PATIENT FOCUSED CERTIFICATION

Regulator's Program Guide for Medical Cannabis

AmericansForSafeAccess
Advancing Legal Medical Marijuana Therapeutics and Research

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a project of Americans for Safe Access Foundation

Regulator's Program Guide for Medical Cannabis

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I. Introduction

Since 1996, states have been experimenting with medical cannabis (marijuana) laws and regulations. Product safety and quality are the newest evolution in these programs. Patients, health care providers, lawmakers, and regulators now have the tools they need to ensure reliable, high-quality hemp, medical cannabis, and medical cannabis products, thanks to the 2011 partnership of Americans for Safe Access (ASA), the American Herbal Products Association (AHPA), and the American Herbal Pharmacopoeia (AHP). This unique partnership 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.

Over the last few years, AHPA's Cannabis Committee, comprised of cannabis industry leaders from around the country and AHPA staff, has issued a series of Recommendations to Regulators for the medical cannabis industry. These regulatory guidelines are based on national nutraceutical and botanical standards that contain cannabis-specific guidelines designed to protect the integrity, quality, purity, and consistency of hemp, medical cannabis, and medical cannabis products. This series provides a comprehensive model of regulations for medical cannabis standards and quality assurances from seed to consumption. The AHPA Recommendations to Regulators are available in four easy-to-reference documents: 1) Cannabis Cultivation and Processing Operations; 2) Cannabis Manufacturing, Packaging, Labeling, and Holding Operations; 3) Cannabis Laboratory Operations; and 4) Cannabis Dispensary Operations (see appendix). In December of 2013, the AHP released a Monograph and Therapeutic Compendium for Cannabis. This comprehensive publication serves as a guide for identifying the quality, purity, and potency of the cannabis plant and includes analytical standards to guide cannabis laboratory operations with a baseline for contaminant testing and standardized methodologies for cannabis analysis.

Since the release of the AHPA and AHP guidelines, states have been using them as legislative and regulatory tools to create comprehensive product safety rules and regulations. However, these new regulations will only be effective with proper oversight and enforcement. To aid government agencies in these efforts, ASA has created the Patients Focused Certification (PFC) program. PFC is a non-profit, third party certification program for the medical cannabis industry and the nation's only certification program for the AHPA and AHP standards. PFC is available to all qualifying companies cultivating, manufacturing, or distributing medical cannabis products, as well as to laboratories providing medical cannabis analytic services. PFC offers a comprehensive program that includes employee training, compliance inspections, ongoing monitoring, regulatory updates and an independent complaint process for consumers.

The PFC program is currently offered as a voluntary certification program in all medical cannabis states and holds the permit to provide the mandatory education required by the District of Columbia's medical marijuana program. The PFC program:

1. offers regulators a third-party auditing option to ensure that licensed businesses are meeting standards required under regulation;
2. 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; and medical cannabis research, pharmacology, biochemistry, and industry practices;
3. provides a logo that lets consumers, policy makers, regulators, community members and health care providers know that companies are meeting compliance and product safety standard requirements;

4. monitors violations of regulations as well as complaints from patients, caregivers, health care practitioners, regulators, and community members;
5. provides trainings that include: Legal Issues, Raid and Robbery Preparedness, Patient Education, Good Neighbor Polices, 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 participants with educational materials for patients, caregivers, health care providers and regulators that describe the certification program.
7. 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;
8. offers third-party certification that can help reduce regulatory program cost and oversight burden;
9. has independent auditors that can be contracted as third-party auditors for regulatory agencies;
10. provides companies and, if required, regulators with annual Audit Reporting.

II. PFC Benefits for Regulators and Consumers

For almost all commercial products that are produced for human consumption there are rules and regulations that ensure legal compliance and product safety. Medical cannabis and medical cannabis-derived products should be no different. Regulators are constantly making decisions that relate to protection of the health and welfare of consumers, the public, and the environment through the development of new regulations, standards and requirements that keep up with innovative industries and expanding consumer needs. Governments and the citizens they protect are increasingly moving towards zero risk tolerance, often resulting in the adoption of stricter, more comprehensive regulations and reporting requirements. Companies navigating evolving regulatory frameworks must continually monitor regulatory changes and adhere to regular audits to demonstrate legal and regulatory compliance.

In order to reduce the cost and operational burden to regulatory oversight agencies, regulators are increasingly relying on independent third-party declarations of compliance to support their enforcement and monitoring activities. Independent third-party declarations demonstrate compliance with legislation and regulations as well as overall performance against industry benchmarks and performance indicators. Third-party certification ensures that an independent organization has reviewed the manufacturing process of a product or the management processes of a service, for example, and has determined that the final product complies with specific standards for safety, quality, purity or performance. This allows the regulatory agency to focus on the development of overall policy requirements or detailed technical requirements while relying on approved third-party certification bodies to ensure a high standard of regulatory compliance. Compliance is demonstrated by the award of a third-party certificate and the ability to add the third party's mark, or seal of approval, to the product or service label.

As with other industries, oversight of medical cannabis and medical cannabis products is constantly evolving. PFC verifies compliance with state and local laws as well as the AHPA and AHP standards. In order to ensure ongoing compliance, PFC requires comprehensive staff training, annual inspections, unannounced random inspections, and product testing to ensure that certified companies continue to meet all program standards. PFC is similar to other nationally recognized certification programs including USP, Good Housekeeping, NSF, and ISO.

III. AHPA and AHP Standards

Patient Focused Certification standards are established guidelines that provide a system of processes, procedures, and documentation to ensure that hemp, medical cannabis, and cannabis-derived products have the strength, composition, purity, and identity they represent to possess and that the companies cultivating, manufacturing, and distributing these products are committed to quality and product safety. These standards also provide the foundation of integrity for the PFC program and have been developed through ASA's partnership with the American Herbal Products Association (AHPA), and the American Herbal Pharmacopoeia (AHP). As such, PFC standards represent the consensus of the world's leading experts on cannabis and botanical product regulations. Released in 2013, PFC standards were developed in two parts: 1. AHPA Recommendations to Regulators, and 2. The AHP Monograph and Therapeutic Compendium for Cannabis.

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, which is to promote the responsible commerce of herbal products, and 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, and to ensure 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 would address sensible regulatory practices for hemp, cannabis, and cannabis-derived products from the propagation of plant matter to consumption by the consumer. As such, the AHPA's Cannabis Committee developed a series of guidelines, or Recommendations to Regulators, 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. This document also establishes 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 (GMP's) for botanical and nutricuetical 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.

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 document 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 Monograph and Therapeutic Compendium for Cannabis. The first edition was released in 2013 and provides scientifically valid standards for companies engaged in laboratory analysis of cannabis and cannabis-derived products with regards to:

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

Laboratory analysis facilities participating in the PFC program have each successfully calibrated their equipment and implemented protocols in accordance with the AHP Monograph and Therapeutic Compendium for Cannabis, 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. Product standardization provides medical practitioners with the confidence necessary to recommend medical cannabis treatments at the beginning of a treatment cycle, as opposed to as a last resort, and provides the foundation for human clinical trials and case studies on cannabis therapeutics.

All PFC companies are required to adhere to these rigid quality standards. Due to the ever-changing and expanding nature of medical cannabis regulations and medical cannabis industry innovations, PFC recognizes the need to adopt new standards and guidelines as regulations change and has been developed as a continually evolving program overseen by a Peer Review Board which along with AHPA and AHP will oversee and approve the ongoing update of PFC program standards. Depending on the extent of standard updates, a PFC auditor may be assigned to the affected companies 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, will be determined by the PFC Peer Review Board.

IV 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, 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, 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 the Patient Focused Certification for 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 Pharmacopeia.

Steph Sherer is a medical marijuana patient with over 11 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 non-profit and for profit organizations, from small businesses to Fortune 100 companies.

Élan 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.

V. PFC Auditor Qualifications

PFC independent auditors have extensive experience in the medical cannabis or auditing similar industry and/or the herbal products industries. All PFC independent auditors are required to success-

fully 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 nutricuetical products. In addition, all manufacturing, packaging, labeling, and holding auditors must also demonstrate a fundamental knowledge of 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 nutricuetical 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 Complimentary Alternative Medicine.

VI. Types of Certification Offered by PFC

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 certification 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 recording, 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 Testing 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 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 operation 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.

VII. PFC Staff Trainings

As state medical cannabis laws and regulations continue to evolve, medical cannabis-specific trainings have become increasingly required. States such as Arizona, Massachusetts, Nevada, Florida, Illinois, Connecticut and the District of Columbia have mandated comprehensive training for all staff working or volunteering in state-licensed medical cannabis facilities. PFC can help state lawmakers and regulators reduce the cost of implementing and operating medical cannabis training programs by providing qualified third-party certification that includes state and discipline-specific staff 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.

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

ASA staff members have over a dozen years experience in implementing medical cannabis laws nationwide and have helped to develop and improve laws at both the local and state level. ASA staff continues to ensure regulatory compliance of patients and providers by offering a variety of hands-on in-person trainings. Patient Focused Certification's comprehensive staff trainings represent the continuing evolution of this important, ever-expanding work.

The PFC trainings include a core curriculum of courses: Understanding Cannabis Laws, Introduction to Cannabis as a Medicine, Cannabis Business Operations, Understanding State and Local Laws, and National Cannabis Standards Training. PFC is constantly developing new course material and can work with any state to meet needed regulatory requirements. PFC trainings are available online or in person by a PFC Certified Instructor.

Understanding Cannabis Law

FEDERAL CANNABIS LAW

This module introduces the federal Controlled Substances Act (CSA) and explains the role of the Drug Enforcement Administration (DEA). The difference between sentencing laws and sentencing guidelines is also explored. A review of other federal laws applicable to the cannabis community concludes the module.

HISTORY OF MEDICAL CANNABIS LAWS

Learn about the many efforts to reform medical cannabis law, as well as opposing efforts to stop reform. Federal legislative efforts (Truth in Trials Act) and federal landmark cases continue the discussion. Finally, protecting state and patient rights and coverage of the current status of medical cannabis law conclude this module.

Introduction to Cannabis as Medicine

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 as well as the physiological role of endocannabinoids are also discussed.

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 and a brief discussion about how cannabis might be incorporated into food and drink.

Cannabis Business Operations

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.

RAID PREPAREDNESS

Cannabis businesses are at risk for being raided. Know what to do should this happen. In this module, learn what operations should be followed during a raid. Discover what legal and logistical preparations should be taken as well as how to activate supporters. Knowing how to handle those inside and outside of the raided facility is also an important consideration. Finally, learn what steps should be taken after a raid is over.

RUNNING A SAFE BUSINESS

Dispensaries, growers, 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.

STATE SPECIFIC

Each State-Specific 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 the patients they will be serving.

STATE AND LOCAL REGULATIONS

This training provides a broad State and local specific, 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 the medical cannabis program. These trainings include, but are not limited to, State Specific Best Management Practices, Integrated Pest Management programs for cultivation operations, Inventory Control Systems, workplace safety, and food safety.

National Cannabis Standards Training

The National Cannabis Standards Training(s) are designed to educate attendees about the particulars of compliance with the discipline specific AHPA and AHP guidelines and are available in four cannabis industry disciplines.

NATIONAL CANNABIS DISTRIBUTION OPERATIONS STANDARDS

This comprehensive training is designed to provide participants with the skills necessary to implement Best Management Practices relating to the distribution of cannabis and cannabis-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 recording.

NATIONAL CANNABIS CULTIVATION AND PROCESSING STANDARDS

Based on the AHPA Recommendations to Regulators for Cultivation and Processing operations, this training applies to all types of cultivation operations: 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 recording, and information disclosure. This course also explores best practices and safe handling procedures for operations that provide post-harvest processing of cannabis.

NATIONAL CANNABIS MANUFACTURING, PACKAGING, LABELING AND HOLDING STANDARDS

Designed for individuals engaged in the manufacturing of cannabis and cannabis-derived products, this training is designed to provide learners with the tools necessary to comply with General Management Practices including general personnel responsibility and safety, physical condition of the plant and surrounding grounds, manufacturing controls, packaging, holding and labeling controls, cannabis material acquisition, inventory and recordkeeping, fielding and documenting complaints and product returns, product safety recalls, and adverse event recording.

NATIONAL CANNABIS LABORATORY STANDARDS

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 samples.

All PFC Certified Instructors are required to successfully complete the PFC courses, as well as the required mentor program. PFC Certified Instructor mentors provide valuable teaching training oversight and must attend, assess, and verify that the instructor-in-training has adequate knowledge, skill, and competency to teach the required PFC course work.

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.

VIII. Process for Certification:

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 ASA. A confidential review of the business operations is completed to determine appropriate inspections and testing.
2. **Quote**—using information generated by the Application, ASA 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 and acceptance of terms.
4. **Preliminary assessment** (optional)—ASA provides procedures for the audit and questions management about 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**—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 employees must have successfully completed all PFC required trainings prior to certification approval.
7. **Facility audit**—trained independent ASA field inspectors conduct a confidential PFC standards audit and a facility inspection.
8. **Product testing**—ASA tests for pesticides, molds, and contaminants with an independent third-party laboratory when available, necessary, and appropriate for certification.
9. **Initial scoring and corrective recommendations**—the licensee receives the results of the PFC audit and is given corrective actions to be taken as needed.
10. **Secondary audit**—as needed
11. **Certification**—the PFC Review Board will issue the licensee's certification once the inspector verifies any required corrective actions were taken and all compliance standards have been met.

Preliminary Assessment

In many cases, the company seeking certification may request an optional preliminary assessment of their operations. 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 actions.

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 to 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 effect recording, 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 as required or suggested corrective actions, depending on the severity of the deficiency, in the audit report. 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 given to management or the primary contact person, and regulators as applicable. If any 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 Review Board, and the Executive Committee will review the application materials and audit documentation 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 including 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 and the PFC's certification logo.
2. A PFC certification window decal.
3. Educational and promotional materials for patients, health care providers and regulators.
4. PFC website links.
5. A Standards Packet including applicable AHPA guidelines and an AHP Monograph and Therapeutic Compendium for Cannabis.
6. Verification that copies of the approved certification(s) have been sent to regulators and localities, as required by law.
7. Annual audit reports.

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)

Ongoing Review and Complaint Resolution

The assigned PFC auditor and PFC staff will monitor certified operations throughout the annual certification period. 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 will notify certified companies of any updates to standards and provide an explanation of actions required by the company to comply with said update, including a required timeframe for compliance. Additionally, if any third-party complaints require an investigation or a large number of complaints are received, 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, requiring 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.

PFC shall investigate complaints related to certified companies, misuse of the PFC logo by certified companies, or use of the PFC logo by non-certified companies. Failure to cooperate in a complaint investigation will result in the immediate termination of PFC certification.

When filing a complaint, a Complaint Investigation Request provided by PFC 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.

IX. Working with PFC

Working with PFC to provide compliance oversight of the medical cannabis industry can help ease the potential knowledge gap between cannabis industry and regulatory agencies, while also easing the financial and staffing burdens of regulators. PFC works directly with regulators and industry trade groups across the country to coordinate the ongoing and evolving development of medical cannabis industry regulations and standards. PFC provides regulators with access to some of the industry's best technical experts, delivering consistent services with the highest levels of integrity, while providing

patients, health care providers, and regulators confidence that the program's participants meet the highest levels of product safety and quality available.

PFC SERVICES AVAILABLE TO GOVERNMENT AND REGULATORS

PFC staff are always available to help lawmakers and regulatory agencies develop and implement state and local medical cannabis programs through the following services.

Legislation and Regulation Development: Americans for Safe Access has over 12 years of experience working with lawmakers to adopt and improve medical cannabis legislation and regulation, including the adoption of model legislative language and the submission of comments to assist in the development of pending regulation. ASA continues to facilitate support for medical cannabis in Congress and administrative agencies and has organized many prestigious advisory boards to assist policy makers and other stakeholders on the science of medical cannabis.

Model legislation for medical cannabis: ASA's model legislation for medical cannabis and medical cannabis facilities can be found online at www.AmericansForSafeAccess.org/model_legislation. ASA model legislation is based on ASA's 12-plus years of experience assisting state and local governments in the development of medical cannabis laws and regulations and is focused on not only sensible policy for the operation of medical cannabis operations but also on the needs and safety of the patients using medical cannabis and cannabis-derived products.

Sensible regulations based on the AHPA and AHP guidelines: These comprehensive guidelines serve as a tool, to be taken in sections or in whole, for the sensible regulation of the medical cannabis industry. Together, these guidelines act to regulate medical cannabis from plant propagation to cannabis and cannabis-derived product consumption. Local and State governments have increasingly utilized these guidelines as the foundation for sensible regulatory development.

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 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. 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 AHPA and AHP guidelines. Companies engaging in this PFC pre-licensing opportunity are held to a rigid timeline for completion of the certification process upon receiving a State approval of license.

Staff Training: PFC's comprehensive training program can be utilized in a multitude of ways, from assisting regulators in the training of regulatory staff and state inspectors to providing consistent and reliable educational programs mandated by state regulators for staff working in the medical cannabis industry.

In-depth training on the AHPA and AHP guidelines: This in-depth training opportunity is designed to not only educate attendees on compliance with the AHPA and AHP guidelines but also provides comprehensive training on handling practices, implementable product recall protocols, adverse impact recording, security guidance, and best practices for industry operations.

Compliance and audit training: All PFC independent auditors are required to successfully complete state and discipline specific training prior to approval to audit for the PFC program. PFC's compliance and auditor training is available to fulfill many opportunities beyond that of training PFC independent auditors. This training experience is offered as a valuable tool to government and regulators, providing an opportunity for regulatory agencies to train department auditors in the specifics necessary to audit cannabis operations in a thorough and knowledgeable manner. Additionally, PFC independent auditors can be made available to assist government and regulatory agencies by fulfilling the audit requirements of the State and regulating agency.

Certified Training Management: As state governments continue to pass and amend medical cannabis laws that include mandatory industry training, PFC courses are continually updated to meet or exceed each state's requirements. A national leader in medical cannabis education, 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. PFC offers a comprehensive array of ready to use and implement training programs designed to train industry staff, health care practitioners, government, regulators, auditors, and consumers in a variety of subjects pertaining to medical cannabis. PFC training courses are available for instruction in two very accessible formats: 1) Online at cannabistraininginstitute.com, and 2) In-person instruction conducted by a PFC Certified Instructor. Corresponding educational materials, ranging from state legal guides to patient handbooks, can be found online at www.AmericansForSafeAccess.org/publications.

Training services to licensed facilities in compliance with state and local regulations: Local and State government and regulators can confidently look for the PFC seal of approval displayed at cannabis businesses to verify that each staff person engaged in the companies operations has been adequately trained. PFC companies are required to successfully complete the program's required staff training courses, which are specifically designed to ensure company compliance with state and local regulations, as well as the AHPA and AHP guidelines.

Instructor training services: PFC's Certified Instructor Training program has trained and certified instructors in California, Nevada, Illinois, Florida, and the District of Columbia who are available to offer PFC trainings on a national level. By working with the PFC Certified Instructor Training program, state governments and regulators, now have the opportunity to bridge the regulatory to industry knowledge gap but also the added confidence of knowing that all training programs required by law meet or exceed state requirements and are conducted in a consistent and professional manner.

Program Oversight: The PFC program verifies state and local compliance protocols as well as product safety and quality standards through the PFC training programs and the PFC independent auditor services. By working with the PFC program, government and regulatory agencies, can reduce the oversight burden and cost of implementing medical cannabis programs.

Compliance protocols: Government and regulatory agencies can now look for the PFC seal of approval to verify that medical cannabis operations are compliant with all local and state laws and regulations, as well as the AHPA and AHP guidelines. By working directly with PFC, government and regulatory agencies can focus on the development and updating of medical cannabis laws and regulations, leaving the compliance verification to Patient Focused Certification and other third party auditor opportunities.

Audit services: PFC Auditor Training programs provide a comprehensive training opportunity for qualified individuals interested in becoming PFC independent auditors, as well as for government and regulatory agency staff requiring cannabis specific auditor training. Government and regulatory agencies can also engage PFC independent auditors to conduct state and local mandated compliance audits in all disciplines of the medical cannabis industry.

X. About ASA, AHPA and AHP

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. See more at: www.americansforsafeaccess.org.

The **American Herbal Products Association** chartered a Cannabis Committee in 2010 to meet the needs of those of its members that grow, 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 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. See more at: www.ahpa.org.

The **American Herbal Pharmacopeia** was formed in 1995 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. See more at: www.herbal-ahp.org.

For more information:

Kristin Nevedal
Patient Focused Certification Director
kristin@safeaccessnow.org
202.857.4272 x106

PFC CONFIDENTIAL COMPLAINT INVESTIGATION REQUEST

PFC-Certified Company Information

Company Name: _____

Street Address: _____

City: _____State: _____Zip: _____

Complaint Description

Describe in detail the specific complaint or action desired (attach additional sheets as necessary). Please include what requirements the company does not meet and attach any available objective evidence. Examples include: misuse of PFC logo, labeling errors, non-compliance with state or local regulations, etc.

_____

_____

_____

_____

_____

_____

_____

CONFIDENTIAL

The complainant named below, if other than regulatory agencies, patients, caregivers or licensed health care providers, agrees to bear all costs of the investigation if the complaint is unsubstantiated and deemed invalid. If this form is received unsigned, PFC has no obligation to investigate or respond.

Name: _____ Position: _____

Organization: _____ Phone 1: _____

Phone 2: _____ Email: _____

SIGNED: _____ Date: _____

Completed Complaint Investigation Request forms should be emailed,

faxed or mailed to: PFC Director
1806 Vernon Street NW, suite 300
Washington, D.C. 20009

email: pfc@safeaccessnow.org

phone: 1.888.929.4367

7. GUIDELINES FOR REGULATORS

The American Herbal Products Association's (AHPA) Cannabis Committee has issued Recommendations to Regulators for medical cannabis operations. The recommendations found below specifically address standards for: 1) Cultivation and Processing; 2) Manufacturing, Packaging. Labeling, and Holding; 3) Laboratory Analysis; and 4) Distribution.

AHPA, the leading group repreesnting the herbal products industry,founded the Cannabis Committee in 2010 with Americans for Safe Access (ASA) to establish guidelines for safe use and responsible commerce of these legally marketed products.

Cannabis Cultivation and Processing Operations

SUBPART A – GENERAL PROVISIONS
Section 1.1 Subject operations
Section 1.2 Other statutory provisions and regulations
Section 1.3 Definitions

SUBPART B – CULTIVATION AND PROCESSING OPERATIONS
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SUBPART C – PERSONNEL
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SUBPART D – FACILITIES
Section 4.1 General compliance
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Section 5.1 Cultivation water management
Section 5.2 Potable water for employee use

SUBPART F – RECORDKEEPING
Section 6 Recordkeeping practices

SUBPART G – INFORMATION DISCLOSURE
Section 7 Information disclosure

SUBPART H – RECALLS
Section 8 Recall plan

SUBPART A – GENERAL PROVISIONS

Section 1.1 Subject operations

(a) Except as provided by paragraph (b) of this section, any person, group of persons, non-profit entity, or business entity that cultivates cannabis for retail or wholesale transactions in the jurisdiction in which this part applies is engaged in a cultivation operation, and is subject to this part.

(b) A compliant individual who cultivates cannabis in accordance with local and state law for personal use is not subject to this part.

(c) Except as provided by paragraph (d) of this section, any person, group of persons, or business entity that processes cannabis for retail or wholesale transactions in the jurisdiction in which this part applies1 is engaged in a processing operation, and is subject to this part.

(d) A compliant individual who processes cannabis in accordance with local and state law for personal use is not subject to this part.

(e) Operations subject to this part are subject only to those sections of this part that directly apply to the operations conducted, such that:

(1) A cultivation operation is not subject to the processing sections of this part unless processing operations are also conducted by the cultivation operation; and

(2) A processing operation is not subject to the cultivation sections of this part unless cultivation operations are also conducted by the processing operation.

Section 1.2 Other statutory provisions and regulations

In addition to this part, cultivation operations and processing operations must comply with all other applicable statutory provisions and regulations related to cannabis cultivation and processing in the jurisdiction in which this part applies, and related to all other business activities undertaken in conducting the cultivation operation or processing operation.

Section 1.3 Definitions

The following definitions apply to this part:

Batch means a specific quantity of cannabis harvested during a specified time period from a specified cultivation area.

Cannabis means any of the aerial parts of a plant in the genus Cannabis, and does not mean hemp.

Cannabis planting material means cannabis seeds, seedlings, cuttings, clones, etc. used by a cultivation operation to grow cannabis.

Cannabis waste means cannabis discarded by the cultivation operation or processing operation.

Compliant individual means an individual who has met all legal requirements to obtain and use cannabis or cannabis-derived products in the jurisdiction where this part applies.

Cultivate means to grow, harvest, dry, and cure cannabis. A person, group of persons, non-profit entity, or business entity that cultivates is a cultivator, and a facility where cannabis plants are cultivated is a cultivation operation.

Cultivation area means the physical location of a structure or property at which cannabis is cultivated.

Curing means the process by which cannabis is prepared, preserved, or finished.

Direct-from-garden or caregiver operation means a dispensing operation whereby compliant individuals obtain cannabis or cannabis-derived product directly from a cannabis cultivator.

Dispensing operation means a person, group of persons, non-profit entity, or business entity that provides cannabis or cannabis-derived product to compliant individuals and includes delivery services, direct-from-garden operations, growing co-ops, and storefront operations .

Drying means the dehydration of harvested cannabis.

Firewall assembly means a fireproof barrier used to prevent the spread of fire between or through buildings or structures.

Greenhouse means a permanent structure located outdoors that is completely covered by a material that allows a controlled level of light transmission.

Greenhouse cultivation means the cultivation of cannabis inside of a greenhouse utilizing natural sun and possible supplemental artificial lighting.

Harvest means to gather cannabis plants from cultivation medium or to gather specific aerial parts of cannabis plants.

Hemp means any part of a plant in the genus Cannabis, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 (three-tenths) percent on a dry weight basis.

High intensity discharge lamps (HID lamps) means a type of electrical gas-discharge lamp which produces light by means of an electric arc between tungsten electrodes housed inside a translucent or transparent fused quartz or fused alumina arc tube.

Identity means the set of characteristics by which an ingredient or product is definitively recognizable or known. In the case of cannabis and other botanical ingredients, identity means the plant part and the botanical genus, species, variety, strain, and/or cultivar, as well as any other applicable characteristics as stated on the label or other labeling.

Indoor cultivation means cultivation of cannabis grown in a fully enclosed location in which the only light source is artificial.

Manufacture means to compound, blend, grind, extract, or otherwise make or prepare cannabis-derived product. A person, group of persons, non-profit entity, or business entity that manufactures is a manufacturer, and a facility where manufacture occurs is a manufacturing operation.

May is used to indicate an action or activity that is permitted.

Medium means the nutritive substrate that the cultivator is using to establish a root system.

Must is used to state a requirement.

Nursery facility means an indoor, greenhouse, or outdoor cultivation operation that produces cannabis plants for the purpose of providing planting material to other cultivation operations.

Outdoor cultivation means cultivation of cannabis out of doors utilizing natural sunlight and possibly supplemental artificial lighting.

Pack (verb) means to place cannabis or cannabis-derived product into containers for distribution, other than to package the cannabis or cannabis-derived product; and includes the placement of cannabis into any type of container by cultivation operations, processing operations, and dispensing operations, as well as the placement of filled primary packaging containers into other containers such as for storage or transport.

Personal use means cannabis that is produced for a compliant individual's personal medical needs and is not sold or distributed in any manner.

Planting means to place cannabis seeds or young plants in soil or medium.

Process means to trim, inspect, grade, or pack cannabis. A person, group of persons, non-profit entity, or business entity that processes cannabis is a processor, and a facility where cannabis is processed is a processing operation.

Processing loss means cannabis that, for any reason, during processing is deemed unfit for human consumption.

Propagation materials means all substances used in the cultivation of cannabis.

Pruning means cutting away dead or overgrown cannabis leaves, branches or stems.

Should is used to state recommended or advisory procedures.

Supplemental lighting means artificial lighting used to help or extend the vegetative life cycle of a cannabis plant.

Trimming means the removal of leaves and stems from harvested cannabis.

Variety means a specific stock, line, or breed of cannabis, also commonly referred to as strain.

Vendor means a person, group of persons, non-profit entity, or business entity that supplies cannabis or cannabis-derived product to storefront or delivery service dispensing operations, and may be either the direct representative of a cultivation or manufacturing operation, or may function independently of such operations by purchasing cannabis or cannabis-derived product from such operations and reselling it to other operations.

SUBPART B – CULTIVATION AND PROCESSING OPERATIONS

Section 2.1 Types of cultivation operations

(a) Cannabis may be cultivated by any of the following types of cultivation operations, as defined in section 1.3 in this part:

(1) Indoor cultivation operations;

(2) Greenhouse cultivation operations;

(3) Outdoor cultivation operations; and

(4) Nursery operations.

(b) Cultivation operations may do the following, as allowed by applicable legislation and regulation:

(1) Produce their own cannabis planting material; and

(2) Obtain cannabis planting material from any of the following:

(i) Other cultivation operations;

(ii) Nursery operations; and

(iii) Compliant individuals.

(c) Processing operations may obtain cannabis from any of the following, as allowed by applicable legislation and regulation:

(1) Cultivation operations;

(2) Compliant individuals, and

(3) Vendors.

(d) Cultivation operations and processing operations may distribute cannabis to any of the following, as allowed by applicable legislation and regulation:

(1) Other cultivation operations;

(2) Other processing operations;

(3) Dispensing operations;

(4) Manufacturing operations;

(5) Vendors; and

(6) Compliant individuals.

Section 2.2 Ancillary operations

(a) Cultivation operations and processing operations may also engage in other operations, including:

(1) Manufacturing, packaging, labeling, and holding of cannabis-derived product;

(2) Laboratory operations;

(3) Dispensing of cannabis and cannabis-derived product; and

(4) Cultivation and marketing of products other than cannabis.

(b) The ancillary operations identified in section 2.2(a) may be conducted:

(1) At the same location as cultivation or processing, so long as such operations are permitted at this location in the jurisdiction in which this part applies; or

(2) At another location at which such operations are permitted in the jurisdiction in which this part applies.

(c) The ancillary operations identified in section 2.2(a) must be conducted in compliance with all regulations relevant to such operations in the jurisdiction in which this part applies.

Section 2.3 Cultivation practices

(a) Propagation materials

(1) Propagation materials used in cultivation operations must be appropriate for use in food production.

(2) Cultivation operations must follow the manufacturer's usage, storage, and disposal recommendations for the propagation material.

(b) Pesticides

(1) Pesticides used in cultivation operations must be one of the following:

(i) Subject to a tolerance established for application to cannabis by the US Environmental Protection Agency (EPA);

(ii) Identified by EPA regulation as exempted from tolerance;

(iii) Subject to a Section 18 emergency exemption under FIFRA ; or

(iv) Permitted for application to cannabis in other countries as long as the pesticide is also permitted for application to one or more food crops in the United States.

(2) Cultivation operations must follow the manufacturer's application and storage recommendations, and disposal recommendations for the pesticide product.

(3) Cultivation operations must follow the EPA Worker Protection Standard when preparing and applying pesticides.

(4) Indoor cultivation operations must comply with the pesticide manufacturer's published re-entry interval time periods when applying pesticides.

(c) Nutrients

(1) Nutrients used in cultivation operations must be appropriate for use in food production.

(2) Cultivation operations must follow the manufacturer's application, storage, and disposal recommendations for the nutrient product.

(3) Cultivation operations must not return unused rooting hormone to the source container.

(4) Nitrate-based and other oxidizing fertilizers must be stored away from solvents, fuels and pesticides.

(d) Carbon dioxide

(1) Indoor cultivation facilities utilizing carbon dioxide must maintain levels under 2000 ppm in cultivation areas when facility personnel may be present.

(2) Indoor cultivation facilities utilizing carbon dioxide at levels above 2000 ppm in a sealed room must prohibit personnel from entering the cultivation area unless personal protective equipment is provided.

(3) All regulators and environmental control systems that regulate carbon dioxide emissions must be maintained in good working order and be serviced in accordance with the manufacturer's recommendations.

(e) Equipment and tools

(1) Equipment used for measuring, regulating, or recording temperatures, pH, humidity, or other conditions related to the cultivation and processing of cannabis must be accurate and adequately maintained.

(2) Cultivation and processing tools that come in direct contact with cannabis plants should be disinfected as needed to protect plant health.

(3) Scales used for the weighing of cannabis must be calibrated at regular intervals.

Section 2.4 Processing practices

(a) Processing operations must be maintained in a clean and sanitary condition including all work surfaces and equipment.

(b) Processing operations must implement protocols which prevent processing contamination and mold and mildew growth on cannabis.

(c) Employees handling cannabis in processing operations must utilize facemasks and gloves in good operable condition as applicable to their job function.

(d) Employees must wash hands sufficiently when handling cannabis or use gloves.

Section 2.5 Distribution practices

Cannabis distributed by cultivation operations and processing operations must be accompanied by the following information:

(1) Cultivation or processing operation's name;

(2) Identity of contents;

(3) Net weight of contents; and

(4) Sufficient information to trace the cannabis to its batch.

SUBPART C – PERSONNEL

Section 3.1 Personnel training

(a) Cultivation and processing operations must:

(1) Ensure that each person engaged in the operation has the education, training, and experience, or any combination thereof, to enable that person to perform all assigned functions.

(2) Maintain records of any training provided to employees for the performance of all assigned functions.

(b) Cultivation and processing operations should provide all employees with training that includes:

(1) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and

(2) Information on U.S. federal laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such employees.

(c) Cultivation and processing operations must implement employee hygiene protocols and training, which at a minimum address:

(1) Policies which prohibit employees who are showing signs of illness, open wounds, sores or skin infections from handling cannabis.

(2) Hygiene training for employees who handle cannabis with specific attention to preventing microbial contamination.

(3) Hand washing requirements including washing hands with soap and hot water before beginning work, after using the bathroom and after meal breaks.

(4) Instructive hand washing signage must be in appropriate areas such as bathrooms, kitchens, and lunch areas, and in multiple languages as needed.

Section 3.2 Employee safety

(a) Cultivation operations and processing operations must implement safety protocols and provide all employees with adequate safety training relevant to their specific job functions, which may include:

(1) Emergency action response planning as necessary;

(2) Employee accident reporting and investigation policies;

(3) Fire prevention;

(4) Hazard communication policies, including maintenance of material safety data sheets (MSDS);

(5) Materials handling, spill, and disposal policies;

(6) Job hazard analyses; and

(7) Personal protective equipment policies, including respiratory protection.

(b) Cultivation operations must 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 working in field operations.

(c) Cultivation operations and processing operations must 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.

SUBPART D – FACILITIES

Section 4.1 General compliance

((a) Cultivation operations must comply with all legal requirements pertaining to the following as applicable:

(1) Restrictions on the size of the cultivation area;

(2) Restrictions on the number of cannabis plants allowed or other quantitative limits; and

(3) Light pollution restrictions.

(b) Location of cultivation operations:

(1) Indoor cultivation operations may be located on any property that is zoned for such use and must be located in a fully permitted, non-residential structure that:

(i) Was constructed in compliance with local building code;

(ii) Has a complete roof enclosure supported by connecting walls extending from the ground to the roof;

(iii) Is secure against unauthorized entry; and

(iv) Minimizes unnecessary visual, auditory or olfactory evidence of indoor cannabis cultivation.

(2) Outdoor cultivation operations and greenhouse cultivation operations may be located on any property that is zoned for such use.

(3) Outdoor cultivation operations and greenhouse operations must be located within any setbacks that pertain to the property where the cultivation is taking place.

(4) Greenhouse cultivation structures must be fully permitted and built to code at the time of construction.

(c) Location of processing operations

(1) Processing operations may be located on any property that is zoned for such use.

(2) Processing operations must be located within any setbacks that pertain to the property where the processing is taking place.

(3) Processing operation structures must be fully permitted and constructed in compliance with local building code.

(d) Outdoor cultivation or greenhouse cultivation operations must shield or downcast supplemental lighting.

(e) Cultivation operations and processing operations that transport cannabis must do so in a secured enclosed container or secured trunk of the delivery vehicle.

Section 4.2 Fire prevention

(a) Any room in an indoor cultivation operation in which operational supplemental lighting, ballasts, or electrical control panels are located must be constructed with a minimum of a one-hour firewall assembly.

(b) Indoor cultivation operations must:

(1) Provide at least one operating fire extinguisher, and

(2) 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 lighting), or in accordance with local fire code.

(c) Fire extinguishers must be:

(1) Easily accessible to employees from every room and in each hallway of the facility;

(2) Maintained annually or as otherwise specified by the manufacturer; and

(3) Of the appropriate class rating for the type of fire associated with the functions being performed in the facility (i.e., electrical, chemical).

(d) Flammable products must be stored in a properly marked fire containment cabinet or area.

(e) Signage that complies with National Fire Protection Association (NFPA) standard 704 must be placed at entrances to exposure areas.

Section 4.3 Sanitation practices

(a) Cultivation operations and processing operations must provide employees with adequate and readily-accessible toilet facilities.

(1) Toilet facilities must be maintained in a sanitary condition;

(2) Toilet facilities must be adequately stocked with toilet paper, soap, and single use paper towels or other drying devices; and

(3) Toilet facilities must be kept in good repair at all times.

(b) Cultivation operations and processing operations must provide adequate and convenient hand-washing stations.

(1) Hand washing stations must be provided with running water of suitable temperature;

(2) Hand washing stations must be provided with effective hand cleaning or sanitizing preparations and single use paper towels or other drying devices;

(3) Hand washing stations must be located at points in the facility where good sanitary practices require employees to wash or sanitize their hands; and

(4) Outdoor and greenhouse cultivation operations must provide hand-washing stations at field locations as appropriate.

(c) Cultivation operations and processing operations must implement sanitation practices, which at a minimum address:

(1) Removal of debris, and control of the growth of mold, mildew and algae in the cultivation area or processing area;

(2) Pest control practices, including maintenance and repair of caulk cracks and drain areas;

(3) Identification of hoses dedicated for use in cultivation; and

(4) Maintenance and cleaning of irrigation systems.

(d) Processing operations must protect cannabis from contact with birds, rodents, insects, and other animals and from exposure to the elements.

Section 4.4 Electrical system

(a) The cultivation operation's electrical system must be of sufficient capacity to handle the actual electrical load and be installed in accordance with an approved electrical permit.

(b) All electrical work and upgrades at cultivation operations must be performed with proper permitting.

(c) All electrical equipment used by a cannabis cultivation operation should be connected to the electrical system in accordance with the equipment manufacturer's recommendations.

Section 4.5 Ventilation system

(a) Enclosed cultivation operations and processing operations must be equipped with adequate ventilation to maintain proper humidity and temperature.

(b) For indoor cultivation operations:

(1) If a mechanically propelled air intake system is used, a filter capable of removing 99.97% of particles with a diameter of 0.3 micrometers (μm) must also be utilized, as necessary to control potential contamination with pathogenic organisms.

(2) If a non-mechanically propelled or passive intake system is being utilized, a grate and filter sufficient to reduce the intrusion of rodents and insects must be installed.

Section 4.6 Disposal and waste practices

(a) Cannabis waste must be disposed of in a manner which prevents unauthorized use and such disposal must be documented.

(b) Bulbs and ballasts utilized during the cultivation of cannabis must be disposed of in accordance with manufacturer's recommendations.

Section 4.7 Security provisions

(a) Outdoor and greenhouse cultivation operations should be enclosed by a secure perimeter fence at least six (6) feet in height. The fence should include a lockable gate that is locked when a qualified employee is not in the immediate area. The fence must not violate any other ordinance, code section or provision of law regarding height and location restrictions.

(b) Indoor cultivation facilities and processing facilities must have locking doors and windows which allow emergency ingress and egress in accordance with applicable regulations.

(c) Cultivation operations and processing operations must implement and communicate security protocols to all personnel.

(d) Visitors must be accompanied by an employee at all times.

SUBPART E – WATER RESOURCE MANAGEMENT

Section 5.1 Cultivation water management

(a) In the absence of local or state water district regulations for cannabis production, cultivation operations must create and implement a cultivation water management plan to address the following:

(1) Erosion prevention; and

(2) Effluent and agricultural discharges.

(b) Chemical solutions must be disposed of in accordance with applicable laws and regulations.

(c) Application of nutrients or pesticides through an irrigation system (chemigation), must be performed in accordance with state or local agricultural regulations.

Section 5.2 Potable water for employee use

(a) Cultivation operations not utilizing a municipal source of potable water must test the potable water supply at least two times per year to ensure compliance with state primary drinking water standards.

(b) Chemicals, fertilizers, pesticides, media and other products must be stored away from the potable water supply.

SUBPART F – RECORDKEEPING

Section 6 Recordkeeping practices

(a) Cultivation operations must record the identity and source of all cannabis propagation material with sufficient specificity to ensure that the material can be traced to its source. Such records must be created whether the propagation material is obtained off-site or produced on-site.

(b) For each batch of cannabis, cultivation operations must maintain cultivation records that include at a minimum:

(1) Planting records:

(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.

(2) Propagation records:

(i) Media used, and whether the media was reused or new product;

(ii) Description of all actions taken to prevent or treat the cannabis for disease or pest issues;

(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).

(3) Pesticide use records:

(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.

(4) Harvest records:

(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).

(c) Processing operations must maintain records for processed cannabis that include at a minimum:

(1) Identity of the variety processed;

(2) Sufficient information to trace the processed 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).

(d) Cultivation operations and processing operations must maintain records of the commercial sale of cannabis to other cultivation and processing operations, to manufacturing operations, and to dispensing operations 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.

(e) Cultivation operations and processing operations are not required to retain records of cannabis distributed for the following purposes:

(1) Samples provided for testing;

(2) Samples provided to other operations at no charge; and

(3) Samples provided to compliant individuals at no charge.

SUBPART G – INFORMATION DISCLOSURE

Section 7 Information disclosure

(a) Cultivation operations must provide the following records to other cultivation operations, processing operations, manufacturing operations, and dispensing operations receiving cannabis from the cultivation operation, upon the receiving operation's 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.

(b) Information provided by a cultivation operation, whether written or verbal, about the identity, quality, and cultivation conditions of cannabis it provides must be accurate.

(c) Cultivation operations and processing operations must disclose the extent and type of testing and analysis conducted on the cannabis it provides, including:

(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. The information required by this paragraph must be disclosed for each of the following:

(i) Pesticides;

(ii) Yeasts and molds; and

(iii) Other microbiological contaminants.

(4) Whether the testing was conducted by the cultivation or processing operation, or by an external laboratory.

SUBPART H – RECALLS

Section 8 Recall plan

(a) Each cultivation operation and processing operation must develop and implement a recall plan addressing at a minimum:

(1) Factors which necessitate a recall procedure;

(2) Personnel responsible for a recall; and

(3) Notification protocols.

(b) Each cultivation operation and processing operation must establish a policy for communicating a recall of cannabis that has been shown to present a reasonable or a remote probability that the use of or exposure to the product will cause serious adverse health consequences, or could cause temporary or medically reversible adverse health consequences. This policy should include:

(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.

(c) Any recalled cannabis that is returned to a cultivation operation or processing operation must be disposed of in a manner that ensures that it cannot be salvaged and will not be used by a compliant individual or by any other person.

Cannabis Manufacturing, Packaging, Labeling and Holding Operations

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SUBPART A – GENERAL PROVISIONS

Section 1.1 Subject operations

(a) 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 , .

(b) A compliant individual that 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.

(c) 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.

(d) 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.

(e) Each operation subject to this part is responsible to comply with only those sections that apply to the activities conducted by that operation.

Section 1.2 Other statutory provisions and regulations

In addition to this part, manufacturing, packaging, labeling and holding operations must comply 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.

Section 1.3 Definitions

The following definitions apply to this part:

Actual yield means the quantity that is actually produced at any appropriate step of manufacture or packaging of a particular cannabis-derived product.

Adulteration means that a cannabis-derived product (1) consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) bears or contains any poisonous or deleterious substance which may render it injurious to health; except that (A) such product shall not be considered adulterated if the quantity of such substance does not ordinarily render it injurious to health and (B) the cannabis content of the product shall not be considered injurious to health; (3)(A) has been manufactured, packaged, labeled, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (B) has been manufactured, packaged, labeled, or held by methods, in facilities, or using controls that do not conform to or are not operated or administered in conformity with this part to assure that the cannabis-derived product meets appropriate requirements as to safety; or (4) fails to meet appropriate requirements as to safety; or (5) is in a container composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (6) bears or contains, for purposes of coloring, a color additive which is not approved in the United States for use in a comparable food product; or (7) (A) has been mixed or packaged with any substance so as to reduce its quality or strength or (B) has been substituted wholly or in part with any substance.

Batch means, with regard to cannabis, a specific quantity of cannabis harvested during a specified time period from a specified cultivation area; and means, with regard to cannabis-derived product, a specific quantity that is uniform, that is intended to meet specifications for identity, strength, purity and composition, and that is manufactured, packaged and/or labeled during a specified time period according to a single manufacturing, packaging, and/or labeling batch record.

Batch number, lot number, or control number means any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacturing, packaging, labeling, or holding of a batch or lot of cannabis or cannabis-derived products can be determined.

Cannabis means any of the aerial parts of a plant in the genus Cannabis, and does not mean hemp.

Cannabis-derived product means a product, other than cannabis itself, which contains or is derived from cannabis by manufacturing as defined herein, and does not mean a product that contains or is derived from hemp.

Cannabis waste means cannabis or cannabis-derived product discarded by a manufacturing, packaging, labeling, or holding operation.

Compliant individual means an individual who has met all legal requirements to obtain and use cannabis or cannabis-derived product in the jurisdiction where this part applies.

Composition means the aggregate mixture which results from the manufacture of a cannabis-derived product according to the formula and process defined in the product's manufacturing protocol.

Component means any substance or item intended for use in the manufacture of a cannabis-derived product, including those that do not appear in the batch of the cannabis-derived product. Component includes cannabis, cannabis-derived products used as ingredients, other ingredients, and processing aids.

Contact surface means any surface that directly contacts cannabis, components, or cannabis-derived product, and any surface from which drainage onto cannabis, components, or cannabis-derived product, or onto surfaces that contact cannabis, components, or cannabis-derived product, may occur during the normal course of operations.

Controlled access area means an area in the physical plant designed to prevent entry by anyone except authorized personnel.

Cultivate means to grow, harvest, dry, and cure cannabis. A person, group of persons, non-profit entity, or business entity that cultivates is a cultivator, and a facility where cannabis plants are cultivated is a cultivation operation.

Dispense means to provide cannabis or cannabis-derived product to compliant individuals.

Dispensing operation means a person, group of persons, non-profit entity, or business entity that provides cannabis or cannabis-derived product to compliant individuals and includes delivery services, direct-from-garden operations, growing co-ops, and storefront operations.

Disposition means review and approval or rejection of a batch, lot, or other item by quality control personnel.

Gang-printed label means a label for one product that is printed simultaneously on the same sheet of paper as labels for other products.

Hemp means any part of a plant in the genus Cannabis, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 (three-tenths) percent on a dry weight basis.

Hold means to store or warehouse cannabis or cannabis-derived product in any context by an operation that is subject to this rule. A person, group of persons, non-profit entity, or business entity that holds is a holder, and a facility where holding occurs is a holding operation.

Identity means the set of characteristics by which an ingredient or product is definitively recognizable or known. In the case of cannabis and other botanical ingredients, identity means the plant part and the botanical genus, species, variety, strain, and/or cultivar, as well as any other applicable characteristics as stated on the label or other labeling. In the case of cannabis-derived products, identity means the product name, strength, key features of its form or composition, grade, and/or other characteristics as applicable.

Ingredient means any substance that is used in the manufacture of a cannabis-derived product and that is intended to be present in the batch of the cannabis-derived product.

In-process material means any material that is compounded, blended, ground, extracted, sifted, sterilized, or prepared in any other way by the operation for use in its manufacturing, packaging, or labeling of cannabis or a cannabis-derived product.

Label (verb) means to affix labeling on packaged cannabis or cannabis-derived product. A person, group of persons, non-profit entity, or business entity that labels is a labeler, and a facility where labeling occurs is a labeling operation.

Labeling (noun) means all labels and other written, printed or graphic matter on or accompanying any article or any of its containers or wrappers.

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

Manufacture means to compound, blend, grind, extract, or otherwise make or prepare cannabis-derived product; the term does not apply to cannabis. A person, group of persons, non-profit entity, or business entity that manufactures is a manufacturer, and a facility where manufacture occurs is a manufacturing operation.

May is used to indicate an action or activity that is permitted; may not is used to indicate an action or activity that is not permitted.

Microorganism means yeasts, molds, bacteria, viruses, and other similar microscopic organisms having public health or sanitary concern. This definition includes species that may cause a component or cannabis or cannabis-derived product to decompose; may indicate that the component or cannabis or

cannabis-derived product is contaminated with filth; or otherwise may cause the component, cannabis or cannabis-derived product to be adulterated.

Must is used to state a requirement.

Package (verb) means to place cannabis or cannabis-derived product into primary packaging for bulk or retail distribution when performed by an operation subject to this part. A person, group of persons, non-profit entity, or business entity that packages is a packager, and a facility where packaging occurs is a packaging operation.

Pack (verb) means to place cannabis or cannabis-derived product into containers for distribution, other than to package the cannabis or cannabis-derived product; and includes the placement of cannabis into any type of container by cultivation operations, processing operations, and dispensing operations, as well as the placement of filled primary packaging containers into other containers such as for storage or transport.

Packaging component means any item intended for use in the primary packaging or labeling of cannabis-derived products.

Personnel means any worker engaged in the performance of operations subject to this rule and includes full and part-time employees, temporary employees, contractors, and volunteers.

Pest means any objectionable insect or other animal at any life stage.

Physical plant means all or any part of a building or facility used for or in functional connection with manufacturing, packaging, labeling, or holding a cannabis-derived product.

Primary packaging means items used in packaging that serve to directly contain, contact, and/or label the product.

Process (verb) means to trim, inspect, grade, or pack cannabis. A person, group of persons, non-profit entity, or business entity that processes is a processor, and a facility where cannabis is processed is a processing operation.

Product complaint means any communication that contains any allegation, written, electronic, or oral, expressing concern, for any reason, with the quality of a product that could be related to its manufacture, packaging, or labeling.

Production means manufacturing, packaging, and/or labeling, as applicable to the firm's operations.

Purity means the relative freedom from extraneous matter, contaminants, or impurities, whether or not harmful to the consumer or deleterious to the product.

Quality means that the product consistently meets the established specifications for identity, purity, strength, composition, packaging, and labeling, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration.

Quality control means a planned and systematic operation or procedure for ensuring the quality of a product.

Quality control personnel means any person, persons, or group, within or outside of a manufacturing, packaging, labeling or holding operation, which is designated to be responsible for the operation's quality control operations.

Quarantine means to segregate and withhold from use lots, batches, or other portions of components, packaging components, in-process materials, cannabis, or products whose suitability for use must be determined by quality control personnel.

Representative sample means a sample that consists of an adequate quantity of material or number of units that is collected in a manner intended to ensure that the sample accurately portrays the material being sampled.

Reprocessing means the performance of a treatment, adjustment, repackaging, relabeling, or other deviation from standard procedures or from the applicable manufacturing protocol, in order to render a nonconforming material suitable for use.

Reserve sample means a representative sample of component, packaging component, or product that is held for a designated period of time.

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

Should is used to state recommended or advisory procedures.

Strength means the potency of cannabis or a cannabis-derived product, whether expressed as (a) the amount or percent of specific chemical constituents or groups of chemical constituents; (b) the concentration or amount of cannabis present in a cannabis-derived product; or (c), in the case of cannabis extracts, the ratio of the input quantity of crude cannabis, on a dry weight basis, to the output quantity of finished extract.

Theoretical yield means the quantity that would be produced at any appropriate step of manufacture or packaging of a particular cannabis-derived product, based upon the quantity of components or packaging to be used, in the absence of any loss or error in actual production.

Water activity (aw) is a measure of the free moisture in a component or product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Vendor means a person, group of persons, non-profit entity, or business entity that supplies cannabis or cannabis-derived product to manufacturing, packaging, labeling or holding operations, and may be either the direct representative of a cultivation, processing, or manufacturing operation, or may function independently of such operations by purchasing cannabis or cannabis-derived product from such operations and reselling it to other operations.

SUBPART B – GENERAL REQUIREMENTS

Section 2.1 Acquisition of cannabis and cannabis-derived products

Manufacturing, packaging, labeling, and holding operations may obtain cannabis or cannabis-derived product from any of the following as allowed by applicable legislation and regulation:

(1) Cultivation operations;

(2) Processing operations;

(3) Vendors;

(4) Other manufacturing, packaging, labeling or holding operations; and

(5) Any other legal entity as allowed in this jurisdiction.

Section 2.2 Distribution of cannabis and cannabis-derived products

(a) Manufacturing, packaging, labeling and holding operations may distribute cannabis and cannabis-derived products to any of the following as allowed by applicable legislation and regulation:

(1) Dispensing operations;

(2) Other manufacturing, packaging, labeling or holding operations subject to this section;

(3) Vendors; and

(4) Any other legal entity as allowed in this jurisdiction.

(b) Manufacturing, packaging, labeling and holding operations that transport cannabis or cannabis-derived products must do so in a secured enclosed container and/or secured cargo area of the delivery vehicle.

Section 2.3 Ancillary operations

In addition to the manufacturing of cannabis-derived product and the packaging, labeling or holding of cannabis or cannabis-derived product, an operation described in section 1.1 may also engage in other operations, so long as such operations are permitted at this location in the jurisdiction in which this part applies.

SUBPART C – PERSONNEL

Section 3.1 Personnel training

(a) Manufacturing, packaging, labeling and holding operations must:

(1) Ensure that each person engaged in the operation has the education, training, and experience, or any combination thereof, to enable that person to perform all assigned functions;

(2) Provide personnel with training in the applicable requirements of this part; and

(3) Maintain records of any training provided to personnel for the performance of all assigned functions.

(b) Personnel training should include:

(1) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and

(2) Information on U.S. federal, state and local laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such personnel.

Section 3.2 Personnel responsibilities

(a) Measures must be taken to exclude from any operation any person that might be a source of

microbial contamination due to a health condition through contact with any material, including components, packaging components, in-process materials, cannabis, cannabis-derived products, and contact surfaces used in manufacturing, packaging, labeling, and holding operations. Such measures include the following:

(1) Excluding from working in any operations that may result in contamination any person 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 microbial contamination, that could result in microbial contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces, until the health condition no longer exists; and

(2) 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 paragraph (a)(1) of this section that could result in microbial contamination of any components, packaging components, in-process materials, cannabis, cannabis-derived products, or any contact surface.

(b) Personnel working in an operation during which adulteration of components, packaging components, cannabis, cannabis-derived products, or contact surfaces could occur must use hygienic practices to the extent necessary to protect against such contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces. These hygienic practices include the following:

(1) Wearing 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;

(2) Maintaining adequate personal cleanliness;

(3) Washing hands thoroughly with soap (and sanitizing if necessary to protect against contamination with microorganisms):

(i) Before starting work;

(ii) After using the restroom; and

(iii) At any other time when the hands may have become soiled or contaminated;

(4) Removing all unsecured jewelry and other objects that might fall into components, packaging components, cannabis, cannabis-derived products, equipment, or packaging, and removing 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 contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces;

(5) Maintaining gloves used in handling components, packaging components, in-process materials, cannabis, or cannabis-derived products in an intact, clean, and sanitary condition. The gloves should be of an impermeable material;

(6) Wearing, where appropriate, in an effective manner, hair nets, caps, beard covers, or other effective hair restraints;

(7) Not storing clothing or other personal belongings in areas where components, packaging components, in-process materials, cannabis, cannabis-derived products, or any contact surfaces are exposed or where contact surfaces are washed;

(8) Not eating food, chewing gum, drinking beverages, or using tobacco products in areas where components, packaging components, in-process materials, cannabis, cannabis-derived products, or any contact surfaces are exposed, or where contact surfaces are washed;

(9) Taking any other precautions necessary to protect against the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces with microorganisms, filth, or any other extraneous materials, including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin;

(10) Taking all precautions 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; and

(11) Entering controlled access areas only as authorized by supervisory personnel.

Section 3.3 Personnel safety

(a) Policies must be implemented to protect personnel in all operations and provide personnel with adequate safety training to comply with these policies. Such policies should be similar to personnel safety policies in comparable industries, such as food processors, and may include, for example:

(1) Personnel accident reporting and investigation policies;

(2) Fire prevention and response plans;

(3) Materials handling and hazard communications policies, including maintenance of material safety data sheets (MSDS); and

(4) Personal protective equipment policies.

(b) An emergency contact list must be visibly posted and maintained 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.

(c) Compliance must also be ensured with all other applicable standards of the federal Occupational Health and Safety Administration and any applicable state or local worker safety requirements.

Section 3.4 Supervisor requirements

(a) Qualified personnel should be assigned to supervise the manufacturing, packaging, labeling, or holding of cannabis and cannabis-derived products.

(b) Each person responsible for supervising the manufacture, packaging, labeling, or holding of a cannabis or cannabis-derived product must have the 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 product has the identity, purity, strength, and composition that it purports or is represented to possess.

(c) One or more qualified personnel should be assigned to supervise overall sanitation. Each of these supervisors must be qualified by education, training, or experience to develop and supervise sanitation procedures.

SUBPART D – PHYSICAL PLANT AND GROUNDS

Section 4.1 Design and construction

(a) The physical plant used in the manufacture, packaging, labeling, or holding of cannabis and cannabis-derived products must be suitable in size, construction, and design to facilitate maintenance, cleaning and/or sanitizing, as applicable to the operation.

(b) Any such physical plant must have adequate space for the orderly placement of equipment and materials to prevent mixups of components, packaging components, in-process materials, cannabis, or cannabis-derived products during manufacturing, packaging, labeling, or holding.

(c) Any such physical plant must be designed to reduce the potential for contamination of components, packaging components, cannabis, cannabis-derived products, or contact surfaces, with microorganisms, chemicals, filth, or other extraneous material. The design and construction must include:

(1) Floors, walls, and ceilings that can be adequately cleaned and kept clean and in good repair;

(2) Fixtures, ducts, and pipes that do not contaminate components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces by dripping or other leakage, or condensate;

(3) 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.

(4) Safety-type light bulbs, fixtures, skylights, or other glass or glass-like materials must be used when the light bulbs, fixtures, skylights or other glass or glass-like materials are suspended over exposed components, packaging components, in-process materials, or cannabis or cannabis-derived products, unless 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 glass or glass-like materials.

(d) Any such physical plant must have separate or defined areas, or other control systems such as computerized inventory controls or automated systems of separation, to prevent cross-contamination and mixups of components, cannabis, or cannabis-derived products during any of following operations that 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 products pending disposition by quality control personnel;

(2) Storage of approved components, packaging components, cannabis, or cannabis-derived products;

(3) Storage of rejected components, packaging components, in-process materials, cannabis, 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.

(e) Water must be provided that is:

(1) 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; and

(2) Compliant with applicable state and local potable 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.

(f) Heating, ventilating, cooling, and air filtration must be installed and maintained in the physical plant as needed to ensure the quality of the product.

(1) Ventilation equipment such as filters, fans, exhausts, dust collection, and other air-blowing equipment must be provided in areas where odors, dust, and vapors (including steam and noxious fumes) may contaminate components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces.

(2) When fans, compressed air, or other air-blowing equipment are used, such equipment must be 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.

(3) Equipment that controls temperature, humidity, and/or microorganisms must be provided, when such equipment is necessary to ensure the quality of the product.

(g) The plumbing in the physical plant must be of an adequate size and design and be adequately installed and maintained to:

(1) Carry sufficient amounts of water to required locations throughout the physical plant;

(2) Properly convey sewage and liquid disposable waste from the physical plant;

(3) 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;

(4) 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; and

(5) Not 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.

(h) Personnel must be provided with adequate, readily accessible toilet facilities that are:

(1) Maintained in a clean and sanitary condition;

(2) Adequately stocked with toilet paper, soap, and single use paper towels or other drying devices;

(3) Kept in good repair at all times;

(4) Equipped with signage advising personnel of the necessity of washing hands prior to returning to work;

(5) Prohibited from being used for activities that support production operations, such as cleaning of production equipment or utensils.

(i) Airborne contamination from toilet facilities must be prevented from contacting components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces, 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.

(j) Adequate and convenient hand-washing facilities must be provided that are:

(1) Provided with running water of suitable temperature;

(2) Provided with effective hand cleaning and/or sanitizing preparations and single use paper towels or other drying devices;

(3) Located at points in the facility where good sanitary practices require personnel to wash their hands;

(4) Prohibited from being used for activities that support production operations, such as cleaning of production equipment or utensils.

(k) Adequate lighting must be provided in:

(1) All areas where components, packaging components, in-process materials, cannabis, or cannabis-derived products are examined, manufactured, packaged, labeled, or held;

(2) All areas where contact surfaces are cleaned; and

(3) Hand-washing areas, dressing and locker rooms, and toilet facilities.

Section 4.2 Sanitation requirements

(a) The grounds of the physical plant must be kept in a condition that protects against the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces. The methods for adequate ground maintenance include:

(1) 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;

(2) Maintaining roads, yards, and parking lots 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;

(3) Adequately draining areas that may contribute to the contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces by seepage, filth or any other extraneous materials, or by providing a breeding place for pests;

(4) 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 or cannabis-derived products, or contact surfaces are exposed; and

(5) If the plant grounds are bordered by grounds not under the operation's control, and if those other grounds are not maintained in the manner described in this section, care should be 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.

(b) The physical plant must be maintained in a clean and sanitary condition and must be maintained in repair sufficient to prevent components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces from becoming contaminated.

(c) Cleaning compounds, sanitizing agents, pesticides, and other toxic materials must be appropriately stored, handled, and controlled.

(1) Cleaning compounds and sanitizing agents must be free from microorganisms of public health significance and be safe and adequate under the conditions of use.

(2) Toxic materials must not be 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 as follows:

(i) To maintain clean and sanitary conditions;

(ii) For use in laboratory testing procedures, where applicable;

(iii) For maintaining or operating the physical plant or equipment; or

(iv) For use in the plant's operations.

(3) Cleaning compounds, sanitizing agents, pesticides, pesticide chemicals, and other toxic materials must be 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.

(d) Adequate pest control must be provided.

(1) Animals or pests must not be allowed in any area of the physical plant, except that guard or guide dogs may be allowed in some areas of the physical plant if the presence of the dogs will not result in contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces;

(2) Effective measures must be 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; and

(3) Insecticides, fungicides, or rodenticides must not be used in or around the physical plant, unless they are registered with 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.

(e) Trash must be regularly conveyed, stored, and disposed in order to:

(1) Minimize the development of odors;

(2) Minimize the potential for the trash to attract, harbor, or become a breeding place for pests;

(3) Protect against contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, any contact surface, water supplies, and grounds surrounding the physical plant; and

(4) Control hazardous waste to prevent contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, and contact surfaces.

(f) Manufacturing, packaging, labeling, or holding operations must have and follow written procedures for sanitation that address the following:

(1) Responsibility for sanitation;

(2) Detailed description of the cleaning schedules, methods, equipment, and materials to be used in cleaning the grounds and buildings; and

(3) Records of cleaning and sanitation that must be kept.

(g) Manufacturing, packaging, labeling, and holding operations must have and follow written procedures for use of rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents that address the following:

(1) Prevention of the contamination of components, packaging components, in process materials, cannabis, cannabis-derived products, or contact surfaces; and

(2) Records of the use of rodenticides, insecticides, fungicides, fumigating agents, and cleaning or sanitizing agents must be kept.

(h) Sanitation procedures must apply to work performed by all personnel during the ordinary course of operations.

(i) All operations must be conducted in accordance with adequate sanitation principles, including, but not limited to:

(1) Cleaning and/or sanitizing production equipment, containers, and other contact surfaces, as needed;

(2) Controlling airborne contamination as needed where components, packaging components, in-process materials, product, or contact surfaces are exposed;

(3) Using sanitary handling procedures.

Section 4.3 Equipment and utensils

(a) Production operations must use equipment and utensils that are of appropriate design, construction, and workmanship.

(1) Equipment and utensils must be suitable for their intended use;

(2) Equipment and utensils must be able to be adequately cleaned and properly maintained; and

(3) Use of equipment and utensils must not result in the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces.

(b) All equipment and utensils used in production operations must be:

(1) Installed and maintained to facilitate cleaning of the equipment, utensils, and adjacent spaces;

(2) Constructed so that contact surfaces are non-toxic and corrosion-resistant, and neither reactive nor absorptive;

(3) 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; and

(4) Maintained to protect components, in-process materials, cannabis, and cannabis-derived products from being contaminated by any source.

(c) Equipment and utensils must be 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 materials or contaminants.

(d) 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 must be filtered or otherwise treated such that the component, packaging component, in-process material, cannabis or cannabis-derived product, or contact surface is not contaminated.

(e) Each freezer, refrigerator, and other cold storage compartment used to hold components, in-process materials, or cannabis or cannabis-derived products:

(1) Must be fitted 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

(2) Must have an automated device for regulating temperature and/or an automated alarm system to indicate a significant temperature change.

(f) Instruments or controls used in manufacturing, packaging, labeling, holding, or testing, and instruments or controls that are used to measure, regulate, or record conditions that control or prevent the growth of microorganisms or other contamination, must be suitably accurate and precise, and adequately maintained.

(g) Where appropriate, instruments and controls used in manufacturing, packaging, holding, or testing components, packaging components, in-process materials, cannabis, and cannabis-derived products must be 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 the resulting data must be periodically reviewed by quality control personnel. Instruments or controls that are past their calibration, inspection, or verification due date, or which cannot be adjusted to provide suitable accuracy and precision, must be removed from use until they are repaired or replaced.

(h) Production operations must establish and use appropriate controls for automated, mechanical, and electronic equipment (including software for a computer controlled process) to ensure that:

(1) Any changes to the equipment are approved by quality control personnel and instituted only by authorized personnel; and

(2) The equipment functions in accordance with its intended use.

(i) Equipment and utensils, and any other contact surfaces used in production operations must be maintained, cleaned, and sanitized, as necessary.

(1) Equipment and utensils must be taken apart as necessary for thorough maintenance, cleaning, and sanitizing.

(2) All contact surfaces used for manufacturing, packaging, or holding low-moisture components, in-process materials, or cannabis or cannabis-derived products, must be in a dry and sanitary condition when in use. When the surfaces are wet-cleaned, they must be sanitized, when necessary, and thoroughly dried before subsequent use.

(3) If wet processing is used during production, all contact surfaces must be 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.

(4) When cleaning and sanitizing is necessary, all contact surfaces must be cleaned before use and after any interruption during which the contact surface may have become contaminated.

(5) If contact surfaces are used in a continuous production operation or in consecutive operations involving different batches of the same product, the contact surfaces must be adequately cleaned and sanitized, as necessary.

(6) Surfaces that do not come into direct contact with components, packaging components, in-

process materials, or cannabis or cannabis-derived products must be cleaned as frequently as necessary to protect against contaminating components or products.

(7) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be 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.

(8) Cleaning compounds and sanitizing agents must be adequate for their intended use and safe under their conditions of use.

(9) Cleaned and sanitized portable equipment and utensils that have contact surfaces must be stored in a location and manner that protects them from contamination.

(j) There must be written procedures for calibration, maintenance, cleaning, and sanitation of equipment, instruments, and utensils, and records of these activities must be kept.

Section 4.4 Security requirements

(a) Security procedures must be established and implemented for authorized access to the physical plant and any controlled access areas therein.

(b) Access to the physical plant and controlled access areas must be limited to current personnel and contractors as appropriate to their job function.

(c) The physical plant must be equipped with one or more controlled access areas for storage of the following:

(1) Labels and other packaging components;

(2) Cannabis and cannabis-derived products;

(3) Cannabis waste;

(4) Quarantined components, packaging components, in-process materials, and cannabis or cannabis-derived products;

(5) Rejected components, packaging components, in-process materials, cannabis, or cannabis-derived products.

(d) There must be written procedures for security.

SUBPART E – MANUFACTURING PROCESS CONTROLS

Section 5.1 Manufacturing protocol

(a) Manufacturing operations must prepare and follow a manufacturing protocol for each unique formulation of cannabis-derived product to be produced. The manufacturing protocol must include the following, as applicable:

(1) Identity of the product;

(2) For each formulation of product:

(i) Nominal batch size;

(ii) Identity of each component to be used in the batch;

(iii) 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 the weight or measure;

(iv) A statement of any intentional overage amount of a component; and

(v) Name and amount of each ingredient that will be declared on the product's labeling.

(3) 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;

(4) Written instructions or cross references to standard procedures for the following:

(i) The execution of each process step;

(ii) Production process specifications per section 5.5;

(iii) Monitoring of production process specifications;

(iv) In-process material specifications per section 5.8;

(v) In-process material sampling, testing, and/or examination;

(vi) Cannabis-derived product sampling, testing, and/or examination; and

(vii) Additional applicable procedures to be followed, if any.

(5) Cannabis-derived product specifications, or a cross-reference to cannabis-derived product specification documents.

(b) Manufacturing protocols must be written with the intent to provide not less than 100 percent of the labeled or specified amount of cannabis and any other ingredient for which a quantitative label claim is made, throughout the shelf life of the product.

(c) The production process described in the manufacturing protocol must ensure that cannabis-derived product specifications are consistently met.

Section 5.2 Manufacturing component control requirements

(a) Manufacturing operations must have written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, review, and approval or rejection of components.

(b) Each container or grouping of containers for components must be 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, the date received, and the name of the component; and forward to the cannabis-derived product batches manufactured or distributed using the lot. This code must be used in recording the disposition of each lot.

(c) Specifications for each component must be established as follows, to the extent they are necessary to ensure that manufactured batches of cannabis-derived product meet specifications.

(1) An identity specification for the component must be established;

(2) Specifications for the strength and composition of the component must be established as necessary to ensure the strength and composition of cannabis-derived products manufactured with the component;

(3) Specifications for the purity of the component must be established 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 may lead to adulteration of cannabis-derived products manufactured with the component, such as filth, insect infestation, microbiological contamination, or other contaminants.

(d) Components must be received and stored pending approval as follows:

(1) Upon receipt and before acceptance, each container or grouping of containers must be examined visually 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 components.

(2) The supplier's documentation for each shipment must be examined to ensure the components are consistent with what was ordered.

(3) Components must be stored under quarantine until they have been sampled, reviewed, and approved or rejected by quality control personnel.

(e) Components must be approved or rejected as follows:

(1) Each lot of components must be withheld from use until the lot has been sampled, reviewed, and released for use by the quality control personnel.

(2) Compliance of the lot with established specifications must be ensured either through review of the supplier's certificate of analysis or other documentation, or through appropriate tests and/or examinations. Any tests and examinations performed must be conducted using appropriate scientifically valid methods.

(3) Any lot of a component that meets its specifications may be approved and released for use for use by quality control personnel.

(4) Any lot of a component that does not meet its specifications must be rejected by quality control personnel, unless quality control personnel 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. Any such treatment, process adjustment, reprocessing, or other deviation must be documented, justified, and approved by quality control personnel.

Section 5.3 Manufacturing batch record

(a) The manufacturing operation must prepare a manufacturing batch record for each batch of cannabis-derived product manufactured.

(b) The manufacturing batch record must:

(1) Cross-reference or reproduce the appropriate manufacturing protocol; and

(2) Form a complete record of the manufacturing and control of the batch.

(c) Each batch must be assigned a batch, lot, or control number which allows the complete history of the production and distribution of the batch to be determined. This code must be used in recording the disposition of each batch.

(d) The manufacturing batch record must include, as applicable to the process:

(1) Identity of the cannabis-derived product;

(2) The batch, lot, or control number of the cannabis-derived product;

(3) Batch size;

(4) For each component used in production of the batch:

(i) Identity of each component used in the batch;

(ii) Batch, lot, or control number of each component used in the batch;

(iii) Actual weight or measure of each batch or lot of component used in the batch, including the unit of measure;

(5) Date(s) on which, and where applicable the time(s) at which, each step of the manufacturing process was performed;

(6) Actual results obtained during monitoring of production process parameters;

(7) Identity of processing lines and major equipment used in producing the batch;

(8) 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;

(9) 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;

(10) 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;

(11) Records of any cannabis waste generated during production of the batch;

(12) Records of any treatment, process adjustment, reprocessing, or other deviation that occurred during production of the batch;

(13) Records of the date, time where applicable, quantity, and person responsible for any sample removed during or after production;

(14) Actual results of any testing or examination of in-process material or cannabis-derived product, or a cross-reference to such results;

(15) Documentation that the cannabis-derived product meets its specifications for identity, purity, strength, and composition, in accordance with the requirements of the manufacturing protocol;

(16) Identity of each person performing each process step in production of the batch, including but not limited to:

(i) Weighing or measuring each component and verifying the weight or measure of each component used in the batch per section 5.4;

(ii) 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;

(v) Directly overseeing each stage of production of the batch;

(vi) Performing any other checks or verifications in production of the batch, as needed; and

(vii) Releasing the batch from one stage of production to the next.

(e) All data in the manufacturing batch record must be recorded at the time at which each action is performed.

(f) The completed manufacturing batch record for each batch must be 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.

Section 5.4 Allocation and charge-in of components

(a) Manufacturing operations must weigh, measure, or subdivide components to be used in a cannabis-derived product batch as appropriate for the batch.

(b) If a component is removed from the original container to another, the new container must be identified with the following information:

(1) Component identity;

(2) Batch, lot, or control number;

(3) Weight or measure in the new container; and

(4) Batch for which component was dispensed, including its identity and batch, lot, or control number.

(c) Each container of component dispensed to manufacturing must be examined by a second person or verified by automated equipment to assure that:

(1) The component was released by quality control personnel;

(2) The weight or measure is correct as stated in the manufacturing protocol; and

(3) The containers are properly identified.

(d) Each component must either be 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.

Section 5.5 Process monitoring and controls during manufacturing

(a) Process specifications must be 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. The process parameters to be monitored may include, but are not limited to, the following as appropriate:

(1) Time;

(2) Temperature;

(3) Pressure; and

(4) Speed.

(b) Production process parameters must be monitored at or during any point, step, or stage where process specifications have been established.

(c) Any deviation from the specified process parameters must be documented and justified, and the associated in-process material or product must be quarantined. The deviation must be reviewed and approved or rejected by quality control personnel. Such deviations must not be approved unless quality control personnel determine that the resulting cannabis-derived product will meet all specifications for identity, purity, strength, and composition and is not otherwise contaminated or adulterated.

(d) If a deviation is rejected, the resulting in-process or finished cannabis-derived product must be 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. Any such treatment, process adjustment, reprocessing, or other deviation must be documented, justified, and approved by quality control personnel.

(e) Manufacturing operations must properly identify 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.

(f) Operations on one component, product, or batch must be physically, spatially, or temporally separated from operations on other components, products, or batches.

(g) All necessary precautions must be taken during the manufacture of a cannabis-derived product to prevent contamination of components and products. These precautions include, but are not limited to:

(1) Washing or cleaning components that contain soil or other contaminants;

(2) Holding components, in-process materials, and cannabis or cannabis-derived products appropriately;

(3) Preventing cross-contamination and mixups between contaminated components, in-process materials, and cannabis or cannabis-derived products and uncontaminated items;

(4) Using effective measures to protect against the inclusion of metal or other foreign material in components or cannabis products, by, for example:

(i) Filters, strainers, or sieves;

(ii) Traps;

(iii) Magnets;

(iv) Electronic metal detectors.

Section 5.6 Manufacturing sampling requirements

(a) A representative sample of each batch or lot of component, cannabis, or cannabis-derived product must be collected by removing and compositing portions of material or units from throughout the containers in the batch or lot.

(b) In addition to representative samples, other samples may be taken as appropriate to:

(1) Monitor the quality of in-process materials during production;

(2) Examine the degree of variability of materials or products; and

(3) Investigate known or suspected non-conformances.

(c) The number of containers and the amount of material or units to be removed from each container must be based on appropriate criteria such as:

(1) Quantity needed for testing, examination, and reserve;

(2) Past quality history of the item;

(3) Expected variability of the material or units being sampled; and

(4) Degree of confidence and precision required.

(d) The containers selected for sampling must be based on rational criteria such as random sampling; directed sampling may be used where appropriate.

(e) Samples must be collected in accordance with the following procedures:

(1) The containers selected for sampling must be cleaned when necessary in a manner to prevent introduction of contaminants into the component, in-process material, cannabis or cannabis-derived product.

(2) The containers must be 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.

(3) Sterile equipment and aseptic sampling techniques must be used when necessary.

(4) 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.

(5) Containers from which samples have been taken must be marked to indicate that samples have been removed from them.

(f) Sample containers must be identified with the following information:

(1) Name of the item sampled;

(2) Batch, lot, or control number of the item sampled;

(3) Container from which the sample was taken, or for samples taken directly from the production line, the equipment line and time at which the sample was taken, unless such information is documented separately;

(4) Date on which the sample was taken;

(5) Name of the person who collected the sample; and

(6) Quantity and unit of measure of the sample.

(g) Each sample removed from a batch or lot must be recorded in the inventory or manufacturing batch record for the batch or lot.

(h) The quantity of sample used for each test or examination must be of sufficient size or number to ensure the results are representative of the batch or lot.

(i) A reserve sample must be prepared from the representative sample of each batch or lot of shelf-stable component, cannabis or cannabis-derived product.

(j) Reserve samples should 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. However, 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 if necessary.

(k) Reserve samples of shelf-stable components should:

(1) Be stored using an appropriate container-closure to protect against contamination or deterioration during storage;

(2) Be stored under conditions consistent with the conditions under which the component is stored at the manufacturing operation; and

(3) Be retained for one year past the expiration date of the last batch of cannabis-derived product manufactured from the lot. However, where state law limits the amount of cannabis and cannabis-derived product permitted to be kept on hand, operations may keep reserve samples for shorter periods of time if necessary.

(l) Reserve samples of cannabis-derived product should:

(1) Be 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;

(2) Be 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.

(3) Be retained for one year past the expiration date of the batch or lot. However, 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 if necessary.

Section 5.7 Cannabis-derived product specifications

(a) Manufacturing operations must establish specifications for each cannabis-derived product as follows:

(1) Manufacturing operations must establish specifications for the identity purity, strength, and composition of each cannabis-derived product manufactured by the operation.

(2) Manufacturing operations which receive cannabis-derived product for further processing must establish specifications to provide sufficient assurance that the product received is adequately identified and is consistent with the purchase order.

(b) For each batch or lot of cannabis-derived product manufactured by the operation, the conformance of the batch or lot to established specifications must be confirmed as follows:

(1) For every batch or lot, or for a subset of cannabis-derived product batches or lots identified through sound statistical sampling plan, the operation must 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.

(2) 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 may be 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.

(3) Where no scientifically valid test method exists for a product specification, compliance with the specification must be established through component and/or in-process testing, examinations, or monitoring and/or review of manufacturing batch records.

(4) Quality control personnel must document and approve the justification for reduced product testing under section 5.7(b)(2) or section 5.7(b)(3) of this part.

(c) Cannabis-derived product which fails to meet its specifications must be 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. Any such treatment, process adjustment, reprocessing, or other deviation must be documented in the manufacturing batch record, justified, and approved by quality control personnel.

(d) Any unexplained occurrence or discrepancy, and any failure of the cannabis-derived product to meet its specifications or requirements, must be 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.

(e) Manufacturing operations must have written procedures describing in sufficient detail the storage, handling, sampling, testing, and approval or rejection of cannabis and cannabis-derived products.

Section 5.8 In-process material specifications, sampling, and testing

(a) In-process specifications must be established 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:

(1) Weight or fill of tablets, capsules, or other units;

(2) Weight or fill variation of tablets, capsules, or other units;

(3) Hardness or friability of tablets;

(4) Disintegration time of unit dosages;

(5) Clarity, viscosity, specific gravity, total dissolved solids, or pH of solutions;

(6) Loss on drying, moisture content, or solvent residue;

(7) Microbiological characteristics; and

(8) Organoleptic characteristics.

(b) In-process specifications for such characteristics must be consistent with the cannabis-derived product specifications.

(c) In-process materials must be 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 must be approved or rejected by quality control personnel.

(d) In-process material which fails to meet its specifications must be 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. Any such treatment, process adjustment, reprocessing, or other deviation must be documented in the manufacturing batch record, justified, and approved by quality control personnel.

Section 5.9 Calculation of yield

(a) Actual yields must be determined at the conclusion of each appropriate phase of manufacturing of the cannabis-derived product. Such calculations must either be performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment, be independently verified by one person.

(b) 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, 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.

SUBPART F – PACKAGING AND LABELING PROCESS CONTROLS

Section 6.1 General considerations for packaging components, including labels

(a) Cannabis to be packaged without undergoing manufacturing to a cannabis-derived product must be received, identified, stored, handled, sampled, reviewed, and approved or rejected as per sections 5.2 and 5.6 above.

(b) Specifications for packaging components must be established 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.

(c) Packaging and labeling operations must establish written procedures describing in sufficient detail the receipt, identification, storage, handling, and approval or rejection of packaging and labeling components.

(d) Labels and other packaging components must be received and stored pending approval as follows:

(1) Upon receipt and before acceptance, each container or grouping of containers of packaging components must be 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; and

(2) The supplier's documentation for each shipment must be examined to ensure the packaging components are consistent with what was ordered.

(3) Each container or grouping of containers for packaging components must be 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, the date received, and the name of the component; and forward to the product batches packaged or labeled using the lot. This code must be used in recording the disposition of each lot.

(4) Labels and other packaging components must be stored under quarantine until they have been examined and approved or rejected by quality control personnel.

(e) Packaging components must be approved or rejected as follows:

(1) Each lot of packaging components must be withheld from use until the lot has been reviewed and released for use by the quality control personnel.

(2) Compliance of the lot with established specifications must be ensured through examination of the components received, and/or review of the supplier's documentation.

(3) Any shipment of a packaging component that meets its specifications may be approved and released for use for use by quality control personnel.

(4) Any packaging component that does not meet its specifications, including any incorrect labels, must be 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. Any such treatment or other deviation must be documented, justified, and approved by quality control personnel.

(f) Use of gang-printed labeling for different products, or different strengths or net contents of the same product, is prohibited unless the labeling from gang-printed sheets is adequately differentiated by size, shape, or color.

Section 6.2 Packaging and/or labeling protocol

(a) Packaging and labeling operations must prepare and follow a written protocol for each unique product to be packaged and/or labeled to assure that correct packaging and labeling components are used for each product packaged or labeled by the operation. Where appropriate, the packaging and/or labeling protocol may be combined with the manufacturing protocol for the product. The protocol must:

(1) Identify the product to be packaged and/or labeled;

(2) Identify each packaging component to be used;

(3) Provide 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);

(4) Provide a statement of the acceptable maximum and minimum percentages of theoretical yield; and

(5) Include written instructions or cross references to standard procedures for the following:

(i) 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;

(ii) Issuance of labels and labeling to a packaging and/or labeling batch;

(iii) 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;

(iv) Each packaging and/or labeling process step;

(v) Monitoring of packaging and/or labeling process steps; and

(vi) Additional applicable procedures to be followed, if any.

(b) Packaging and/or labeling protocols must be

written with the intent to provide not less than 100 percent of the labeled amount of product.

(c) The packaging and/or labeling process described in the protocol must ensure that product specifications are consistently met.

Section 6.3 Packaging and/or labeling batch record

(a) The packaging and/or labeling operation must prepare 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.

(b) The packaging and/or labeling batch record must:

(1) Cross-reference or reproduce the appropriate packaging and/or labeling protocol; and

(2) Form a complete record of the packaging and/or labeling and sampling of the batch.

(c) The packaging and/or labeling batch record must include, as applicable to the process:

(1) Identity of the product;

(2) Batch, lot, or control number of the product;

(3) Packaging and/or labeling batch size;

(4) For each packaging component used in production of the batch:

(i) Identity of each packaging component;

(ii) Batch, lot, or control number of each packaging component used in the batch;

(iii) Quantity of each lot of packaging components used, including the unit of measure.

(5) Date(s) on which, and where applicable the time(s) at which, each step of the packaging and/or labeling protocol was performed;

(6) Identity of packaging lines and major equipment used in packaging and/or labeling the batch;

(7) 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;

(8) 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;

(9) 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 6.2(a)(4) at the end of packaging and/or labeling;

(10) 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.

(11) Label reconciliation, as per section 6.3(f) of this part;

(12) Records of any labeling scrap or cannabis waste generated during packaging and/or labeling of the batch;

(13) Identity of each person performing each process step in packaging and/or labeling of the batch, including but not limited to:

(i) Inspecting labels and other packaging components to ensure suitability and correctness prior to use in the batch;

(ii) Inspecting packaging and labeling areas before and after use;

(iii) Reconciling label issuance and usage and verifying the reconciliation of label issuance and usage;

(iv) Examining packaged and labeled products to ensure proper labeling and coding;

(v) Performing any other checks or verifications in packaging and/or labeling of the batch as needed; and

(vi) Releasing the batch from one stage of packaging and/or labeling to the next.

(d) All data in the packaging and/or labeling batch record must be recorded at the time at which each action is performed.

(e) Printing devices located on, or associated with, production lines must be monitored to assure that

all printing conforms to the requirements of the packaging and/or labeling protocol when used to imprint labeling or coding directly on the following:

(1) Primary packaging for the product; or

(2) Secondary packaging (e.g., a case containing several individual packages of product).

(f) Packaging and labeling operations must reconcile the quantities of labels or labeling issued, used, and returned to storage.

(1) Narrow limits for the labeling reconciliation must be established, based where possible on historical operating data, for the amount of allowed variation in the labeling reconciliation.

(2) When a labeling reconciliation 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.

(3) Labeling reconciliation is waived for cut or roll labels if a 100-percent examination for correct labels is performed, either manually or by appropriate electronic or electromechanical equipment during or after completion of finishing operations.

(4) All excess labeling bearing batch, lot, or control numbers must be destroyed.

(5) Care must be taken when returning labeling to storage, to prevent mixups and ensure proper identification.

(g) Representative and reserve samples of each batch or lot of retail packaged and/or labeled product must be collected as per section 5.6 of this part.

(h) The completed packaging and/or labeling batch record for each batch or lot must 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.

(i) Packaged or labeled product which fails to meet its packaging or labeling specifications or other packaging requirements must be rejected, unless quality control personnel approve repackaging, relabeling, or other deviation that will ensure 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.

Section 6.4 Label content for cannabis and cannabis-derived products

(a) Each packaged and labeled product must bear on the label of its primary packaging:

(1) Name and place of business of the manufacturer or distributor;

(2) Identity of the product;

(3) Net quantity of contents in terms of weight, numerical count, or other appropriate measure;

(4) A batch, lot, or control number;

(5) 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;

(6) Instructions for use, including any types of compliant individuals for whom the product is recommended, as appropriate;

(7) Appropriate warnings for use, including any types of compliant individuals for whom the product is contraindicated, as appropriate;

(8) Instructions for appropriate storage; and

(9) Any other statements or information required by state regulators.

(b) For edible products, each product label must contain a "Product Facts" box listing quantitative content and nutrient information relevant to the product, including, as applicable to the product's content:

(1) Cannabis ingredient;

(2) Cannabinoid and/or terpenoid content;

(3) Total calories and fat calories (when greater than 5 calories per serving);

(4) Total fat, saturated fat, and trans fat (when greater than 0.5 g per serving);

(5) Cholesterol (when greater than 2 mg per serving);

(6) Sodium (when greater than 5 mg per serving);

(7) Total carbohydrates (when greater than 1 g per serving);

(8) Dietary fiber (when greater than 1 g per serv-

ing);

(9) Sugars (when greater than 1 g per serving);

(10) Protein (when greater than 1 g per serving); and

(11) Vitamin A, vitamin C, calcium, and iron (when present at greater than 2% of the recommended daily intake).

SUBPART G – HOLDING CONTROLS

Section 7.1 Identification

(a) Each container of component, packaging component, in-process material, and product must be appropriately identified at all times with the following:

(1) Identity of the item;

(2) Batch, lot, or control number;

(3) Status (e.g., quarantined, approved, recalled, rejected).

(b) Product packages that are held in unlabeled condition for future labeling operations must be identified and handled to preclude 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.

(c) Identification information required in sections 7.1(a) and (b) may be:

(1) Affixed to the individual container or to an appropriate grouping of containers; or

(2) Assigned to the room or other defined physical location of the container(s).

Section 7.2 Storage and handling

(a) Components, packaging components, in-process materials, and products must at all times be handled, stored, and distributed in a manner to avoid deterioration, prevent contamination, and avoid mixups. Where necessary, appropriate conditions of temperature, humidity, and light must be 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.

(b) Containers of components, packaging components, in-process materials, and product must be stored off the floor and suitably spaced to permit cleaning and inspection.

(c) Components, in-process materials, and products that can support the rapid growth of microorganisms of public health significance must be held in a manner that prevents them from becoming adulterated.

(d) Labels, labeling, cannabis, cannabis-derived products, and cannabis waste must be stored in a controlled access area.

(e) Components, packaging components, and products must be 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.

Section 7.3 Withholding materials from use or distribution

(a) Manufacturing, packaging, and labeling operations must establish and implement written procedures for quarantine of 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. This includes:

(1) Newly received components and packaging components for use in manufacturing, packaging and/or labeling;

(2) Batches newly completed in production;

(3) Product returned to the operation for any reason;

(4) Components, packaging components, in-process materials, or products that are or may be contaminated or adulterated; or

(5) Components, packaging components, in-process materials, or products that are under investigation by quality control personnel for any other reason.

(b) 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) must be appropriately segregated, controlled, and held in a controlled access area pending destruction or other disposal.

(c) Cannabis waste other than cannabis and cannabis-derived product that is rejected and

returned to the vendor, and rejected labels and other labeling, must be destroyed in a manner which prevents unauthorized use. Destruction of any cannabis waste must be documented and witnessed by at least two workers, one of whom must be supervisory, managerial, or quality control personnel; except that if video surveillance is used, only one worker is necessary. Destruction may include composting.

SUBPART H – INVENTORY AND RECORDKEEPING

Section 8.1 Materials inventory

(a) Manufacturing, packaging, labeling and holding operations must keep written records for each shipment of component, packaging component, cannabis, and cannabis-derived product received from another company or individual.

(b) Records must be kept of the following:

(1) Identity of the received item, as applicable to the item; and any component number or product number if such are in use by the supplier;

(2) Supplier or vendor from which the shipment was received;

(3) Original cultivation operation, processing operation, or manufacturing operation, if known and where applicable;

(4) The cultivation operation's, processing operation's, manufacturing operation's, or supplier's batch, lot, or control number, if known and where applicable;

(5) Date of receipt; and

(6) Shipment delivery method, including where applicable the name of the commercial or private carrier.

(c) Additionally, manufacturing, packaging, and labeling operations must keep records, or establish cross references to other records such as manufacturing batch records, of the following information:

(1) Batch, lot, or other control number assigned by the manufacturing, packaging, and/or labeling operation to the shipment;

(2) Inspection, sampling, testing, and examinations performed on the batch or lot, and the conclusions derived therefrom, as applicable to the scope of the operation;

(3) Any treatment, reprocessing, or other deviation performed by the operation on the batch or lot prior to use;

(4) Disposition of the batch or lot by quality control personnel, including the date and the signature of the person responsible for approving or rejecting the batch or lot and any treatment, reprocessing, or other deviation performed thereon;

(5) A record of each use of the batch or lot in production, including:

(i) Quantity used, including unit of measure;

(ii) Name and batch, lot, or other control number of the product batch in which the batch or lot is used; and

(iii) Initials of the person(s) responsible for removing from storage the necessary quantity for use in the designated batch.

(6) A record of any portion of the batch or lot returned from production to storage, including:

(i) Quantity returned, including unit of measure;

(ii) Name and batch, lot, or other control number of the batch or lot from which the portion is returned; and

(iii) Initials of the persons responsible for verifying the quantity returned.

(7) 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.

Section 8.2 Distributed materials

(a) Manufacturing, packaging, labeling and holding operations must keep written records for each batch or lot of cannabis or cannabis-derived product distributed by the operation.

(b) Records must be kept of the following:

(1) 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;

(2) A record of each distribution of the batch or lot, including:

(i) Quantity distributed, including unit of measure;

(ii) 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;

(iii) Shipping method by which each shipment is distributed, including where applicable the name of the commercial or private carrier;

(iv) Initials of the persons responsible for removing from storage the necessary quantity for each shipment. Each distribution must be verified by a second person.

(3) A record of any portion of the batch or lot returned to storage, including:

(i) Quantity returned, including the unit of measure;

(ii) Company, non-profit entity, individual, or location from which the portion is returned;

(iii) Shipment return method, including where applicable the name of the commercial or private carrier;

(iv) Initials of the person(s) responsible for verifying the quantity returned;

(4) 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.

(c) Additionally, manufacturing, packaging, and labeling operations must keep records or establish cross references to other records such as manufacturing batch records, for the following:

(1) Batch, lot, or other control number assigned by the manufacturing, packaging, and/or labeling operation to the batch or lot;

(2) Inspection, sampling, testing, and examinations performed on the batch or lot by the operation, and the conclusions derived therefrom;

(3) Any treatment, reprocessing, or other deviation performed on the batch or lot by the operation prior to distribution; and

(4) Disposition of the batch or lot by quality control personnel, including the date and the signature of the person responsible for approving the batch or lot for distribution; and the date and the signature of the person responsible for approving or rejecting any treatment, reprocessing, or other deviation performed thereon.

Section 8.4 Reconciliation

(a) Records of receipt, use or distribution, return, and disposal of each batch or lot of components, packaging components, cannabis or cannabis-derived products must be kept chronologically, and the quantities must be recorded with an appropriate level of precision.

(b) After each batch or lot is used or distributed, manufacturing, packaging, labeling, and holding operations must perform a reconciliation of the quantity received into storage against the quantity used, distributed, returned, and/or disposed. Such calculations must be performed by one person and independently verified by a second person.

(c) Narrow limits must be established, based where possible on historical operating data, for the amount of allowed variation in the reconciliation.

(d) When a reconciliation falls outside the allowed limits, quality control personnel must 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.

Section 8.5 Record retention

(a) Except as required in sections 8.5(b) and (c), manufacturing, packaging, labeling, and holding operations must retain the records required by this part for a period of at 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.

(b) Product complaint records must be 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.

(c) Records for returned products must be 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

Section 9.1 Complaint files

(a) Manufacturing, packaging, labeling, and holding operations must establish written procedures describing the handling of product complaints received regarding a cannabis or cannabis-derived product.

(b) A qualified person must:

(1) 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

(2) 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.

(c) Quality control personnel must 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.

(d) 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, must extend 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.

(e) A written record of the complaint and where applicable its investigation must be kept, including:

(1) Identity of the product;

(2) Batch, lot or other control number of the product;

(3) Date the complaint was received and the name, address, or telephone number of the complainant, if available;

(4) Nature of the complaint including, if known, how the product was used;

(5) Names of personnel who do the following:

(i) Review and approve the decision about whether to investigate a product complaint;

(ii) Investigate the complaint, and

(iii) Review and approve the findings and follow-up action of any investigation performed.

(6) Findings of the investigation and follow-up action taken when an investigation is performed; and

(7) Response to the complainant, if applicable.

(f) Manufacturing, packaging, labeling, and holding operations must establish a procedure 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:

(1) Reporting to any public health authority;

(2) Reporting to the physician of record for the individual reported to have experienced the adverse event, if known; and

(3) Product recall.

Section 9.2 Returned products

(a) Manufacturing, packaging, and/or labeling operations must establish written procedures describing the receipt, handling, and disposition of returned cannabis or cannabis-derived products.

(b) Returned products must be identified as such and be quarantined upon receipt.

(c) Returned product must be reviewed and approved or rejected by quality control personnel.

(d) 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.

(e) If the reason a product is returned implicates

associated batches, an appropriate investigation must be conducted and must extend 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.

(f) Rejected returned product returned to the manufacturing, packaging, labeling, and holding operation must be destroyed as per section 7.3(c).

(g) A written record must be kept of the return, and where applicable its investigation, including:

(1) Identity of the product;

(2) Batch, lot or other control number of the product;

(3) Date the returned product was received;

(4) Name and address from which it was returned, and the means by which it was returned;

(5) Reason for the return;

(6) Results of any tests or examinations conducted on the returned product, or on related batches, if any;

(7) Findings of the investigation and follow-up action taken when an investigation is performed;

(8) Any reprocessing performed on the returned product;

(9) The ultimate disposition of the returned product, and the date of disposition; and

(10) Names of the quality control personnel who do the following:

(i) Review the reason for the product return;

(ii) Review and approve any reprocessing, as applicable, and

(iii) Review and approve the findings and follow-up action of any investigation performed.

Section 9.3 Recall procedures

(a) Manufacturing, packaging, labeling, and holding operations must establish 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. This procedure should include:

(1) Factors which necessitate a recall;

(2) Personnel responsible for a recall; and

(3) Notification protocols.

(b) Manufacturing, packaging, labeling, and holding operations must establish a procedure for communicating a recall of product distributed by the operation. This procedure should include:

(1) A mechanism to contact all customers that have, or could have, obtained the product from the operation;

(2) A mechanism to contact the vendor that supplied the recalled product to the operation, if applicable;

(3) Instructions for the return or destruction of any recalled product by customers;

(4) Instructions for contacting the relevant manufacturing, packaging, labeling, and/or holding operations; and

(5) Communication and outreach via media, as necessary and appropriate.

Cannabis Laboratory Operations

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SUBPART A – GENERAL PROVISIONS

Section 1.1 Subject operations

(a) Except as provided in paragraph (b) of this section, any person, group of persons, non-profit entity, or business entity that conducts analytical testing of cannabis, cannabis-derived products, hemp, or hemp-derived products in the jurisdiction in which this part applies is a laboratory operation and is subject to this part.

(b) A cannabis cultivation, manufacturing, or dispensing operation which performs analytical testing solely as a function of its internal operations is not subject to this part.

Section 1.2 Other statutory provisions and regulations

In addition to this part, laboratory operations must comply 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.

Section 1.3 Definitions

The following definitions apply to this part:

Cannabis means any of the aerial parts of a plant in the genus Cannabis, and does not mean hemp.

Cannabis-derived product means a product, other than cannabis itself, which contains or is derived from cannabis, and does not mean a product that contains or is derived from hemp.

Cannabis waste means cannabis or cannabis-derived product discarded by a laboratory operation.

Compliant business means a business that has met all legal requirements to obtain, possess, manufacture, distribute, or sell cannabis and cannabis-derived products in the jurisdiction where this part applies.

Compliant individual means an individual who has met all legal requirements to obtain and use cannabis or cannabis-derived product in the jurisdiction where this part applies.

Controlled access area means an area in a laboratory facility designed to physically prevent entry by anyone except authorized personnel.

Controlled substance means a drug or other substance, or immediate precursor, included in schedule I, II, III, IV, or V of part B of 21 U.S.C. 802. It does not include distilled spirits, wine, malt beverages, or tobacco, as those terms are defined or used in subtitle E of the Internal Revenue Code of 1986.

Hemp means any part of a plant in the genus Cannabis, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 (three-tenths) percent on a dry weight basis.

Hemp-derived product means a product, other than hemp itself, which contains or is derived from hemp.

Identity means the set of characteristics by which an ingredient or product is definitively recognizable or known. In the case of cannabis and hemp, identity means the plant part and the botanical genus, species, variety, strain, and/or cultivar, as well as any other applicable characteristics and as stated on the label or other labeling. In the case of cannabis-derived products or hemp-derived products, identity means the product name, strength, key features of its form or composition, grade, and/or other characteristics as applicable.

Laboratory facility means the physical location(s) of a laboratory operation.

Laboratory operation means a person, group of persons, non-profit entity, or business entity that conducts analytical testing of cannabis, cannabis-derived products, hemp, or hemp-derived products.

Macroscopic examination means using the naked eye or minor magnification (e.g., with a 10x magnifying glass) to observe and/or measure a sample or object.

May is used to indicate an action or activity that is permitted.

Microscopic examination means using a microscope to view samples and objects that cannot be seen with the unaided eye (objects that are not within the resolution range of the normal eye).

Must is used to state a requirement.

Organoleptic examination means testing by using sense organs to evaluate flavor, aroma, appearance, or texture.

Primary reference standard means a reference standard whose purity is determined with a high degree of confidence through comprehensive analysis using multiple test methods based on differing principles, such as HPLC or GC, MS, NMR, Karl-Fisher, etc.

Purity means the relative freedom from extraneous matter, contaminants, or impurities, whether or not harmful to the consumer or deleterious to the product.

Secondary reference standard means a reference standard whose purity is established by assaying it against a primary standard.

Should is used to state recommended or advisory procedures.

Strength means the potency of cannabis or a cannabis-derived product, whether expressed as (a) the amount or percent of specific chemical constituents or groups of chemical constituents; (b) the concentration or amount of cannabis present in a cannabis-derived product; or (c), in the case of cannabis extracts, the ratio of the input quantity of crude cannabis, on a dry weight basis, to the output quantity of finished extract.

Test sample means the specific portion of cannabis, cannabis-derived product, hemp, or hemp-derived product submitted for analysis.

Volumetric solution means a solution used for volumetric analysis, such as titration, wherein the content of analyte is determined by reacting the analyte with a known quantity of standardized reagent.

SUBPART B – LABORATORY FUNCTIONS

Section 2 Scope of laboratory functions

(a) Laboratory operations may conduct any analytical testing of cannabis, cannabis-derived products, hemp, or hemp-derived products.

(b) Analytical testing of cannabis or hemp may include, among other things, analysis for:

(1) Identity;

(2) Purity, such as analysis of:

(i) Heavy metals;

(ii) Microbiological organisms (e.g., total plate count; pathogens; yeasts; molds; etc.) or microbial toxins;

(iii) Residues of pesticide or plant growth regulators;

(iv) Residual solvents;

(v) Foreign matter.

(3) Strength, such as analysis of:

(i) Cannabinoid content;

(ii) Terpenoid content.

(4) Other quality factors, such as weight loss on drying, oil content, ash, acid-insoluble ash, etc.

(c) Analytical testing of cannabis-derived products may include, among other things:

(1) Any of the analyses identified in paragraph (b) of this section that are relevant to such product;

(2) Determination of any factor of a product's composition or nutritional content.

(d) Laboratory operations may utilize any appropriate tests and examinations in its analyses, including:

(1) Gross organoleptic analysis;

(2) Macroscopic analysis;

(3) Microscopic analysis;

(4) Chemical analysis;

(5) Genetic (DNA) analysis; or

(6) Other scientifically valid methods.

SUBPART C – PERSONNEL

Section 3 Personnel training

(a) Each person engaged in a laboratory operation must:

(1) Have education, training, and experience, or any combination thereof, to enable that person to perform all assigned functions.

(2) Have records of any training received for the performance of all assigned functions.

(b) Laboratory operations should provide all employees with training that includes:

(1) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and

(2) Information on U.S. federal laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such employees.

SUBPART D – FACILITIES

Section 4.1 Physical facilities

(a) Laboratory operations must:

(1) Be operated in adherence with any regulation in the jurisdiction in which this part applies that is relevant to its specific operations, including:

(i) Locations and zoning;

(ii) Business hours;

(iii) Parking;

(iv) Drive-through services; and

(v) Signage.

(2) Be maintained in a clean and orderly condition;

(3) Be equipped with such utensils and equipment as are necessary to conduct all operations that occur at the laboratory facility; and

(4) Provide adequate space for laboratory operations, sample storage, and document storage.

Section 4.2 Security

(a) Laboratory operations must establish and adhere to such security procedures as are provided by applicable regulation in the jurisdiction in which this part applies.

(b) Laboratory operations should:

(1) Provide additional security as needed to protect the employees during working hours and in a manner appropriate for the community where it operates; and

(2) Provide training to make all employees aware of the operation's security procedures, and each individual employee's security roles and responsibilities.

(c) Laboratory operations analyzing cannabis, cannabis-derived product, hemp, or hemp-derived product samples must be equipped with one or more controlled access areas for storage of the following:

(1) Cannabis and cannabis-derived test samples;

(2) Cannabis waste;

(3) Reference standards for analysis of cannabinoids; and

(4) Any other controlled substances.

(d) Access to controlled access areas must be limited by locks, electronic badge readers, biometric identifiers, or other means.

(e) Appropriate steps must be 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.

(f) There must be written procedures for security.

SUBPART E – SAMPLE RECEIPT, HANDLING, AND DISPOSITION

Section 5.1 Sample receipt

(a) Laboratory operations may receive test samples from any compliant business or compliant individual, or may be contracted to collect test samples on behalf of those entities.

(b) Laboratory operations should establish and implement policies for:

(1) Collecting test samples in a manner that ensures that the test sample accurately represents the material being sampled; and

(2) Other parameters affecting sample preparation, documentation, and transport, including, if applicable:

(i) Accepted test sample types;

(ii) Minimum test sample size;

(iii) Recommended test sample container;

(iv) Test sample labeling;

(v) Transport and storage conditions, such as refrigeration if required;

(vi) Other requirements, such as use of preservatives, inert gas, or other measures designed to protect sample integrity; and

(vii) Use of sample chain of custody forms.

(c) Laboratory operations must:

(1) Record each receipt of a test sample. This record must include:

(i) The name and contact information of any compliant business or compliant individual that was the source of the sample;

(ii) An appropriately complete and specific description of the sample;

(iii) The date of receipt of the sample;

(iv) A statement of the quantity (weight, volume, number, or other amount) of the sample; and

(v) A unique sample identifier for the sample.

(2) Inform each compliant business and compliant individual that submits test samples of the policies established in paragraph (b) of this section.

Section 5.2 Sample handling and disposal

(a) Laboratory operations must establish sample handling procedures for the tracking of test samples through the analytical process (by weight, volume, number, or other appropriate measure) to prevent any diversion.

(b) Laboratory operations must store each test sample under the appropriate conditions to protect the physical and chemical integrity of the sample.

(c) Analyzed test samples consisting of cannabis or cannabis-derived product must be appropriately segregated, controlled, and held in a controlled access area pending destruction or other disposal.

(d) Any portion of a cannabis or cannabis-derived test sample that is not destroyed during analysis must be:

(1) Returned to the same compliant individual or compliant business that provided the sample;

(2) Stored and retained in conformity with a laboratory operation's sample retention policy, if any; or

(3) Destroyed in a manner which prevents unauthorized use. Such destruction must be documented and witnessed by at least two employees, one of whom must be supervisory, managerial, or quality control personnel; except that if video surveillance is used, only one employee is required.

(e) Any portion of a hemp or hemp-derived product test sample that is not destroyed during analysis may be:

(1) Returned to the same compliant individual or compliant business that provided the sample;

(2) Stored and retained in conformity with a laboratory operation's sample retention policy, if any; or

(3) Disposed of in any appropriate manner.

SUBPART F – EQUIPMENT AND REAGENTS

Section 6.1 Equipment

(a) Equipment used for the analysis of test samples must be adequately inspected, cleaned, and maintained. Equipment used for the generation or measurement of data must be adequately tested and calibrated on an appropriate schedule, as applicable.

(b) Laboratory operations must document procedures setting forth in sufficient detail the methods and schedules to be used in the routine inspection, cleaning, maintenance, testing, and calibration of equipment, and must specify, when appropriate, remedial action to be taken in the event of failure or malfunction of equipment. The procedures must designate the personnel responsible for the performance of each operation.

(c) Records must be maintained of all inspection, maintenance, testing, and calibrating operations. These records must include the date of the operation, the person who performed it, the written procedure used, and any deviations from the written procedure. Records must be kept of non-routine repairs performed on equipment as a result of failure and malfunction. Such records must document the nature of the repair, how and when the need for the repair was discovered, and any remedial action taken in response to the repair.

(d) Computer systems used for the analysis of samples, retention of data, sample tracking, calibration scheduling, management of reference standards, or other critical laboratory management functions should ensure that electronic records, electronic signatures, and handwritten signatures executed to electronic records are trustworthy, reliable, and generally equivalent to paper records and handwritten signatures executed on paper.

Section 6.2 Reagents, solutions, and reference standards

(a) Analytical reagents, solutions, and reference standards must be:

(1) Labeled to indicate identity, date received or prepared, and expiration or requalification date, and, where applicable, concentration or purity, storage requirements, and date opened.

(2) Stored under appropriate conditions to minimize degradation or deterioration of the material.

(3) Be within their expiration or requalification dates at the time of use.

(b) Deteriorated or outdated reagents and solutions must be properly discarded.

(c) Laboratory operations may acquire commercial reference standards for cannabinoids including, but not limited to:

(1) Tetrahydrocannabinolic acid (THC-acid);

(2) Delta-9 tetrahydrocannabinol (Δ9 THC);

(3) Cannabidiolic acid (CBD-acid);

(4) Cannabidiol (CBD);

(5) Cannabichromene (CBC);

(6) Cannabigerol (CBG);

(7) Cannabinol (CBN); and

(8) Delta-8 tetrahydrocannabinol (Δ8 THC).

(d) Laboratory operations may elect to internally produce reference standards. When internally produced, laboratory operations should utilize standard analytical techniques to document the purity and concentration of the internally produced reference standards.

(e) Laboratory operations must obtain or, for internally-produced standards, create a certificate of analysis (COA) for each lot of reference standard. Each COA must be kept on file and the lot number of the reference standard used should be recorded in the documentation for each analysis, where applicable.

SUBPART G – ANALYSIS OF SAMPLES

Section 7.1 Analytical procedures

(a) Laboratory operations must:

(1) Utilize analytical methods that are fit for purpose in their testing of cannabis, cannabis-derived products, hemp, and hemp-derived products.

(2) Require analysts to demonstrate proficiency in the performance of the analytical methods used.

(3) Have written procedures for the analytical method used for the analysis of each test

sample, including for each of the following:

(i) Sample preparation;

(ii) Reagent, solution, and reference standard preparation;

(iii) Instrument setup, where applicable;

(iv) Standardization of volumetric reagent solutions, as applicable;

(v) Data acquisition; and

(vi) Calculation of results.

(4) Specify, as applicable to each analytical method used, requirements for accuracy, precision, linearity, specificity, limit of detection, limit of quantitation, and other data quality parameters.

(5) Ensure that no deviations from approved protocols or standard operating procedures are made during any analytical process without proper authorization and documentation.

(b) Laboratory operations should use only primary standards or secondary standards for quantitative analyses.

Section 7.2 Recording of analytical data

(a) All data generated during the testing of a test sample, except those that are generated by automated data collection systems, must be recorded directly, promptly, and legibly in ink. All data must be annotated with the date of entry and signed or initialed by the person recording the data. Any change in entries must be made so as not to obscure the original entry, must indicate the reason for such change, and must be dated and signed or initialed at the time of the change.

(b) In automated data collection systems, the individual responsible for direct data input must be identified at the time of data input. Any change in automated data entries must be made so as not to void or delete the original entry, must indicate the reason for change, must be dated, and the responsible individual must be identified.

Section 7.3 Data review

For each final result reported, laboratory operations must verify that:

(1) Any calculations or other data processing steps were performed correctly;

(2) The data meet any data quality requirements such as for accuracy, precision, linearity, etc.;

(3) Any reference standards used were of the appropriate purity and within their expiration or requalification dates;

(4) Any volumetric solutions were properly standardized before use;

(5) Any test or measuring equipment used has been properly tested, verified, and/or calibrated and is within its verification or calibration period.

Section 7.4 Data storage

(a) All raw data, documentation, protocols, and final reports associated with analysis of a test sample must be retained for two years from the date of the completion of analysis.

(b) Laboratory operations must maintain the records identified in paragraph (a) of this section, either on the laboratory operation's premises or remotely. Such records must be maintained:

(1) In a manner that allows retrieval as needed;

(2) Under conditions of storage that minimize deterioration throughout the retention period; and

(3) In a manner that prevents unauthorized alteration.

(c) Laboratory operation must designate an individual as responsible for records maintenance.

(d) Only authorized personnel may enter or access the maintained records.

Section 7.5 Data reporting

(a) All analytical results related to any test sample are the property of the compliant business or compliant individual which provided the sample, unless contracts or other written agreements specify otherwise.

(b) A laboratory report given to a compliant business or compliant individual must contain the following information:

(1) Date of receipt of the test sample;

(2) Description of the type or form of the test sample (leaf, flower, powder, oil, specific edible product, etc.);

(3) The unique sample identifier as established in accordance with subparagraph 5.1 (b)(1)(v) of this part;

(4) 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;

(5) Date on which analysis occurred;

(6) The analytical method used, including at a minimum identification of the type of analytical equipment used (e.g., GC, HPLC, UV, etc.);

(7) The analytical results, including units of measure where applicable;

(8) 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;

(9) The name, address, and contact information of the laboratory operation.

(c) If a laboratory operation reports cannabinoid values other than those directly measured in the test sample, the laboratory report must include the following:

(1) All calculations or conversion factors used to determine the reported non-measured results; and

(2) Written explanation of any assumptions, if any, associated with the reported non-measured results, such as the route of consumption of the product represented by the test sample.

(d) The laboratory report must state that reported analytical results apply only to the test sample received.

Cannabis Dispensing Operations

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SUBPART A – GENERAL PROVISIONS

Section 1.1 Subject operations

(a) 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 , .

(b) A compliant individual that 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.

(c) 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.

(d) 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.

(e) Each operation subject to this part is responsible to comply with only those sections that apply to the activities conducted by that operation.

Section 1.2 Other statutory provisions and regulations

In addition to this part, manufacturing, packaging, labeling and holding operations must comply 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.

Section 1.3 Definitions

The following definitions apply to this part:

Actual yield means the quantity that is actually produced at any appropriate step of manufacture or packaging of a particular cannabis-derived product.

Adulteration means that a cannabis-derived product (1) consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) bears or contains any poisonous or deleterious substance which may render it injurious to health; except that (A) such product shall not be considered adulterated if the quantity of such substance does not ordinarily render it injurious to health and (B) the cannabis content of the product shall not be considered injurious to health; (3)(A) has been manufactured, packaged, labeled, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (B) has been manufactured, packaged, labeled, or held by methods, in facilities, or using controls that do not conform to or are not operated or administered in conformity with this part to assure that the cannabis-derived product meets appropriate requirements as to safety; or (4) fails to meet appropriate requirements as to safety; or (5) is in a container composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (6) bears or contains, for purposes of coloring, a color additive which is not approved in the United States for use in a comparable food product; or (7) (A) has been mixed or packaged with any substance so as to reduce its quality or strength or (B) has been substituted wholly or in part with any substance.

Batch means, with regard to cannabis, a specific quantity of cannabis harvested during a specified time period from a specified cultivation area; and means, with regard to cannabis-derived product, a specific quantity that is uniform, that is intended to meet specifications for identity, strength, purity and composition, and that is manufactured, packaged and/or labeled during a specified time period according to a single manufacturing, packaging, and/or labeling batch record.

Batch number, lot number, or control number means any distinctive group of letters, numbers, or symbols, or any combination of them, from which the complete history of the manufacturing, packaging, labeling, or holding of a batch or lot of cannabis or cannabis-derived products can be determined.

Cannabis means any of the aerial parts of a plant in the genus Cannabis, and does not mean hemp.

Cannabis-derived product means a product, other than cannabis itself, which contains or is derived from cannabis by manufacturing as defined herein, and does not mean a product that contains or is derived from hemp.

Cannabis waste means cannabis or cannabis-derived product discarded by a manufacturing, packaging, labeling, or holding operation.

Compliant individual means an individual who has met all legal requirements to obtain and use cannabis or cannabis-derived product in the jurisdiction where this part applies.

Composition means the aggregate mixture which

results from the manufacture of a cannabis-derived product according to the formula and process defined in the product's manufacturing protocol.

Component means any substance or item intended for use in the manufacture of a cannabis-derived product, including those that do not appear in the batch of the cannabis-derived product. Component includes cannabis, cannabis-derived products used as ingredients, other ingredients, and processing aids.

Contact surface means any surface that directly contacts cannabis, components, or cannabis-derived product, and any surface from which drainage onto cannabis, components, or cannabis-derived product, or onto surfaces that contact cannabis, components, or cannabis-derived product, may occur during the normal course of operations.

Controlled access area means an area in the physical plant designed to prevent entry by anyone except authorized personnel.

Cultivate means to grow, harvest, dry, and cure cannabis. A person, group of persons, non-profit entity, or business entity that cultivates is a cultivator, and a facility where cannabis plants are cultivated is a cultivation operation.

Dispense means to provide cannabis or cannabis-derived product to compliant individuals.

Dispensing operation means a person, group of persons, non-profit entity, or business entity that provides cannabis or cannabis-derived product to compliant individuals and includes delivery services, direct-from-garden operations, growing co-ops, and storefront operations.

Disposition means review and approval or rejection of a batch, lot, or other item by quality control personnel.

Gang-printed label means a label for one product that is printed simultaneously on the same sheet of paper as labels for other products.

Hemp means any part of a plant in the genus Cannabis, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 (three-tenths) percent on a dry weight basis.

Hold means to store or warehouse cannabis or cannabis-derived product in any context by an operation that is subject to this rule. A person, group of persons, non-profit entity, or business entity that holds is a holder, and a facility where holding occurs is a holding operation.

Identity means the set of characteristics by which an ingredient or product is definitively recognizable or known. In the case of cannabis and other botanical ingredients, identity means the plant part and the botanical genus, species, variety, strain, and/or cultivar, as well as any other applicable characteristics as stated on the label or other labeling. In the case of cannabis-derived products, identity means the product name, strength, key features of its form or composition, grade, and/or other characteristics as applicable.

Ingredient means any substance that is used in the manufacture of a cannabis-derived product and that is intended to be present in the batch of the cannabis-derived product.

In-process material means any material that is compounded, blended, ground, extracted, sifted, sterilized, or prepared in any other way by the operation for use in its manufacturing, packaging, or labeling of cannabis or a cannabis-derived product.

Label (verb) means to affix labeling on packaged cannabis or cannabis-derived product. A person, group of persons, non-profit entity, or business entity that labels is a labeler, and a facility where labeling occurs is a labeling operation.

Labeling (noun) means all labels and other written, printed or graphic matter on or accompanying any article or any of its containers or wrappers.

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

Manufacture means to compound, blend, grind, extract, or otherwise make or prepare cannabis-derived product; the term does not apply to cannabis. A person, group of persons, non-profit entity, or business entity that manufactures is a manufacturer, and a facility where manufacture occurs is a manufacturing operation.

May is used to indicate an action or activity that is permitted; may not is used to indicate an action or activity that is not permitted.

Microorganism means yeasts, molds, bacteria, viruses, and other similar microscopic organisms having public health or sanitary concern. This definition includes species that may cause a component or cannabis or cannabis-derived product to decompose; may indicate that the component or cannabis or cannabis-derived product is contaminated with filth;

or otherwise may cause the component, cannabis or cannabis-derived product to be adulterated.

Must is used to state a requirement.

Package (verb) means to place cannabis or cannabis-derived product into primary packaging for bulk or retail distribution when performed by an operation subject to this part. A person, group of persons, non-profit entity, or business entity that packages is a packager, and a facility where packaging occurs is a packaging operation.

Pack (verb) means to place cannabis or cannabis-derived product into containers for distribution, other than to package the cannabis or cannabis-derived product; and includes the placement of cannabis into any type of container by cultivation operations, processing operations, and dispensing operations, as well as the placement of filled primary packaging containers into other containers such as for storage or transport.

Packaging component means any item intended for use in the primary packaging or labeling of cannabis-derived products.

Personnel means any worker engaged in the performance of operations subject to this rule and includes full and part-time employees, temporary employees, contractors, and volunteers.

Pest means any objectionable insect or other animal at any life stage.

Physical plant means all or any part of a building or facility used for or in functional connection with manufacturing, packaging, labeling, or holding a cannabis-derived product.

Primary packaging means items used in packaging that serve to directly contain, contact, and/or label the product.

Process (verb) means to trim, inspect, grade, or pack cannabis. A person, group of persons, non-profit entity, or business entity that processes is a processor, and a facility where cannabis is processed is a processing operation.

Product complaint means any communication that contains any allegation, written, electronic, or oral, expressing concern, for any reason, with the quality of a product that could be related to its manufacture, packaging, or labeling.

Production means manufacturing, packaging, and/or labeling, as applicable to the firm's operations.

Purity means the relative freedom from extraneous matter, contaminants, or impurities, whether or not harmful to the consumer or deleterious to the product.

Quality means that the product consistently meets the established specifications for identity, purity, strength, composition, packaging, and labeling, and has been manufactured, packaged, labeled, and held under conditions to prevent adulteration.

Quality control means a planned and systematic operation or procedure for ensuring the quality of a product.

Quality control personnel means any person, persons, or group, within or outside of a manufacturing, packaging, labeling or holding operation, which is designated to be responsible for the operation's quality control operations.

Quarantine means to segregate and withhold from use lots, batches, or other portions of components, packaging components, in-process materials, cannabis, or products whose suitability for use must be determined by quality control personnel.

Representative sample means a sample that consists of an adequate quantity of material or number of units that is collected in a manner intended to ensure that the sample accurately portrays the material being sampled.

Reprocessing means the performance of a treatment, adjustment, repackaging, relabeling, or other deviation from standard procedures or from the applicable manufacturing protocol, in order to render a nonconforming material suitable for use.

Reserve sample means a representative sample of component, packaging component, or product that is held for a designated period of time.

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

Should is used to state recommended or advisory procedures.

Strength means the potency of cannabis or a cannabis-derived product, whether expressed as (a) the amount or percent of specific chemical constituents or groups of chemical constituents; (b) the concentration or amount of cannabis present in a cannabis-derived product; or (c), in the case of cannabis extracts, the ratio of the input quantity of crude cannabis, on a dry weight basis, to the output quantity of finished extract.

Theoretical yield means the quantity that would be

produced at any appropriate step of manufacture or packaging of a particular cannabis-derived product, based upon the quantity of components or packaging to be used, in the absence of any loss or error in actual production.

Water activity (aw) is a measure of the free moisture in a component or product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

Vendor means a person, group of persons, non-profit entity, or business entity that supplies cannabis or cannabis-derived product to manufacturing, packaging, labeling or holding operations, and may be either the direct representative of a cultivation, processing, or manufacturing operation, or may function independently of such operations by purchasing cannabis or cannabis-derived product from such operations and reselling it to other operations.

SUBPART B – GENERAL REQUIREMENTS

Section 2.1 Acquisition of cannabis and cannabis-derived products

Manufacturing, packaging, labeling, and holding operations may obtain cannabis or cannabis-derived product from any of the following as allowed by applicable legislation and regulation:

(1) Cultivation operations;

(2) Processing operations;

(3) Vendors;

(4) Other manufacturing, packaging, labeling or holding operations; and

(5) Any other legal entity as allowed in this jurisdiction.

Section 2.2 Distribution of cannabis and cannabis-derived products

(a) Manufacturing, packaging, labeling and holding operations may distribute cannabis and cannabis-derived products to any of the following as allowed by applicable legislation and regulation:

(1) Dispensing operations;

(2) Other manufacturing, packaging, labeling or holding operations subject to this section;

(3) Vendors; and

(4) Any other legal entity as allowed in this jurisdiction.

(b) Manufacturing, packaging, labeling and holding operations that transport cannabis or cannabis-derived products must do so in a secured enclosed container and/or secured cargo area of the delivery vehicle.

Section 2.3 Ancillary operations

In addition to the manufacturing of cannabis-derived product and the packaging, labeling or holding of cannabis or cannabis-derived product, an operation described in section 1.1 may also engage in other operations, so long as such operations are permitted at this location in the jurisdiction in which this part applies.

SUBPART C – PERSONNEL

Section 3.1 Personnel training

(a) Manufacturing, packaging, labeling and holding operations must:

(1) Ensure that each person engaged in the operation has the education, training, and experience, or any combination thereof, to enable that person to perform all assigned functions;

(2) Provide personnel with training in the applicable requirements of this part; and

(3) Maintain records of any training provided to personnel for the performance of all assigned functions.

(b) Personnel training should include:

(1) Instructions regarding regulatory inspection preparedness and law-enforcement interactions; and

(2) Information on U.S. federal, state and local laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such personnel.

Section 3.2 Personnel responsibilities

(a) Measures must be taken to exclude from any operation any person that might be a source of microbial contamination due to a health condition through contact with any material, including components, packaging components, in-process materials, cannabis, cannabis-derived products, and contact

surfaces used in manufacturing, packaging, labeling, and holding operations. Such measures include the following:

(1) Excluding from working in any operations that may result in contamination any person 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 microbial contamination, that could result in microbial contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces, until the health condition no longer exists; and

(2) 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 paragraph (a)(1) of this section that could result in microbial contamination of any components, packaging components, in-process materials, cannabis, cannabis-derived products, or any contact surface.

(b) Personnel working in an operation during which adulteration of components, packaging components, cannabis, cannabis-derived products, or contact surfaces could occur must use hygienic practices to the extent necessary to protect against such contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces. These hygienic practices include the following:

(1) Wearing 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;

(2) Maintaining adequate personal cleanliness;

(3) Washing hands thoroughly with soap (and sanitizing if necessary to protect against contamination with microorganisms):

(i) Before starting work;

(ii) After using the restroom; and

(iii) At any other time when the hands may have become soiled or contaminated;

(4) Removing all unsecured jewelry and other objects that might fall into components, packaging components, cannabis, cannabis-derived products, equipment, or packaging, and removing 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 contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces;

(5) Maintaining gloves used in handling components, packaging components, in-process materials, cannabis, or cannabis-derived products in an intact, clean, and sanitary condition. The gloves should be of an impermeable material;

(6) Wearing, where appropriate, in an effective manner, hair nets, caps, beard covers, or other effective hair restraints;

(7) Not storing clothing or other personal belongings in areas where components, packaging components, in-process materials, cannabis, cannabis-derived products, or any contact surfaces are exposed or where contact surfaces are washed;

(8) Not eating food, chewing gum, drinking beverages, or using tobacco products in areas where components, packaging components, in-process materials, cannabis, cannabis-derived products, or any contact surfaces are exposed, or where contact surfaces are washed;

(9) Taking any other precautions necessary to protect against the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces with microorganisms, filth, or any other extraneous materials, including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin;

(10) Taking all precautions 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; and

(11) Entering controlled access areas only as authorized by supervisory personnel.

Section 3.3 Personnel safety

(a) Policies must be implemented to protect person-

nel in all operations and provide personnel with adequate safety training to comply with these policies. Such policies should be similar to personnel safety policies in comparable industries, such as food processors, and may include, for example:

(1) Personnel accident reporting and investigation policies;

(2) Fire prevention and response plans;

(3) Materials handling and hazard communications policies, including maintenance of material safety data sheets (MSDS); and

(4) Personal protective equipment policies.

(b) An emergency contact list must be visibly posted and maintained 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.

(c) Compliance must also be ensured with all other applicable standards of the federal Occupational Health and Safety Administration and any applicable state or local worker safety requirements.

Section 3.4 Supervisor requirements

(a) Qualified personnel should be assigned to supervise the manufacturing, packaging, labeling, or holding of cannabis and cannabis-derived products.

(b) Each person responsible for supervising the manufacture, packaging, labeling, or holding of a cannabis or cannabis-derived product must have the 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 product has the identity, purity, strength, and composition that it purports or is represented to possess.

(c) One or more qualified personnel should be assigned to supervise overall sanitation. Each of these supervisors must be qualified by education, training, or experience to develop and supervise sanitation procedures.

SUBPART D – PHYSICAL PLANT AND GROUNDS

Section 4.1 Design and construction

(a) The physical plant used in the manufacture, packaging, labeling, or holding of cannabis and cannabis-derived products must be suitable in size, construction, and design to facilitate maintenance, cleaning and/or sanitizing, as applicable to the operation.

(b) Any such physical plant must have adequate space for the orderly placement of equipment and materials to prevent mixups of components, packaging components, in-process materials, cannabis, or cannabis-derived products during manufacturing, packaging, labeling, or holding.

(c) Any such physical plant must be designed to reduce the potential for contamination of components, packaging components, cannabis, cannabis-derived products, or contact surfaces, with microorganisms, chemicals, filth, or other extraneous material. The design and construction must include:

(1) Floors, walls, and ceilings that can be adequately cleaned and kept clean and in good repair;

(2) Fixtures, ducts, and pipes that do not contaminate components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces by dripping or other leakage, or condensate;

(3) 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.

(4) Safety-type light bulbs, fixtures, skylights, or other glass or glass-like materials must be used when the light bulbs, fixtures, skylights or other glass or glass-like materials are suspended over exposed components, packaging components, in-process materials, or cannabis or cannabis-derived products, unless 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 glass or glass-like materials.

(d) Any such physical plant must have separate or defined areas, or other control systems such as computerized inventory controls or automated systems

of separation, to prevent cross-contamination and mixups of components, cannabis, or cannabis-derived products during any of following operations that 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 products pending disposition by quality control personnel;

(2) Storage of approved components, packaging components, cannabis, or cannabis-derived products;

(3) Storage of rejected components, packaging components, in-process materials, cannabis, 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.

(e) Water must be provided that is:

(1) 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; and

(2) Compliant with applicable state and local potable 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.

(f) Heating, ventilating, cooling, and air filtration must be installed and maintained in the physical plant as needed to ensure the quality of the product.

(1) Ventilation equipment such as filters, fans, exhausts, dust collection, and other air-blowing equipment must be provided in areas where odors, dust, and vapors (including steam and noxious fumes) may contaminate components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces.

(2) When fans, compressed air, or other air-blowing equipment are used, such equipment must be 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.

(3) Equipment that controls temperature, humidity, and/or microorganisms must be provided, when such equipment is necessary to ensure the quality of the product.

(g) The plumbing in the physical plant must be of an adequate size and design and be adequately installed and maintained to:

(1) Carry sufficient amounts of water to required locations throughout the physical plant;

(2) Properly convey sewage and liquid disposable waste from the physical plant;

(3) 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;

(4) 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; and

(5) Not 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.

(h) Personnel must be provided with adequate, readily accessible toilet facilities that are:

(1) Maintained in a clean and sanitary condition;

(2) Adequately stocked with toilet paper, soap, and single use paper towels or other drying devices;

(3) Kept in good repair at all times;

(4) Equipped with signage advising personnel of the necessity of washing hands prior to returning to work;

(5) Prohibited from being used for activities that support production operations, such as cleaning of production equipment or utensils.

(i) Airborne contamination from toilet facilities must be prevented from contacting components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces, 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.

(j) Adequate and convenient hand-washing facilities must be provided that are:

(1) Provided with running water of suitable temperature;

(2) Provided with effective hand cleaning and/or sanitizing preparations and single use paper towels or other drying devices;

(3) Located at points in the facility where good sanitary practices require personnel to wash their hands;

(4) Prohibited from being used for activities that support production operations, such as cleaning of production equipment or utensils.

(k) Adequate lighting must be provided in:

(1) All areas where components, packaging components, in-process materials, cannabis, or cannabis-derived products are examined, manufactured, packaged, labeled, or held;

(2) All areas where contact surfaces are cleaned; and

(3) Hand-washing areas, dressing and locker rooms, and toilet facilities.

Section 4.2 Sanitation requirements

(a) The grounds of the physical plant must be kept in a condition that protects against the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces. The methods for adequate ground maintenance include:

(1) 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;

(2) Maintaining roads, yards, and parking lots 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;

(3) Adequately draining areas that may contribute to the contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces by seepage, filth or any other extraneous materials, or by providing a breeding place for pests;

(4) 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 or cannabis-derived products, or contact surfaces are exposed; and

(5) If the plant grounds are bordered by grounds not under the operation's control, and if those other grounds are not maintained in the manner described in this section, care should be 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.

(b) The physical plant must be maintained in a clean and sanitary condition and must be maintained in repair sufficient to prevent components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces from becoming contaminated.

(c) Cleaning compounds, sanitizing agents, pesticides, and other toxic materials must be appropriately stored, handled, and controlled.

(1) Cleaning compounds and sanitizing agents must be free from microorganisms of public health significance and be safe and adequate under the conditions of use.

(2) Toxic materials must not be 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 as fol-

lows:

(i) To maintain clean and sanitary conditions;

(ii) For use in laboratory testing procedures, where applicable;

(iii) For maintaining or operating the physical plant or equipment; or

(iv) For use in the plant's operations.

(3) Cleaning compounds, sanitizing agents, pesticides, pesticide chemicals, and other toxic materials must be 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.

(d) Adequate pest control must be provided.

(1) Animals or pests must not be allowed in any area of the physical plant, except that guard or guide dogs may be allowed in some areas of the physical plant if the presence of the dogs will not result in contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, or contact surfaces;

(2) Effective measures must be 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; and

(3) Insecticides, fungicides, or rodenticides must not be used in or around the physical plant, unless they are registered with 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.

(e) Trash must be regularly conveyed, stored, and disposed in order to:

(1) Minimize the development of odors;

(2) Minimize the potential for the trash to attract, harbor, or become a breeding place for pests;

(3) Protect against contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, any contact surface, water supplies, and grounds surrounding the physical plant; and

(4) Control hazardous waste to prevent contamination of components, packaging components, in-process materials, cannabis or cannabis-derived products, and contact surfaces.

(f) Manufacturing, packaging, labeling, or holding operations must have and follow written procedures for sanitation that address the following:

(1) Responsibility for sanitation;

(2) Detailed description of the cleaning schedules, methods, equipment, and materials to be used in cleaning the grounds and buildings; and

(3) Records of cleaning and sanitation that must be kept.

(g) Manufacturing, packaging, labeling, and holding operations must have and follow written procedures for use of rodenticides, insecticides, fungicides, fumigating agents, and cleaning and sanitizing agents that address the following:

(1) Prevention of the contamination of components, packaging components, in process materials, cannabis, cannabis-derived products, or contact surfaces; and

(2) Records of the use of rodenticides, insecticides, fungicides, fumigating agents, and cleaning or sanitizing agents must be kept.

(h) Sanitation procedures must apply to work performed by all personnel during the ordinary course of operations.

(i) All operations must be conducted in accordance with adequate sanitation principles, including, but not limited to:

(1) Cleaning and/or sanitizing production equipment, containers, and other contact surfaces, as needed;

(2) Controlling airborne contamination as needed where components, packaging components, in-process materials, product, or contact surfaces are exposed;

(3) Using sanitary handling procedures.

Section 4.3 Equipment and utensils

(a) Production operations must use equipment and utensils that are of appropriate design, construction, and workmanship.

(1) Equipment and utensils must be suitable for their intended use;

(2) Equipment and utensils must be able to be adequately cleaned and properly maintained; and

(3) Use of equipment and utensils must not result in the contamination of components, packaging components, in-process materials, cannabis, cannabis-derived products, or contact surfaces.

(b) All equipment and utensils used in production operations must be:

(1) Installed and maintained to facilitate cleaning of the equipment, utensils, and adjacent spaces;

(2) Constructed so that contact surfaces are nontoxic and corrosion-resistant, and neither reactive nor absorptive;

(3) 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; and

(4) Maintained to protect components, in-process materials, cannabis, and cannabis-derived products from being contaminated by any source.

(c) Equipment and utensils must be 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 materials or contaminants.

(d) 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 must be filtered or otherwise treated such that the component, packaging component, in-process material, cannabis or cannabis-derived product, or contact surface is not contaminated.

(e) Each freezer, refrigerator, and other cold storage compartment used to hold components, in-process materials, or cannabis or cannabis-derived products:

(1) Must be fitted 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

(2) Must have an automated device for regulating temperature and/or an automated alarm system to indicate a significant temperature change.

(f) Instruments or controls used in manufacturing, packaging, labeling, holding, or testing, and instruments or controls that are used to measure, regulate, or record conditions that control or prevent the growth of microorganisms or other contamination, must be suitably accurate and precise, and adequately maintained.

(g) Where appropriate, instruments and controls used in manufacturing, packaging, holding, or testing components, packaging components, in-process materials, cannabis, and cannabis-derived products must be 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 the resulting data must be periodically reviewed by quality control personnel. Instruments or controls that are past their calibration, inspection, or verification due date, or which cannot be adjusted to provide suitable accuracy and precision, must be removed from use until they are repaired or replaced.

(h) Production operations must establish and use appropriate controls for automated, mechanical, and electronic equipment (including software for a computer controlled process) to ensure that:

(1) Any changes to the equipment are approved by quality control personnel and instituted only by authorized personnel; and

(2) The equipment functions in accordance with its intended use.

(i) Equipment and utensils, and any other contact surfaces used in production operations must be maintained, cleaned, and sanitized, as necessary.

(1) Equipment and utensils must be taken apart as necessary for thorough maintenance, cleaning, and sanitizing.

(2) All contact surfaces used for manufacturing, packaging, or holding low-moisture components, in-process materials, or cannabis or cannabis-derived products, must be in a dry and sanitary condition when in use. When the surfaces are wet-cleaned, they must be sanitized, when necessary, and thoroughly dried before subsequent use.

(3) If wet processing is used during production, all contact surfaces must be 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.

(4) When cleaning and sanitizing is necessary, all contact surfaces must be cleaned before use

and after any interruption during which the contact surface may have become contaminated.

(5) If contact surfaces are used in a continuous production operation or in consecutive operations involving different batches of the same product, the contact surfaces must be adequately cleaned and sanitized, as necessary.

(6) Surfaces that do not come into direct contact with components, packaging components, in-process materials, or cannabis or cannabis-derived products must be cleaned as frequently as necessary to protect against contaminating components or products.

(7) Single-service articles (such as utensils intended for one-time use, paper cups, and paper towels) must be 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.

(8) Cleaning compounds and sanitizing agents must be adequate for their intended use and safe under their conditions of use.

(9) Cleaned and sanitized portable equipment and utensils that have contact surfaces must be stored in a location and manner that protects them from contamination.

(j) There must be written procedures for calibration, maintenance, cleaning, and sanitation of equipment, instruments, and utensils, and records of these activities must be kept.

Section 4.4 Security requirements

(a) Security procedures must be established and implemented for authorized access to the physical plant and any controlled access areas therein.

(b) Access to the physical plant and controlled access areas must be limited to current personnel and contractors as appropriate to their job function.

(c) The physical plant must be equipped with one or more controlled access areas for storage of the following:

(1) Labels and other packaging components;

(2) Cannabis and cannabis-derived products;

(3) Cannabis waste;

(4) Quarantined components, packaging components, in-process materials, and cannabis or cannabis-derived products;

(5) Rejected components, packaging components, in-process materials, cannabis, or cannabis-derived products.

(d) There must be written procedures for security.

SUBPART E – MANUFACTURING PROCESS CONTROLS

Section 5.1 Manufacturing protocol

(a) Manufacturing operations must prepare and follow a manufacturing protocol for each unique formulation of cannabis-derived product to be produced. The manufacturing protocol must include the following, as applicable:

(1) Identity of the product;

(2) For each formulation of product:

(i) Nominal batch size;

(ii) Identity of each component to be used in the batch;

(iii) 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 the weight or measure;

(iv) A statement of any intentional overage amount of a component; and

(v) Name and amount of each ingredient that will be declared on the product's labeling.

(3) 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;

(4) Written instructions or cross references to standard procedures for the following:

(i) The execution of each process step;

(ii) Production process specifications per section 5.5;

(iii) Monitoring of production process specifications;

(iv) In-process material specifications per sec-

tion 5.8;

(v) In-process material sampling, testing, and/or examination;

(vi) Cannabis-derived product sampling, testing, and/or examination; and

(vii) Additional applicable procedures to be followed, if any.

(5) Cannabis-derived product specifications, or a cross-reference to cannabis-derived product specification documents.

(b) Manufacturing protocols must be written with the intent to provide not less than 100 percent of the labeled or specified amount of cannabis and any other ingredient for which a quantitative label claim is made, throughout the shelf life of the product.

(c) The production process described in the manufacturing protocol must ensure that cannabis-derived product specifications are consistently met.

Section 5.2 Manufacturing component control requirements

(a) Manufacturing operations must have written procedures describing in sufficient detail the receipt, identification, storage, handling, sampling, review, and approval or rejection of components.

(b) Each container or grouping of containers for components must be 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, the date received, and the name of the component; and forward to the cannabis-derived product batches manufactured or distributed using the lot. This code must be used in recording the disposition of each lot.

(c) Specifications for each component must be established as follows, to the extent they are necessary to ensure that manufactured batches of cannabis-derived product meet specifications.

(1) An identity specification for the component must be established;

(2) Specifications for the strength and composition of the component must be established as necessary to ensure the strength and composition of cannabis-derived products manufactured with the component;

(3) Specifications for the purity of the component must be established 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 may lead to adulteration of cannabis-derived products manufactured with the component, such as filth, insect infestation, microbiological contamination, or other contaminants.

(d) Components must be received and stored pending approval as follows:

(1) Upon receipt and before acceptance, each container or grouping of containers must be examined visually 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 components.

(2) The supplier's documentation for each shipment must be examined to ensure the components are consistent with what was ordered.

(3) Components must be stored under quarantine until they have been sampled, reviewed, and approved or rejected by quality control personnel.

(e) Components must be approved or rejected as follows:

(1) Each lot of components must be withheld from use until the lot has been sampled, reviewed, and released for use by the quality control personnel.

(2) Compliance of the lot with established specifications must be ensured either through review of the supplier's certificate of analysis or other documentation, or through appropriate tests and/or examinations. Any tests and examinations performed must be conducted using appropriate scientifically valid methods.

(3) Any lot of a component that meets its specifications may be approved and released for use for use by quality control personnel.

(4) Any lot of a component that does not meet its specifications must be rejected by quality control personnel, unless quality control personnel 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. Any such treatment, process adjustment, reprocessing, or other deviation must be documented, justified, and approved by quality control personnel.

Section 5.3 Manufacturing batch record

(a) The manufacturing operation must prepare a manufacturing batch record for each batch of cannabis-derived product manufactured.

(b) The manufacturing batch record must:

(1) Cross-reference or reproduce the appropriate manufacturing protocol; and

(2) Form a complete record of the manufacturing and control of the batch.

(c) Each batch must be assigned a batch, lot, or control number which allows the complete history of the production and distribution of the batch to be determined. This code must be used in recording the disposition of each batch.

(d) The manufacturing batch record must include, as applicable to the process:

(1) Identity of the cannabis-derived product;

(2) The batch, lot, or control number of the cannabis-derived product;

(3) Batch size;

(4) For each component used in production of the batch:

(i) Identity of each component used in the batch;

(ii) Batch, lot, or control number of each component used in the batch;

(iii) Actual weight or measure of each batch or lot of component used in the batch, including the unit of measure;

(5) Date(s) on which, and where applicable the time(s) at which, each step of the manufacturing process was performed;

(6) Actual results obtained during monitoring of production process parameters;

(7) Identity of processing lines and major equipment used in producing the batch;

(8) 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;

(9) 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;

(10) 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;

(11) Records of any cannabis waste generated during production of the batch;

(12) Records of any treatment, process adjustment, reprocessing, or other deviation that occurred during production of the batch;

(13) Records of the date, time where applicable, quantity, and person responsible for any sample removed during or after production;

(14) Actual results of any testing or examination of in-process material or cannabis-derived product, or a cross-reference to such results;

(15) Documentation that the cannabis-derived product meets its specifications for identity, purity, strength, and composition, in accordance with the requirements of the manufacturing protocol;

(16) Identity of each person performing each process step in production of the batch, including but not limited to:

(i) Weighing or measuring each component and verifying the weight or measure of each component used in the batch per section 5.4;

(ii) 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;

(v) Directly overseeing each stage of produc-

tion of the batch;

(vi) Performing any other checks or verifications in production of the batch, as needed; and

(vii) Releasing the batch from one stage of production to the next.

(e) All data in the manufacturing batch record must be recorded at the time at which each action is performed.

(f) The completed manufacturing batch record for each batch must be 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.

Section 5.4 Allocation and charge-in of components

(a) Manufacturing operations must weigh, measure, or subdivide components to be used in a cannabis-derived product batch as appropriate for the batch.

(b) If a component is removed from the original container to another, the new container must be identified with the following information:

(1) Component identity;

(2) Batch, lot, or control number;

(3) Weight or measure in the new container; and

(4) Batch for which component was dispensed, including its identity and batch, lot, or control number.

(c) Each container of component dispensed to manufacturing must be examined by a second person or verified by automated equipment to assure that:

(1) The component was released by quality control personnel;

(2) The weight or measure is correct as stated in the manufacturing protocol; and

(3) The containers are properly identified.

(d) Each component must either be 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.

Section 5.5 Process monitoring and controls during manufacturing

(a) Process specifications must be 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. The process parameters to be monitored may include, but are not limited to, the following as appropriate:

(1) Time;

(2) Temperature;

(3) Pressure; and

(4) Speed.

(b) Production process parameters must be monitored at or during any point, step, or stage where process specifications have been established.

(c) Any deviation from the specified process parameters must be documented and justified, and the associated in-process material or product must be quarantined. The deviation must be reviewed and approved or rejected by quality control personnel. Such deviations must not be approved unless quality control personnel determine that the resulting cannabis-derived product will meet all specifications for identity, purity, strength, and composition and is not otherwise contaminated or adulterated.

(d) If a deviation is rejected, the resulting in-process or finished cannabis-derived product must be 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. Any such treatment, process adjustment, reprocessing, or other deviation must be documented, justified, and approved by quality control personnel.

(e) Manufacturing operations must properly identify 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.

(f) Operations on one component, product, or batch must be physically, spatially, or temporally separated from operations on other components, products, or batches.

(g) All necessary precautions must be taken during the manufacture of a cannabis-derived product to prevent contamination of components and products. These precautions include, but are not limited to:

(1) Washing or cleaning components that contain soil or other contaminants;

(2) Holding components, in-process materials, and cannabis or cannabis-derived products appropriately;

(3) Preventing cross-contamination and mixups between contaminated components, in-process materials, and cannabis or cannabis-derived products and uncontaminated items;

(4) Using effective measures to protect against the inclusion of metal or other foreign material in components or cannabis products, by, for example:

(i) Filters, strainers, or sieves;

(ii) Traps;

(iii) Magnets;

(iv) Electronic metal detectors.

Section 5.6 Manufacturing sampling requirements

(a) A representative sample of each batch or lot of component, cannabis, or cannabis-derived product must be collected by removing and compositing portions of material or units from throughout the containers in the batch or lot.

(b) In addition to representative samples, other samples may be taken as appropriate to:

(1) Monitor the quality of in-process materials during production;

(2) Examine the degree of variability of materials or products; and

(3) Investigate known or suspected non-conformances.

(c) The number of containers and the amount of material or units to be removed from each container must be based on appropriate criteria such as:

(1) Quantity needed for testing, examination, and reserve;

(2) Past quality history of the item;

(3) Expected variability of the material or units being sampled; and

(4) Degree of confidence and precision required.

(d) The containers selected for sampling must be based on rational criteria such as random sampling; directed sampling may be used where appropriate.

(e) Samples must be collected in accordance with the following procedures:

(1) The containers selected for sampling must be cleaned when necessary in a manner to prevent introduction of contaminants into the component, in-process material, cannabis or cannabis-derived product.

(2) The containers must be 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.

(3) Sterile equipment and aseptic sampling techniques must be used when necessary.

(4) 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.

(5) Containers from which samples have been taken must be marked to indicate that samples have been removed from them.

(f) Sample containers must be identified with the following information:

(1) Name of the item sampled;

(2) Batch, lot, or control number of the item sampled;

(3) Container from which the sample was taken, or for samples taken directly from the production line, the equipment line and time at which the sample was taken, unless such information is documented separately;

(4) Date on which the sample was taken;

(5) Name of the person who collected the sample; and

(6) Quantity and unit of measure of the sample.

(g) Each sample removed from a batch or lot must be recorded in the inventory or manufacturing batch record for the batch or lot.

(h) The quantity of sample used for each test or examination must be of sufficient size or number to ensure the results are representative of the batch or lot.

(i) A reserve sample must be prepared from the representative sample of each batch or lot of shelf-stable component, cannabis or cannabis-derived

product.

(j) Reserve samples should 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. However, 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 if necessary.

(k) Reserve samples of shelf-stable components should:

(1) Be stored using an appropriate container-closure to protect against contamination or deterioration during storage;

(2) Be stored under conditions consistent with the conditions under which the component is stored at the manufacturing operation; and

(3) Be retained for one year past the expiration date of the last batch of cannabis-derived product manufactured from the lot. However, where state law limits the amount of cannabis and cannabis-derived product permitted to be kept on hand, operations may keep reserve samples for shorter periods of time if necessary.

(l) Reserve samples of cannabis-derived product should:

(1) Be 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;

(2) Be 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.

(3) Be retained for one year past the expiration date of the batch or lot. However, 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 if necessary.

Section 5.7 Cannabis-derived product specifications

(a) Manufacturing operations must establish specifications for each cannabis-derived product as follows:

(1) Manufacturing operations must establish specifications for the identity purity, strength, and composition of each cannabis-derived product manufactured by the operation.

(2) Manufacturing operations which receive cannabis-derived product for further processing must establish specifications to provide sufficient assurance that the product received is adequately identified and is consistent with the purchase order.

(b) For each batch or lot of cannabis-derived product manufactured by the operation, the conformance of the batch or lot to established specifications must be confirmed as follows:

(1) For every batch or lot, or for a subset of cannabis-derived product batches or lots identified through sound statistical sampling plan, the operation must 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.

(2) 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 may be 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.

(3) Where no scientifically valid test method exists for a product specification, compliance with the specification must be established through component and/or in-process testing, examinations, or monitoring and/or review of manufacturing batch records.

(4) Quality control personnel must document and approve the justification for reduced product testing under section 5.7(b)(2) or section 5.7(b)(3) of this part.

(c) Cannabis-derived product which fails to meet its specifications must be rejected, unless quality control personnel approve a treatment, process adjustment, reprocessing, or other deviation that will ensure the cannabis-derived product batches manu-

factured with the affected material will meet all specifications for identity, purity, strength, and composition, and will not be otherwise contaminated or adulterated. Any such treatment, process adjustment, reprocessing, or other deviation must be documented in the manufacturing batch record, justified, and approved by quality control personnel.

(d) Any unexplained occurrence or discrepancy, and any failure of the cannabis-derived product to meet its specifications or requirements, must be 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.

(e) Manufacturing operations must have written procedures describing in sufficient detail the storage, handling, sampling, testing, and approval or rejection of cannabis and cannabis-derived products.

Section 5.8 In-process material specifications, sampling, and testing

(a) In-process specifications must be established 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:

(1) Weight or fill of tablets, capsules, or other units;

(2) Weight or fill variation of tablets, capsules, or other units;

(3) Hardness or friability of tablets;

(4) Disintegration time of unit dosages;

(5) Clarity, viscosity, specific gravity, total dissolved solids, or pH of solutions;

(6) Loss on drying, moisture content, or solvent residue;

(7) Microbiological characteristics; and

(8) Organoleptic characteristics.

(b) In-process specifications for such characteristics must be consistent with the cannabis-derived product specifications.

(c) In-process materials must be 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 must be approved or rejected by quality control personnel.

(d) In-process material which fails to meet its specifications must be 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. Any such treatment, process adjustment, reprocessing, or other deviation must be documented in the manufacturing batch record, justified, and approved by quality control personnel.

Section 5.9 Calculation of yield

(a) Actual yields must be determined at the conclusion of each appropriate phase of manufacturing of the cannabis-derived product. Such calculations must either be performed by one person and independently verified by a second person, or, if the yield is calculated by automated equipment, be independently verified by one person.

(b) 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, 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.

SUBPART F – PACKAGING AND LABELING PROCESS CONTROLS

Section 6.1 General considerations for packaging components, including labels

(a) Cannabis to be packaged without undergoing manufacturing to a cannabis-derived product must be received, identified, stored, handled, sampled, reviewed, and approved or rejected as per sections 5.2 and 5.6 above.

(b) Specifications for packaging components must be established 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.

(c) Packaging and labeling operations must establish written procedures describing in sufficient detail the receipt, identification, storage, handling, and approval or rejection of packaging and labeling components.

(d) Labels and other packaging components must be received and stored pending approval as follows:

(1) Upon receipt and before acceptance, each container or grouping of containers of packaging components must be 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; and

(2) The supplier's documentation for each shipment must be examined to ensure the packaging components are consistent with what was ordered.

(3) Each container or grouping of containers for packaging components must be 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, the date received, and the name of the component; and forward to the product batches packaged or labeled using the lot. This code must be used in recording the disposition of each lot.

(4) Labels and other packaging components must be stored under quarantine until they have been examined and approved or rejected by quality control personnel.

(e) Packaging components must be approved or rejected as follows:

(1) Each lot of packaging components must be withheld from use until the lot has been reviewed and released for use by the quality control personnel.

(2) Compliance of the lot with established specifications must be ensured through examination of the components received, and/or review of the supplier's documentation.

(3) Any shipment of a packaging component that meets its specifications may be approved and released for use for use by quality control personnel.

(4) Any packaging component that does not meet its specifications, including any incorrect labels, must be 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. Any such treatment or other deviation must be documented, justified, and approved by quality control personnel.

(f) Use of gang-printed labeling for different products, or different strengths or net contents of the same product, is prohibited unless the labeling from gang-printed sheets is adequately differentiated by size, shape, or color.

Section 6.2 Packaging and/or labeling protocol

(a) Packaging and labeling operations must prepare and follow a written protocol for each unique product to be packaged and/or labeled to assure that correct packaging and labeling components are used for each product packaged or labeled by the operation. Where appropriate, the packaging and/or labeling protocol may be combined with the manufacturing protocol for the product. The protocol must:

(1) Identify the product to be packaged and/or labeled;

(2) Identify each packaging component to be used;

(3) Provide 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);

(4) Provide a statement of the acceptable maximum and minimum percentages of theoretical yield; and

(5) Include written instructions or cross references to standard procedures for the following:

(i) 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;

(ii) Issuance of labels and labeling to a packaging and/or labeling batch;

(iii) 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;

(iv) Each packaging and/or labeling process step;

(v) Monitoring of packaging and/or labeling process steps; and

(vi) Additional applicable procedures to be followed, if any.

(b) Packaging and/or labeling protocols must be written with the intent to provide not less than 100 percent of the labeled amount of product.

(c) The packaging and/or labeling process described in the protocol must ensure that product specifications are consistently met.

Section 6.3 Packaging and/or labeling batch record

(a) The packaging and/or labeling operation must prepare 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.

(b) The packaging and/or labeling batch record must:

(1) Cross-reference or reproduce the appropriate packaging and/or labeling protocol; and

(2) Form a complete record of the packaging and/or labeling and sampling of the batch.

(c) The packaging and/or labeling batch record must include, as applicable to the process:

(1) Identity of the product;

(2) Batch, lot, or control number of the product;

(3) Packaging and/or labeling batch size;

(4) For each packaging component used in production of the batch:

(i) Identity of each packaging component;

(ii) Batch, lot, or control number of each packaging component used in the batch;

(iii) Quantity of each lot of packaging components used, including the unit of measure.

(5) Date(s) on which, and where applicable the time(s) at which, each step of the packaging and/or labeling protocol was performed;

(6) Identity of packaging lines and major equipment used in packaging and/or labeling the batch;

(7) 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;

(8) 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;

(9) 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 6.2(a)(4) at the end of packaging and/or labeling;

(10) 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.

(11) Label reconciliation, as per section 6.3(f) of this part;

(12) Records of any labeling scrap or cannabis waste generated during packaging and/or labeling of the batch;

(13) Identity of each person performing each process step in packaging and/or labeling of the batch, including but not limited to:

(i) Inspecting labels and other packaging components to ensure suitability and correctness prior to use in the batch;

(ii) Inspecting packaging and labeling areas before and after use;

(iii) Reconciling label issuance and usage and

verifying the reconciliation of label issuance and usage;

(iv) Examining packaged and labeled products to ensure proper labeling and coding;

(v) Performing any other checks or verifications in packaging and/or labeling of the batch as needed; and

(vi) Releasing the batch from one stage of packaging and/or labeling to the next.

(d) All data in the packaging and/or labeling batch record must be recorded at the time at which each action is performed.

(e) Printing devices located on, or associated with, production lines must be monitored to assure that all printing conforms to the requirements of the packaging and/or labeling protocol when used to imprint labeling or coding directly on the following:

(1) Primary packaging for the product; or

(2) Secondary packaging (e.g., a case containing several individual packages of product).

(f) Packaging and labeling operations must reconcile the quantities of labels or labeling issued, used, and returned to storage.

(1) Narrow limits for the labeling reconciliation must be established, based where possible on historical operating data, for the amount of allowed variation in the labeling reconciliation.

(2) When a labeling reconciliation 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.

(3) Labeling reconciliation is waived for cut or roll labels if a 100-percent examination for correct labels is performed, either manually or by appropriate electronic or electromechanical equipment during or after completion of finishing operations.

(4) All excess labeling bearing batch, lot, or control numbers must be destroyed.

(5) Care must be taken when returning labeling to storage, to prevent mixups and ensure proper identification.

(g) Representative and reserve samples of each batch or lot of retail packaged and/or labeled product must be collected as per section 5.6 of this part.

(h) The completed packaging and/or labeling batch record for each batch or lot must 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.

(i) Packaged or labeled product which fails to meet its packaging or labeling specifications or other packaging requirements must be rejected, unless quality control personnel approve repackaging, relabeling, or other deviation that will ensure 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.

Section 6.4 Label content for cannabis and cannabis-derived products

(a) Each packaged and labeled product must bear on the label of its primary packaging:

(1) Name and place of business of the manufacturer or distributor;

(2) Identity of the product;

(3) Net quantity of contents in terms of weight, numerical count, or other appropriate measure;

(4) A batch, lot, or control number;

(5) 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;

(6) Instructions for use, including any types of compliant individuals for whom the product is recommended, as appropriate;

(7) Appropriate warnings for use, including any types of compliant individuals for whom the product is contraindicated, as appropriate;

(8) Instructions for appropriate storage; and

(9) Any other statements or information required by state regulators.

(b) For edible products, each product label must contain a "Product Facts" box listing quantitative con-

tent and nutrient information relevant to the product, including, as applicable to the product's content:

(1) Cannabis ingredient;

(2) Cannabinoid and/or terpenoid content;

(3) Total calories and fat calories (when greater than 5 calories per serving);

(4) Total fat, saturated fat, and trans fat (when greater than 0.5 g per serving);

(5) Cholesterol (when greater than 2 mg per serving);

(6) Sodium (when greater than 5 mg per serving);

(7) Total carbohydrates (when greater than 1 g per serving);

(8) Dietary fiber (when greater than 1 g per serving);

(9) Sugars (when greater than 1 g per serving);

(10) Protein (when greater than 1 g per serving); and

(11) Vitamin A, vitamin C, calcium, and iron (when present at greater than 2% of the recommended daily intake).

SUBPART G – HOLDING CONTROLS

Section 7.1 Identification

(a) Each container of component, packaging component, in-process material, and product must be appropriately identified at all times with the following:

(1) Identity of the item;

(2) Batch, lot, or control number;

(3) Status (e.g., quarantined, approved, recalled, rejected).

(b) Product packages that are held in unlabeled condition for future labeling operations must be identified and handled to preclude 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.

(c) Identification information required in sections 7.1(a) and (b) may be:

(1) Affixed to the individual container or to an appropriate grouping of containers; or

(2) Assigned to the room or other defined physical location of the container(s).

Section 7.2 Storage and handling

(a) Components, packaging components, in-process materials, and products must at all times be handled, stored, and distributed in a manner to avoid deterioration, prevent contamination, and avoid mixups. Where necessary, appropriate conditions of temperature, humidity, and light must be 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.

(b) Containers of components, packaging components, in-process materials, and product must be stored off the floor and suitably spaced to permit cleaning and inspection.

(c) Components, in-process materials, and products that can support the rapid growth of microorganisms of public health significance must be held in a manner that prevents them from becoming adulterated.

(d) Labels, labeling, cannabis, cannabis-derived products, and cannabis waste must be stored in a controlled access area.

(e) Components, packaging components, and products must be 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.

Section 7.3 Withholding materials from use or distribution

(a) Manufacturing, packaging, and labeling operations must establish and implement written procedures for quarantine of 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. This includes:

(1) Newly received components and packaging components for use in manufacturing, packaging and/or labeling;

(2) Batches newly completed in production;

(3) Product returned to the operation for any reason;

(4) Components, packaging components, in-process materials, or products that are or may be contaminated or adulterated; or

(5) Components, packaging components, in-process materials, or products that are under investigation by quality control personnel for any other reason.

(b) 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) must be appropriately segregated, controlled, and held in a controlled access area pending destruction or other disposal.

(c) Cannabis waste other than cannabis and cannabis-derived product that is rejected and returned to the vendor, and rejected labels and other labeling, must be destroyed in a manner which prevents unauthorized use. Destruction of any cannabis waste must be documented and witnessed by at least two workers, one of whom must be supervisory, managerial, or quality control personnel; except that if video surveillance is used, only one worker is necessary. Destruction may include composting.

SUBPART H – INVENTORY AND RECORDKEEPING

Section 8.1 Materials inventory

(a) Manufacturing, packaging, labeling and holding operations must keep written records for each shipment of component, packaging component, cannabis, and cannabis-derived product received from another company or individual.

(b) Records must be kept of the following:

(1) Identity of the received item, as applicable to the item; and any component number or product number if such are in use by the supplier;

(2) Supplier or vendor from which the shipment was received;

(3) Original cultivation operation, processing operation, or manufacturing operation, if known and where applicable;

(4) The cultivation operation's, processing operation's, manufacturing operation's, or supplier's batch, lot, or control number, if known and where applicable;

(5) Date of receipt; and

(6) Shipment delivery method, including where applicable the name of the commercial or private carrier.

(c) Additionally, manufacturing, packaging, and labeling operations must keep records, or establish cross references to other records such as manufacturing batch records, of the following information:

(1) Batch, lot, or other control number assigned by the manufacturing, packaging, and/or labeling operation to the shipment;

(2) Inspection, sampling, testing, and examinations performed on the batch or lot, and the conclusions derived therefrom, as applicable to the scope of the operation;

(3) Any treatment, reprocessing, or other deviation performed by the operation on the batch or lot prior to use;

(4) Disposition of the batch or lot by quality control personnel, including the date and the signature of the person responsible for approving or rejecting the batch or lot and any treatment, reprocessing, or other deviation performed thereon;

(5) A record of each use of the batch or lot in production, including:

(i) Quantity used, including unit of measure;

(ii) Name and batch, lot, or other control number of the product batch in which the batch or lot is used; and

(iii) Initials of the person(s) responsible for removing from storage the necessary quantity for use in the designated batch.

(6) A record of any portion of the batch or lot returned from production to storage, including:

(i) Quantity returned, including unit of measure;

(ii) Name and batch, lot, or other control number of the batch or lot from which the portion is returned; and

(iii) Initials of the persons responsible for verifying the quantity returned.

(7) 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.

Section 8.2 Distributed materials

(a) Manufacturing, packaging, labeling and holding operations must keep written records for each batch or lot of cannabis or cannabis-derived product distributed by the operation.

(b) Records must be kept of the following:

(1) 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;

(2) A record of each distribution of the batch or lot, including:

(i) Quantity distributed, including unit of measure;

(ii) 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;

(iii) Shipping method by which each shipment is distributed, including where applicable the name of the commercial or private carrier;

(iv) Initials of the persons responsible for removing from storage the necessary quantity for each shipment. Each distribution must be verified by a second person.

(3) A record of any portion of the batch or lot returned to storage, including:

(i) Quantity returned, including the unit of measure;

(ii) Company, non-profit entity, individual, or location from which the portion is returned;

(iii) Shipment return method, including where applicable the name of the commercial or private carrier;

(iv) Initials of the person(s) responsible for verifying the quantity returned;

(4) 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.

(c) Additionally, manufacturing, packaging, and labeling operations must keep records or establish cross references to other records such as manufacturing batch records, for the following:

(1) Batch, lot, or other control number assigned by the manufacturing, packaging, and/or labeling operation to the batch or lot;

(2) Inspection, sampling, testing, and examinations performed on the batch or lot by the operation, and the conclusions derived therefrom;

(3) Any treatment, reprocessing, or other deviation performed on the batch or lot by the operation prior to distribution; and

(4) Disposition of the batch or lot by quality control personnel, including the date and the signature of the person responsible for approving the batch or lot for distribution; and the date and the signature of the person responsible for approving or rejecting any treatment, reprocessing, or other deviation performed thereon.

Section 8.4 Reconciliation

(a) Records of receipt, use or distribution, return, and disposal of each batch or lot of components, packaging components, cannabis or cannabis-derived products must be kept chronologically, and the quantities must be recorded with an appropriate level of precision.

(b) After each batch or lot is used or distributed, manufacturing, packaging, labeling, and holding operations must perform a reconciliation of the quantity received into storage against the quantity used, distributed, returned, and/or disposed. Such calculations must be performed by one person and independently verified by a second person.

(c) Narrow limits must be established, based where possible on historical operating data, for the amount of allowed variation in the reconciliation.

(d) When a reconciliation falls outside the allowed limits, quality control personnel must 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.

Section 8.5 Record retention

(a) Except as required in sections 8.5(b) and (c), manufacturing, packaging, labeling, and holding operations must retain the records required by this part for a period of at 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.

(b) Product complaint records must be 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.

(c) Records for returned products must be 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

Section 9.1 Complaint files

(a) Manufacturing, packaging, labeling, and holding operations must establish written procedures describing the handling of product complaints received regarding a cannabis or cannabis-derived product.

(b) A qualified person must:

(1) 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

(2) 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.

(c) Quality control personnel must 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.

(d) 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, must extend 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.

(e) A written record of the complaint and where applicable its investigation must be kept, including:

(1) Identity of the product;

(2) Batch, lot or other control number of the product;

(3) Date the complaint was received and the name, address, or telephone number of the complainant, if available;

(4) Nature of the complaint including, if known, how the product was used;

(5) Names of personnel who do the following:

(i) Review and approve the decision about whether to investigate a product complaint;

(ii) Investigate the complaint, and

(iii) Review and approve the findings and follow-up action of any investigation performed.

(6) Findings of the investigation and follow-up action taken when an investigation is performed; and

(7) Response to the complainant, if applicable.

(f) Manufacturing, packaging, labeling, and holding operations must establish a procedure 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:

(1) Reporting to any public health authority;

(2) Reporting to the physician of record for the individual reported to have experienced the adverse event, if known; and

(3) Product recall.

Section 9.2 Returned products

(a) Manufacturing, packaging, and/or labeling operations must establish written procedures describing the receipt, handling, and disposition of returned cannabis or cannabis-derived products.

(b) Returned products must be identified as such and be quarantined upon receipt.

(c) Returned product must be reviewed and approved or rejected by quality control personnel.

(d) 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.

(e) If the reason a product is returned implicates associated batches, an appropriate investigation must be conducted and must extend 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.

(f) Rejected returned product returned to the manufacturing, packaging, labeling, and holding operation must be destroyed as per section 7.3(c).

(g) A written record must be kept of the return, and where applicable its investigation, including:

(1) Identity of the product;

(2) Batch, lot or other control number of the product;

(3) Date the returned product was received;

(4) Name and address from which it was returned, and the means by which it was returned;

(5) Reason for the return;

(6) Results of any tests or examinations conducted on the returned product, or on related batches, if any;

(7) Findings of the investigation and follow-up action taken when an investigation is performed;

(8) Any reprocessing performed on the returned product;

(9) The ultimate disposition of the returned product, and the date of disposition; and

(10) Names of the quality control personnel who do the following:

(i) Review the reason for the product return;

(ii) Review and approve any reprocessing, as applicable, and

(iii) Review and approve the findings and follow-up action of any investigation performed.

Section 9.3 Recall procedures

(a) Manufacturing, packaging, labeling, and holding operations must establish 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. This procedure should include:

(1) Factors which necessitate a recall;

(2) Personnel responsible for a recall; and

(3) Notification protocols.

(b) Manufacturing, packaging, labeling, and holding operations must establish a procedure for communicating a recall of product distributed by the operation. This procedure should include:

(1) A mechanism to contact all customers that have, or could have, obtained the product from the operation;

(2) A mechanism to contact the vendor that supplied the recalled product to the operation, if applicable;

(3) Instructions for the return or destruction of any recalled product by customers;

(4) Instructions for contacting the relevant manufacturing, packaging, labeling, and/or holding operations; and

(5) Communication and outreach via media, as necessary and appropriate.