects to eventually publish more than 300 monographs, covering the most widely used western, Ayurvedic, and Chinese botanicals. To learn more about the AHP go to: www.herbal-ahp.org.

XII. Frequently Asked Questions

What is Third-Party Certification?

Third-party certification ensures that an independent organization has reviewed the cultivation and/or manufacturing process of a product or the management process of a service in order to determine that the final product complies with a specific set of standards designed to ensure safety, quality, or performance. PFC certifies compliance with AHPA and AHP standards for medical cannabis products and services. This review typically includes comprehensive reviews of formulations and materials, independent testing, and facility inspections. Certified products typically exhibit the certifier's 'mark' on their packaging to help consumers make educated decisions about the products or services they are purchasing. PFC requires annual inspections, unannounced random inspections, employee training and product testing to ensure that certified companies continue to meet all AHPA standards after the initial certification. Other nationally recognized certification programs include Good Housekeeping, NSF and ISO.

What is the difference between PFC and ISO 17025 for Lab Certification?

ISO compliance will help an operator pass a PFC inspection. ISO 17025 accreditation ensures compliance with a specific set of laboratory methods, PFC compliance ensures compliance with botanical health and safety standards, and criteria for validating specific methods. Both PFC and ISO require significant documentation and method validation, but ISO depends on the operators being forthright whereas PFC compliance hinges on the operator providing requested documentation i.e. ISO (e.g., 17025) audits whatever an operator presents as part of a "quality manual." There could be a 1,000 procedures being used in the lab and only 1 could be in the quality manual. For an ISO audit, an operator is expected to show/help auditors identify "conflict" or corrective action areas, while PFC asks for specific criteria provided by the AHPA's Recommendations to Regulators and the AHP Cannabis Monograph..

ISO is used for commercial labs operating outside stateliness, laboratories are encouraged to get ISO but even their guidebooks suggest that local guidelines and standards are important for operating locally, if such guidelines are available. ISO is often used when there is absence of a compliance or certification body, such as in a small country with a few labs.

ISO is context deficient for medical cannabis operators. It doesn't tell you if the business is a good cannabis operation or not because it only informs on what is needed to do an aspect of their work, regardless if it is legal or meant for human consumption. PFC offers training in specific areas of cannabis that are used by operators and health department inspectors in compliance audits, ISO does not require that the staff be trained in specific areas essential for operation in the cannabis industry. Sample handling, storage, security, legal operations issues (ISO does not check licensing or permits from the state) are examples of best practices and regulatory requirements that ISO does not fully address for the cannabis industry.

Analytical Chemistry cannot be properly dealt with if its relationships with written standards are not taken into account in order to efficiently contribute to the continuous improvement of human activities.

> *…the key issue in selecting an accreditation body is to ensure that it has recognition in the context in which the laboratory's data needs to be used. Where a laboratory operates purely in a domestic market and where the data is used only within the country, for example for local food safety or environmental protection, then a national accreditation body, even one with no international recognition, will normally be entirely suitable.*

(From "Complying with ISO 17025: A practical guidebook for meeting the requirements of laboratory accreditation schemes based on ISO 17025:2005 or equivalent national standards published by (United Nations Industrial Development Organization)

PATIENT FOCUSED CERTIFICATION

STANDARD. EDUCATION. VERIFICATION.

Difference Between PFC and ISO for Lab Certification

Laboratory Testing Facilities	PFC	Notes on PFC	ISO (i.e., 17025)	Notes on ISO
General requirements for laboratory competence	✓		✓	
Document review (management systems, technical requirements)	✓		✓	*only protocols submitted in quality manual
Equipment calibration	✓		✓	
Document control protocols	✓		✓	
Protocol evaluation	✓	*all protocols used in reporting of data	✓	*only protocols submitted in quality manual
Methodology standardization	✓		✓	
Requires proficiency testing	✓		✓	
Requires adherence to documented, validated, methodology & specification of technical competence	✓		✓	
Training audit for instrument/equipment	✓		✓	
Assists with cGMP compliance	✓		✓	
Requirements for customer service	✓		✓	
Cannabis specific safety and waste disposal criteria	✓		✗	
State and local regulatory complinace for cannabis	✓		✗	
Training audit for local, state and federal laws regarding cannabis	✓		✗	
Training in Cannabis chemistry and pharmacology	✓		✗	
Security training for cannabis operations	✓		✗	
Requries continuing education credits	✓		✗	
Cannabis industry specific method audits	✓		✗	
Proper cannabis handling, transporting and disposal	✓		✗	
Customer reporting of data compliant with botanical health and safety standards	✓		✗	
Acceptable for PFC dispensary certification	✓		✗	
Acceptable for PFC manufacturing certification	✓		✗	
Acceptable for PFC cultivation certification	✓		✗	
(Require a recall plan)	✓	*if applicable	✗	
(Requires adverse event reporting)	✓	*if applicable	✗	
(Batch/lot tracking)	✓	*if applicable	✗	

PFC and ISO Harmonization

- Mutual Recognition Agreements (MRAs), ISO:17011 compliance
- European Cooperation for the Accreditation of Laboratories (EAL)
- Asia Pacific Accreditation Cooperation (APLAC)
- Quality Systems Training
- Method Validation reports
- Audits

APPLICATION

Patient Focused Certification

For your free quote, please completely fill out the application below. Upon completion, and submitting the application, your company's information will be securely transmitted to PFC staff. You will automatically receive a confirmation email verifying that PFC has received your application and inviting you to create a secure PFC client profile where you can safely view and store documents to track your company's certification process. Within 7 business days, PFC staff will send you a price quote and contract that will list the responsibilities of all parties involved including financial obligations, nondisclosure agreements and acceptance of terms.

Business Trade Name (required) _____

Business Legal Name (required) _____

Mailing Street Address:_____

City: _____ State:_____ Zip:_____

Primary Contact Name (required) _____

Primary Contact Email (required) _____

Primary Contact Phone (required)_____

Number of Facilities (required) _____
(Organizations with multiple locations, please fill out Additional Locations section at the end of the application.)

Number of Employees (required) _____

A. Service Requested (check all that apply)

❑ Advisory Services ❑ Pre-Licensing Certification ❑ Industry Certification

B. Facilities to be Certified / Types of Certification Sought (check one)

❑ Cultivation ❑ Distribution ❑ Manufacturing ❑ Laboratory ❑ Cultivation & Distribution

❑ Cultivation & Manufacturing ❑ Manufacturing & Distribution ❑ Cultivation, Manufacturing, & Distribution

How many square ft of cultivated space (if applicable)

❑ 0-5,000 ❑ 5,000-10,000 ❑ 10,000-20,000 ❑ 20,000-40,000 ❑ 40,000 or above

Number of products manufactured (if applicable): _____

Please describe the types of products to be manufactured (choose all that apply)

❑ Extracts/Concentrates ❑ Edible or Ingestible Products ❑ Topical Products

Additional Product Information_____

_____

C. Licensing. Please describe the state and local licensing or registrations relevant to your operations. Please note if no licenses are available for your operation. _____

_____

_____

D. MACHINERY AND INFRASTRUCTURE

Please describe the major machinery, software and infrastructure used in your operations. This might include inventory and tracking software, manufacturing equipment, trim machines, etc.

_____

_____

_____

_____

E. SUBCONTRACTORS

If applicable, please list any sub-contractors used in your operations, including name and the activities they perform. Examples of sub-contractors include the nursery that provides the company's propagation material. Or, if manufacturing edible products, the name of the company who supplies your company with extracted cannabis products.

_____

_____

_____

_____

F. OTHER CERTIFICATIONS

Please list any certifications, past or present, your operation has received and the name of the certifying organization. If cancelled or no longer current, please describe why.

_____

_____

G. ORGANIZATION AFFILIATION

Companies with membership in AHPA, various trade organizations, or those under UFCW contracts are eligible for discounts. Please choose all that apply:

- ❑ American Herbal Products Association
- ❑ United Food & Commercial Workers Union
- ❑ Emerald Growers Association
- ❑ International Hemp Association
- ❑ Coalition for Cannabis Standards and Ethics

Please list additional organizational memberships or affiliations: _____

_____

_____

If you belong to an organization or association whose members would benefit from a discount, please contact us for details. **info@patientfocusedcertification.org**

H. ADDITIONAL LOCATIONS

Name _____

Address:_____

City: _____ State:_____ Zip:_____

Type (choose one): ❑ Cultivation ❑ Distribution ❑ Manufacturing

Number of Employees _____

Name _____

Address:_____

City: _____ State:_____ Zip:_____

Type (choose one): ❑ Cultivation ❑ Distribution ❑ Manufacturing

Number of Employees _____

Name _____

Address:_____

City: _____ State:_____ Zip:_____

Type (choose one): ❑ Cultivation ❑ Distribution ❑ Manufacturing

Number of Employees _____

I. Where did you hear about us?

❑ Mail ❑ Peer ❑ Internet

❑ Organization or Association (Please list): _____

❑ Other: _____

All application information shall remain CONFIDENTIAL. Based on the information contained in this application, PFC will prepare a no-obligation offer for certification. If PFC staff requires additional information to generate a quote, a representative will contact you directly via email.

PATIENT FOCUSED CERTIFICATION, a project of Americans for Safe Access
1806 Vernon Street NW, Washington, D.C. 20009
Phone: (202) 857-4272 Fax: (202) 618-6977

CULTIVATION CERTIFICATION AUDIT

Patient Focused Certification

APPLICANT NAME: _____

AUDITOR NAME: _____

FACILITY LOCATION: _____

DATE OF AUDIT: _____

TIME ON SITE: _____

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
A1.1 (b) • Subject operations – Does this cultivation operation also include a processing operation?	☐	☐	☐	
A1.1 (a) • Subject operations – Is this operation subject to state and/or local oversight?	☐	☐	☐	
A1.2 • Other statutory provisions and regulations – Is this operation compliant with all applicable regulations in the jurisdiction it operates? (e.g. has a license in good standing, certificate of occupancy, confidentiality requirements, labeling and testing requirements, etc.)	☐	☐	☐	
B2.1(a)(1) Operations – Does the operation include indoor cultivation operations?	☐	☐	☐	
B2.1(a)(2) Operations – Does the operation include greenhouse cultivation operations?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
B2.1(a)(3) Operations – Does the operation include outdoor cultivation operations?	☐	☐	☐	
B2.1(a)(4) Operations – Does the operation include nursery operations?	☐	☐	☐	
B2.1(b)(1) Operations – Does this operation produce its own cannabis planting material?	☐	☐	☐	
B2.1(b)(2)(i) Operations – Does this operation obtain cannabis planting material from other cultivation operations?	☐	☐	☐	
B2.1(b)(2)(ii) Operations – Does this operation obtain cannabis from a nursery operation?	☐	☐	☐	
B2.1(b)(2)(ii) Operations – Does this operation obtain cannabis from compliant individuals?	☐	☐	☐	
B2.1(c)(1) Operations – If this facility contains a processing operation, is cannabis obtained from a cultivation operation?	☐	☐	☐	
B2.1(c)(2) Operations – If this facility contains a processing operation, is cannabis obtained from compliant individuals?	☐	☐	☐	
B2.1(c)(3) Operations – If this facility contains a processing operation, is cannabis obtained from vendors?	☐	☐	☐	
B2.1(d)(1) Operations – Does this operation distribute cannabis to other cultivation operations?	☐	☐	☐	
B2.1(d)(2) Operations – Does this operation distribute cannabis to other processing operations?	☐	☐	☐	
B2.1(d)(3) Operations – Does this operation distribute cannabis to operations with distribution practices or dispensing operations?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
B2.1(d)(4) Operations – Does this operation distribute cannabis to manufacturing operations?	☐	☐	☐	
B2.1(d)(5) Operations – Does this operation distribute cannabis to vendors?	☐	☐	☐	
B2.1(d)(6) Operations – Does this operation distribute cannabis to compliant individuals?	☐	☐	☐	
B2.2(a)(1) Operations – Does this operation also engage in ancillary operations such as the manufacturing, packaging, labeling, and/or holding of cannabis-derived products? (Indicate all those that apply by circling the ancillary operation in the list above.)	☐	☐	☐	
B2.2(a)(2) Operations – Does this operation also engage in laboratory operations?	☐	☐	☐	
B2.2(a)(3) Operations – Does this operation engage in distribution practices for cannabis and cannabis-derived products?	☐	☐	☐	
B2.2(a)(4) Operations – Does this operation engage in cultivation and marketing of products other than cannabis?	☐	☐	☐	
B2.3(a)(1) Cultivation practices – Are all propagation materials used in cultivation operations approved for use in food production?	☐	☐	☐	
B2.3(a)(1) Cultivation practices – Are all propagation materials handled following the manufacturer's usage, storage, and disposal recommendation?	☐	☐	☐	
B2.3(b)(1)(i-iv) Cultivation practices – Is the operation compliant with permitted use of pesticides as recommended in Section 2.3B(1)(i-iv) and any other applicable regulations for their jurisdiction?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
B2.3(b)(2) Cultivation practices – Is the operation following the manufacturer's application and storage recommendations, and disposal recommendations, for any pesticide products?	☐	☐	☐	
B2.3(b)(3) Cultivation practices – Is the operation following the EPA Worker Protection Standard when preparing and applying pesticides?	☐	☐	☐	
B2.3(b)(4) Cultivation practices – If this operation is indoor, is it complying with the pesticide manufacturer's published re-entry interval time periods when applying pesticides?	☐	☐	☐	
B2.3(c)(1) Cultivation practices – Are the nutrients used in cultivation appropriate for use in food production? (Not required by AHPA document.)	☐	☐	☐	
B2.3(c)(2) Cultivation practices – Is the operation following the manufacturer's application, storage, and disposal recommendations for the nutrient product?	☐	☐	☐	
B2.3(c)(3) Cultivation practices – Is the operation returning unused plant solutions (e.g., rooting hormone) to the source container? (Not allowed.)	☐	☐	☐	
B2.3(c)(4) Cultivation practices – Are nitrate-based and other oxidizing fertilizers stored away from solvents, fuels, and pesticides?	☐	☐	☐	
B2.3(d)(1) Cultivation practices – If the operation is indoor, are carbon dioxide levels kept under 2000 ppm when facility personnel may be present in cultivation areas?	☐	☐	☐	
B2.3(d)(2) Cultivation practices – Is the indoor cultivation facility utilizing carbon dioxide at levels above 2000 ppm in a sealed room? If so, is there protective equipment provided for personnel and warning signs present to prevent other personnel from entering?	☐	☐	☐	
B2.3(d)(3) Cultivation practices – Are all regulators and environmental control systems that regulate carbon dioxide emissions in good working order	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
and serviced in accordance with the manufacturer's recommendations?				
B2.3(e)(1) Cultivation practices – Is equipment used for measuring, regulating, or recording temperatures, pH, humidity, or other conditions related to the cultivation and processing of cannabis accurate and adequately maintained (as evident by documentation or monitoring in a maintained log)?	☐	☐	☐	
B2.3(e)(2) Cultivation practices – Are cultivation and processing tools that come in direct contact with cannabis plants disinfected as needed?	☐	☐	☐	
B2.3(e)(3) Cultivation practices – Are scales used for the weighing of cannabis calibrated at regular intervals?	☐	☐	☐	
B2.4(a) Processing practices – Are all work surfaces and equipment clean and sanitary?	☐	☐	☐	
B2.4(b) Processing practices – Are there protocols in place which prevent processing contamination and mold and mildew growth on cannabis?	☐	☐	☐	
B2.4(c) Processing practices – Are facemasks and gloves used by employees handling cannabis in good operable condition, as applicable to job function?	☐	☐	☐	
B2.4(d) Processing practices – Do employees wash hands sufficiently when handling cannabis or use gloves (with proper anti-septic techniques)?	☐	☐	☐	
B2.5(1) Distribution practices – Is the cannabis distributed by the operation accompanied with the cultivation or processing operation's name?	☐	☐	☐	
B2.5(2) Distribution practices – Is the cannabis distributed by the operation accompanied with the appropriate information for the identity of the contents?	☐	☐	☐	
B2.5(3) Distribution practices – Is the cannabis distributed by the operation accompanied with the appropriate information for the net weight of contents?	☐	☐	☐	
B2.5(4) Distribution practices – Is the cannabis distributed by the operation	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
accompanied with sufficient information to trace the cannabis to its batch?				
C3.1(a)(1) Personnel – Does the operation ensure that all employees have education, training, and experience, or any combination thereof, to enable that person to perform all assigned functions?	☐	☐	☐	
C3.1(a)(2) Personnel – Are there records of trainings provided to employees for the performance of all assigned functions?	☐	☐	☐	
C3.1(b)(1) Personnel – Does the operation provide all employees with training regarding regulatory inspection preparedness?	☐	☐	☐	
C3.1(b)(1) Personnel – Does the operation provide all employees with training regarding law-enforcement interactions?	☐	☐	☐	
C3.1(b)(2) Personnel – Does the operation provide all employees with training regarding U.S. federal laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such employees?	☐	☐	☐	
C3.1(c)(1) Personnel – Does the operation implement employee hygiene protocols and training, which at a minimum address policies which prohibit employees who are showing signs of illness, open wounds, sores, or skin infections from handling cannabis?	☐	☐	☐	
C3.1(c)(2) Personnel – Does the operation implement employee hygiene protocols and training, which at a minimum address hygiene training for employees who handle cannabis with specific attention to preventing microbial contamination (including a microbial contamination prevention manual on handling cannabis aseptically)?	☐	☐	☐	
C3.1(c)(3) Personnel – Does the operation implement employee hygiene protocols and training, which at a minimum address hand washing requirements including washing hands with soap and hot water before beginning work, after using the bathroom, and after meal breaks?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
C3.1(c)(4) Personnel – Does the operation have hand washing signage in appropriate areas such as bathrooms, kitchens, and lunch areas, and in multiple languages as needed?	☐	☐	☐	
C3.2(a) Employee safety – Does the operation implement safety protocols and provide all employees with adequate safety training relevant to their specific job functions?	☐	☐	☐	
C3.2(a)(1) Employee safety – Does the operation provide employees with emergency action response planning as necessary?	☐	☐	☐	
C3.2(a)(2) Employee safety – Does the operation provide training and protocols for employee accident reporting and investigation policies?	☐	☐	☐	
C3.2(a)(3) Employee safety – Does the operation provide training and protocols for fire prevention?	☐	☐	☐	
C3.2(a)(4) Employee safety – Does the operation provide training and protocols for hazard communication policies, including maintenance of material safety data sheets (MSDS)?	☐	☐	☐	
C3.2(a)(5) Employee safety – Does the operation provide training and protocols for materials handling, spill, and disposal policies?	☐	☐	☐	
C3.2(a)(6) Employee safety – Does the operation provide training and protocols for job hazard analyses?	☐	☐	☐	
C3.2(a)(7) Employee safety – Does the operation provide training and protocols for personal protective equipment (PPE) policies, including respiratory protection?	☐	☐	☐	
C3.2(b) Employee safety – Does the operation provide and maintain at least one emergency eye flushing station readily accessible to all employees and access to adequate eye flushing water for each employee?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
C3.29(c) Employee safety – Does the operation visibly post and maintain an emergency contact list which includes at a minimum:(1) Operation manager contacts; (2) Emergency responder contacts; (3) Poison control contacts; (4) Fire department contacts; and (5) Spill response team contacts? (Indicate the missing emergency contacts, if any)	☐	☐	☐	
D4.1(a)(1) Facilities compliance – Does the operation comply with all legal requirements for restrictions on the size of the cultivation area?	☐	☐	☐	
D4.1(a)(2) Facilities compliance – Does the operation comply with all legal requirements for restrictions on the number of cannabis plants allowed or other quantitative limits?	☐	☐	☐	
D4.1(a)(3) Facilities compliance – Does the operation comply with all legal requirements for light pollution restrictions?	☐	☐	☐	
D4.1(b)(1) Facilities compliance – Is cultivation operation located on property that is zoned for such use and located in a fully permitted, non-residential structure?	☐	☐	☐	
D4.1(b)(1)(i) Facilities compliance – Is cultivation operation constructed in compliance with local building codes?	☐	☐	☐	
D4.1(b)(1)(ii) Facilities compliance – If indoors, does the operation have a complete roof enclosure supported by connecting walls extending from the ground to the roof?	☐	☐	☐	
D4.1(b)(1)(iii) Facilities compliance – Is the operation secure against unauthorized entry?	☐	☐	☐	
D4.1(b)(1)(iv) Facilities compliance – Does the operation minimize unnecessary visual, auditory, or olfactory evidence of indoor cannabis cultivation?	☐	☐	☐	
D4.1(b)(2) Facilities compliance – If there is an outdoor cultivation operation and/or greenhouse cultivation operation located on a property, is it zoned for	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
such use?				
D4.1(b)(3) Facilities compliance – Is the outdoor cultivation operation and/or greenhouse operations located within any setbacks that pertain to the property?	☐	☐	☐	
D4.1(b)(4) Facilities compliance – If the operation includes a greenhouse, is the greenhouse cultivation structure fully permitted and built to code?	☐	☐	☐	
D4.1(c)(1) Facilities compliance – If there is a processing operation, is it located on a property that is zoned for such use?	☐	☐	☐	
D4.1(c)(2) Facilities compliance – If there is a processing operation, is it located within any setbacks that pertain to the property where the processing is taking place?	☐	☐	☐	
D4.1(c)(3) Facilities compliance – If there is a processing operation, is the structure fully permitted and constructed in compliance with local building code?	☐	☐	☐	
D4.1(d) Facilities compliance – Does the outdoor cultivation or greenhouse cultivation operation (if any) shield or downcast supplemental lighting?	☐	☐	☐	
D4.1(e) Facilities compliance – Does the operation transport cannabis in a secured enclosed container or secured trunk of the delivery vehicle?	☐	☐	☐	
D4.2(a) Facilities fire prevention – Are the rooms of the indoor cultivation operation (if any) in which operational supplemental lighting, ballasts, or electrical control panels are located constructed with a minimum of a one-hour firewall assembly?	☐	☐	☐	
D4.2(b)(1) Facilities fire prevention – Does the operation provide at least one operating fire extinguisher?	☐	☐	☐	
D4.2(b)(2) Facilities fire prevention – Does the operation provide additional fire extinguishers in a number proportional to the watts of supplemental lighting used in the facility (one fire extinguisher per every 10,000 watts of	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
lighting), or in accordance with local fire code?				
D4.2(c)(1) Facilities fire prevention – Are the fire extinguishers easily accessible to employees from every room and in each hallway of the facility?	☐	☐	☐	
D4.2(c)(2) Facilities fire prevention – Are the fire extinguishers maintained annually or as otherwise specified by the manufacturer?	☐	☐	☐	
D4.2(c)(3) Facilities fire prevention – Are the fire extinguishers of the appropriate class rating for the type of fire associated with the functions being performed in the facility (e.g., electrical, chemical)?	☐	☐	☐	
D4.2(d) Facilities fire prevention – Are flammable products stored in a properly marked fire containment cabinet or area?	☐	☐	☐	
D4.2(e) Facilities fire prevention – Does the operation have signage that complies with National Fire Protection Association (NFPA) standard 704?	☐	☐	☐	
D4.3(a) Facilities sanitation – Does the operation provide employees with adequate and readily-accessible toilet facilities?	☐	☐	☐	
D4.3(a)(1) Facilities sanitation – Does operation provide employees with adequate and readily-accessible toilet facilities that are maintained in a sanitary condition?	☐	☐	☐	
D4.3(a)(2) Facilities sanitation – Does operation provide employees with adequate and readily-accessible toilet facilities that are adequately stocked with toilet paper, soap, and single-use paper towels or other drying devices?	☐	☐	☐	
D4.3(a)(3) Facilities sanitation – Does operation provide employees with adequate and readily-accessible toilet facilities that are kept in good repair at all times?	☐	☐	☐	
D4.3(b) Facilities sanitation – Does the operation provide adequate and convenient hand-washing stations?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
D4.3(b)(1) Facilities sanitation – Does the operation provide hand-washing stations with running water of suitable temperature?	☐	☐	☐	
D4.3(b)(2) Facilities sanitation – Does the operation provide hand-washing stations stocked with effective hand-cleaning or sanitizing preparations and single-use paper towels or other drying devices?	☐	☐	☐	
D4.3(b)(3) Facilities sanitation – Does the operation provide hand-washing stations located at points in the facility where good sanitary practices require employees to wash or sanitize their hands?	☐	☐	☐	
D4.3(b)(4) Facilities sanitation – Does the operation provide hand-washing stations at field locations as appropriate?	☐	☐	☐	
D4.3(c)(1) Facilities sanitation – Does the operation implement sanitation practices that address removal of debris?	☐	☐	☐	
D4.3(c)(1) Facilities sanitation – Does the operation implement sanitation practices for the control of the growth of mold, mildew, and algae in the cultivation area or processing area?	☐	☐	☐	
D4.3(c)(2) Facilities sanitation – Does the operation implement pest control practices, including maintenance and repair of caulk cracks and drain areas?	☐	☐	☐	
D4.3(c)(3) Facilities sanitation – Does the operation implement practices for the identification of hoses dedicated for use in cultivation?	☐	☐	☐	
D4.3(c)(4) Facilities sanitation – Does the operation implement practices for maintenance and cleaning of irrigation systems?	☐	☐	☐	
D4.3(d) Facilities sanitation – Does the processing operation protect cannabis from contact with birds, rodents, insects, and other animals and from exposure to the elements?	☐	☐	☐	
D4.4(a) Facilities electrical – Is the operation's electrical system of sufficient capacity to handle the actual electrical load and installed in accordance with an	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
approved electrical permit?				
D4.4(b) Facilities electrical – Have all electrical work and upgrades been performed with proper permitting?	☐	☐	☐	
D4.4(c) Facilities electrical – Is all the electrical equipment connected to the electrical system in accordance with the equipment manufacturer's recommendations?	☐	☐	☐	
D4.5(a) Facilities ventilation – Is the operation equipped with adequate ventilation to maintain proper humidity and temperature?	☐	☐	☐	
D4.5(b)(1) Facilities ventilation – Does the indoor cultivation operation's mechanically propelled air intake system use a filter capable of removing 99.97% of particles with a diameter of 0.3 micrometers (µm) to control potential contamination with pathogenic organisms?	☐	☐	☐	
D4.5(b)(2) Facilities ventilation – Does the indoor cultivation operation's non-mechanically propelled or passive intake system use a grate and filter sufficient to reduce the intrusion of rodents and insects?	☐	☐	☐	
D4.6(a) Facilities disposal – Is cannabis waste disposal documented, done in a manner which prevents unauthorized use, and compliant with any regulations and recommendations in the jurisdiction in which it operates?	☐	☐	☐	
D4.6(b) Facilities disposal – Are bulbs and ballasts disposed of in accordance with manufacturer's recommendations?	☐	☐	☐	
D4.7(a) Facilities security – Is the outdoor and/or greenhouse cultivation operation enclosed by a secure perimeter fence at least six (6) feet in height that includes a lockable gate that is locked and does not violate any other ordinance, code section or provision of law regarding height and location restrictions?	☐	☐	☐	
D4.7(b) Facilities security – Does the indoor cultivation facility or processing facility have locking doors and windows which allow emergency ingress and	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
egress in accordance with applicable regulations?				
D4.7(c) Facilities security – Does the operation implement and communicate security protocols to all personnel?	☐	☐	☐	
D4.7(d) Facilities security – Does the operation maintain a visitor log and have a policy requiring visitors to be accompanied by an employee at all times?	☐	☐	☐	
E5.1(a) Water Resource cultivation – Is the operation following local or state water district regulations for cannabis production or implementing a cultivation water management plan?	☐	☐	☐	
E5.1(a)(1) Water Resource cultivation – Does the cultivation water management plan address erosion prevention?	☐	☐	☐	
E5.1(a)(2) Water Resource cultivation – Does the cultivation water management plan address effluent and agricultural discharges?	☐	☐	☐	
E5.1(b) Water Resource cultivation – Is the operation disposing of chemical solutions in accordance with applicable laws and regulations?	☐	☐	☐	
E5.1(c) Water Resource cultivation – Is the application of nutrients or pesticides through an irrigation system (chemigation) performed in accordance with state or local agricultural regulations?	☐	☐	☐	
E5.2(a) Water Resource potable – If the operation is not utilizing a municipal source of potable water, is the operation testing the potable water supply at least two times per year to ensure compliance with state primary drinking water standards?	☐	☐	☐	
E5.2(b) Water Resource potable – Are chemicals, fertilizers, pesticides, media, and other products stored away from the potable water supply?	☐	☐	☐	
F6(a) Recordkeeping – Does the operation have records to identity and source all cannabis propagation material with sufficient specificity to ensure	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
that the material can be traced to its source?				
F6 (b)(1)(i-iv) Recordkeeping – Does the operation maintain planting records for each batch of cannabis that include at a minimum: i) Form of cannabis planted (e.g., seed, clone, seedlings, etc.); (ii) Date(s) that planting took place; (iii) Variety(ies) planted; (iv) Size of the cultivation area; and (v) Location of the cultivation area? (Indicate any parameters that are missing from planting records)	☐	☐	☐	
F6 (b)(2) Recordkeeping propagation – Does the operation maintain propagation records for each batch of cannabis that include at a minimum: (i) Media used and whether the media was reused or new product; (ii) Description of all actions taken to prevent disease or pest issues or treat the cannabis for them; (iii) Soil amendments added and strength of the application; (iv) Nutrients added and strength of the application; (v) All substances applied to the plant(s) surface or used as a fumigant in the cultivation and/or nursery area; and (vi) Pruning or other physical technique(s)? (Indicate any parameters that are missing from propagation records.)	☐	☐	☐	
F6(b)(3) Recordkeeping pesticide – Does the operation maintain pesticide records for each batch of cannabis that include at a minimum: (i) Pesticide chemical name; (ii) Brand name and manufacturer name; (iii) Amount of pesticide applied; (iv) Date pesticide applied; (v) Identification or location of plants to which pesticide was applied; and (vi) Name of applicator, if required? (Indicate any parameters that are missing from pesticide records.)	☐	☐	☐	
F6(b)(4) Recordkeeping harvest – Does the operation maintain harvest records for each batch of cannabis that include at a minimum: (i) Identity of each variety harvested; (ii) Date of harvest; (iii) Gross weight of the cannabis harvested for processing (generally recorded after drying); (iv) Total weight of cannabis waste resulting from the harvest; and (v) Net weight of harvested cannabis (gross weight less waste)? (Indicate any parameters that are missing from harvest records.)	☐	☐	☐	
F6(c) Recordkeeping processing – Does the operation maintain processing records for each batch of cannabis that include at a minimum: (1) Identity of the variety processed; (2) Sufficient information to trace the processed	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
cannabis to its cultivation source; (3) Date of processing; (4) Initial weight; and (5) Total weight of any processing loss (based on wet or dry weight)? (Indicate any parameters that are missing from processing records.)				
F6(d) Recordkeeping sales – Does the operation maintain sales records for each batch of cannabis that include at a minimum: (1) Identity of the variety distributed; (2) Total weight of each variety distributed; (3) Date of distribution; and (4) Identity of the receiving operation? (Indicate any parameters that are missing from sales records.)	☐	☐	☐	
G7(a) Information disclosure – Can the operation provide the following records upon request: (1) Nutrients used during cultivation; (2) All substances applied to the plant(s) surface or used as a fumigant in the cultivation area; (3) Pesticides applied during cultivation; and (4) Other substances used during cultivation that may result in a residue on cannabis? (Indicate which parameters that cannot be provided, if any.)	☐	☐	☐	
G7(b) Information disclosure – Is information provided by the operation about the identity, quality, and cultivation conditions of cannabis accurate?	☐	☐	☐	
G7(c) Information disclosure – Does the operation disclose the extent and type of testing and analysis conducted on the cannabis it provides?	☐	☐	☐	
G7(c)(1-3) Information disclosure – Does the disclosure contain the following: (1) The type of test, analysis, or examination used, if any, to determine the particular strain or cultivar of each batch of cannabis provided; (2) Any tests to determine the quantitative levels of contained constituents and, if so, the type of testing used; (3) Any tests to determine the absence or presence of specific classes of potential contaminants and, if so, the type of testing used? (Indicate which parameters are missing from the disclosure.)	☐	☐	☐	
G7(c)(3)(i-iii) Information disclosure – Does the disclosure of contaminant testing contain information regarding: (i) Pesticides; (ii) Yeasts and molds; and (iii) Other microbiological contaminants? (Indicate which parameters are missing from the disclosure regarding contaminant testing. Is it clear which tests were conducted?)	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
G7(c)(4) Information disclosure – Does the operation disclose whether the testing was conducted by the cultivation or processing operation or by an external laboratory?	☐	☐	☐	
H8(a) Recalls – Does the operation have a recall plan that addresses at minimum: (1) Factors which necessitate a recall procedure; (2) Personnel responsible for a recall; and (3) Notification protocols? (Indicate which parameters are missing, if any.)	☐	☐	☐	
H8(b) Recalls – Does the operation have a established policy for communicating a recall of cannabis that includes: (1) A mechanism to contact all customers who have, or could have, obtained the cannabis from the cultivation operation or processing operation; (2) Information on the return or destruction of any recalled product; (3) A mechanism to contact the cultivation operation; and (4) Communication and outreach via media, as necessary and appropriate. (Indicate any parameters that missing from the recall policy.)	☐	☐	☐	
H8(c) Recalls – Does the recall plan include disposal of recalled materials in a manner that ensures that they cannot be salvaged and will not be used by a compliant individual or any other person?	☐	☐	☐	

MANUFACTURING CERTIFICATION AUDIT

Patient Focused Certification

APPLICANT NAME: _____

AUDITOR NAME: _____

FACILITY LOCATION: _____

DATE OF AUDIT: _____

TIME ON SITE: _____

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
A1.1(a) • Subject operations – Except as provided by paragraphs (b), (c), and (d) of this section, any person, group of persons, non-profit entity, or business entity is subject to this part if engaged in manufacturing, packaging, labeling, or holding operations for cannabis or cannabis- derived products in the jurisdiction in which this part applies.	☐	☐	☐	
A1.1(b) • Subject operations – A compliant individual who manufactures, packs, labels, or holds cannabis or cannabis-derived products in accordance with local and state law for personal use, or for another compliant individual at no charge, is not subject to this part.	☐	☐	☐	
A1.1(c) • Subject operations - Cultivation and processing operations are not subject to this part; however, this exemption does not apply to any off-site warehouse or storage facility that serves the cultivation or processing operation.	☐	☐	☐	
A1.1(d) • Subject operations - Dispensing operations are not subject to this part; however, this exemption does not apply to any off-site warehouse or storage facility that serves the dispensing operation.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
A1.1(e) • Subject operations - Each operation subject to this part is responsible to comply with only those sections that apply to the activities conducted by that operation.	☐	☐	☐	
A1.2 • Other statutory provisions and regulations – Is the manufacturing, packaging, labeling, and holding operation presently compliant with all other applicable statutory provisions and regulations related to these operations in the jurisdiction in which this part applies, and related to all other business activities undertaken in conducting these operations?	☐	☐	☐	
SUBPART B – GENERAL PROVISIONS				
B2.1(1-5) •Acquisition of cannabis and cannabis-derived products – Does the operation have standardized protocols, procedures, and reports (i.e., SOPs, work instructions, etc.) for the acquisition of cannabis and cannabis-derived products?	☐	☐	☐	
B2.2(a)(1-4) •Distribution of cannabis and cannabis-derived products – Does the operation have standardized protocols, procedures, and reports (i.e., SOPs, work instructions, etc.) for the distribution of cannabis and cannabis-derived products to legal entities as allowed in accordance with the jurisdiction of facility?	☐	☐	☐	
B2.2(b) •Transportation of cannabis and cannabis-derived products – Does the operation have standardized protocols, procedures, and reports (i.e., SOPs, work instructions, etc.) for the transportation of cannabis and cannabis-derived products in compliance with jurisdiction guidelines?	☐	☐	☐	
B2.3•Ancillary operations – Does the operation engage in permitted ancillary operations other than the manufacturing, packaging, labeling. or holding of cannabis or cannabis-derived products?	☐	☐	☐	
SUBPART C - PERSONNEL				
C3.1(a)(1-3) • Personnel training – Does the manufacturing operation provide training and documentation showing that all personnel are trained to perform all assigned functions and applicable requirements?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
C3.1(b)(1) • Personnel training – Does the manufacturing operation provide training and documentation of training for personnel in the areas of regulatory inspection preparedness and law-enforcement interactions?	☐	☐	☐	
C3.1(b)(2) Personnel training – Does the manufacturing operation provide training and the documentation of training for personnel in the areas of U.S. federal, state and local laws, regulations, and policies relating to the manufacturing activities of the legally operating entity?	☐	☐	☐	
C3.2(a)(1) • SOPs for personnel responsibilities – Does the manufacturing operation have standardized protocols, procedures, and reports for the exclusion from work of personnel who by medical examination, the person's acknowledgement, or supervisory observation, is shown to have or appears to have an illness, infection, open lesion, or any other abnormal source of potential microbial contamination that could result in the microbial contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces, until the health condition no longer exists?	☐	☐	☐	
C3.2(a)(2) • SOPs for personnel responsibilities – Does the manufacturing operation have standardized protocols, procedures, and reports instructing personnel to notify their supervisor(s) if they have or if there is a reasonable possibility that they have a health condition described in C3.2(a)(1) that could result in microbial contamination of any components, packaging components, in-process materials, cannabis, cannabis-derived products, or any contact surface(s)?	☐	☐	☐	
C3.2(b)(1-2) • SOPs for personnel hygiene – Does the manufacturing operation have standardized protocols, procedures, and reports that include the wearing of outer garments in a manner that protects against the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or any contact surface and maintaining adequate personal cleanliness?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
C3.2(b)(3)(i-iii) • SOPs for personnel hygiene – Does the manufacturing operation have standardized protocols, procedures, and signage in place requiring personnel to thoroughly wash hands with soap (and sanitizing if necessary to protect against contamination with microorganisms) before starting work, after using the restroom, and at any other time when their hands may have become soiled or contaminated?	☐	☐	☐	
C3.2(b)(4) • SOPs for personnel hygiene – Does the manufacturing operation have standardized protocols, procedures, and reports for the removal of all unsecured jewelry and other objects that might fall into components, packaging components, cannabis, cannabis-derived products, equipment, or packaging and for the removal of hand jewelry that cannot be adequately cleaned during periods in which components, packaging components, in-process materials, cannabis, or cannabis-derived products are manipulated by hand? If hand jewelry cannot be removed, it must be covered by material that is maintained in an intact, clean, and sanitary condition and that effectively protects against the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces.	☐	☐	☐	
C3.2(b)(5) • SOPs for personnel hygiene – Does the manufacturing operation have standardized protocols and procedures for the maintaining of gloves used in handling components, packaging components, in-process materials, cannabis, or cannabis-derived products in an intact, clean, and sanitary condition? Gloves should be of an impermeable material.	☐	☐	☐	
C3.2(b)(6) • SOPs for personnel hygiene – Does the manufacturing operation have standardized protocols and procedures for the wearing, where appropriate, of hair nets, caps, beard covers, or other effective hair restraints?	☐	☐	☐	
C3.2(b)(7) • SOPs for personnel hygiene – Does the manufacturing operation have standardized protocols and procedures for the storage of clothing or other personal belongings in areas where it cannot come into contact with or potentially contaminate components, packaging components, in-process materials, cannabis, or cannabis-derived products ?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
C3.2(b)(8) • SOPs for personnel hygiene – Does the manufacturing operation have standardized protocols and procedures in place restricting staff from eating food, chewing gum, drinking beverages, or using tobacco products where components, packaging components, in-process materials, cannabis, or cannabis-derived products or any contact surfaces are exposed or where contact surfaces are washed?	☐	☐	☐	
C3.2(b)(9) • SOPs for personnel hygiene – Does the manufacturing operation have standardized protocols, procedures, and reports in place necessary to protect against the contamination of components, packaging components, in-process materials, cannabis, or cannabis-derived products, or any contact surfaces with microorganisms, filth, or any other extraneous materials, including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin?	☐	☐	☐	
C3.2(b)(10) • SOPs for personnel hygiene – Does the manufacturing operation have standardized protocols, procedures, and reports in place necessary to maintain the security of the physical plant, to prevent unauthorized access to controlled access areas, and to maintain strict control of in-process materials, cannabis, cannabis-derived products, and cannabis waste?	☐	☐	☐	
C3.2(b)(11) • SOPs for personnel hygiene – Does the manufacturing operation have standardized protocols, procedures, and reports in place necessary to control access to areas only as authorized by supervisory personnel?	☐	☐	☐	
C3.3(a)(1-2) • Personnel safety – Does the operation have policies, procedures, and evidence of adequate safety training for personnel to comply with personnel safety policies, including personnel accident reporting and investigation policies, as well as fire prevention and response plans?	☐	☐	☐	
C3.3(a)(3-4) • Personnel safety – Does the operation have policies, procedures, and evidence of adequate safety training for personnel to comply with required materials handling and hazard communications policies, including maintenance of material safety data sheets (MSDS) and personal protective equipment policies?	☐	☐	☐	
C3.3(b)(1-5) • Personnel safety – Does the operation have an emergency contact list visibly posted and maintained that includes contact information for the operation manager(s), emergency responders, poison control, local fire department, and spill response team(s)?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
C3.3(c) • Personnel safety– Does the operation have evidence that it operates in adherence with all applicable standards of the federal Occupational Health and Safety Administration, as well as any applicable state or local worker safety requirements?	☐	☐	☐	
C3.4(a-b) • Supervisor requirements – Does the operation have evidence that each supervisor responsible for the manufacturing, packaging, labeling, and holding of cannabis and cannabis-derived products has received either adequate education, training, and experience, or any combination thereof, to perform assigned functions in such a manner as to provide assurance that the cannabis or cannabis-derived products has the identity, purity, strength, and composition that it purports or is represented to possess?	☐	☐	☐	
C3.4(c) • Supervisor requirements – Does the operation have evidence that one or more supervisors qualified by education, training, or experience are assigned to supervise and develop sanitation procedures?	☐	☐	☐	
SUBPART D - PHYSICAL PLANT AND GROUNDS				
D4.1(a) • Design and construction – Does the operation have evidence that the physical plant used in the manufacturing, packaging, labeling, or holding of cannabis or cannabis-derived products is of suitable size, construction and design to facilitate maintenance, cleaning and/or sanitizing, as applicable to the operation?	☐	☐	☐	
D4.1(b) • Design and construction – Does the operation have evidence that the physical plant is designed in a manner that provides adequate space for the orderly placement of equipment and materials to prevent mix-ups of components, packaging components, in-process materials, cannabis, or cannabis-derived products during manufacturing, packaging, labeling, or holding?	☐	☐	☐	
D4.1(c)(1) • Design and construction – Does the operation have evidence that the physical plant was designed and constructed in a manner that reduces the potential for contamination of components, packaging components, cannabis, cannabis-derived products, or contact surfaces with microorganisms, chemicals, filth, or other extraneous material, including the construction of floors, walls, and ceilings that can be adequately cleaned, kept clean, and in good repair.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
D4.1(c)(2) • Design and construction – Does the operation have evidence that the physical plant was designed and constructed using fixtures, ducts, and pipes that do not contaminate components, packaging components, in-process materials, cannabis, or cannabis-derived products or contact surfaces by dripping, other leakage, or condensation?	☐	☐	☐	
D4.1(c)(3) • Design and construction – Is the physical plant was designed and constructed in such a manner as to provide aisles or working spaces between equipment and walls that are adequately unobstructed and of adequate width to permit all persons to perform their duties and to protect against contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces with clothing or personal contact?	☐	☐	☐	
D4.1(c)(4) • Design and construction – Does the operation have evidence that the physical plant was designed and constructed using safety-type light bulbs, fixtures, skylights, or other glass or glass-like materials in all areas that are suspended over exposed components, packaging components, in-process materials, or cannabis or cannabis-derived products? Is the physical plant is otherwise constructed in a manner that will protect against contamination of components, packaging components, in-process materials, or cannabis or cannabis-derived products in case of breakage of overhead glass or glass-like materials?	☐	☐	☐	
D4.1(d) • Design and construction – Does the operation have evidence that the physical plant was designed and constructed in such a manner as to provide separate or defined areas, or other control systems such as computerized inventory controls or automated systems of separation, to prevent cross-contamination and mix-ups of components, cannabis, or cannabis-derived products during the following operations that might take place in the physical plant:	☐	☐	☐	
(1) Receipt, identification, storage, and withholding from use of quarantined components, packaging components, in-process materials, cannabis, or cannabis-derived product pending disposition by quality-control personnel;	☐	☐	☐	
(2) Storage of approved components, packaging components, in-process materials, cannabis, or cannabis-derived products**;**	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
(3) Storage of rejected components, packaging components, in-process materials, cannabis, or cannabis-derived products, and cannabis waste pending return to their supplier or destruction;	☐	☐	☐	
(4) Storage of in-process materials pending normal further processing;	☐	☐	☐	
(5) Storage of components, packaging components, in-process materials, and products pending reprocessing;	☐	☐	☐	
(6) Manufacturing operations;	☐	☐	☐	
(7) Packaging and labeling operations;	☐	☐	☐	
(8) Separation of the manufacturing, packaging, labeling, and holding of different product types including different types of cannabis or cannabis-derived products and other products handled in the same physical plant;	☐	☐	☐	
(9) Performance of laboratory analyses and storage of laboratory supplies and samples, as applicable;	☐	☐	☐	
(10) Cleaning and sanitation of contact surfaces.	☐	☐	☐	
D4.1(e)(1) • Design and construction/water – Does the operation have evidence that the water provided is safe and sanitary, at suitable temperatures, and under pressure as needed, for all uses where water does not become a component of the cannabis-derived product?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
D4.1(e)(2) • Design and construction/water – Does the operation have evidence that the water provided is compliant with applicable state and local potable water requirements and with other requirements as necessary to ensure the water requirements and with other requirements as necessary to ensure the water does not contaminate the cannabis-derived product, for all uses where such water may become a component of the cannabis-derived product, e.g., when such water contacts components, packaging components, in-process materials, cannabis or cannabis-derived products, or any contact surface?	☐	☐	☐	
D4.1(f) • Design and construction/ventilation – Does the operation have evidence that the heating, ventilation, cooling, and air filtration has been installed and maintained in the physical plant as needed to ensure the quality of the product?	☐	☐	☐	
D4.1(f)(1) • Design and construction/ventilation – Does the operation have SOPs, procedures, and maintenance reports for all ventilation equipment such as filters, fans, exhausts, dust collections, and other air-blowing equipment as required in all areas where odors, dust, and vapors (including steam and noxious fumes) that may contaminate components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces?	☐	☐	☐	
D4.1(f)(2) • Design and construction/ventilation – Does the operation have evidence that when fans, compressed air, or other air-blowing equipment is used, such equipments is designed, located, and operated in a manner that minimizes the potential for microorganisms and particulate matter to contaminate components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces?	☐	☐	☐	
D4.1(f)(2) • Design and construction/ventilation – Does the operation have evidence that the equipment used to control temperature, humidity, and/or microorganisms is provided and maintained as necessary to ensure the quality of the product?	☐	☐	☐	
D4.1(g)(1-2) • Design and construction/plumbing – Does the operation have evidence that the plumbing in the physical plant is of an adequate size and design and has been adequately installed and maintained to both carry sufficient amounts of water to required locations throughout the plant and properly convey sewage and liquid disposable waste from the physical plant?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
D4.1(g)(3) • Design and construction/plumbing – Does the operation have evidence that the plumbing in the physical plant is of an adequate size and design and has been adequately installed and maintained to avoid being a source of contamination to components, packaging components, in-process materials, cannabis or cannabis-derived products, water supplies, or any contact surface, or creating an unsanitary condition?	☐	☐	☐	
D4.1(g)(4) • Design and construction/plumbing – Does the operation have evidence that the plumbing in the physical plant is of an adequate size and design and has been adequately installed and maintained to provide adequate floor drainage in all areas where floors are subject to flooding-type cleaning or where normal operations release or discharge water or other liquid waste on the floor?	☐	☐	☐	
D4.1(g)(5) • Design and construction/plumbing – Does the operation have evidence that the plumbing in the physical plant is of an adequate size and design and has been adequately installed and maintained to no allow backflow from, or cross connection between, piping systems that discharge waste water or sewage and piping systems that carry water used for manufacturing cannabis-derived products, for cleaning contact surfaces, or for use in bathrooms or hand-washing facilities?	☐	☐	☐	
D4.1(h)(1-3) • Design and construction/plumbing – Does the operation have evidence that personnel has been provided with adequate, readily accessible toilet facilities that are maintained in a clean and sanitary condition, adequately stocked with toilet paper, soap, and single-use paper towels or other drying devices, and kept in good repair at all times?	☐	☐	☐	
D4.1(h)(1-3) • Design and construction/plumbing – Does the operation have evidence that personnel has been provided with adequate, readily accessible toilet facilities that are equipped with signage advising personnel of the necessity of washing hands prior to returning to work?	☐	☐	☐	
D4.1(h)(5) • Design and construction/toilet facility – Does the operation have evidence that the toilet facilities are prohibited from being used for activities that support production operations, such as cleaning of production equipment or utensils?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
D4.1(i) • Design and construction/toilet facility – Does the operation have evidence that it has taken action to prevent airborne contamination from toilet facilities from contacting components, packaging components, in-process materials, cannabis, cannabis-derived products, or contacts sources; for example, by providing adequate physical separation of toilet facilities from manufacturing, packaging, labeling, and holding operations, or by use of negative air pressure within the toilet facility?	☐	☐	☐	
D4.1(j)(1-3) • Design and construction/hand washing – Does the operation have evidence that it has provided adequate and convenient hand-washing facilities that provide running water of suitable temperature, effective hand cleaning and/or sanitizing preparations and single-use paper towels or other drying devices, and that are located at points in the facility where good sanitary practices as required for personnel to wash their hands?	☐	☐	☐	
D4.1(j)(4) • Design and construction/hand washing – Does the operation have evidence that it has SOPs prohibiting hand-washing facilities from being used for activities that support production operations, such as cleaning of production equipment or utensils ?	☐	☐	☐	
D4.1(k)(1-3) • Design and construction/lighting – Does the operation have evidence that adequate lighting is provided in all areas where components, packaging components, in-process materials, cannabis, or cannabis-derived products are examined, manufactured, packaged, labeled, or held, as well as where contact surfaces are cleaned, in hand-washing areas, dressing and locker rooms, and toilet facilities?	☐	☐	☐	
D4.2(a)(1) • Sanitation requirements - Does the operation have evidence that the grounds of the physical plant are kept in a condition that protects against contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces by properly storing equipment, removing litter and waste, and cutting weeds or grass within the immediate vicinity of the physical plant so that it does not attract pests, harbor pests, or provide pests a place for breeding?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
D4.2(a)(2) • Sanitation requirements - Does the operation have evidence that the grounds of the physical plant are kept in a condition that protects against contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces by properly maintaining roads, yards, and parking lots so that they do not constitute a source of contamination in areas where components, in-process materials, cannabis, cannabis-derived products, or contact surfaces are exposed?	☐	☐	☐	
D4.2(a)(3) • Sanitation requirements - Does the operation have evidence that the grounds of the physical plant are kept in a condition that provides adequately drainage of areas that may contribute to the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces by seepage, filth, or any other extraneous materials, or by providing a breeding place for pests?	☐	☐	☐	
D4.2(a)(4) • Sanitation requirements - Does the operation have evidence that the grounds of the physical plant are kept in a condition that provides adequately operating systems for waste treatment and disposal so that they do not constitute a source of contamination in areas where components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces are exposed?	☐	☐	☐	
D4.2(a)(5) • Sanitation requirements - Does the operation have evidence that if the grounds of the physical plant are bordered by grounds not under the operation's control, and if those other grounds are not maintained n the manner described in this section, care has been exercised in the plant by inspection, extermination, or other means to exclude pests, dirt, and filth or any other extraneous materials that may be a source of contamination?	☐	☐	☐	
D4.2(b) • Sanitation requirements – Does the operation have evidence that the physical plant is maintained in a clean and sanitary condition and maintained in sufficient repair to prevent components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces from becoming contaminated?	☐	☐	☐	
D4.2(c)(1) • Sanitation requirements – Does the operation have evidence that the physical plant has SOPs, procedures, and records in place for the proper storage, handling, and control of cleaning compounds, sanitizing agents, pesticides, and other toxic materials so as to keep the products free from microorganisms of public health significance?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
D4.2(c)(2)(i-iv) • Sanitation requirements – Does the operation have evidence that toxic materials are not used or held in a physical plant in which components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces are manufactured or exposed, unless those materials are necessary to maintain clean and sanitary conditions, for use in laboratory testing procedures, for maintaining or operating the physical plant or equipment, or for the use in the plant's operations?	☐	☐	☐	
D4.2(c)(3) • Sanitation requirements – Does the operation have evidence that all cleaning compounds, sanitizing agents, pesticides, pesticide chemicals, and other toxic materials are properly identified, stored, and used in a manner that protects against contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces?	☐	☐	☐	
D4.2(d)(1) • Sanitation requirements – Does the operation have SOPs, procedures, and record keeping in place providing adequate pest control prohibiting animals or pests in areas of the physical plant? (Guard dogs may be allowed in some areas of the physical plant if their presence will not result in contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces.)	☐	☐	☐	
D4.2(d)(2) • Sanitation requirements – Does the operation have evidence that effective measures have been taken to exclude pests from the physical plant and to protect against contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, and contact surfaces on the premises by pests?	☐	☐	☐	
D4.2(d)(3) • Sanitation requirements – Does the operation have SOPs, procedures, and record keeping in place showing that insecticides, fungicides, and rodenticides are not used in or around the physical plant, unless they are registered with the EPA and used in accordance with the label instructions, and effective precautions are taken to protect against the contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
D4.2(e)(1-3) • Sanitation requirements – Does the operation have evidence that trash is regularly conveyed, stored, and disposed of in order to minimize the development of odors, minimize the potential to attract, harbor, or become a breeding place for pests, protect against the contamination of components, packaging components, in-process material, cannabis, cannabis-derived products, any contact surfaces, water supplies, and grounds surrounding the physical plant?	☐	☐	☐	
D4.2(e)(4) • Sanitation requirements – Does the operation have evidence that trash is regularly conveyed, stored, and disposed of in order to control hazardous waste to prevent the contamination of components, packaging components, in-process material, cannabis, cannabis-derived products, any contact surfaces?	☐	☐	☐	
D4.2(f)(1-3) • Sanitation requirements – Does the manufacturing, packaging, labeling, or holding operation(s) have SOPs, procedures, and record keeping in place addressing the responsibility for and description of the cleaning schedules, methods, equipment, and materials to be used in cleaning the grounds and buildings?	☐	☐	☐	
D4.2(g)(1-2) • Sanitation requirements – Does the manufacturing, packaging, labeling, or holding operation(s) have SOPs, procedures, and record keeping in place for use and storage of rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents that address the prevention of the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces?	☐	☐	☐	
D4.2(h) • Sanitation requirements – Does the manufacturing, packaging, labeling, or holding operation(s) have SOPs, procedures, and record keeping in place for sanitation procedures performed by all personnel during the ordinary course of operations?	☐	☐	☐	
D4.2(i)(1-2) • Sanitation requirements – Does the operation have evidence that all operations are conducted in accordance with adequate sanitation principles including the cleaning and/or sanitizing of production equipment, containers, and other contact surfaces, controlling airborne contamination as needed where components, packaging components, in-process materials, product, or contact surfaces are exposed?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
D4.2(i)(3) • Sanitation requirements – Does the operation have SOPs, procedures, and record keeping in place for proper sanitary handling procedures?	☐	☐	☐	
D4.3(a)(1-3) • Equipment and utensils – Does the production operation have evidence of the required use of equipment and utensils that are of appropriate design, construction, and workmanship suitable for their intended use, are able to be adequately cleaned and properly maintained, and will not result in the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces?	☐	☐	☐	
D4.3(b)(1) • Equipment and utensils – Does the production operation have evidence that all equipment and utensils used in the production operation are installed and maintained to facilitate cleaning of the equipment, utensils, and adjacent spaces?	☐	☐	☐	
D4.3(b)(2) • Equipment and utensils – Does the production operation have evidence that all equipment and utensils are constructed so that contact surfaces are nontoxic and corrosion-resistant, and neither reactive nor absorptive?	☐	☐	☐	
D4.3(b)(3) • Equipment and utensils – Does the production operation have evidence that all equipment and utensils are designed and constructed to withstand the environment in which they are used, the action of components, in-process materials, cannabis or cannabis-derived products, and, if applicable, cleaning compounds and sanitizing agents?	☐	☐	☐	
D4.3(b)(4) • Equipment and utensils – Does the production operation have evidence that all equipment and utensils are maintained to protect components, in-process materials, cannabis, and cannabis-derived products from being contaminated by any source?	☐	☐	☐	
D4.3(c) • Equipment and utensils – Does the production operation have evidence that all equipment and utensils are designed and maintained to minimize accumulation of dirt, filth, organic material, particles of components, in-process materials, cannabis and cannabis-derived products, or any other extraneous material or contaminants?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
D4.3(d) • Equipment and utensils – Does the production operation have evidence that compressed air or other gases introduced mechanically into or onto a component, packaging component, in-process material, cannabis or cannabis-derived product, or contact surface, or used to clean any contact surface has been filtered or otherwise treated such that the component, packaging component, in-process material, cannabis or cannabis-derived product, or contact surface is not contaminated?	☐	☐	☐	
D4.3(e)(1,2) • Equipment and utensils – Does the production operation have evidence that each freezer, refrigerator, and other cold-storage compartment used to hold components, in-process materials, or cannabis or cannabis-derived products is equipped with an indicating thermometer, temperature-measuring device, or temperature-recording device that indicates and records, or allows for recording by hand, the temperature accurately within the compartment; and is equipped with an automated device for regulating temperature and/or an automated alarm system to indicate a significant temperature change?	☐	☐	☐	
D4.3(f) • Equipment and utensils – Does the production operation have evidence that all instruments or controls used in the manufacturing, packaging, labeling, holding, or testing; or used to measure, regulate, or record conditions that control or prevent the growth of microorganisms or other contamination, are suitably accurate, precise, and adequately maintained?	☐	☐	☐	
D4.3(g) • Equipment and utensils – Does the operation have SOPs, procedures, and record keeping in place that, where appropriate, ensure that instruments and controls used in manufacturing, packaging, holding, or testing components, packaging components, in-process materials, cannabis, and cannabis-derived products are calibrated, inspected, or otherwise verified before first use and at routine intervals or as otherwise necessary to ensure the accuracy and precision of the instrument or control, and that the resulting data are periodically reviewed by quality-control personnel? Are instruments or controls that are past their calibration, inspection, or verification due date, or which cannot be adjusted to provide suitable accuracy and precision, removed from use until they are repaired or replaced?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
D4.3(h) (1,2) • Equipment and utensils – Does the operation have SOPs, procedures, and record keeping in place that establish and use appropriate controls for automated, mechanical, and electronic equipment (including software for a computer-controlled process) to ensure that any changes to the equipment are approved by quality-control personnel and instituted only by authorize personnel, as well as ensure that the equipment functions in accordance with its intended use?	☐	☐	☐	
D4.3(i) (1) • Equipment and utensils – Does the operation have SOPs, procedures, and record keeping in place that ensure all equipment and utensils, and any other contact surfaces used are properly maintained, cleaned, and sanitized, as necessary, including the taking apart, as necessary, for thorough maintenance, cleaning, and sanitizing?	☐	☐	☐	
D4.3(i) (2) • Equipment and utensils – Does the operation have SOPs, procedures, and record keeping in place that ensures all contact surfaces used for manufacturing, packaging, or holding low- moisture components, in-process materials, or cannabis or cannabis-derived products are in a dry and sanitary condition when in use? When the surfaces are wet-cleaned, are they sanitized, when necessary, and thoroughly dried before subsequent use?	☐	☐	☐	
D4.3(i) (3) • Equipment and utensils – Does the operation have SOPs, procedures, and record keeping in place ensuring that, if wet processing is used during production, all contact surfaces are cleaned and sanitized, as necessary, to protect against the introduction of microorganisms into components, packaging components, in-process materials, or cannabis or cannabis-derived products?	☐	☐	☐	
D4.3(i) (4) • Equipment and utensils – Does the operation have SOPs, procedures, and record keeping in place ensuring that, when cleaning and sanitizing is necessary, all contact surfaces are properly cleaned before use and after any interruption during which the contact surface may have become contaminated?	☐	☐	☐	
D4.3(i) (5) • Equipment and utensils – Does the operation have SOPs, procedures, and record keeping in place ensuring that, if contact surfaces are used in a continuous production operation or in consecutive operations involving different batches of the same product, the contact surfaces are adequately cleaned and sanitized, as necessary?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
D4.3(i) (6) • Equipment and utensils – Does the operation have SOPs, procedures, and record keeping in place ensuring all surfaces that do not come into direct contact with components, packaging components, in-process materials, or cannabis or cannabis-derived products are cleaned as frequently as necessary to protect against contaminating components or products?	☐	☐	☐	
D4.3(i) (7) • Equipment and utensils – Does the operation have SOPs, procedures, and record keeping in place ensuring that single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) are stored in appropriate containers and handled, dispensed, used, and disposed of in a manner that protects against contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, or any contact surface?	☐	☐	☐	
D4.3(i) (8) • Equipment and utensils – Does the operation have SOPs, procedures, and record keeping in place ensuring that cleaning compounds and sanitizing agents are adequate for their intended use and safe under their conditions of use?	☐	☐	☐	
D4.3(i) (9) • Equipment and utensils – Does the operation have SOPs, procedures, and record keeping in place ensuring necessary cleaning and sanitizing of portable equipment and utensils that have contact surfaces are stored in a location and manner that protects them from contamination?	☐	☐	☐	
D4.3(i) (10) • Equipment and utensils – Does the operation have SOPs, procedures, and record keeping in place for the calibration, maintenance, cleaning, and sanitation of equipment, instruments, and utensils?	☐	☐	☐	
D4.4(a) • Security requirements – Does the operation have SOPs, procedures, and record-keeping protocols established and implemented for authorized access to the physical plant and any controlled access areas therein?	☐	☐	☐	
D4.4(b) • Security requirements – Does the operation have SOPs, procedures, and record keeping protocols in place restricting access to the physical plant and controlling access, as necessary, to current personnel and contractors as appropriate to their job function?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
D4.4(c)(1-5)(d) • Security requirements – Does the operation have SOPs, procedures, and record-keeping protocols in place providing one or more controlled access areas for the storage of: • Labels and other packaging components; • Cannabis and cannabis-derived productsp; • Cannabis waste; • Quarantined components, packaging components, in-process materials, cannabis, or cannabis-derived products.	☐	☐	☐	
SUBPART E – MANUFACTURING PROCESS CONTROLS				
E5.1(a)(1) • Manufacturing protocol - Does the operation have SOPs, procedures, and record-keeping protocols in place for each unique formulation of cannabis-derived product produced, including the identity of the product?	☐	☐	☐	
E5.1(a)(2)(i-v) • Manufacturing protocol - Does the operation have SOPs, protocols, and record-keeping protocols in place for each formulation of product, including nominal batch size; identity of each component to be used in the batch; weight or measure of each component to be used in the batch, including the unit of measure and a statement of any range or variation in weight or measure and a statement of any intentional overage amount of a component; and the name and amount of each ingredient that will be declared on the product's labeling?	☐	☐	☐	
E5.1(a)(3) • Manufacturing protocol - Does the operation have SOPs, procedures, and record keeping protocols in place for maintaining a statement of theoretical yield for each significant process step and at the end of manufacture, including the acceptable maximum and minimum percentages of theoretical yield?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.1(a)(4)(i-vii) • Manufacturing protocol - Does the operation have SOPs, protocols, and record keeping in writing or available for cross reference for the execution of each process step; production process specifications per section 5.5; monitoring of production process specifications; in-process material specification per section 5.8; in-process material sampling, testing, and/or examination; cannabis-derived product sampling, testing, and/or examination; and additional applicable procedures to be followed, if any?	☐	☐	☐	
E5.1(a)(4)(i-vii) • Manufacturing protocol - Does the operation have SOPs, protocols, and record keeping describing the production process that ensures all cannabis-derived product specifications are consistently met?	☐	☐	☐	
E5.2(a) • Manufacturing component control requirements - Does the operation have the required written SOPs, protocols, and record keeping in place describing, in sufficient detail, the receipt, identification, storage, handling, sampling, review, and approval or rejection of components?	☐	☐	☐	
E5.2(b) • Manufacturing component control requirements - Does the operation have the required written SOPs, protocols, and record keeping in place to properly identify each container or group of containers for components with a distinctive code (e.g. lot or control number) for each lot in each shipment received that allows the lot to be traced backward to the supplier, the date received, and the name of the component; and forward to the cannabis-derived product batches manufactured or distributed using the lot? Is the code used in recording the disposition of each lot, as required?	☐	☐	☐	
E5.2(c)(1,2) • Manufacturing component control requirements - Does the operation have the required written SOPs, protocols, and record keeping in place properly describing the specifications for each component, to the extent they are necessary to ensure that manufactured batches of cannabis-derived product meet specifications as follows: required establishment of identity specification for the component; and required specifications for the strength and composition of the component as necessary to ensure the strength and composition of cannabis-derived products manufactured with the component?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.2(c)(3) • Manufacturing component control requirements - Does the operation have the required written SOPs, protocols, and record keeping in place properly describing the required specifications for the purity of the component as necessary to ensure the purity of cannabis-derived products manufactured with the component, including limits on those types of contamination that may adulterate or lead to adulteration of cannabis-derived products manufactured with the component, such as filth, insect infestation, microbiological contamination, or other contaminants?	☐	☐	☐	
E5.2(d)(1) • Manufacturing component control requirements - Does the operation have written SOPs, protocols, and record keeping in place ensuring that all components received and stored pending approval are handled as follows: upon receipt and before acceptance, each container or grouping of containers is required to be examined visually for appropriate labeling as to contents, container damage or broken seals, and contamination, determining whether the container condition may have resulted in contamination or deterioration of the components?	☐	☐	☐	
E5.2(d)(2,3) • Manufacturing component control requirements - Does the operation have written SOPs, protocols, and record keeping in place ensuring that all components received and stored pending approval are handled as follows: the suppliers documentation for each shipment is thoroughly examined to ensure the components are consistent with what was ordered; and that the components are stored under quarantine until they have been sampled, reviewed, and approved or rejected by quality-control personnel?	☐	☐	☐	
E5.2(e)(1) • Manufacturing component control requirements - Does the operation have written SOPs, protocols, and record keeping in place ensuring that all components are approved or rejected as follows: each lot of components must be withheld from use until the lot has been sampled, reviewed, and released for use by quality- control personnel?	☐	☐	☐	
E5.2(e)(2) • Manufacturing component control requirements - Does the operation have written SOPs, protocols, and record keeping in place ensuring that all components are determined to be in compliance with established specification either through review of the supplier's certificate of analysis or other documentation, or through appropriate test and/or examinations? Are any tests and examinations conducted using appropriate scientifically valid methods, as required?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.2(e)(3) • Manufacturing component control requirements - Does the operation have written SOPs, protocols, and record keeping in place ensuring that any lot of a component that meets its specifications is approved and released for use by quality-control personnel?	☐	☐	☐	
E5.2(e)(4) • Manufacturing component control requirements - Does the operation have written SOPs, protocols, and record keeping in place ensuring that any lot of a component that does not meet its specifications is rejected by quality-control personnel, unless quality-control personnel justify and approve a treatment, process adjustment, reprocessing, or other deviation that will render the component or packaging component suitable for use and will ensure the finished cannabis product batches manufactured with the affected lot will meet all specifications for identity, purity, strength, and composition and will not be otherwise contaminated or adulterated.	☐	☐	☐	
E5.3(a) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping in place documenting a manufacturing batch record of each batch of cannabis-derived product manufactured?	☐	☐	☐	
E5.3(b)(1-2) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping in place ensuring that the manufacturing batch number is able to be cross-referenced or reproduce the appropriate manufacturing protocol as well as form a complete record of the manufacturing and control of the batch?	☐	☐	☐	
E5.3(c) • Manufacturing batch record- Does the operation have written SOPs, protocols, and record keeping in place ensuring that each batch is assigned a batch, lot, or control number allowing the complete history of the production and distribution of the batch to be determined? Is the code used in recording the disposition of each batch, as required?	☐	☐	☐	
E5.3(d)(1-3) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping in place requiring the batch record to include, as applicable to the process, the identity of the cannabis-derived product; the batch, lot or control number of the cannabis-derived product; and the batch size?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.3(d)(4)(i-iii) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping in place for each component used in production of a batch that includes the identity of each component used in the batch; the batch, lot, or control number of each component used in the batch; and the actual weight or measure of each batch or lot of component used in the batch, including the unit of measure?	☐	☐	☐	
E5.3(d)(5) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping in place noting the date(s) on which and, where applicable, the time(s) at which each step of the manufacturing process was performed?	☐	☐	☐	
E5.3(d)(6) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping in place noting the actual results obtained during monitoring of production process parameters?	☐	☐	☐	
E5.3(d)(7) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping in place noting the identity of processing lines and major equipment used in producing the batch?	☐	☐	☐	
E5.3(d)(8) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping in place noting the date and, where applicable, the time of the maintenance, cleaning, and/or sanitizing of the major equipment used in producing the batch, or a cross- reference to records such as individual equipment logs where this information is recorded.	☐	☐	☐	
E5.3(d)(9) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping in place noting, if manufacture of the batch uses equipment or instruments requiring periodic calibration, inspection, or verification, the date and, where applicable, the time of the last calibration, inspection, or verification, or the date on which such is next due; or a cross-reference to records, such as individual equipment logs, where this information is recorded?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.3(d)(10) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping in place including a statement of the actual yield and a statement regarding whether the actual yield is within the acceptable range of the theoretical yield as per section 5.1(a)(3) after each significant process step and at the end of manufacturing?	☐	☐	☐	
E5.3(d)(11) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping regarding any cannabis waste generated during the production of a batch?	☐	☐	☐	
E5.3(d)(12) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping documenting any treatment, process adjustment, reprocessing, or other deviation that occurred during production of the batch ?	☐	☐	☐	
E5.3(d)(13) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping including records of the date, time where applicable, quantity, and person responsible for any sample removed during or after production?	☐	☐	☐	
E5.3(d)(14) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping of the actual results of any testing or examination of in-process material or cannabis-derived product, or a cross-reference to such results?	☐	☐	☐	
E5.3(d)(15) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping including documentation that the cannabis-derived product meets its specifications for identity, purity, strength, and composition, in accordance with the requirements of the manufacturing protocol?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.3(d)(15)(i-vii) • Manufacturing batch record - Does the operation have written SOPs, protocols, and record keeping adequate to record the identity of each person performing each process step in production of the batch, including but not limited to: • Weighing or measuring each component and verifying the weight or measure of each component used in the batch per section 5.4; • Adding each component to the batch and verifying the addition of each component to the batch per section 5.4; • (iii) Monitoring production process parameters; • (iv) Performing and verifying calculations of the actual yield and any other mathematical calculations; • Directly overseeing each stage of production of the batch; • Performing any other checks or verifications in production of the batch, as needed; and • Releasing the batch from one stage of production to the next.	☐	☐	☐	
E5.3(e) • Manufacturing batch record - Does the operation have evidence that all data in the manufacturing batch record is recorded at the time at which each action is performed?	☐	☐	☐	
E5.3(f) • Manufacturing batch record - Does the operation have evidence that the completed manufacturing batch record for each batch has been reviewed and signed by quality-control personnel to determine compliance with all applicable specifications and other requirements of the manufacturing protocol before a batch is approved?	☐	☐	☐	
E5.4(a) • Allocation and charge-in of components - Does the operation have written SOPs, protocols, and record keeping for the weighing, measuring, and subdividing of components to be used in a cannabis-derived product batch as appropriate for the batch?	☐	☐	☐	
E5.4(b)(1-4) • Allocation and charge-in of components - Does the operation have written SOPs, protocols, and record keeping if a component is removed from the original container to another identifying the new container with the following information: • Component identity; • Batch, lot, or control number; • Weight or measure in the new container; and • Batch for which component was dispensed, including its identity and batch, lot, or control number.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.4(c)(1-3) • Allocation and charge-in of components - Does the operation have written SOPs, protocols, and record keeping verifying that each container of component dispensed to manufacturing has been examined by a second person or verified by automated equipment to assure that the component was released by quality-control personnel; the weight or measure is correct as stated in the manufacturing protocol; and the container(s) are properly identified?	☐	☐	☐	
E5.4(d) • Allocation and charge-in of components - Does the operation have written SOPs, protocols, and record keeping verifying that each component has been added to the batch by one person and verified by a second person or, if the components are added by automated equipment, verified by one person?	☐	☐	☐	
E5.5(a)(1-4) • Process monitoring and controls during manufacturing – Does the operation have evidence that required process specifications have been established for production process parameters at or during any point, step, or stage where control is necessary to ensure the quality of the batch of cannabis-derived product, and to detect any unanticipated occurrence that may result in contamination, adulteration, or a failure to meet specifications. Do the process parameters monitored include the following as appropriate: time; temperature, pressure; and speed?	☐	☐	☐	
E5.5(b) • Process monitoring and controls during manufacturing – Does the operation have evidence that the production process parameters are monitored at or during any point, step, or stage when process specifications have been established?	☐	☐	☐	
E5.5(c) • Process monitoring and controls during manufacturing - Does the operation have written SOPs, protocols, and record keeping in place documenting and justifying any deviation from the specified process parameters and quarantine any associated in-process material or product? Are any deviations reviewed and approved or rejected by quality-control personnel? Do quality-control personnel approve such deviations only after determining that the resulting cannabis-derived product will meet all specifications for identity, purity, strength, and composition and is not otherwise contaminated or adulterated?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.5(d) • Process monitoring and controls during manufacturing - Does the operation have written SOPs, protocols, and record keeping in place showing that if a deviation is rejected, the resulting in-process or finished cannabis-derived product shall be rejected, unless quality-control personnel approve a treatment, process adjustment, reprocessing, or other deviation that ensures the cannabis- derived product batches manufactured with the affected material will meet all specifications for identity, purity, strength, and composition and will not be otherwise contaminated or adulterated? Is any such treatment, process adjustment, reprocessing, or other deviation documented, justified, and approved by quality-control personnel, as required?.	☐	☐	☐	
E5.5(e) • Process monitoring and controls during manufacturing - Does the operation have written SOPs, protocols, and record keeping in place ensuring the proper identification of all compounding and storage containers, processing lines, and major equipment used during the production of a batch of cannabis-derived product at all times to indicate their contents and, when necessary, the phase of processing of the batch?	☐	☐	☐	
E5.5(f) • Process monitoring and controls during manufacturing – Does the operation have evidence that operations on one component, product, or batch is, as required, physically, spatially, or temporally separated from operations on other components, products, or batches?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.5(g)(1-4) • Process monitoring and controls during manufacturing - Does the operation have written SOPs, protocols, and record keeping in place ensuring that all necessary precautions have been taken during the manufacture of a cannabis-derived products to prevent contamination of components and products? These precautions include, but are not limited to: • Washing or cleaning components that contain soil or other contaminants; • Holding components, in-process materials, and cannabis or cannabis-derived products appropriately; • Preventing cross-contamination and mix-ups between contaminated components, in-process materials, and cannabis or cannabis-derived products and uncontaminated items • Using effective measures to protect against the inclusion of metal or other foreign material in components or cannabis products, by, for example: ◦ Filters, strainers, or sieves; ◦ Traps; ◦ Magnets; ◦ Electronic metal detectors.	☐	☐	☐	
E5.6(a) • Manufacturing sampling requirements - Does the operation have evidence that a representative sample of each batch or lot of component, cannabis, or cannabis-derived product has been collected by removing and compositing portions of material or units from throughout the containers in the batch or lot?	☐	☐	☐	
E5.6(b) • Manufacturing sampling requirements – Does the operation have SOPs, protocols, and record keeping in place ensuring that, if additional representative samples or other samples are taken as appropriate, the following takes place? • Monitoring of the quality of in-process materials during production; • Examination of the degree of variability of materials or products; and • Investigation of known or suspected non-conformances.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.6(c)(1-4) • Manufacturing sampling requirements - Does the operation have SOPs, protocols, and record keeping in place documenting the number of containers and the amount of material or units to be removed from each container based on appropriate criteria, such as: • Quantity needed for testing, examination, and reserve; • Past quality history of the item; • Expected variability of the material or units being sampled; and • Degree of confidence and precision required?	☐	☐	☐	
E5.6(d) • Manufacturing sampling requirements - Does the operation have SOPs, protocols, and record keeping in place ensuring that the containers selected for sampling have been based on rational criteria such as random sampling or directed sampling, as appropriate?				
E5.6(e) • Manufacturing sampling requirements - Does the operation have SOPs, protocols, and record keeping in place ensuring that samples are collected in accordance with the following procedures? • The containers selected for sampling have been cleaned when necessary in a manner to prevent introduction of contaminants into the component, in- process material, cannabis or cannabis-derived product. • The containers have been opened, sampled, and resealed in a manner designed to prevent contamination of their contents and contamination of other components, in-process materials, cannabis, or cannabis-derived product. • Sterile equipment and aseptic sampling techniques have been used when necessary. • Where appropriate for the purpose of the sample and the nature of the material being sampled, sample portions are removed from the top, middle, and bottom of containers. Such sample portions may be composited in forming the representative sample or may be tested separately, as appropriate to the purpose. • Containers from which samples have been taken must be marked to indicate that samples have been removed from them.				

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.6(f) • Manufacturing sampling requirements – Does the operation have evidence that all sample containers are identified with the following information? • Name of the item sampled; • Batch, lot, or control number of the item sampled; • Container from which the sample was taken, or for samples taken directly for the production line, the equipment line and time at which the sample was taken, unless such information is documented separately; • Date on which the sample was taken; • Name of the person who collected the sample; and • Quantity and unit of measure of the sample.				
E5.6(g) • Manufacturing sampling requirements – Does the operation have SOPs, protocols, and record keeping in place ensuring that each sample removed from a batch or lot is recorded in the inventory or manufacturing batch record for the batch or lot?	☐	☐	☐	
E5.6(h) • Manufacturing sampling requirements - Does the operation have SOPs, protocols, and record keeping in place ensuring that the quantity of sample used for each test or examination is of sufficient size or number to ensure the results are representative of the batch or lot?	☐	☐	☐	
E5.6(i) • Manufacturing sampling requirements - Does the operation have SOPs, protocols, and record keeping in place ensuring that a reserve sample has been prepared from the representative sample of each batch or lot of shelf-stable component, cannabis, or cannabis-derived product?	☐	☐	☐	
E5.6(j) • Manufacturing sampling requirements - Does the operation have SOPs, protocols, and record keeping to ensure that all reserve samples consist of at least twice the quantity necessary for tests and examinations to determine whether the shelf-stable component, cannabis, or cannabis-derived product meets established critical quality specifications? Where state law limits the amount of cannabis and cannabis-derived product permitted to be kept on hand, operations may keep smaller amounts in reserve, as necessary.	☐	☐	☐	
E5.6(k)(1) • Manufacturing sampling requirements - Does the operation have SOPs, protocols, and record keeping to ensure that reserve samples of shelf-stable components are stored using an appropriate container-closure to protect against contamination or deterioration during storage?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.6(k)(2) • Manufacturing sampling requirements - Does the operation have SOPs, protocols, and record keeping to ensure that reserve samples of shelf-stable components are stored under conditions consistent with the conditions under which the component is stored at the manufacturing operation?	☐	☐	☐	
E5.6(k)(3) • Manufacturing sampling requirements - Does the operation have SOPs, protocols, and record keeping to ensure that reserve samples of shelf-stable components are retained for one year past the expiration date of the last batch of cannabis- derived product manufactured from the lot? Where state law limits the amount of cannabis and cannabis-derived product permitted are kept on hand, operations may keep reserve samples for shorter periods of time, as necessary.	☐	☐	☐	
E5.6(l)(1) • Manufacturing sampling requirements - Does the operation have SOPs, protocols, and record keeping in place to ensure that the reserve samples of cannabis-derived product is properly stored using the same container-closure system in which the packaged and labeled cannabis-derived product is distributed or, for bulk products, using a container-closure system that provides essentially the same characteristics to protect against contamination or deterioration as the one in which the bulk product is distributed?	☐	☐	☐	
E5.6(l)(2) • Manufacturing sampling requirements - Does the operation have SOPs, protocols, and record keeping in place to ensure that reserve samples of cannabis-derived product(s) are stored under conditions consistent with the storage conditions recommended on the product label or, if no storage conditions are recommended on the label, under ordinary storage conditions?	☐	☐	☐	
E5.6(l)(3) • Manufacturing sampling requirements - Does the operation have SOPs, protocols, and record keeping in place to ensure that reserve samples of cannabis-derived product are retained for one year past the expiration date of the batch or lot? Where state law limits the amount of cannabis and cannabis-derived products permitted to be kept on hand, operations may keep reserve samples for shorter periods of time, as necessary.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.7(a)(1-2) • Cannabis-derived product specifications - Does the operation have SOPs, protocols, and record keeping in place establishing specifications for each cannabis-derived product? Including; • The establishing specification for the identity, purity, strength, and composition of each cannabis-derived product manufactured by the operation; and • If receiving cannabis-derived products for further processing, specifications to provide sufficient assurance that the product received is adequately identified and is consistent with the purchase order.	☐	☐	☐	
E5.7(b)(1) • Cannabis-derived product specifications - Does the operation have SOPs, protocols, and record keeping in place confirming that each batch or lot of cannabis-derived product or subset of cannabis-derived product manufactured by the operation has been identified through sound statistical sampling plan? Does the operation verify that the batch or lot meets product specifications for identity, purity, strength, and composition, to the extent that scientifically valid test methods exist for these specifications?	☐	☐	☐	
E5.7(b)(2) • Cannabis-derived product specifications - Does the operation have SOPs, protocols, and record keeping in place confirming that for each batch or lot of cannabis-derived product, in lieu of testing every established strength and composition specification for which scientifically valid test methods exist, one or more strength and/or composition specifications has been selected for testing, where it can be established that testing for this reduced panel of specifications is sufficient to ensure that the production and process control system is producing product that meets all specifications?	☐	☐	☐	
E5.7(b)(3) • Cannabis-derived product specifications - Does the operation have SOPs, protocols, and record keeping in place confirming that for each batch or lot of cannabis-derived product, where no scientifically valid test method exists for a product specification, compliance with the specification has been established through component and/or in-process testing, examinations, or monitoring and/or review of manufacturing batch records?	☐	☐	☐	
E5.7(b)(4) • Cannabis-derived product specifications - Does the operation have SOPs, protocols, and record keeping in place confirming that each batch or lot of cannabis-derived product has been approved by quality-control personnel and justified for reduced product testing under section 5.7(b)(2) or section 5.7(b)(3) of this part?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.7(c) • Cannabis-derived product specifications - Does the operation have SOPs, protocols, and record keeping in place confirming that each batch or lot of cannabis-derived product that fails to meet its specifications is rejected, unless quality-control personnel approve a treatment, process adjustment, reprocessing, or other deviation that ensures the cannabis-derived product batches manufactured with the affected material will meet all specifications for identity, purity, strength, and composition, and will not be otherwise contaminated or adulterated? Is any such treatment, process adjustment, reprocessing, or other deviation documented in the manufacturing batch record, justified, and approved by quality-control personnel, as required?	☐	☐	☐	
E5.7(d) • Cannabis-derived product specifications - Does the operation have SOPs, protocols, and record keeping in place confirming that each batch or lot of cannabis-derived product experiencing any unexplained occurrence or discrepancy, and any failure of the cannabis-derived product to meet its specifications or requirements, has been documented and investigated? The investigation must extend to any related batches that may have been associated with the same specific failure, discrepancy, or problem; this may include, but is not limited to, batches of the same cannabis-derived product, other batches processed on the same equipment or during the same time period, and other batches produced using the same lots of components.	☐	☐	☐	
E5.7(e) • Cannabis-derived product specifications - Does the operation have SOPs, protocols, and record keeping in place describing, in sufficient detail, the storage, handling, sampling, testing, and approval or rejection of all cannabis and cannabis-derived products?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.8(a)(1-8) • In-process material specifications, sampling, and testing - Does the operation have SOPs, protocols, and record keeping in place establishing in-process specification for any point, step, or stage in the manufacturing protocol where control is necessary to help ensure that specifications are met for the identity, purity, strength, and composition of the cannabis-derived product? Such specifications may include, but are not limited to, the following, as appropriate: • Weight or fill of tablets, capsules, or other units; • Weight or fill variation of tablets, capsules, or other units; • Hardness or friability of tablets; • Disintegration time of unit dosages; • Clarity, viscosity, specific gravity, total dissolved solids, or pH of solutions; • Loss of drying, moisture content, or solvent residue; • Microbiological characteristics; and • Organoleptic characteristics.	☐	☐	☐	
E5.8(b) • In-process material specifications, sampling, and testing - Does the operation have evidence that the in-process specifications for such characteristics meet the required consistency with the cannabis-derived product specifications?	☐	☐	☐	
E5.8(c) • In-process material specifications, sampling, and testing - Does the operation have SOPs, protocols, and record keeping in place ensuring that all in-process materials have been sampled and tested or examined for conformance with in-process specifications as appropriate during the production process (e.g., at commencement or completion of significant process stages or after storage for long periods), and where appropriate have been approved or rejected by quality-control personnel?	☐	☐	☐	
E5.8(d) • In-process material specifications, sampling, and testing - Does the operation have SOPs, protocols, and record keeping in place ensuring that all in-process material that fails to meet its specifications are rejected, unless quality-control personnel approve a treatment, process adjustment, reprocessing, or other deviation that will ensure the cannabis-derived product batches manufactured with the affected material will meet all specifications for identity, purity, strength, and composition and will not be otherwise contaminated or adulterated? Is any such treatment, process adjustment, reprocessing, or other deviation documented in the manufacturing batch record, justified, and approved by quality-control personnel, as required?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.9(a) • Calculation of yield - Does the operation have SOPs, protocols, and record keeping in place ensuring that all actual yields are determined at the conclusion of each appropriate phase of manufacturing of the cannabis-derived product? Are such calculations either performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment, independently verified by one person, as required?	☐	☐	☐	
E5.9(b) • Calculation of yield - Does the operation have SOPs, protocols, and record keeping in place ensuring that if the percentage of theoretical yield, at any process step or at the end of production, falls outside the maximum or minimum percentage of theoretical yield allowed in the manufacturing protocol, that quality-control personnel are required to conduct an investigation of the batch and determine, to the extent possible, the source of the discrepancy? Are deviations documented, explained, and approved by quality-control personnel, as required?.	☐	☐	☐	
SUBPART F – PACKAGING AND LABELING PROCESS CONTROLS				
F6.1(a) • General consideration for packaging components, including labels - Does the operation have SOPs, protocols, and record keeping in place for cannabis to be packaged without undergoing manufacturing to a cannabis-derived product, documenting it as received, identified, stored, handled, sampled, reviewed, and approved or rejected as per sections 5.2 and 5.6 above?	☐	☐	☐	
F6.1(b) • General consideration for packaging components, including labels - Does the operation have SOPs, protocols, and record keeping in place establishing specifications for packaging components as necessary to ensure the identity, purity, strength, and composition of the packaged products? Packaging components that may come into contact with products must be safe and suitable for their intended use and must not be reactive or absorptive or otherwise affect the safety, purity, or quality of the product.	☐	☐	☐	
F6.1(c) • General consideration for packaging components, including labels - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place establishing procedures describing, in sufficient detail, the receipt, identification, storage, handling, and approval or rejection of packaging and labeling components?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
F6.1(d)(1) • General consideration for packaging components, including labels - Does the operation have written SOPs, protocols, and record keeping in place for the receiving and storage of labels and other packaging components to ensure that, upon receipt and before acceptance, each container or grouping of containers of packaging components is visually examined for appropriate labeling as to contents, container damage or broken seals, and contamination, to determine whether the container condition may have resulted in contamination or deterioration of the packaging components?	☐	☐	☐	
F6.1(d)(2) • General consideration for packaging components, including labels - Does the operation have written SOPs, protocols, and record keeping in place verifying that the supplier's documentation for each shipment has been examined to ensure the packaging components are consistent with what was ordered?	☐	☐	☐	
F6.1(d)(3) • General consideration for packaging components, including labels - Does the operation have written SOPs, protocols, and record keeping in place ensuring that each container or grouping of containers for packaging components has been identified with a distinctive code (i.e. lot or control number) for each lot in each shipment received, which allows the lot to be traced backward to the supplier, including the date received, and the name of the component, and forwarded to the product batches packaged or labeled using the lot? This code must be used in recording the disposition of each lot.	☐	☐	☐	
F6.1(d)(4) • General consideration for packaging components, including labels - Does the operation have written SOPs, protocols, and record keeping in place ensuring that labels and other packaging components are stored under quarantine until they have been examined and approved or rejected by quality-control personnel?	☐	☐	☐	
F6.1(e)(1) • General consideration for packaging components, including labels - Does the operation have written SOPs, protocols, and record keeping in place ensuring that packaging components are withheld from use until the lot has been reviewed and released for use by the quality-control personnel?	☐	☐	☐	
F6.1(e)(2) • General consideration for packaging components, including labels - Does the operation have written SOPs, protocols, and record keeping in place ensuring that packaging components are in compliance with established specifications and have been thoroughly examined upon receipt, and/or has undergone a review of the supplier's documentation?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
F6.1(e)(3) • General consideration for packaging components, including labels - Does the operation have written SOPs, protocols, and record keeping in place ensuring that all shipments of a packaging component have been determined to meet its specification and released for use by quality-control personnel?	☐	☐	☐	
F6.1(e)(4) • General consideration for packaging components, including labels - Does the operation have written SOPs, protocols, and record keeping in place ensuring that all packaging component that does not meet its specifications, including any incorrect labels, are rejected by quality-control personnel, unless quality-control personnel approve a treatment or other deviation that will render the packaging component suitable for use, and will ensure the product batches packaged and labeled with the affected component will meet all specifications for identity, purity, strength, composition, packaging, and labeling and will not be otherwise contaminated or adulterated? Is any such treatment or other deviation documented, justified, and approved by quality-control personnel, as required?	☐	☐	☐	
F6.1(f) • General consideration for packaging components, including labels - Does the operation have written SOPs, protocols, and record keeping in place prohibiting the use of gang-printed labeling for different products, or different strengths or net contents of the same product, unless the labeling from gang-printed sheets is adequately differentiated by size, shape, or color?	☐	☐	☐	
F6.2(a)(1) • Packaging and/or labeling protocol - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place for each unique product to be packaged and/or labeled that assures the correct packaging and labeling components are used for each product packaged or labeled by the operation including the identity of the product to be packaged and/or labeled? Where appropriate, the packaging and/or labeling protocol may be combined with the manufacturing protocol for the product.	☐	☐	☐	
F6.2(a)(2) • Packaging and/or labeling protocol - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place for each unique product to be packaged and/or labeled that assures the correct packaging and labeling components are used for each product packaged or labeled by the operation, including the identity of each packaging component to be used? Where appropriate, the packaging and/or labeling protocol may be combined with the manufacturing protocol for the product.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
F6.2(a)(3) • Packaging and/or labeling protocol - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place for each unique product to be packaged and/or labeled that assures the correct packaging and labeling components are used for each product packaged or labeled by the operation including providing a specimen of the label and other labeling to be used, or a cross-reference to the labeling (such as by label number and version number)? Where appropriate, the packaging and/or labeling protocol may be combined with the manufacturing protocol for the product.	☐	☐	☐	
F6.2(a)(4) • Packaging and/or labeling protocol - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place for each unique product to be packaged and/or labeled that assures the correct packaging and labeling components are used for each product packaged or labeled by the operation providing a statement of the acceptable maximum and minimum percentages of theoretical yield?	☐	☐	☐	
F6.2(a)(5)(i-vi) • Packaging and/or labeling protocol - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place for each unique product to be packaged and/or labeled that assures the correct packaging and labeling components are used for each product packaged or labeled by the operation, to include written instructions or cross references to standard procedures for the following? • Inspection of packaging and labeling equipment before and after use to assure that all products and packaging and labeling materials from previous operations have been removed; • Issuance of labels and labeling and labeling specified in the packaging and/or labeling protocol; • Careful examination of labels and labeling issued to each batch prior to use, to ensure conformity to the labeling specified in the packaging and/or labeling protocol; • Each packaging and/or labeling process step; • Monitoring of packaging and/or labeling process steps; and • Additional applicable procedures to be followed, if any.	☐	☐	☐	
F6.2(b) • Packaging and/or labeling protocol - Does the operation have written SOPs, protocols, and record keeping in place ensuring that the packaging and/or labeling process meets all product specifications?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
F6.2(c) • Packaging and/or labeling protocol - Does the operation have written SOPs, protocols, and record keeping in place for the packaging and/or labeling process described in the protocols that ensure the product specifications are consistently met?	☐	☐	☐	
F6.3(a) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for the preparation of a packaging and/or labeling batch record for each batch or lot of product packaged and/or labeled by the operation? Where appropriate, the packaging and labeling batch record may be combined with the manufacturing batch record for the batch or lot.	☐	☐	☐	
F6.3(b)(1-2) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for the packaging and/or labeling of batch records, including cross-reference or reproduction of appropriate packaging and/or labeling protocol, and a complete record of the packaging and/or labeling and sampling of the batch?	☐	☐	☐	
F6.3(c)(1-3) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for the packaging and/or labeling with batch records including, as applicable to the process, the identity of the product; batch, lot, or control number of the product; packaging and/or labeling batch size?	☐	☐	☐	
F6.3(c)(4)(i-iii) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for packaging and/or labeling of batch records that include, as applicable to the process, for each packaging component used in the production of the batch, the following information: • Identity of each packaging component; • Batch, lot, or control number of each packaging component used in the batch; • Quantity of each lot of packaging components used, including the unit of measure.	☐	☐	☐	
F6.3(c)(5) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for packaging and/or labeling of batch records that include the date(s) on which, and where applicable, the times at which, each step of the packaging and/or labeling protocol was performed?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
F6.3(c)(6) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for packaging and/or labeling of batch records including the identity of packaging lines and major equipment used in packaging and/or labeling the batch?	☐	☐	☐	
F6.3(c)(7) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for packaging and/or labeling of batch records including the date and time of the maintenance, cleaning, and/or sanitizing of the packaging lines and major equipment used in packaging and labeling of the batch, or a cross-reference to records, such as individual equipment logs, where this information is recorded?	☐	☐	☐	
F6.3(c)(8) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for packaging and/or labeling of batch records, including, if packaging or labeling of the batch uses equipment or instruments requiring periodic calibration, inspection, or verification, the date and time of the last calibration, inspection, or other verification of instruments or equipment or the date on which such is next due, or a cross-reference to records, such as individual equipment logs, where this information is recorded?	☐	☐	☐	
F6.3(c)(9) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for packaging and/or labeling of batch records including a statement of actual yield and a statement regarding whether the actual yield is within the acceptable range of the theoretical yield as per section 6.2(a)(4) at the end of packaging and/or labeling?	☐	☐	☐	
F6.3(c)(10) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for packaging and/or labeling of batch records including documentation for when the actual yield falls outside the allowed limits, quality-control personnel must conduct an investigation of the batch and determine, to the extent possible, the source of the discrepancy? The deviation must be documented, explained, and approved by quality-control personnel.	☐	☐	☐	
F6.3(c)(11) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for packaging and/or labeling of batch records including label reconciliation, as per section 6.3(f) of this part?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
F6.3(c)(12) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for packaging and/or labeling of batch records including records of any labeling scrap or cannabis waste generated during packaging and /or labeling of the batch?	☐	☐	☐	
F6.3(c)(13)(i-vi) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for packaging and/or labeling of batch records, including records identifying each person performing each process step in packaging and/or labeling of the batch? This includes but is not limited to: • Inspecting labels and other packaging components to ensure suitability and correctness prior to use in the batch; • Inspecting packaging and labeling areas before and after use; • Reconciling label issuance and usage and verifying the reconciliation of label issuance and usage; • Examining packaged and labeled products to ensure proper labeling and coding; • Performing any other checks or verifications in packaging and/or labeling of the batch as needed; and • Releasing the batch from one stage of packaging and/or labeling to the next.	☐	☐	☐	
F6.3(d) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for packaging and/or labeling of batch records, including the recording of all data, at the time at which each action was performed?	☐	☐	☐	
F6.3(e)(1-2) • Packaging and/or labeling batch record - Does the operation have written SOPs, protocols, and record keeping in place for packaging and/or labeling of batch records ensuring that all printing devices located on, or associated with, production lines are monitored to assure that all printing conforms to the requirements of the packaging and/or labeling protocol used to imprint labeling or coding directly on the following? • Primary packaging for the product; • Secondary packaging (e.g., a case containing several individual packages of product).	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
F6.3(f)(1) • Packaging and/or labeling batch record - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place reconciling the quantities of labels or labeling issued, used, and returned to storage, that establishes narrow limits for the labeling reconciliation to be based, where possible, on historical operating data, for the amount of allowed variation in the labeling reconciliation?	☐	☐	☐	
F6.3(f)(2) • Packaging and/or labeling batch record - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place reconciling when labeling falls outside the allowed limits such that quality-control personnel must conduct an investigation of the batch and determine, to the extent possible, the source of the discrepancy? The deviation must be documented, explained, and approved by quality-control personnel.	☐	☐	☐	
F6.3(f)(3) • Packaging and/or labeling batch record - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place documenting all reconciliation waived for cut or roll labels if a 100% examination for correct labels has been performed, either manually or by appropriate electronic or electromechanical equipment during or after completion of finishing operations?	☐	☐	☐	
F6.3(f)(4) • Packaging and/or labeling batch record - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place requiring all excess labeling bearing batch, lot, or control numbers be destroyed?	☐	☐	☐	
F6.3(f)(5) • Packaging and/or labeling batch record - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place outlining the care that must be taken when returning labeling to storage, to prevent mix-ups, and ensuring proper identification?	☐	☐	☐	
F6.3(g) • Packaging and/or labeling batch record - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place identifying representative and reserve samples of each batch or lot of retail packaged and/or labeled product, as required to be collected per section 5.6 of this part?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
F6.3(h) • Packaging and/or labeling batch record - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place noting the completed packaging and/or labeling batch record for each batch or lot? These records much be reviewed and signed by quality-control personnel to determine compliance with all applicable specifications and other requirements of the packaging and/or labeling protocol before a batch or lot is approved.	☐	☐	☐	
F6.3(i) • Packaging and/or labeling batch record - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place ensuring that packaged or labeled products that fail to meet packaging or labeling specifications or other packaging requirements are rejected, unless quality-control personnel approve repackaging, relabeling, or other deviation that ensures the product batch or lot will meet all packaging and labeling specifications and other packaging requirements, and will not be otherwise contaminated or adulterated? Any such repackaging, relabeling, or other deviation must be documented, justified, and approved by quality-control personnel.	☐	☐	☐	
F6.4(a)(1-4) • Label content for cannabis and cannabis-derived products - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place ensuring that packaged or labeled products bear on the label of its primary packaging the name and place of business of the manufacturer or distributor; identity of the product; net quantity of contents in terms of weight, numerical count, or other appropriate measure; and a batch, lot, or control number?	☐	☐	☐	
F6.4(a)(5) • Label content for cannabis and cannabis-derived products - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place ensuring that packaged or labeled products bear on the label of its primary packaging either a production date or an expiration date? Products capable of supporting the rapid and progressive growth of infectious, toxigenic, or spoilage microorganisms must bear a “use by” date and/or a “freeze by” date. Any shelf life or expiration period indicated on the label of an edible product must be supported by appropriate data.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
F6.4(a)(6-9) • Label content for cannabis and cannabis-derived products - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place ensuring that packaged or labeled products bear on the label of its primary packaging instruction for use, including any types of compliant individuals for whom the product is recommended, as appropriate; instructions for appropriate storage; and any other statements or information required by state regulators?	☐	☐	☐	
F6.4(b)(1-11) • Label content for cannabis and cannabis-derived products - Does the packaging and labeling operation have written SOPs, protocols, and record keeping in place ensuring that packaged or labeled products bear on the label of primary packaging for all edible products a "Product Facts" box listing quantitative content and nutrient information relevant to the product, including, as applicable, the following content? • Cannabis ingredient; • Cannabinoid and/or terpenoid content; • Total calories and fat calories (when greater than 5 calories per serving); • Total fat, saturated fat, and trans fat (when greater than 0.5 g per serving); • Cholesterol (when greater than 2 mg per serving); • Sodium (when greater than 5 mg per serving); • Total carbohydrates (when greater than 1 g per serving); • Dietary fiber (when greater than 1 g per serving); • Sugars (when greater than 1 g per serving); • Protein (when greater than 1 g per serving; and • Vitamin A, vitamin C, calcium, and iron (when present at greater than 2% of the recommended daily intake).	☐	☐	☐	
SUBPART G – HOLDING CONTROLS				
G7.1(a)(1-3) • Identification - Does the operation have SOPs, protocols, and record keeping in place ensuring the proper identification, at all times, of each container of component, packaging component, in-process material, and product, including the following? • Identity of the item; • Batch, lot, or control number; • Status (e.g., quarantined, approved, recalled, rejected).	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
G7.1(b) • Identification - Does the operation have SOPs, protocols, and record keeping in place ensuring the proper identification and handling of product packages that are held in unlabeled condition for future labeling operation, precluding mislabeling of individual containers, lots, or batches? Identification need not be applied to each individual container but must be sufficient to determine the identity of the product, quantity of contents, and batch, lot, or control number of each container.	☐	☐	☐	
G7.1(c)(1-2) • Identification - Does the operation have SOPs, protocols, and record keeping in place ensuring that the identification information required in section 7.1(a) and (b) has been affixed to the individual container or to an appropriate grouping of containers, or assigned to the room or other defined physical location of the container(s)?	☐	☐	☐	
G7.2(a) • Storage and handling - Does the operation have SOPs, protocols, and record keeping in place ensuring that all components, packaging components, in-process materials, and products are, at all times, handled, stored, and distributed in a manner to avoid deterioration, prevent contamination, and mix-ups? Where necessary, are appropriate conditions of temperature, humidity, and light established and maintained so that the identity, purity, strength, and composition of components, in-process materials, and products are not affected and that adulteration is prevented, as required?	☐	☐	☐	
G7.2(b) • Storage and handling - Does the operation have SOPs, protocols, and record keeping in place ensuring that all containers of components, packaging components, in-process materials and product are properly stored off the floor and suitably spaced to permit cleaning and inspection?	☐	☐	☐	
G7.2(c) • Storage and handling - Does the operation have SOPs, protocols, and record keeping in place ensuring that all components, in-process materials, and products that can support the rapid growth of microorganisms of public health significance are held in a manner that prevents them from becoming adulterated?	☐	☐	☐	
G7.2(d) • Storage and handling - Does the operation have SOPs, protocols, and record keeping in place ensuring that all labels, labeling, cannabis, cannabis-derived products, and cannabis waste are stored in a controlled access area?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
G7.2(e) • Storage and handling - Does the operation have SOPs, protocols, and record keeping in place ensuring that all components, packaging components, and products are used or distributed in a manner whereby the oldest batches or lots are used or distributed first? Deviation from this requirement is permitted if such deviation is temporary and appropriate.	☐	☐	☐	
G7.3(a)(1-5) • Withholding materials from use or distribution - Does the manufacturing, packaging, and labeling operation have SOPs, protocols, and record keeping in place ensuring the ability to quarantine any lot, batch, or other portion of component, packaging component, in-process material, or product whose suitability for use or distribution is in question, to prevent its use and distribution pending disposition by quality-control personnel, including the following? • Newly received components and packaging components for use in manufacturing, packaging, and/or labeling; • Batches newly completed in production; • Product returned to the operation for any reason; • Components, packaging components, in-process materials, or products that are or may be contaminated or adulterated; • Components, packaging components, in-process material or products that are under investigation by quality-control personnel for any other reason.	☐	☐	☐	
G7.3(b) • Withholding materials from use or distribution - Does the operation have SOPs, protocols, and record keeping in place ensuring that rejected components, packaging components, in-process materials, finished product, cannabis waste, and rejected labels and labeling (including any excess labeling bearing lot, batch, or control numbers which is not immediately destroyed after packaging operations are complete) will be appropriately segregated, controlled, and held in a controlled-access area pending destruction or other disposal?	☐	☐	☐	
G7.3(c) • Withholding materials from use or distribution - Does the operation have SOPs, protocols, and record keeping in place ensuring that cannabis waste (other than cannabis and cannabis-derived product that has been rejected and returned to the vendor) and rejected labels and other labeling are destroyed in a manner which prevents unauthorized use? Is destruction of any cannabis waste documented and witnessed by at least two workers, one of whom must be supervisory, managerial, or quality-control personnel, unless video surveillance is used, in which case only one worker is necessary, as required? Destruction may include composting.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
SUBPART H – INVENTORY AND RECORDKEEPING				
H8.1(a) • Materials inventory - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping for each shipment of component, packaging component, cannabis, and cannabis-derived product received from another company or individual?	☐	☐	☐	
H8.1(b)(1-2) • Materials inventory - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping noting the identity of the received item, as applicable to the item; any component number or product number if such are in use be the supplier; and the supplier or vendor from which the shipment was received?	☐	☐	☐	
H8.1(b)(3-6) • Materials inventory - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping evidence noting the following information? • The original cultivation operation, processing operation, or manufacturing operation, if known and where applicable; • The cultivation operation, processing operation, manufacturing operation, or supplier's batch, lot or control number, if known and where applicable; • Date of receipt; and • Shipment delivery method, including where applicable, the name of the commercial or private carrier.	☐	☐	☐	
H8.1(c)(1) • Materials inventory - Does the manufacturing, packaging, and labeling operation have SOPs and protocols, for the record keeping or establishment of cross references to other records such as manufacturing batch records including the batch, lot, or other control number assigned by the manufacturing, packaging, and/or labeling operation to the shipment?	☐	☐	☐	
H8.1(c)(2) • Materials inventory - Does the manufacturing, packaging, and labeling operation have SOPs, protocols, and record keeping, or have established cross reference systems to other records such as manufacturing batch records, recording the inspection, sampling, testing and examinations performed on the batch or lot, and the conclusions derived there from, as applicable to the scope of the operation?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
H8.1(c)(3) • Materials inventory - Does the manufacturing, packaging, and labeling operation have SOPs, protocols, and record keeping, or have established cross reference systems to other records such as manufacturing batch records, recording all treatment, reprocessing, or other deviation performed by the operation on the batch or lot prior to use?	☐	☐	☐	
H8.1(c)(4) • Materials inventory - Does the manufacturing, packaging, and labeling operation have SOPs, protocols, and record keeping, or have established cross reference systems to other records such as manufacturing batch records, recording the disposition of the batch or lot by quality-control personnel, including the date and signature of the person responsible for approving or rejecting the batch or lot and any treatments, reprocessing, or other deviation performed thereon?	☐	☐	☐	
H8.1(c)(5)(i-iii) • Materials inventory - Does the manufacturing, packaging, and labeling operation have SOPs, protocols, and record keeping, or have established cross reference systems to other records such as manufacturing batch records, noting each use of the batch or lot in production, including the quantity used, including unit of measure; name and batch, lot or other control number of the product batch in which the batch or lot is used, and the initials of the person(s) responsible for removing from storage the necessary quantity for use in the designated batch?	☐	☐	☐	
H8.1(c)(6)(i-iii) • Materials inventory - Does the manufacturing, packaging, and labeling operation have SOPs, protocols, and record keeping, or have established cross reference systems to other records such as manufacturing batch records, noting a record of any portion of the batch or lot returned from production to storage including the quantity returned; unit of measure; name and batch, lot, or other control number of the batch or lot from which the portion is returned; and the initials of the persons responsible for verifying the quantity returned?	☐	☐	☐	
H8.1(c)(7)(i-iii) • Materials inventory - Does the manufacturing, packaging, and labeling operation have SOPs, protocols, and record keeping, or have established cross reference systems to other records such as manufacturing batch records, including a record of any portion of the batch or lot disposed of from storage, including the quantity, unit of measure, reason, and persons responsible for measuring the quantity?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
H8.2(a) • Distributed materials - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping for each batch or lot of cannabis or cannabis-derived product distributed by the operation?	☐	☐	☐	
H8.2(b)(1) • Distributed materials - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping that includes the identity of the cannabis or cannabis-derived product and any item code or product number, if such are in use by the manufacturing, packaging, labeling, or holding operation?	☐	☐	☐	
H8.2(b)(2)(i-iv) • Distributed materials - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping that includes a record of each distribution of the batch or lot, including the following? • Quantity distributed, including unit of measure; • Name and address of each company or non-profit entity to which, or individual to whom, the batch is distributed, unless a system exists to unambiguously cross-reference the name to the corresponding address maintained on file separately; • Shipping method by which each shipment is distributed, including where applicable the name of the commercial or private carrier; • Initials of the persons responsible for removing from storage the necessary quantity for each shipment. Each distribution must be verified by a second person	☐	☐	☐	
H8.2(b)(3)(i-iv) • Distributed materials - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping that includes a record of any portion of the batch or lot returned to storage, including the following? • Quantity returned, including the unit of measure; • Company, non-profit entity, individual, or location from which the portion is returned; • Shipment return method, including where applicable the name of the commercial or private carrier; • Initials of the person(s) responsible for verifying the quantity returned.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
H8.2(c)(1-4) • Distributed materials - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping, or established the ability to cross reference to other records such as manufacturing batch records, for the following? • Batch, lot, or other control number assigned by the manufacturing, packaging, and/or labeling operation to the batch or lot; • Inspection, sampling, testing, and examinations performed on the batch or lot by the operation, and the conclusions derived there from; • Any treatment, reprocessing, or other deviation performed on the batch or lot by the operation prior to distribution; • Disposition of the batch or lot by quality-control personnel, including the date and the signature of the person responsible for the approving the batch or lot for distribution; and • The date and the signature of the person responsible for approving or rejecting ay treatment, reprocessing, or other deviation performed thereon.	☐	☐	☐	
H8.4(a) • Reconciliation - Does the operation have SOPs, protocols, and record keeping for records of receipt, use or distribution, return, and disposal of each batch or lot of components, packaging components, cannabis or cannabis-derived products to be kept chronologically, and the quantities must be recorded with an appropriate level of precision?	☐	☐	☐	
H8.4(b) • Reconciliation - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place ensuring that after each batch or lot is used or distributed a reconciliation of the quantity received into storage against the quantity used, distributed, returned, and/or disposed can be assessed? Are such calculations performed by one person and independently verified by a second person, as required?	☐	☐	☐	
H8.4(c) • Reconciliation - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place ensuring that narrow limits are established, based where possible on historical operating data, for the amount of allowed variation in the reconciliation?	☐	☐	☐	
H8.4(d) • Reconciliation - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place ensuring that when a reconciliation falls outside the allowed limits, quality-control personnel will conduct an investigation to determine, to the extent possible, the source of the discrepancy? The deviation must be documented, explained, and approved by quality-control personnel.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
H8.5(a) • Record retention - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place ensuring that, except as required in sections 8.5(b) and (c), the operation retains the records required by this part for a period of at least three years past date of creation of the record, or one year past the expiration date of the related product, whichever is longer, as applicable to the operation?	☐	☐	☐	
H8.5(b) • Record retention - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place ensuring that product complaint records are retained for one year past the expiration date of the batch or lot affected, or for one year past the date of receipt of the complaint, whichever is longer?	☐	☐	☐	
H8.5(c) • Record retention - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place ensuring that records for returned products are retained for one year past the expiration date of the batch or lot affected, or for one year past the date of receipt of the return, whichever is longer?	☐	☐	☐	
SUBPART I – COMPLAINTS, RETURNS, AND RECALLS				
I9.1(a) • Complaint files - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place describing the handling of product complaints received regarding a cannabis or cannabis-derived product?	☐	☐	☐	
I9.1(b)(1-2) • Complaint files - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place requiring a qualified person to do the following? • Review product complaints to determine whether the product complaint involves a possible failure of a product to meet any of its specifications, or any other requirements, including but not limited to those specifications and other requirements that, if not met, may result in a risk of illness or injury; and • Investigate any product complaint that involves a possible failure of a product to meet any of its specifications, or any other requirements of this part, including but not limited to those specifications and other requirements that, if not met, may result in a risk of illness or injury.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
I9.1(c) • Complaint files - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place ensuring that quality-control personnel review and approve decisions about whether to investigate a product complaint and review and approve the findings and follow-up action of any investigation performed?	☐	☐	☐	
I9.1(d) • Complaint files - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place ensuring the review and investigation of the product complaint, and the review by quality-control personnel about whether to investigate a product complaint, and the findings and follow-up action of any investigation performed, extends to all related batches and relevant records? Related batches may include, but are not limited to, batches of the same product, other batches processed on the same equipment or during the same time period, or other batches produced using the same batches or lots of components or packaging components.	☐	☐	☐	
I9.1(e) • Complaint files - Does the manufacturing, packaging, labeling, and holding operation have a written record of the complaint(s) and where applicable its investigation report, to include the following information? • Identity of the product; • Batch, lot or other control number of the product; • Date the complaint was received and the name, address, or telephone number of the complainant, if available; • Nature of the complaint including, if known, how the product was used • Names of personnel who do the following; review and approve the decision about whether to investigate a product complaints; investigate the complaint; and review and approve the findings and follow-up action of any investigation performed; • Findings of the investigation and follow-up action taken when an investigation is performed; and • Response to the complainant, if applicable.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
I9.1(f) • Complaint files - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place for a product complaint that includes a report of an adverse event? For purposes of this section, an adverse event is a health-related event associated with use of a product that is undesirable, and that is unexpected or unusual. The procedure must address whether the adverse event requires the following: • Reporting to any public health authority; • Reporting to the physician of record for the individual reported to have experienced the adverse event, if known; and • Product recall.	☐	☐	☐	
I9.2(a) • Returned products - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place describing the receipt, handling, and disposition of returned cannabis or cannabis-derived products?	☐	☐	☐	
I9.2(b) • Returned products - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place ensuring that returned products are properly identified as such and quarantined upon receipt?	☐	☐	☐	
I9.2(c) • Returned products - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place ensuring returned product is reviewed and approved or rejected by quality-control personnel?	☐	☐	☐	
I9.2(d) • Returned products - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place ensuring that if the conditions under which returned product has been held, stored, or shipped before or during its return, or if the condition of the product, its containers, or labeling, as a result of storage or shipping, casts doubt on the identity, purity, strength, composition, or freedom from contamination or adulteration of the product, the returned product shall be rejected unless examination, testing, or other investigations prove the product meets appropriate standards of identity, purity, strength, and composition and its freedom from contamination or adulteration?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
I9.2(e) • Returned products - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place ensuring that if the reason a product is returned implicates associated batches, an appropriate investigation is conducted that extends to all related batches and relevant records? Related batches may include, but are not limited to, batches of the same product, other batches processed on the same equipment or during the same time period, or other batches produced using the same components or packaging components.	☐	☐	☐	
I9.2(f) • Returned products - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping in place ensuring the destruction, as per section 7.3(c), of rejected returned product returned to the operation?	☐	☐	☐	
I9.2(g)(1-10) • Returned products - Does the manufacturing, packaging, labeling, and holding operation have a written record of all returns and, where applicable, its investigation, including the following? • Identity of product; • Batch, lot, or other control number of the product • Date the returned product was received; • Name and address from which it was returned and the means by which it was returned; • Reason for the return; • Results of any tests or examination conducted on the returned product or on related batches, if any; • Findings of the investigation and follow-up action taken when an investigation is performed; • Any reprocessing performed on the returned product; • The ultimate disposition of the returned product and the date of disposition; and • Names of the quality-control personnel who do the following: ◦ Review the reason for the product return; ◦ Review and approve any reprocessing, as applicable, and ◦ Review and approve the findings and follow-up action of any investigation performed.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
I9.3(a) • Recall procedures - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping establishing a procedure for recalling a product that has been shown to present a reasonable or remote probability that the use of the product will cause serious adverse health consequences or could cause temporary or medically reversible adverse health consequences? Does this procedure include the following, as required? • Factors which necessitate a recall; • Personnel responsible for a recall; and • Notification protocols.	☐	☐	☐	
I9.3(b) • Recall procedures - Does the manufacturing, packaging, labeling, and holding operation have SOPs, protocols, and record keeping establishing a procedure for communicating a recall of product distributed by the operation? Does this procedure include the following, as required? • A mechanism to contact all customers that have, or could have, obtained the product from the operation; • A mechanism to contact the vendor that supplied the recalled product to the operation, if applicable; • Instructions for the return or destruction of any recalled product by customers; • Instructions for contracting the relevant manufacturing, packaging, labeling, and/or holding operations; and • Communication and outreach via media, as necessary and appropriate.	☐	☐	☐	

*Not required by AHPA document, not necessarily an audit point.

LABORATORY CERTIFICATION AUDIT

Patient Focused Certification

APPLICANT NAME: _____

AUDITOR NAME: _____

FACILITY LOCATION: _____

DATE OF AUDIT: _____

TIME ON SITE: _____

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
A1.1 • Subject operations – Is this operation subject to state and/or local oversight? *	☐	☐	☐	
A1.2 • Other statutory provisions and regulations – Is the laboratory operation presently compliant with all other applicable statutory provisions and regulations related to cannabis laboratory operations in the jurisdiction in which this part applies, and related to all other business activities undertaken in conducting a laboratory operation?	☐	☐	☐	
B2.1(b)(1) • Scope of Laboratory functions – Does the operation have standardized protocols, procedures, and reports (e.g., SOPs, work instructions, etc.) for analytical testing of cannabis?*	☐	☐	☐	
B2.1(b)(2)(i-iv) • Scope of Laboratory functions – Does the operation have standardized protocols, procedures, and reports (i.e., SOPs, work instructions, etc.) for analytical testing of cannabis for purity (microbiological organisms, pesticides, heavy metals, solvents, foreign matter)?*	☐	☐	☐	
B2.1(b)(3)(i-ii) • Scope of Laboratory functions – Does the operation have standardized protocols, procedures, and reports (i.e., SOPs, work instructions, etc.) for analytical testing of cannabis for potency (cannabinoid content, terpenoid content)?*	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
B2.1(b)(4) • Scope of Laboratory functions – Does the operation have standardized protocols, procedures, and reports (i.e., SOPs, work instructions, etc.) for analytical testing of cannabis for other quality factors (% water content, oil content, ash)?*	☐	☐	☐	
B2.1(c)(1) • Cannabis-derived product analysis – Does the laboratory have standardized protocols, procedures, and reports for analytical testing of cannabis-derived products?*	☐	☐	☐	
B2.1(c)(2) • Cannabis-derived product analysis – Does the laboratory have standardized protocols, procedures, and reports for analytical testing of cannabis-derived products for determination of any factor of a product's composition or nutritional content?*	☐	☐	☐	
B2.1(d)(1) • SOPs for other tests and examination – Does the laboratory have standardized protocols, procedures, and reports for gross organoleptic analysis?*	☐	☐	☐	
B2.1(d)(2) • SOPs for tests and examination – Does the laboratory have standardized protocols, procedures, and reports for macroscopic?*	☐	☐	☐	
B2.1(d)(3) • SOPs for tests and examination – Does the laboratory have standardized protocols, procedures, and reports for microscopic?*	☐	☐	☐	
B2.1(d)(4) • SOPs for tests and examination – Does the laboratory have standardized protocols, procedures, and reports for chemical analysis?*	☐	☐	☐	
B2.1(d)(5) • SOPs for tests and examination – Does the laboratory have standardized protocols, procedures, and reports for genetic analysis?*	☐	☐	☐	
B2.1(d)(6) • SOPs for tests and examination – Does the laboratory have standardized protocols, procedures, and reports for other scientifically valid methods?*	☐	☐	☐	
B3.1(a)(1-2) • Personnel training – Does each person engaged in a laboratory operation have education, training, experience, and supervision, or any combination thereof, to enable that person to perform all assigned functions?	☐	☐	☐	
B3.1(a)(1-2) • Personnel training – Is the level of education and training documented or known for directors, managers, and instrument operators?*	☐	☐	☐	
B3.1(b) • Personnel training – Does the laboratory provide all employees with trainings, and document attendance at trainings for each employee?	☐	☐	☐	
B3.1(b)(1) • Personnel training – Does the laboratory provide all employees with Instructions regarding regulatory inspection preparedness?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
B3.1(b)(1) • Personnel training – Does the laboratory provide all employees with instructions regarding law-enforcement interactions?	☐	☐	☐	
B3.1(b)(2) • Personnel training – Does the laboratory provide all employees with instruction on U.S. federal laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such employees?	☐	☐	☐	
B3.1(b) • Personnel training – Does the laboratory provide all employees with safety seminars and/or annual refresher trainings for employee conduct within lab workspace (e.g., chemical waste handling)?*	☐	☐	☐	
D4.1(a)(1)(i) • Physical facilities – Does the operation have evidence that it operates in adherence with any regulation in the jurisdiction it operates for locations and zoning for all type of operations at the facility?	☐	☐	☐	
D4.1(a)(1)(ii) • Physical facilities – Does the operation have evidence that it operates in adherence with any regulation in the jurisdiction it operates for business hours?	☐	☐	☐	
D4.1(a)(1)(iii) • Physical facilities – Does the operation have evidence that it operates in adherence with any regulation in the jurisdiction it operates for parking?	☐	☐	☐	
D4.1(a)(1)(iv) • Physical facilities – Does the operation have evidence that it operates in adherence with any regulation in the jurisdiction it operates for drive-through services?	☐	☐	☐	
D4.1(a)(1)(v) • Physical facilities – Does the operation have evidence that it operates in adherence with any regulation in the jurisdiction it operates for signage?	☐	☐	☐	
D4.1(a)(2) • Physical facilities – Does the laboratory have evidence of being maintained in a clean and orderly fashion?	☐	☐	☐	
D4.1(a)(3) • Physical facilities – Is the laboratory equipped with such utensils as are necessary to conduct all operations that occur at the facility?	☐	☐	☐	
D4.1(a)(4) • Physical facilities – Does the laboratory provide adequate space for operations, sample storage, and document storage?	☐	☐	☐	
D4.2 - SECURITY				
B4.2(a) • Security – Does the operation have evidence that it has established and adheres to such security procedures as provided by regulation in the jurisdiction in which this part applies?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
B4.2(b)(1) • Security – Does the operation provide additional security as needed to protect employees during working hours and in a manner appropriate for the community where it operates?	☐	☐	☐	
B4.2(b)(2) • Security – Does the facility provide training to make all employees aware of the operation's security procedures, and each individual employee's security roles and responsibilities?	☐	☐	☐	
B4.2(c)(1) • Security – Does the operation have one or more controlled access areas for the storage of cannabis and cannabis-derived test samples?	☐	☐	☐	
B4.2(c)(2) • Security – Does the operation have one or more controlled access areas for the storage of cannabis waste?	☐	☐	☐	
B4.2(c)(3) • Security – Does the operation have one or more controlled access areas for the storage of reference standards for analysis of cannabinoids?	☐	☐	☐	
B4.2(c)(4) • Security – Does the operation have one or more controlled access areas for the storage of any other controlled substances?	☐	☐	☐	
D4.2(d) • Security – Does the operation limit access to controlled areas by locks, electronic badge readers, biometric identifiers or other means?	☐	☐	☐	
D4.2(e) • Security – Are appropriate steps taken to ensure access privileges to the laboratory facility and to controlled access areas, as applicable, are revoked for personnel who are no longer employed by the operation?	☐	☐	☐	
D4.2(f) • Security Documentation – Are the procedures for security documented in a written format accessible to employees?	☐	☐	☐	
E5 - SAMPLE RECEIPT, HANDLING, AND DISPOSITION				
E5.1(a) • Sample receipt – Does the operation document and track samples taken from any compliant business or collected on behalf of those entities?*	☐	☐	☐	
E5.1(b)(1) • Sample receipt – Does the operation have established and implemented policies for collecting test samples in a manner that ensures that the test sample accurately represents the material being sampled?	☐	☐	☐	
E5.1(b)(1) • Sample receipt – Does the operation have established and implemented policies for other parameters affecting sample preparation, documentation, and transport?	☐	☐	☐	
E5.1(b)(2)(i) • Sample receipt – Does the operation's policy contain the accepted test sample types?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.1(b)(2)(ii) • Sample receipt – Does the operation's policy contain the accepted minimum test sample size?	☐	☐	☐	
E5.1(b)(2)(iii) • Sample receipt – Does the operation's policy contain the information on the recommended test sample container?	☐	☐	☐	
E5.1(b)(2)(iv) • Sample receipt – Does the operation's policy contain information on test sample labeling?	☐	☐	☐	
E5.1(b)(2)(v) • Sample receipt – Does the operation's policy contain information on appropriate transport and storage conditions, such as refrigeration if required?	☐	☐	☐	
E5.1(b)(2)(vi) • Sample receipt – Does the operation's policy contain information on other requirements, such as the use of preservatives, inert gas, or other measures to protect sample integrity?	☐	☐	☐	
E5.1(b)(2)(vii) • Sample receipt – Does the operation's policy contain the accepted use of sample chain of custody forms?	☐	☐	☐	
E5.1(c)(1) • Sample receipt – Does the laboratory have documentation or a record of each test sample?	☐	☐	☐	
E5.1(c)(1)(i) • Sample receipt – Does the record include the name and contact of compliant business or individual that was the source of the material?	☐	☐	☐	
E5.1(c)(1)(ii) • Sample receipt – Does the record include an appropriately complete and specific description of the sample?	☐	☐	☐	
E5.1(c)(1)(iii) • Sample receipt – Does the record include the date of receipt of the sample?	☐	☐	☐	
E5.1(c)(1)(iv) • Sample receipt – Does the record include a statement of the quantity (weight, volume, number, or other amount) of the sample?	☐	☐	☐	
E5.1(c)(1)(v) • Sample receipt – Does the record include a unique sample identifier for the sample?	☐	☐	☐	
E5.1(c)(2) • Sample receipt – Does the operation inform businesses and compliant individuals that submit test samples of the policies established in section E5.1(b)?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
E5.2 - SAMPLE HANDLING AND DISPOSAL				
E5.2(a) • Sample Handling – Does the operation have procedures documenting the tracking of the samples through the entire analytical process (by weight, volume, number, or other appropriate measure) to prevent diversion?	☐	☐	☐	
E5.2(b) • Sample Handling – Does the operation store each sample under the appropriate conditions to protect the physical and chemical integrity of the sample?	☐	☐	☐	
E5.2(c) • Sample Handling – Does the operation appropriately segregate, control, or hold samples consisting of cannabis or cannabis-derived products in controlled areas pending destruction or disposal?	☐	☐	☐	
E5.2(d)(1-3) • Sample Handling – Does the operation have a documented procedure for cannabis or cannabis-derived product test samples that are not destroyed during the analysis, such as the following? • Returning the sample to the individual or complaint business; • Storing and retaining the sample in conformity with operation's sample retention policy; or • Destroying in a manner which prevents unauthorized use and is documented according to Section 5.2 (d)(3).	☐	☐	☐	
E5.2(e)(1-3) • Sample Handling –Does the operation dispose of any portion of hemp or hemp-derived product that is not destroyed during analysis, by a method such as the following? • Returning the sample to the same complaint individual or business that provides a sample, or • Storage and retention of the sample in conformity with the laboratory operations sample retention policy, if any; or • Disposed of in any appropriate manner?	☐	☐	☐	
F6.1 - EQUIPMENT				
F6.1(a) • Equipment – Does the operation document inspection, cleaning, maintenance, and calibration of equipment, on an appropriate schedule, as applicable?	☐	☐	☐	
F6.1(b) • Equipment – Does the operation document procedures used in the routine inspection, cleaning, maintenance, testing, and calibration of equipment?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
F6.1(b) • Equipment – Does the operation specify and document when remedial action must be taken in the event of failure or malfunction of equipment? The procedures must designate the personnel responsible for the performance of each operation.	☐	☐	☐	
F6.1(c) • Equipment – Are records maintained of all inspections, maintenance, testing, and calibrating?	☐	☐	☐	
F6.1(c) • Equipment – Do the records include the date of the operation performed, the procedure used, and any deviations of a written procedure?	☐	☐	☐	
F6.1(c) • Equipment – Do the records include non-routine repairs on equipment as a result of failure and malfunction?	☐	☐	☐	
F6.1(c) • Equipment – Do the records include the documentation of repairs with the nature of repair, how and when the need for repair was discovered, and any remedial action taken in response to repair?	☐	☐	☐	
F6.1(d) • Equipment – Does the operation ensure that computer systems used for laboratory functions such as electronic records, electronic signatures, and handwritten signatures executed to electronic records are trustworthy, reliable, and generally equivalent to handwritten signatures executed on paper?	☐	☐	☐	
F6.2 - REAGENTS, SOLUTIONS, AND REFERENCE STANDARDS				
F6.2(a)(1) • Reagents – Does the operation label analytic reagents, solutions, and reference standards with appropriate indications of identity, date received or prepared, expiration or requalification date, and, where applicable, concentration or purity, storage requirements, and date opened?	☐	☐	☐	
F6.2(a)(2) • Reagents – Are analytical reagents, solutions, and reference standards stored under appropriate conditions to minimize degradation or deterioration of the material?	☐	☐	☐	
F6.2(a)(3) • Reagents – Are analytical reagents, solutions, reference standards within their expiration requalification dates at the time of use?	☐	☐	☐	
F6.2(b) • Reagents – Does the operation properly discard deteriorated or outdated reagents and solutions?	☐	☐	☐	
F6.2(c) • Reagents – Does a laboratory operation acquire commercial reference standards for the cannabinoids being analyzed?	☐	☐	☐	
F6.2(d) • Reagents – If the operation internally produces standards, are standard analytical techniques used to document the purity and concentration of the internally produced standard?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
F6.2(e) • Reagents – If the operation internally produces standards, does the operation create a certificate of analysis (COA) for each lot of reference standards?*	☐	☐	☐	
F6.2(e) • Reagents – If the operation internally produces standards, is each COA kept on file and lot number of the reference standard used and recorded in the documentation for each analysis, where applicable?	☐	☐	☐	
G7.1 - ANALYSIS OF SAMPLES				
G7.1(a)(1) • Analytical Procedures – Does the operation utilize analytical methods that are fit for purpose in their testing of each cannabis product?	☐	☐	☐	
G7.1(a)(2) • Analytical Procedures – Does the operation have documentation demonstrating the proficiency of each analyst?	☐	☐	☐	
G7.1(a)(3) • Analytical Procedures – Does the operation have written procedures for the following, where applicable: • Sample preparation • Reagent solution, and reference standard preparation • Instrument set up • Standardization of volumetric reagent solutions • Data acquisition • Calculation of results	☐	☐	☐	
G7.1(a)(4) • Analytical Procedures – Has the operation, as applicable to each analytical method used, specified the requirements for accuracy, precision, linearity, specificity, limit of detection, limit of quantitation, and other data quality parameters?	☐	☐	☐	
G7.1(a)(5) • Analytical Procedures – Does the operation document any deviations from approved protocols or standard operating procedures?	☐	☐	☐	
G7.1(b) • Analytical Procedures – Does the laboratory use only primary or secondary standards for quantitative analyses?	☐	☐	☐	
G7.2 - RECORDING OF ANALYTICAL DATA				
G7.2(a) • Recording of analytical data (non-automated systems) – Are data from test samples recorded directly, promptly and legibly?	☐	☐	☐	
G7.2(a) • Recording of analytical data (non-automated systems) – Is the data annotated with the date of entry and signed or initialed by the person recording the data?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
G7.2(a) • Recording of analytical data (non-automated systems) – Do any changes in entries not obscure original entries and indicate the reason for such change, with date and signature or initial at the time of change?	☐	☐	☐	
G7.2(b) • Recording of analytical data (automated systems) – Is the operator or technician responsible for inputting data into automated data collection systems identified with the date of data input?	☐	☐	☐	
G7.3 DATA REVIEW				
G7.3(1) • Data review – In the reporting of the final result, is there verification that calculations or other data processing steps were performed correctly?	☐	☐	☐	
G7.3(2) • Data review – In the reporting of the final result, does the data meet any specified data quality requirements, such as for accuracy, precision, and linearity, etc.?	☐	☐	☐	
G7.3(3) • Data review – In the reporting of the final result, were reference standards used of appropriate purity and within expiration or requalification dates?	☐	☐	☐	
G7.3(4) • Data review – In the reporting of the final result, were volumetric solutions properly standardized before use?	☐	☐	☐	
G7.3(5) • Data review – In the reporting of the final result, has any test or measuring equipment used been properly tested, verified, and/or calibrated and is within its verification or calibration period?	☐	☐	☐	
G7.4 DATA STORAGE				
G7.4(a) • Data storage – Does the operation retain all raw data, documentation, protocols, and final reports associated with analysis of test samples for a period of 2 years from the date of completion of the analysis?	☐	☐	☐	
G7.4(b)(1) • Data storage – Are laboratory records indicated in G7.4(a), whether stored on the premises or remotely, maintained in a manner that allows retrieval as needed?	☐	☐	☐	
G7.4(b)(2) • Data storage – Are laboratory records indicated in G7.4(a), whether stored on the premises or remotely, maintained in conditions of storage that minimize deterioration throughout the retention period?	☐	☐	☐	
G7.4(b)(3) • Data storage – Are laboratory records indicated in G7.4(a), whether stored on the premises or remotely, maintained in a manner that prevents unauthorized alteration?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
G7.4(c) • Data storage – Does the operation designate an individual responsible for records maintenance?	☐	☐	☐	
G7.4(d) • Data storage – Does the operation ensure that only authorized personnel may enter or access the maintained records?	☐	☐	☐	
G7.5 - DATA REPORTING				
G7.5(a) • Data reporting - Are the analytical results of any test sample the property of the compliant business or compliant individual which provided the sample (unless contracts or other written agreements specify otherwise)?*	☐	☐	☐	
G7.5(b)(1) • Data reporting - Does the operation's laboratory report given to a client contain the date of receipt of the test sample?	☐	☐	☐	
G7.5(b)(2) • Data reporting - Does the operation's laboratory report given to a client contain a description of the type or form of the test sample (leaf, flower, powder, oil, specific edible product, etc.)?	☐	☐	☐	
G7.5(b)(3) • Data reporting - Does the operation's laboratory report given to a client contain the unique sample identifier as established in accordance with subparagraph 5.1 (b)(1)(v)?	☐	☐	☐	
G7.5(b)(4) • Data reporting - Does the operation's laboratory report given to a client contain information on whether sampling was performed by the laboratory operation, by the compliant business or individual which submitted the test sample, or by a third-party?	☐	☐	☐	
G7.5(b)(5) • Data reporting - Does the operation's laboratory report given to a client contain the date on which analysis occurred?	☐	☐	☐	
G7.5(b)(6) • Data reporting - Does the operation's laboratory report given to a client contain the analytical method used, including at a minimum identification of the type of analytical equipment used (e.g., GC, HPLC, UV, etc.)?	☐	☐	☐	
G7.5(b)(7) • Data reporting - Does the operation's laboratory report given to a client contain the analytical results, including units of measure where applicable?	☐	☐	☐	
G7.5(b)(8) • Data reporting - Does the operation's laboratory report given to a client contain the identity of the supervisory or management personnel who reviewed and verified the data and results and ensured that data quality, calibration, and other applicable requirements were met?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
G7.5(b)(9) • Data reporting - Does the operation's laboratory report given to a client contain the name, address, and contact information of the laboratory operation?	☐	☐	☐	
G7.5(c)(1) • Data reporting - If a laboratory operation reports cannabinoid values other than those directly measured in the test sample, does the report contain all calculations or conversion factors used to determine the reported non-measured results?	☐	☐	☐	
G7.5(c)(2) • Data reporting - If a laboratory operation reports cannabinoid values other than those directly measured in the test sample, does the report contain a written explanation of assumptions, if any, associated with the reported non-measured results, such as the route of consumption of the product represented by the test sample?	☐	☐	☐	
G7.5(d) • Data reporting – Does the laboratory report state that reported analytical results apply only to the test sample received?	☐	☐	☐	

*Not required by AHPA document, not necessarily an audit point.

DISTRIBUTION CERTIFICATION AUDIT

Patient Focused Certification

APPLICANT NAME: _____

AUDITOR NAME: _____

FACILITY LOCATION: _____

DATE OF AUDIT: _____

TIME ON SITE: _____

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
A1.1 • Subject operations – Is this operation is subject to state and/or local oversight?	☐	☐	☐	
A1.2 • Other statutory provisions and regulations – Is this operation compliant (i.e. has a license in good standing, certificate of occupancy, confidentiality requirements, labeling and testing requirements, etc.) with all applicable regulations in the jurisdiction it operates?	☐	☐	☐	
B2.1(a) • Types of distribution operations – Is this operation a storefront, a storefront with a delivery service, delivery service, or direct from garden operation? Or is this operation a growing cooperative subject to regulatory oversight?	☐	☐	☐	
B2.1(b)(1) • Cannabis acquisition and distribution – Does the operation have policies and procedures to limit the distribution of cannabis to cannabis that has been: • Cultivated by the operation itself; • Cultivated by a co-owned operation; or • Obtained from a cultivation operation or vendor?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
B2.1(b)(2) • Cannabis-derived product distribution – Does the operation have policies and procedures to limit the distribution of cannabis-derived products to cannabis-derived products that have been: • Manufactured by the operation itself; • Manufactured by a co-owned operation; or • Obtained from a manufacturing operation or vendor?	☐	☐	☐	
B2.2 • Ancillary operations – If there are operations other than cannabis distribution conducted at the location, is there sufficient evidence that these ancillary operations are conducted in compliance with all regulations in the jurisdiction it operates?	☐	☐	☐	
B2.3(a, b, c) • Personnel training – Does the operation have a mechanism for communicating with all employees and have evidence that employees have received training, including the following? • Specific uses of cannabis or a specific cannabis-derived product; • Clinical application of the specific constituents; • The laws, regulations, and policies relevant to providing cannabis products in its jurisdiction as well as U.S. federal laws and regulations; and • Instruction for regulatory inspection preparedness and law-enforcement interactions.	☐	☐	☐	
B2.3(d, e) • CPR – If the operation is a storefront operation, has it ensured that a properly trained employee is prepared to administer CPR at all times when the operation is open for business? NOTE: there may be valid legal reasons to prohibit compliance with this regulation in certain jurisdictions.	☐	☐	☐	
B2.4(a)(1) • Physical facilities – Does the operation have sufficient evidence that it operates in adherence with all regulations in the jurisdiction it operates, including: • Locations and zoning, for all type of operations at the facility; • Business hours; • Parking; • Drive-through services; and • Signage?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
B2.4(a)(2) • Physical facilities – Does the operation have SOPs and record keeping in place sufficient to provide evidence that it is maintained in a clean and orderly fashion?	☐	☐	☐	
B2.4(a)(3) • Physical facilities – Is this operation equipped with utensils and equipment as are necessary to conduct operations, including ancillary operations as described in section 2.2, that occur at the facility?	☐	☐	☐	
B2.4(a)(4) • Privacy of transactions – Does the operation have evidence it has implemented a privacy of financial transactions policy?	☐	☐	☐	
B2.4(a)(5) • Patient legal information – Does the operation have information available to patients and caregivers regarding local, state and federal laws on cannabis possession?	☐	☐	☐	
B2.4(b) • Storage of product and cash – Does the operation do the following? • Adequately refrigerate products that require refrigeration; • Provide and use a secure area for storage of all cannabis products; and • Provide and use a secure area to store money and have procedures in place to remove money from the premises frequently?	☐	☐	☐	
B2.4(c)(1) • ADA – Does the operation have sufficient evidence that it is in compliance with applicable Americans with Disabilities Act provisions or equivalent regulations in the jurisdiction it operates?	☐	☐	☐	
B2.4(c)(2) • On-site consumption – Does the operation have a policy in place regarding on-site consumption? If the operation allows on-site consumption, is it in compliance with all regulations in the jurisdiction which it operates? Does the consumption policy address the following? • The type or types of consumption allowed; • A time limit to on-site consumption if advisable; • A ventilation plan if needed; • A protocol to prevent and address over-medication; and • Any additional issues as needed.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
B2.5(a),(b)(1)(i) • Security practices – Does the operation have significant evidence that it is in compliance with required security regulations in the jurisdiction it operates, including sufficient in-store security personnel to ensure staff and patient security; in-store security cameras; and either security personnel or video monitoring of dedicated parking area?	☐	☐	☐	
B2.5(b)(1)(ii)(A)&(B) • Security practices – If this operation is a delivery service, does the operation have significant evidence that it is in compliance with required security regulations in the jurisdiction it operates, including sufficient security personnel at the facility where products are acquired, stored, and/or processed to ensure the safety of staff and the security of all products? Does it provide appropriate training for delivery staff to ensure awareness on how to maintain personal and product safety, including contact information for police and other emergency personnel?	☐	☐	☐	
B2.5(b)(1)(ii)(C)&(D) • Security practices – Does the deliver operation have significant evidence that it delivers ONLY to private addresses and never to a public location, and that it is in compliance with all local regulations regarding permissible delivery areas and hours of operation?	☐	☐	☐	
B2.5(b)(1)(iii)(A) • Security practices – If this operation is a direct-from-garden or a growing co-op, does it have significant evidence that it has the necessary security practices in place at the growing facility and at any associated locations where cannabis or cannabis-derived products or money are kept to ensure the safety of staff and the security of cannabis on site?	☐	☐	☐	
B2.5(b)(2) • Armed security – Does the operation refrain from using armed security personnel or have sufficient evidence that they are using armed security in strict accordance with all relevant legal requirements in the jurisdiction they operate?	☐	☐	☐	
B2.5(b)(3) • Security training – Does the operation have sufficient evidence that it provides staff with security procedures and ensures staff is aware of their individual roles and responsibilities?	☐	☐	☐	
B2.5(c) • Security at ancillary operations – If the operation is also engaged in cultivation, processing, or manufacturing operations, does it have sufficient evidence that it is compliant with security requirements for such operations?	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
C3.1(a) • Cannabis provision records – Does the operation offer the following items, as allowed by regulations in the jurisdiction if operates: smoked cannabis, vaporized cannabis, oral cannabis, and/or topical cannabis?	☐	☐	☐	
C3.1(b)(1), (2), (3) • Cannabis provision records – Does the operation maintain up-to-date records on all cannabis products it provides (see C3.1(a)) including the following? • Identification of each cannabis and cannabis-derived product it provides is provided by a co-owned operation or from an operation that is not co-owned; or • Information to indicate identification of the cultivator, processor, manufacturer and/or vendor of each cannabis product, if produced by an operation that is not co-owned?	☐	☐	☐	
C3.1(b)(4) • Cannabis provision restrictions – If the operation is subject to restrictions on the provision of cannabis, such as limitation regarding what employees may and may not provide various cannabis products to compliant individuals or limitations on which compliant individuals may or may not obtain specific products, does it have sufficient evidence to show that it is in compliance?	☐	☐	☐	
C3.2(a) • Cannabis product acquisition – If the operation receives cannabis products from one or more cultivation, processing, or manufacturing operation, or from one or more vendors, has it established and implemented policies for the acquisition of cannabis or cannabis-derived product that are compliant with any regulation in the jurisdiction it operates, including policies on the following? • Locations for receipt of cannabis products; • Scheduling of deliveries to be made by either vendors with specific appointments, or by establishing open vending times, during which any vendor may make a delivery without a specific appointment; and • Appropriate practices for vendors and cultivation, processing, or manufacturing operation with regard to cultivation practices, processing or manufacturing practices, packaging and/or labeling, chemical analysis, or appropriate transportation conditions (such as refrigeration).	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
C3.2(b)(1) • Cannabis product records – Does the operation maintain adequate records of each receipt of cannabis product, including the following? • The name (or identification) of the cultivation, processing, or manufacturing operation or vendor providing the cannabis product; • A description of the cannabis product of sufficient specificity; and • A statement of the quantity of each cannabis product?	☐	☐	☐	
C3.2(b)(2), (3) • Cannabis product records – If the operation is a storefront, does it have policies and procedures in place that minimize the delivery of products at times and in locations where compliant individuals are present (space allowing)? Does it inform all operations and vendors of such policies?	☐	☐	☐	
C3.3(a) • Cannabis information – Does the operation have sufficient evidence that any information it provides, whether written or verbal, about the identity, quality, and cultivation conditions of cannabis is accurate?	☐	☐	☐	
C3.3(b)(1), (2), & (3) • Cannabis product testing – If the operation conducts testing on cannabis products does it properly disclose the extent and type of testing it conducts, or causes to have conducted, on the cannabis it provides, including the following? • The type of test or examination used, if any, to determine the particular strain or cultivar of each lot of cannabis provided; • Whether or not the cannabis provided is tested to determine the quantitative levels of constituents and, if so, the type of testing used; and • Whether or not the cannabis provided is tested to determine the absence or presence of specific classes of potential contaminants and, if so, the type of testing used for any of the following: pesticides, yeasts and molds, or other microbiological contaminants.	☐	☐	☐	

AUDIT CHECKLIST	NOT APPLICABLE	YES	ACTION NEEDED	ITEMS NEEDED FOR COMPLIANCE
C3.3(b)(4) • Cannabis product testing – If the operation conducts testing on the products it provides, does it have significant evidence that the information required to be disclosed is made available at each physical facility maintained by a storefront distribution operation via one or more of the following methods? • Posting readily visible signage; • Providing printed handouts; • Posting on any website at which products are available for ordering and purchase; or • Posting the information so that compliant individuals will see the information prior to ordering or purchasing products?	☐	☐	☐	
C3.3(c) • Cannabis-derived product information – Is the information provided by the operation about the cannabis-derived products it provides available in a manner that is compliant with information required by the jurisdiction it operates? Does the operation have significant evidence that the information provided is as follows? • Accurately conveyed through labeling or other accurate markings or communications, in a manner compliant with all relevant requirements; and • If provided by another manufacturer, the information is as provided by each product's manufacturer without modification to the labeling or other information. Does the operation have policies and procedures in place to seek clarification or correction of any information provided by a manufacturer that it has reason to believe may not accurate?	☐	☐	☐	
C3.4(a) • Cannabis product recalls – Does the operation have an established policy for communicating a recall of a cannabis product that has been shown to present a reasonable or a remote probability that the use of, or exposure to, the product could cause serious adverse health consequences, or could cause temporary or medically reversible adverse health consequences? Does that policy include the following? • A mechanism to contact all customers who have, or could have, obtained the product from the operation, including information on the policy for return or destruction of the recalled product; • A mechanism to contact the cultivation, processing ,or manufacturing operation or vendor which supplied the product; and • Communication and outreach via media, as necessary and appropriate.	☐	☐	☐	