FOCUS

Foundation of
Cannabis Unified Standards

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Cultivation Standard

Cultivation Reference/Citation:

Foundation of Cannabis Unified Standards. FS-1001-1:2016. *Cannabis Cultivation*. United States: FOCUS; 2016.

Overview

FOCUS Standards are the foundation of a rigorous, comprehensive quality and safety system providing cannabis business owners, consumers, regulators and the public with a single, concise, accepted standard that protects public health and consumer safety, and safeguards the environment.

FOCUS Standards are developed according to internationally accepted voluntary consensus processes to ensure robust, impartial standards. Volunteer members of FOCUS Standards development committees include professionals from the cannabis industry, regulatory agencies, quality assurance, occupational safety, medical services, law enforcement, education, science and research, consumers, patients and the public.

Scope

This FOCUS Standard provides direction for cannabis cultivation operations to meet safety and quality requirements.

This document uses the word operation to indicate a cannabis company, business, facility, laboratory or individual location that is applying the FOCUS Standard.

The terms must and shall are used interchangeably to indicate requirements; the terms should, could, may and can are used to indicate flexibility or to provide examples.

The standards identify job titles for specific responsibilities to add clarity. The organization's job descriptions, work assignments and training will define each worker's actual title and responsibilities. Depending on an operation's size and structure, one worker may cover several roles (or job titles) to meet a requirement.

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1. Management Summary

1.A Management Capability

1. A cannabis cultivation operation must have a defined manager or management team responsible for operating the business according to documented policies and procedures and all applicable laws and regulations.
2. Managers must possess the qualifications (training, experience and credentials) required to effectively execute the quality, safety, procedural, workforce and compliance requirements assigned to them.
3. Management shall:
    a. Provide evidence that all managers have completed management training and instruction in the organization's standard operating procedures and record keeping related to GAP and GMP including worker/staff management, safety, sanitation, regulatory compliance and maintenance, and other defined topics critical to the organization's efficient and safe operation.
    b. Implement and maintain robust programs as defined in the FOCUS Standard to ensure business viability and continuity, and environmental sustainability.

c. Engage all stakeholders to contribute to safe, quality products and services.

1.B Product Quality

1. Management shall ensure all products manufactured, processed or sold by the operation meet all product quality specifications and requirements.
2. Management shall:
    a. Implement a product quality program that ensures all facilities, equipment, processes and people operate to produce safe, quality products.
    b. Conduct and document an annual assessment of the product quality program; record updates to the program and corrective action taken.
    c. Designate managers responsible for product quality programs that have the skills, time allotment and defined job descriptions to perform the requirements of the positions

1.C Health and Safety

1. Management shall develop and maintain a safe and healthy work environment for all workers, contractors and visitors.
2. The health and safety program shall be documented and include annual training and periodic assessment for all workers.

1.D Security

1. Management shall rigorously protect the people, products, information, systems and assets associated with business operations from risks and threats.
2. Management shall stay current with evolving security risks, conduct periodic risk assessments and make appropriate improvements to the security program.
3. Management shall ensure all workers receive ongoing security training and follow security procedures.

1.E Procedures and Training

1. Management shall ensure that work processes are documented using standard operating procedures.

2. Managers shall ensure workers receive appropriate training and refresher training to perform assigned responsibilities.
3. Workers must have full access to current procedures and training materials.

1.F Regulatory Compliance

1. Management shall ensure the operation remains compliant with all applicable federal, state/provincial, county and local regulations related to cannabis business operations.
2. The operation must provide appropriate training and retain compliance records for review.
3. The operation must regularly monitor regulatory changes, make appropriate revisions to procedures and update worker training.

1.G Organization Structure

1. Management shall maintain an organization chart that documents the organization structure, reporting relationships and decision-making paths.
2. Management shall maintain current job documentation including job descriptions, qualifications, responsibilities, training requirements, compensation processes and evaluation methods.

2. Business Practices

2.A Goal Setting

1. Business leaders should set, maintain and communicate ongoing goals that are aligned to the business plan, strategy and mission.
2. Workers should set and maintain goals based on position responsibilities, projects and related manager goals.
3. Managers and workers should review goals monthly or more and update as required; managers should retain goal plans to support performance evaluations.

2.B Business Assessments

1. The operation shall conduct periodic assessments of the business to expose and mitigate anomalies and vulnerabilities.
2. The operation must document assessments and the corrective action taken, and retain assessment and audit reports permanently for authorized review.
3. Business Operations Assessments – conduct an annual self-assessment that:
    a. Reviews the business climate and adjusts strategies (legal, regulatory, legislative, investment, competition, products, community, etc.)
    b. Analyzes markets and customer preferences
    c. Analyzes product supply chain (relationships with suppliers, distributors, wholesalers and others integral to production)
    d. Analyzes critical business risks and mitigation plans
    e. Reviews business locations
    f. Reviews and improves core business processes

g. Updates policies, standard operating procedures, workplace practices and training

4. Financial Assessments – conduct an annual self-assessment of:
    a. Financial results against auditable, valid business plans as reported to regulators
    b. Performance to budget
    c. Payables/receivables, cash management and bank transactions
    d. Contracts, agreements and partnerships
    e. Projections and data for future business requirements
5. Third-Party Audits – conduct assessments as required by company policy:
    a. Business finances and operations
    b. Partnerships, joint ventures, contracts and agreements
    c. Use certified, impartial auditors

2.C Licenses and Permits

1. The operation must have appropriate permits and licenses to operate compliantly, including:
    a. Business license or operating permit
    b. Tax license (if required)
    c. Zoning permit or variance
    d. Building, signage and alarm permits
    e. Safety permits (fire, environmental)
    f. Health permit

2.D Business Insurance

1. The operation must have valid insurance policies in place:
    a. Liability: protection from lawsuits, negligence
    b. Property: loss/damage to location, contents
    c. Casualty: loss/damage to the business
    d. Business interruption/continuation

2.E Accounting Standards

1. The operation must maintain an auditable accounting system or ledger.
2. Management should be trained on tax and accounting issues unique to the cannabis business such as IRS 280E.
3. The operation should use qualified, certified third-party financial service providers (advisors, bankers, accountants).
4. Operation can provide affidavit or other written proof from accounting firm/accountant certifying use of Generally Accepted Accounting Practices.

2.F Operational Controls

1. The operation must maintain appropriate internal financial and operational controls to measure operational effectiveness and efficiency, provide reliable financial reporting, uncover fraud and protect organizational assets (tangible and intellectual property).
2. The operation must assess operational controls to ensure effectiveness and comprehensiveness during annual business assessments and as part of third-party audits (business and financial)

2.G Document Control

1. The operation must have procedures to control documents related to production, product quality, worker safety and work operations that include:
    a. Approval of documents prior to issue
    b. Review and revision as required including re-approval
    c. Documented changes and current revision status
    d. Ensuring documents remain legible and readily identifiable
    e. Ensuring correct versions of relevant documents are available at points of use
    f. Preventing obsolete documents from unintended use

    Controlled documents may include policies, procedures, forms, product formulas and specifications, audits, assessments and proprietary information.

    Reference ISO 9001:2008 Quality Management Systems — Requirements

2.H Advertising Methods

1. The operation's advertising and marketing activities, including websites and social media, must be current, accurate and support truth-in-advertising principles (not deceptive, false or misleading).
2. The operation must not make unsubstantiated medical claims and must provide an accurate representation of the level of medical expertise available.
3. No advertising shall be targeted at minors.
    a. No use of cartoons or graphics targeted at minors.
    b. No imitation of popular consumer product labeling or graphics.
    c. For web/mobile devices, operation should use "over 21" qualifying questions to enter site/application and provide easy opt-out features.
4. Advertising must comply with all applicable federal, state and local advertising regulations for cannabis products and services including compliance with specific regulations for television, radio, billboards, websites, print, mailings, social media, signage and other forms of advertising.

2.I Records Management

1. The operation must maintain a Records Management System and follow established procedures to ensure the organized storage, retention and protection of all records and supporting data that includes:
    a. Records Inventory List – A master list of records and control requirements
    b. Destruction process – Retention time and destruction/deletion methods
    c. HIPAA compliance – Patient records control and destruction requirements

2. The operation must manage all digital files according to procedures including:
    a. System access controls
    b. User controls and tracking (viewing, printing, editing and deleting)
    c. Standard file labeling and organized storage hierarchy
    d. Data encryption
    e. File deletion schedules and processes including deletion of data on obsolete computers and data storage devices
    f. Data backup: cloud storage, digital storage service, offsite storage of backup hard drives
    g. Automatic file backup
    h. Long-term protection and file integrity
3. The operation must manage all physical files according to procedures including:
    a. Restricted storage areas
    b. Lockable filing systems
    c. Sign in/sign out procedures for file review/removal
    d. Organized filing systems
    e. Physical records are filed in a timely manner
    f. Destruction schedules and processes
    g. Crisis protection
    h. Long-term storage/environmental controls
4. The operation must assign a worker to manage the records system, and the worker must have the time allotment, skills and experience to adequately meet the position requirements.
5. Management must conduct a self-assessment of the records process at least every 90 days, document the assessment and complete any corrective action.
6. Records management procedures must comply with applicable federal, state and local regulations.

2.J Records Inventory List

1. The operation must list all records used or received by the business on a Records Inventory List.
    a. The Records Inventory List should identify:

1. Each record by title
2. Persons/positions authorized to view the record
3. Revision or deletion authorizations
4. Retention period
5. Destruction method
6. Storage and back-up requirements
7. Record location (if electronic, file path and filename)

8. Other controls as required

    b. Records Inventory List must identify all records related to the following categories (there may be multiple records per category):

        1. Accounting ledgers and reports
        2. Tax returns, tax correspondence and supporting information
        3. Payroll and wages
        4. Contracts and agreements
        5. Corporate organization, bylaws, organization charts
        6. Insurance
        7. Intellectual property
        8. Legal files, court documents, attorney files
        9. Public filings
        10. Security records
        11. Logins and electronic permissions
        12. Electronic mail
        13. Employment and worker files
        14. Training records and program documentation
        15. Safety and health (OSHA, worker's comp, medical, SDS)
        16. Audit reports, inspection reports and self-assessments
        17. Quality control procedures, logs and records
        18. Vendor records
        19. Customer information
        20. Patient/customer records
        21. Inventory records
        22. Production records
        23. Product test data and test lab reports
        24. Product transfers
        25. Test method documentation (lab only)
        26. Sample management and control records
        27. Sales and marketing plans
        28. Sales transactions
        29. Press releases
        30. Maintenance logs for facilities and equipment

31. Calibration, maintenance and repair logs

32. Sanitation logs

2.1 Fair Labor Practices

2.1A Fair Labor Standards

1. The business operates with fair labor standards and has evidence that it:
    a. Pays minimum wage or more
1. If piece-rate pay is used, the operation maintains an accurate system to ensure rate meets or exceeds the minimum wage.
    b. Pays overtime rates if overtime is required
    c. Bases all pay deductions on a formula documented in work contract
    d. Complies with child labor laws

2.1B Workplace Discrimination

1. The operation must display an Equal Opportunity Employment Commission poster or equivalent that indicates the illegality of discrimination and provides processes to report violations.
2. The company shall prohibit discrimination for age, gender, marital status, sexual orientation, race, color, national origin or ancestry, religious or spiritual beliefs, disabilities or mental conditions; business shall prohibit sexual harassment.

2.1C Work Contracts

1. The operation must have work contracts for all workers on file.
2. The contracts must specify:
    a. Terms and schedule for payment of wages
    b. Job title and job description
    c. Terms for dismissal from job
    d. Terms of dispute resolution between worker and employer
    e. Weekly maximum hours worked before overtime is calculated
    f. Details of any vacation time paid, mandatory overtime, sick leave or other compensated time off, if provided
    g. Background checks required; bonding if required

2.1D Worker Policies

The operation must publish a worker policy manual and distribute it to all workers at the start of their job. The manual should define company policies, procedures, benefits and expectations to support worker success. The policy manual shall be consistent with employment and safety laws and must be reviewed and updated as required by changes in regulations and employment law.

2.1E Worker's Compensation Insurance

The operation must maintain a state-approved worker's compensation plan for all workers and must provide appropriate communication and processes to manage work-related injuries according to laws and regulations.

2.1F Worker Data

1. The operation must maintain a unified worker data file that is secure, automatically backed up in a secure location or system, centrally located and accessible for review.
2. Worker data must be retained for at least two years after termination date or as required by local regulations.

2.2 Social Sustainability

2.2A Community Relations

1. The operation should conduct a community impact study that explores cooperative strategies for minimizing negative impacts and highlighting positive impacts.
2. The operation should contribute to the community through employee volunteerism, community outreach programs, education programs, charitable donations (cash and in-kind) and other methods.
3. The operation should conduct periodic assessments of its community reputation using methods such as surveys, comment cards, focus groups, joining/participating in local business groups, reviewing media coverage and publicity, and participating in community awards and recognition programs.

2.2B ADA Compliance

The operation must meet requirements of the Americans with Disabilities Act (ADA) for all U.S. locations (or local equivalent where applicable).

Reference ADA.gov

2.2C Business Certifications

1. The operation should identify any business certifications it has achieved and related benefits or activities:
    a. LEED – green buildings
    b. ISO 9000 or similar quality or professional certifications
    c. WEBNC/woman-owned business
    d. Minority-owned business
    e. Native American-owned business
    f. Veteran-owned business

2.2D Cannabis Industry Support

The operation should take action to support cannabis industry growth and integrity by joining cannabis trade or advocacy groups; participating in public outreach and education campaigns; joining and participating in organizations that promote fair trade and fair labor conditions; attending, sponsoring or presenting at industry conferences; participating in award programs; and participating in local networks and cannabis groups.

2.3 Crisis Management

2.3A Crisis Management Plan

1. The operation must have a documented Crisis Management Plan that management reviews and updates annually.
2. At a minimum, the Crisis Management Plan must document the following:

   a. Risk assessment – Probability and impact of potential risks including natural disasters, fire, flood, chemical spill, loss of key staff, sabotage, vandalism, terrorism, theft, robbery, workplace violence, seizure of assets or property, traceability, product contamination and product recall

b. Action steps – Management actions to restore the business to operation and specific responses for each identified risk

c. Crisis team (core and extended) roles, responsibilities and authorizations

d. Contact list and calling tree – Include key phone numbers for crisis team, staff, emergency authorities, local regulators and agencies, utilities, insurance representatives and suppliers

e. Locations of products, hazardous materials, equipment and document storage

f. Document management and protection plan

g. Financial and legal considerations

h. Media relations plan and contacts

2.3B Crisis Plan Training and Testing

1. All personnel involved in the Crisis Management Plan must participate in crisis plan training and tests (annually or more).

a. Crisis team must have up-to-date contact and response information.

b. Crisis team must understand how to return business to operation after an interruption.

2. Management shall ensure preparedness for potential risks and crisis events by testing and improving the crisis plan annually.

a. Process should test scenarios, responsibilities, procedures, communications, involvement of external stakeholders, etc.

b. Crisis plan test reports, including corrective actions, must be approved by senior management.

c. Test reports must be retained for two years.

3. Training

3.A Worker Training Program

1. Management shall ensure all workers receive adequate training to complete assigned responsibilities safely and effectively prior to beginning the work.
2. Managers shall reinforce comprehension by observing behaviors in the workplace and providing timely feedback.
3. The operation must maintain a documented training program that ensures all workers are trained on the

following at a minimum:

a. Company policies and procedures
b. Emergency procedures
c. Government laws and regulations
d. Hazardous materials
e. Hygiene and food-handling safety
f. Industry policies and standards
g. Labeling and packaging
h. Product quality
i. Product testing
j. Regulatory inspections
k. Required record keeping
l. Sanitation and cleaning procedures
m. Sexual harassment
n. Security and interaction with law enforcement
o. Specific job training as required
p. Violations and enforcement
q. Worker health and safety

4. State-certified cannabis training or apprenticeship certifications may fulfill training requirements for certain training topics.
5. The training manager shall retain training plans and participation records for two years

3.B Hygiene Training

1. All workers, management and staff must participate in a documented workplace hygiene-training course to ensure Good Agricultural Practices (GAP) and Good Manufacturing Practices (GMP).
2. All new workers must receive training in product handling, sanitation responsibilities, cleanliness standards and reporting requirements prior to working.
3. All workers, including management, must participate in documented refresher training on hygiene practices annually at a minimum.
4. Managers must ensure workers demonstrate expected practices.

3.C Quality Control Training

1. All workers must have periodic and documented training in the operation's quality management system and quality control procedures.
2. All workers must demonstrate application of quality procedures and working knowledge of the operation's quality management system.

3.D Training Manager

1. The operation must designate a training manager that develops training plans, ensures training is delivered to workers, tracks training participation, maintains all training documentation and improves the training program to meet business needs.
2. The training manager must have a working knowledge of the facility processes and procedures

3.E Comprehensive Training Materials

1. Training materials must provide adequate quality, safety and operational detail for all work responsibilities and cover all topics listed in the training program.
2. Training materials must be available to workers.

3.F Regulatory and Law Enforcement Interaction

1. The operation must provide training to management and all workers to prepare them for interaction with regulatory and law enforcement agencies.
2. Training must include preparation for scheduled and unscheduled regulatory inspections and potential actions that might be taken by law enforcement affecting business operations.
3. Training should cover regulatory policies and federal laws as they apply to employees and the operation of the business

3.G Agricultural Expertise

1. Production manager must have documented Good Agricultural Practices (GAP) training and experience demonstrated by:
    a. Presence of robust production processes and supporting documentation
    b. Job experience in the industry
    c. Agriculture, horticulture or cannabis cultivators' certifications
    d. University agriculture degrees
    e. Agriculture awards or industry recognition
    f. Participation in documented agricultural programs
    g. Certification by government or accredited organizations

4. Worker Practices

4.A Worker Cleanliness

1. Workers must practice personal cleanliness including:
    a. Outer garments such as smocks, aprons and lab coats must be clean and appropriate for the assigned tasks.
    b. Nails must be trimmed and clean.
    c. Work shoes must be clean and free of external debris or contaminants; when practical, workers should change into designated work shoes while in the facility.
    d. If foot dips are required and operational, workers must clean shoes according to procedures (see

21.D Foot Disinfectant Dips).

4.B Hand Sanitation

1. All workers must wash and sanitize their hands before and after doing any work, after each visit to a toilet, after handling contaminated material, after smoking, eating or drinking, and at any other time when their hands may have become contaminated.
2. Disposable protective gloves must be in stock and available.
3. Gloves must be discarded when damaged and after using toilets, eating or contacting a foreign substance.

4.C Wounds and Infections

1. A written policy must prohibit workers with open and/or infected wounds on exposed parts of the body, or those showing signs of infectious illness, from working with exposed product or in product storage areas.
2. Workers with observable or reportable infections must be excused from work according to the organization's procedures.
3. Management must evaluate all situations and take corrective action when any communicable disease is observed and document the corrective action taken.
4. The operation can establish procedures to cover wounds with bandages and/or gloves to eliminate contamination risk.

4.D Protective Clothing

1. Workers who handle open product during processing must wear:
    a. Aprons
    b. Gloves
    c. Hairnets
    d. Beard nets (if beard can be grasped with fingers – longer than 3 mm)
    e. Other protective clothing required in production procedures
2. Protective clothing must be issued to all affected workers and must be clean and in good condition (not frayed, torn or stained).
3. Shoes must be appropriate for the position; open-sole or open-toed shoes must not be worn in cultivation or processing areas.

4.E Prohibited Items

1. Procedures must prohibit workers from wearing false eyelashes, false nails, magnetic jewelry or other items that can detach during production.
2. Workers can wear jewelry that does not affect job tasks if gloves are worn, or they may wear a plain (no jewels) band unless operating machinery or if prohibited by site safety procedures.
3. Gloves must be used to cover nail polish; other cosmetics may be restricted by procedures.

4.F Eating and Drinking

1. Written procedures must prohibit employees from eating, drinking, gum chewing and spitting in product handling areas.

2. Closed containers of clearly marked drinking water kept separate from production materials are acceptable if documented in facility procedures and enforced.

4.G Smoking and Tobacco Products

Smoking, vaporizing (including e-cigarettes) and the use of oral tobacco products are prohibited in all production, storage and work areas and any area not specifically designated as a smoking area.

4.H Control of Drug Use

Policies and procedures must prohibit the use of alcohol, cannabis, illegal drugs and performance-impairing substances and the misuse of prescribed or over-the-counter medications, while working; policy must also prohibit working and work-related driving if impaired.

4.I Violence and Weapons

1. The operation must have an anti-violence policy that prohibits workers from threatening or committing any act of violence in the workplace or while on company business.
2. The policy must prohibit managers, workers, customers, contractors and anyone connected to the business from possessing a firearm at work or while on work business – the policy must prohibit possession of lethal and prohibited knives (see federal, state and local laws) on premises (pocket knives and common tools excluded).

   FOCUS does not recommend the use of security personnel armed with firearms – all exceptions must be justified in the security plan.

4.J GAP/GMP Signage

1. Signage supporting Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP) or (cGMP), worker safety and hygiene must be posted in all appropriate work areas.
2. Signage must require:
   a. Hand washing
   b. Use of personal protective equipment
   c. Other hygienic practices
3. Signs must be presented in languages appropriate for workers, contractors and visitors.
4. Applicable graphic signs also may be used.

5. Health and Safety

5.A Health and Safety Program

The operation must implement and maintain a comprehensive worker health and safety program that includes physical safety, safely designed work processes, safe tools and equipment, facility and environmental safety, regular safety assessments, worker engagement and ongoing safety training.

5.B Health and Safety Risk Assessment

1. The operation must complete a Health and Safety Risk Assessment that examines all risks to worker health and safety throughout all processes related to the operation.
2. Risk assessment must detail specific risks such as, but not limited to, use of hazardous chemicals, machinery use, dust, pollen, noise, exposure to toxic materials, flammable materials and fire, electricity,

glass breakage, asphyxiation and fall hazards.

3. In conjunction with the security plan, Health and Safety Risk Assessment must address worker safety in case of external threat such as robbery or intrusion.
4. Risk assessment must document risk mitigation in the injury and illness prevention plan and they must be reviewed annually.
5. If required by state regulations, the operation must retain signed consent forms for workers who apply any chemicals.

5.C Health and Safety Procedures and Training

1. The operation must have written health and safety procedures and related training programs to maintain a safe work environment for all workers. Procedures and training must meet all federal, state and local regulations including OSHA and must address risks identified in the Health and Safety Risk Assessment.
2. Injury and Illness Prevention Plan must be documented and implemented.
3. All workers shall participate in health and safety training and ongoing training updates; training completion shall be documented and repeated for all workers annually.
4. Safety training must include OSHA-based electrical safety, slip/trip/fall protection, ergonomics, personal protective equipment and workplace violence.
5. Workers that operate forklifts or power pallet jacks must be trained, certified, tracked and recertified according to written procedures that comply with OSHA requirements. Retain documentation in worker files or safety program file.
6. The operation shall install and maintain protective devices and systems such as shields, guards, barriers, detectors, warning alarms, automatic shut offs and access controls.
7. The operation shall install and maintain portable fire extinguishers as specified by 29 CFR 1910.157 — Portable Fire Suppression Equipment. All workers must be trained on fire safety procedures.
8. Lighted exit signs must be installed as required by OSHA standards; in dark grow rooms, reflective exit and safety signs may be used if each worker entering the room is equipped with a working flashlight.
9. Safety data sheets for all chemicals must be on file and available to workers.

5.D Health and Safety Manager

The operation must designate a worker to implement and maintain the worker health and safety program, and the worker must have the skills, time allotment and defined job description to perform the requirements of the position.

5.E Personal Protective Equipment

1. As identified by the Health and Safety Risk Assessment, personal protective equipment (PPE) for eyes, ears, face, head and extremities, protective clothing and respiratory devices shall be provided, used and maintained in a sanitary and reliable condition wherever necessary due to hazards from processes, environmental conditions, chemicals, radiation, mechanical irritants or other risks capable of causing injury or impairment to any part of the body through absorption, inhalation, noise or physical contact.
2. PPE must be assigned to workers in proper working order and may include glasses, goggles, ear protection, gloves, masks, respirators, aprons, boots, etc.
3. If respirators are required:
    a. Written respirator protection usage and training plan must be on file.

b. All workers must undergo a medical exam.

c. Operation must train workers.

d. Workers must get a fit test for the equipment.

e. Respirators must be serviced and tagged to manufacturer's specifications.

4. For reusable PPE, procedures for cleaning and proper storage must be in place and followed.

5. PPE must be stored separately from personal clothing, production and storage areas.

Reference 29 CFR 1910.132 — Personal Protective Equipment

5.F Safety Signage

1. The operation must post signage for all hazardous areas identified in the Health and Safety Risk Assessment. Information signs must provide clear instructions and general safety information for material handling and equipment operation.

2. Signage must be in languages appropriate for onsite workers, contractors and visitors.

5.G Accident and Emergency Procedures

1. The operation must document emergency procedures, train workers and display emergency signage.

2. Procedures and training must cover evacuation, emergency contacts and emergency response actions for specific situations. All procedures must comply with applicable government safety and fire regulations and codes.

3. The operation must develop a fire safety plan that includes fire prevention, suppression systems, evacuation routes and exits, fire extinguishers, signage and notification process. All workers must receive ongoing training; operation should conduct quarterly safety and evacuation drills.

4. The operation should meet with local first responders such as fire and police to clarify risks, specify electrical systems and chemicals, determine fire-fighting methods, plan for access to the facility and discuss worker protection.

5. The operation should provide copies of safety data sheets to the fire department and local OSHA office.

6. During operational hours, the facility must have workers onsite that are trained in liquid and chemical spill clean up; appropriate cleanup personal protective equipment and supplies must be available.

5.H First Aid

1. The operation must ensure there is always at least one person on premises with documented first aid training.

a. Operations with more than 50 workers must have one trained person present for every 50 workers onsite.

2. The operation must maintain well-stocked first aid kits that are checked and restocked monthly; kits should include blood spill kit.

5.I Eyewash Stations

1. The operation must install emergency eyewash stations as required by safety procedures and OSHA regulations – specifically, in any area where workers handle or contact hazardous materials.

2. Gravity fed portable and plumbed eyewash stations require flushing of 0.4 gallons per minute (1.5 liters) for a full 15 minutes with valves that activate in one second or less and stay open to leave the hands free. A plumbed unit should provide the flushing fluid at 30 pounds per square inch (PSI) with an uninterrupted water supply.

5.J Protection from UV Light Exposure

1. Outdoor operations must ensure workers who work in direct sunlight are protected from overexposure to ultraviolet (UV) light.
2. Indoor or greenhouse operations that use high intensity discharge lamps (HID) must ensure worker protection.
3. Signage must indicate UV exposure risk and personal protective equipment requirements.
4. UV light protection requirements must be included in safety procedures and training.
5. Workers exposed to UV light should wear personal protective equipment to cover eyes and exposed skin:
    a. Clothing – dark, tightly woven fabrics or SPF-rated
    b. Brimmed hats – must meet GMP and security procedures
    c. Sunscreen – should be approved for direct contact with plants
    d. Glasses – high UV rating with peripheral protection

6. Security

6.A Security Program

1. The operation must develop, document, implement and maintain a comprehensive security program that protects the business assets, facilities, products, workers, visitors and the community from risks and threats.
2. The security program must include:
    a. Company security mission and purpose
    b. Security roles and responsibilities
    c. Confidentiality and information security
    d. Security systems – access, alarms and video surveillance
    e. Cash revenue management
    f. Record keeping and reporting
    g. Employee policies and disciplinary action
    h. Dynamic entry, intrusion, theft, loss and diversion
    i. Facility access, worker ingress/egress
    j. Inventory control – seed to sale
    k. Safety policy
    l. Emergency policies and procedures

6.B CPTED Approach

1. The operation should design crime prevention mechanisms and methods into the physical and operational environment using Crime Prevention Through Environmental Design (CPTED) or similar security methodology.

2. Operation applies methods such as natural access controls, target hardening, image management, security-based maintenance and formal surveillance, and activity support methods such as resident/neighbor engagement and local law enforcement collaboration, to increase security effectiveness when practical.

6.C Security Risk Assessment

1. An annual Security Risk Assessment must review all threats (crime) and hazards (natural/man-made events) to assets (staff, public, product, currency, materials, information).
2. Security program must include specific action plans to mitigate all risks including:
    a. Exteriors/perimeter
    b. Doors, windows and other openings
    c. Interior areas of site or building
    d. Property and equipment
    e. General security processes/protocol
    f. Alarm systems
    g. Security employees and contractors
    h. Cash management procedures
    i. Worker procedures
    j. Worker and background checks
    k. Opening and closing the facility
    l. Managing and removing trash
    m. Working with vendors
    n. Working with contractors
    o. Threats from neighbors
    p. Training and monitoring employees
    q. General management practices
    r. Managing security emergencies
    s. Plans for dynamic entry or intentional threats
3. Retain annual Security Risk Assessment documentation for at least two years.

6.D Security Qualifications

1. The operation must establish qualifications and procedures for onsite security personnel and ensure all security personnel are trained in and follow company and security policies and procedures.
2. Security managers must have documented security training and demonstrated security experience that qualifies them to competently oversee all security responsibilities.
3. The operation must have an organization chart that identifies security titles and responsibilities.

6.E Security Training

1. The operation must provide and document security training for all workers including dynamic entry, alarm system operations, emergency procedures, crisis management, evacuation procedures, law enforcement interaction and other topics vital to worker, customer, supplier and facility security.
2. The operation must designate a qualified security trainer to provide security training to all workers; evidence of qualifications includes documented security training or verified security experience.
3. The security manager should observe and interview all workers monthly to ensure they understand and follow company security policies and procedures.

6.F Security of Records

1. All electronic records must be stored in a system that is secure, password-protected and limits data access to those who need it.
    a. Data should be encrypted if feasible.
    b. A secure offsite backup/storage system must be in place.
2. All hard copy files and records must be controlled by limiting access to file storage areas, locking filing systems when not in use and requiring sign-out logs when records are removed for review.

6.G Security Incident Reporting

The operation must implement written procedures that define report writing protocols, forms, resources and templates to ensure all security breaches, attempted/actual crimes, unusual disappearance of cannabis, etc., are identified, reported, investigated, tracked, followed up and closed.

6.H Background Checks

1. The operation must complete a criminal background check on all workers, including management and contract workers, using a bonded, certified or authorized service.
    a. Workers must pre-authorize the background check in writing or using e-signature.
    b. Background reports must be kept confidential except as required for procedural decisions.
    c. Reports must be stored in a secure filing system or computer records management system; retain for two years after worker termination.
2. The operation must establish criteria for hiring/not hiring before conducting a background check and it must document all rejections.
3. Criminal background checks must review at least five years history for felony convictions in all U.S. states and territories; international reports may be required depending on candidates and location.
4. Theft, embezzlement or felony drug convictions should prevent employment; all employment restrictions should be clearly documented on the operation's pre-employment information.
5. A written policy should require workers to notify their manager if they are convicted of a felony, receive any drug-related conviction or experience an occurrence known to be a violation of the worker policy manual at any time during their employment or work contract.
6. Background checks must comply with federal, state and local employment and privacy laws.

6.1 Physical Security

6.1A Physical Barriers

1. The operation must apply methods to prevent unauthorized access to buildings, production areas and products, shipping/receiving, storage and parking areas.
2. Prevention methods include fencing, locked gates, secure doors, window protection, automatic access systems and other physical barriers and reinforcements.
3. Security barriers must comply with local security, fire safety and zoning regulations and GMP.

6.1B Grounds and External Areas

1. The security plan must ensure external areas are clear of obstructions, well illuminated and covered by surveillance systems.

a. Include adjacent buildings, neighboring businesses and residential areas, ingress and egress and exterior signage.

2. Workers should be trained on safe ingress/egress processes.

6.1C Door Locks

1. Sturdy commercial-grade locks must be installed on all doors and gates.
2. External doors must have deadbolt locks and comply with local fire and building code regulations.
3. Key distribution must be controlled, monitored and documented.
4. RFID access cards must be controlled and monitored; use cards in conjunction with a PIN code; to increase control, operation can issue RFID cards for each shift and collect at the end of the shift.
5. Biometric entry systems must be monitored, controlled and documented.
6. Procedures must ensure keys, locks, codes and biometrics are changed immediately as required by personnel access privilege changes or breaches.
7. Keypad locks (used solo without key card or biometrics) are not permitted for restricted areas or external entry.

6.1D Facility Access Controls

1. The operation must have documented procedures to control access to the operation's facilities. Procedure should detail access for workers, contractors, managers and visitors including customers, inspectors, law enforcement and regulators.

a. Workers must wear visible identification badges.

b. Process is in place to remove access for terminated workers.

c. At least weekly, the security manager or designee shall review entrance access logs to prevent unauthorized access after hours or off shift.

6.1E Restricted Area Access Controls

1. The operation must have procedures to control access to restricted areas including areas containing controlled products, safety hazards, contamination risks or sensitive information.

    a. Procedures must identify restricted areas, set parameters for authorized access and document the physical controls implemented.

    b. Active controls such as locks, keypads, barriers and/or security personnel must be in use to restrict access.

c. Restricted areas must have logs or digital records to indicate time, date and person accessing the area.

d. Restricted areas must have appropriate inventory controls and documentation for products and materials.

e. Restricted areas must be marked with signage indicating "Restricted Area – Authorized Personnel Only."

f. Procedures must cover access by visitors, contractors, suppliers, regulatory and law enforcement officials.

g. Managers must monitor restricted area access reports on a periodic basis.

6.1F Visitor Access Controls

1. An authorized worker must ensure all visitors sign in and out of the facility (name, organization, purpose of visit, date, time, escort) in a visitor log.
2. All visitors must be escorted by an authorized person at all times while in controlled areas of the facility.
3. Visitors should wear a visible identification badge while on the premises.
4. Visitor log shall be retained for two years.

6.1G Product Control

1. All areas where cannabis or cannabis-derived products are processed or stored must be controlled and access restricted to authorized personnel.
2. Current inventory records must be maintained for work-in-process and finished goods.
3. A commercial vault should be installed as required by the Security Risk Assessment and security program.
4. Signs that read "Restricted Area – Authorized Personnel Only" or equivalent must be posted in all areas where cannabis or cannabis products are processed and stored.

6.1H Theft/Product Loss Plan

1. The operation must implement emergency procedures for securing all product and currency following any instance of diversion, theft or loss of cannabis.
2. The facility manager and/or security manager must conduct a Security Risk Assessment to determine whether additional safeguards are required; they must update procedures and implement changes.

6.1I Cash Management

The operation must provide documented cash management training to workers who handle cash including managing cash transactions with customers and suppliers.

6.2 Alarm Systems

6.2A Facility Alarm System

1. The operation must be continuously monitored by a building-wide alarm system.
2. Alarm must be linked to security, management and police as required by Security Risk Assessment.
3. Alarm should have dual pass-through communication capability.
4. Redundant phone and Internet lines must be installed and operational.

5. System delivers automatic power outage notification – automatic check every 5 minutes.
6. Alarm system includes fire and smoke detection, monitoring and notification of fire department and facility personnel.
7. Pedestrian doors, overhead doors and roof access points must be equipped with door contact sensors connected to an intrusion alarm system; if necessary and practical, roof area should be monitored by motion sensors to prevent cut-and-drop intrusion.

6.2B Alarm Monitoring

1. Alarms must be monitored 24/7 by bonded, accredited or certified professional security company.
2. Alarm triggers and breaches require a 2-minute response time or less and a clearing code process validated via phone by authorized representatives.
3. Monitoring includes fire and smoke detection and notification of fire department and company managers.
4. Automatic alarm is activated for all power outages – automatic check every 5 minutes; monitoring company provides immediate outage notification to authorized managers.

6.2C Motion Detection

Motion detectors should be part of the security monitoring system and linked to active alarms, automatic lighting and automatic notification reporting. Motion detection can be used to slow video recording frames per second when no motion is present to reduce digital storage requirements.

6.2D Panic Buttons

1. Panic buttons (silent alarms) should be placed within sightlines of all entrances/exits and in each separate physical area of the facility (e.g., reception, office, customer service, product processing, storage and receiving). Panic buttons must be linked to the monitored security system.
2. Establish a code word for emergencies to alert fellow workers to an active emergency.

6.2E Alarm System Maintenance

1. Security manager must schedule alarm system preventative maintenance at least annually by a qualified vendor to ensure continuity of coverage, check signal loss and integrity of anti-tampering features, etc.
2. Security manager must ensure alarm sensors and triggers are functional and alarm system is operational 24/7.

6.3 Video Surveillance

6.3A Video Monitoring

1. The operation must install video monitoring equipment that satisfies all local regulations pertaining to monitoring of cannabis facilities.
2. The video monitoring system must be equipped with an automatic failure notification system that promptly notifies management or employees if there is any prolonged surveillance interruption or failure.
3. Date and time must be embedded on every frame of all surveillance recordings without obscuring any useable areas of the image.
4. An automatic battery backup system must be installed to support a minimum of one hour of recording time.

5. The operation shall retain a current copy of local security laws and maintenance logs for all video surveillance equipment.

   FOCUS Standards provide specifications and requirements for professional-level video security surveillance – the security program must document and justify the level of equipment and depth of security processes used.

6.3B Video Recording Security

1. All video surveillance equipment and recordings must be stored in a locked secure area that is accessible only to management and authorized employees of the facility.
2. Digital video files must be password protected and reviewed only by authorized personnel.

6.3C Video Quality and Coverage

1. Video surveillance recording system provides coverage of all internal and external areas of the facility. Video quality must allow for clear visual identification of individuals and activities on the premises.
2. Placement must ensure camera is capable of identifying activity occurring within 20 feet of all points of entry to and exit from the registered facility.
3. Equipment specifications must be based on operational requirements but no less than HD quality (1920 x 1080 – 2.1 megapixel).
   a. External Areas: High-resolution (2048 x 1536 – 3.1 megapixel recommended) IP66 rated camera with wide dynamic range capable of recording in all lighting and weather conditions
   b. Internal Areas: Medium resolution HD
4. Video camera coverage must include:
   a. All secure and restricted access areas
   b. All point of sale areas
   c. All points of entry to or exit from secure and restricted access areas
   d. All points of entry to or exit from the registered facility

6.3D Continuous Video Monitoring

1. Views of all entries, exits and secure and restricted access areas must be continuously recorded by video surveillance equipment 24 hours a day, 365 days a year.
2. Adequate internal and external signage is posted stating “Premises under video surveillance.”
3. To manage digital storage volume, cameras can be set to record low frame rate for general surveillance, then activate to high frame rate (15 fps or more) with motion activation. This is the only authorized use of motion-activated camera functionality.

6.3E Video Retention

1. All video recordings must be stored in a raw non-editable and unedited format that preserves it as a legitimately captured video and guarantees that no image alterations have occurred.
2. All surveillance recordings must be retained for a minimum of 45 days and in a format that can be easily accessed for viewing.
3. Access must be password protected and limited to authorized personnel.

6.3F Video System Maintenance

1. Security manager must schedule video system preventative maintenance at least annually by a qualified vendor to ensure continuity of coverage, check signal loss and integrity of anti-tampering features, etc.
2. Security manager must ensure camera domes/lenses are unobstructed, properly targeted and kept clean.

6.4 Transport Security

6.4A Transport Security Procedures

1. The operation must have written procedures that protect all aspects of the transportation of cannabis and cannabis products.
2. Procedures are required for each physical location the company operates and must include:
    a. Departure
    b. In transit
    c. Arrival requirements for all legs of the route regardless of destination
3. The operation must train all workers involved in the transportation process on transportation procedures and ensure they can conduct them as required prior to transporting product without supervision
4. Destinations may include licensed cannabis facilities in and outside of the company's system, patient and caregiver locations, laboratories and research facilities and disposal locations.
5. The operation shall document transportation training, policies and procedures, agent driver's licenses, driving records, regulatory updates, assessments and incident reports, and retain records for two years.
6. Procedures must align with all state and local laws and must be implemented as specified.

6.4B Transport Manager

1. The operation must designate a qualified person to manage the company's product transport program including:
    a. Product and document control
    b. Verification and training of transport agents
    c. Vehicle security, vehicle inspections and sanitation requirements
    d. Route management
    e. Risk assessments
2. Managers must assess transportation security and transport agent compliance quarterly at a minimum. Nonconformances must be documented and corrective action completed.

6.4C Transport Agents

1. Transport agents are the only workers authorized to transport cannabis and cannabis products and must be listed on documentation for each route they drive.
2. Transport agents must receive training specific to their responsibilities and receive refresher training at least once per year or more often if procedures or regulations change.

3. Transport agents should not wear or display any information identifying them as a cannabis transporter (unless transport security uniforms are part of the operation's procedure).
4. Transport agents must obey all traffic laws; management shall assess each agent's safe driving performance periodically.
5. Transport agents must file a security incident report for any threat, accident or unusual event experienced during the transportation process.

6.4D Transport Agent Credentials

1. All company transport agents must have valid state and/or local registration documents that clearly identify the person as an approved cannabis transport agent.
2. All transport agents must have a valid driver's license; a copy must be on file.
3. The operation must obtain a current driving record for all new transport agents and annually for all transport agents.
4. Procedures must require existing transport agents to report all moving violations and motor vehicle accidents (not just work-related) to their manager.
5. The operation shall establish parameters for transport agent eligibility; the operation must not permit workers to transport products if they do not meet driving parameters established in the transportation procedures.

6.4E Delivery Route Process

1. The operation must document date, time and delivery route of all shipments of cannabis and cannabis products.
2. Transport agents must carry the manifest with copies for the origin site and destination locations.
3. Transport manager must inspect incoming and outgoing product transport vehicles according to 16. Receiving and Transport procedures.
4. Delivery times and routes should be changed on a routine basis to safeguard deliveries; limit authorized delivery windows to daylight hours.
5. When practical, transport agents should call ahead to ensure readiness at destination.
6. Active cellular phones must be issued to all transport agents. Phones should be programmed with appropriate business numbers and agents should be trained to dial 911 for emergencies. Private two-way radio system is acceptable if monitored.
7. Delivery and receiving areas, doors, parking and physical access should be separate from worker or customer entrances and exits.

6.4F Shipment Invoice

1. The shipment invoice, manifest or bill of lading must include at a minimum:
    a. Name, location and registration number of origin facility
    b. Date of invoice
    c. Name, location and registration number of destination
    d. Total product quantity delivered to each location if more than one with detailed bill of lading for each location

e. Date and time of departure

f. Date an estimated time of arrival

g. Delivery route

h. Vehicle manufacturer, model and license plate number

2. Invoices must be protected as confidential information.

6.4G Transport Packaging

1. Transport agents must use an approved, sanitary container sealed with tamper-evident tape or equivalent control.
2. Traceability information must be clearly marked on the outside of the container.
3. Packages inside of sealed containers (if applicable) must be closed to protect contents and sealed if required by product specification.

6.4H Transport Vehicle Controls

1. The operation shall not mark transport vehicles with any signage, lettering or other visual information that indicates the vehicle and driver are transporting cannabis or cannabis products.
2. The operation must segregate an area of the vehicle for secure, sanitary cannabis storage during transport.
3. All product must be concealed from the view of moving vehicles and pedestrians and concealed while parked. Operation should use vehicles with windowless transport compartments or conceal product with tinted glass, barriers or opaque containers.
4. The operation should install active GPS or security tracking on vehicles.
5. Vehicle glove box should contain an “accident and emergency packet” that contains all required information in case of collision or other emergency.
6. The bill of lading, manifest or delivery documentation must list vehicle manufacturer, model and license plate number and remain with the shipment at all times.

7. Product Quality

7.A Quality Management System

1. The operation shall implement a quality management system (QMS) to ensure products are continually produced to established standards and specifications.
2. The QMS must provide systems, methods, tools and training to ensure workers follow standard operating procedures at all times, and ensure all structures, equipment, control systems and production processes continuously operate as designed and specified.
3. The QMS shall require continuous assessment, corrective action for nonconformance, accurate and detailed documentation, and open sharing and use of quality data within the operation.
4. To remain current with quality control requirements and individual responsibilities, all workers must have documented training in the QMS and receive refresher training annually or when the operation changes the system.

7.B Land or Site Assessment

1. The operation shall perform an initial site inspection to determine if location, ingress/egress, production areas, utilities and structures can support the production plan with minimum risk to product and environment.
    a. Assess the primary production risks and mitigation plans.
    b. Determine odor risk according to zoning; mitigate as required.
    c. Complete annual review of site risks, more often depending on site changes.

7.C Buildings and Facilities

1. The operation must have designated and controlled buildings and facilities to adequately meet all requirements for cultivating and processing cannabis.
    a. The operation's structures must be constructed of easily cleanable materials (non-porous) and maintained in good repair. All surfaces, such as roofs, ceilings, walls, floors, windows, vents, drains and overhead fixtures (e.g., pipes, air vents and lights) should be readily cleanable.
    b. Buildings must be designed to control the environmental parameters of all phases of the production cycle (see 7.D Environmental Controls).
    c. Buildings must be designed to protect plants and products against pests, animals, chemicals and other sources of contamination.
    d. Buildings must be secured to prevent unauthorized access.
    e. Buildings must not be used for any other business or private purpose.

7.D Environmental Controls

1. The operation must maintain appropriate lighting, ventilation, air quality (viable and non-viable airborne contaminants), temperature, pressure and humidity in all areas used for packaging, weighing, trimming, preparation, modification, processing and storage.
2. The operation must set environmental control parameters and list them in product specifications or production procedures.
3. The operation shall periodically monitor and record conditions in areas where environmentally sensitive products are processed, analyze collected data and take corrective action as required.
4. Records of environmental monitoring and corrective action shall be retained for two years..

7.E Hazard Control Plan

1. The operation must develop and maintain an ongoing Hazard Control Plan to ensure product quality throughout the production process.
2. The Hazard Control Plan establishes monitoring points (called critical control points) in the production process, sets parameters for each point, assigns workers to monitor and record product quality at those points, and requires them to identify and report any product or processing nonconformance.
3. The operation must designate a team member to coordinate the control process, manage records and implement improvements.
4. The coordinator should include representatives from all functions of the operation such as production, maintenance, packaging, sanitation, customer service, inventory control, etc., in hazard control planning.
5. The operation's hazard control coordinator, managers and production workers must be trained in

appropriate quality control methods.

6. The operation shall review and update the Hazard Control Plan annually or when adding new products or processes to production.

7.F Production Hazard Analysis

1. The operation shall analyze all steps in each production process and document all potential biological, chemical and physical hazards that could affect product quality.
2. Workers must record all hazards in the Hazard Control Plan in a Critical Control Points Responsibilities Chart.
3. The operation shall update the Production Hazard Analysis annually or when formulations, production processes or equipment changes; it must make relevant revisions to processes, procedures and training.

7.G Production Flow Charts

1. The operation must document product-related processes using flow diagrams, process maps, procedures and checklists, etc., to ensure the production of safe, quality products that meet product specifications.
2. The operation layout must provide physical separation of production processes to ensure product quality.
3. Production flow should separate incoming material, staging, manufacturing, processing, finishing, packaging, inspection and storage functions to the maximum extent practical.

7.H Product Manufacturing Processes

1. The operation shall classify all materials and products in the production process and control them according to documented procedures:
    a. Raw Materials – A substance in its natural, modified or semi-processed state used as an input to a production process for subsequent modification or transformation into a finished good.
    b. Work-in-Process – Material dispersed from inventory and released into the manufacturing process that has not been fully processed into a finished good.
    c. Finished Goods – Materials or products that have received final increments of value through manufacturing or processing operations and are released for storage, delivery, sale or use.
    d. Quarantine – Material or products physically isolated from production, marked and controlled until formally authorized for release.
    e. Rejected – Material, work-in-process or finished goods that do not meet product quality specifications. Rejected material is dispositioned as “rework” or “dispose.”

7.I Product Specifications

1. The operation shall document product specifications for each final product produced for sale or transfer. Product specifications shall include the following at a minimum:
    a. Materials and raw ingredients used
    b. Manufacturing processes used to produce products including special processing, additives and sub-processes
    c. Product parameters that define chemical and physical characteristics such as color, texture, odor, viscosity, physical contaminant limits and packaging specifications or restrictions
    d. Unique product code or SKU

e. Intended consumption process (i.e., edible, topical, inhalant, combustible, etc.) by the patient/consumer (if known)

f. Expected shelf life, perishability and special storage requirements

g. Packaging and labeling specifications including traceability (producer and batch/lot), contents and dosage recommendations if applicable

h. Potential risks associated with the product and materials used (see 17.C Warning Labels)

i. Intended customers if known (general public, patients, over 21) and use restrictions (allergies, sensitivities or health conditions), etc.

7.J Control of Contaminants

1. During the Production Hazard Analysis, the operation shall identify contamination risks to products, production and people.
2. The operation shall identify and implement appropriate control systems and devices such as visual inspection, metal detectors, magnets, traps, sieves, filters, screens and x-ray screeners designed to prevent, collect or detect contaminants in raw materials, work-in-process and finished goods.
    a. Control systems must be tested, maintained and calibrated to ensure proper operation. Tests, calibrations, maintenance, performance history, corrective actions and improvements must be documented in the Master Equipment List.
    b. Control systems must be cleaned and sanitized to ensure proper operation. Equipment must be listed in the Master Sanitation Schedule and cleaning logs.
    c. Contaminants include insects or insect parts, feathers, fingernails, cosmetics, jewelry, hair, feces, mold, decomposition or visible growth, visible adulterants, lubricants, glass shards from glassware or lighting, metal shavings from equipment, staples, plastic, wood splinters, stones, sand and foreign plant parts.
3. Procedures must identify worker actions if glass breakage occurs or if glass or brittle plastic is detected in production or storage areas.
4. If used in production, food-grade lubricants must be clearly labeled and stored in an area separate from all other non-food-grade materials. All food-grade materials must have safety data sheets available for review.

7.K Production Records

1. The operation must maintain accurate production records for each batch (or lot) of product it produces.
    a. Production records include pre-production inspections, process monitoring records, control point records, deviation logs and corrective action reports.
2. A batch record must include the product identity, batch or lot number, package volume and production date.
3. Records must document traceability to prerequisite records and components linked to each product batch.
4. Workers should record unexpected findings, process failures or unusual occurrences at any processing step in a deviation log and report them to the quality manager or hazard control coordinator immediately for corrective action.
5. The operation must verify that each batch of product meets product specifications; records should document production inspection results, sample methods and laboratory test results as required by the operation's quality management system and product testing procedures.
6. A certificate of analysis (COA) should accompany each batch to certify the product meets the product specification and that accompanying test results match that batch.

7. All production records must be retained in a secure location for two years after production date. Records involved in an open legal or regulatory action shall not be destroyed or altered.

7.L Yield Analysis and Reconciliation

1. To maintain product quality and production controls, the operation must calculate and document actual yields at the conclusion of appropriate control points in the manufacturing process.
2. Yields must be calculated by one person and independently verified by a second person, or if the yield is calculated by automated equipment, one person must verify it.
3. The operation must have procedures in place to investigate and document yields outside of established minimum or maximum yield parameters as defined in production procedures and product specifications.
4. Records of deviations, corrective actions and product disposition must be on file for review.

7.M Product Rejection Process

1. The operation must establish procedures to reject all products that do not meet established product specifications.
2. Workers must have documented training in the selection/rejection process.
3. Rejected product must be labeled and quarantined in a secure location until released.
    a. Rejected product can be either reworked or disposed.
    b. Reworked product must be tracked, retested and must meet product specifications before release.
    c. Workers must render cannabis waste unusable and record the waste amount in harvest/inventory records.
4. All rejected, quarantined product should be dispositioned within 30 days.

    (see 24.E Cannabis Waste Disposal)

7.N Quarantined Products and Materials

1. All products or materials that are suspended or removed from the production process for any reason must be placed in a controlled storage area (see 19.C Quarantined Material Segregation), physically separated from other products and materials, and be marked adequately with signage or a coding system to ensure segregation of product.
2. Quarantined products and materials shall be identified by batch, lot or production code and tracked in production records.
3. Logs of quarantined finished goods, work-in-process or raw materials must identify the reason for the quarantine, the worker responsible for disposition, the quarantine date and required resolution date.
4. An authorized quality control worker must review each quarantined product or material, provide documented disposition instructions and ensure the products or materials are dispositioned accordingly.
5. Quarantined material can be released to inventory, work-in-process or finished goods, or be rejected.
6. Rejected material must include disposition instructions that identify the product for “rework” or “disposal” and provide the appropriate routing and tracking instructions.
7. Products or material rejected at incoming inspection must include documented disposition instructions and corrective actions, including actions by suppliers.

7.O Corrective Action Plans

1. Workers must document product and process failures in production records.

2. Failure documentation must include a detailed description of the situation (date, time, critical control points, issue, people involved), corrective actions taken and preventative actions implemented.

3. Records must identify specific effects to the product, how the product was dispositioned and how the worker returned the process to conformance.

7.P Cannabis Inventory

The operation must maintain an ongoing inventory of cannabis and cannabis-derived products (raw materials, work-in-process, quarantine, finished goods and transit) and cannabis waste material to the level required to support production integrity and as required by applicable government regulations.

8. Production Equipment

8.A Equipment Management

1. All production equipment must be documented on a Master Equipment List that identifies each piece of equipment used in the production process including machinery, test systems, computing and measuring equipment, appliances, devices, vessels, wares, utensils and tools. The Master Equipment List should include the following as applicable:

    a. Name/description, serial number, supplier and supplier contact

    b. Date received, installed and activated, condition at receipt and current location

    c. Maintenance and calibration requirements and work performed

    d. Relocation, sale or disposal of equipment

    e. History of equipment malfunction, mishandling, damage or recall

2. The operation must maintain all production equipment to manufacturer's specifications to ensure it is available for use and continually meets production requirements.

    a. Maintenance procedures must define maintenance requirements, preventative maintenance, frequency of maintenance, manufacturer's specifications and instructions, calibration requirements and relevant equipment performance history.

    b. Operation shall ensure equipment maintenance is performed as scheduled by qualified workers or third-party service providers.

    c. Workers shall document maintenance activity in the Master Equipment List and record details on the work performed, mechanic or worker performing the maintenance, and the service date.

    d. Manuals, technical sheets and safety instructions should be accessible for all listed equipment and used to support maintenance, calibration, sanitation and training plans.

3. Equipment surfaces that make contact with product and production materials, including supporting equipment (racks, tables, bins, pipes, tubing, back splashes, sinks and exterior housings, etc.), must be maintained in a clean and sanitary condition.

    a. Equipment surfaces must not show any flaking paint, corrosion, oil, grease, food residue or other unhygienic materials.

    b. All non-contact equipment surfaces, including any supporting equipment in the work area that may contaminate the production process, must be clean at all times to prevent potential contamination.

4. All maintenance records shall be retained for the life of the equipment.

8.B Equipment Design

1. Equipment must be constructed of materials appropriate for the intended purpose, preclude contamination of products and promote sanitation.
2. The following types of equipment and materials are not recommended:
    a. Corrosive metals (iron, unfinished steel)
    b. Glass (unless accompanied by safety controls and training)
    c. Brittle plastic
    d. Porous materials
    e. Materials that are difficult to clean or likely to harbor filth
3. Equipment must be made of easily cleanable materials with non-porous, smooth surfaces, tight weld seams, non-toxic materials and no wood surfaces.
4. Equipment should be designed with no unreachable areas to allow access for cleaning and maintenance.
5. Dried cannabis must be produced, packaged, labeled and stored using equipment that is designed, constructed, maintained, operated and arranged in a manner that:
    a. Permits the effective cleaning of its surfaces
    b. Permits it to function as it was designed
    c. Prevents it from contaminating the dried cannabis

8.C Equipment Calibration

1. The operation must calibrate all variable equipment listed on the Master Equipment List.
    a. Variable equipment includes scales, sprayers, irrigation systems, lighting timers and ventilation/filtration systems.
2. Documented calibration procedures must define frequency of testing, testing methods, accepted range of variation and corrective action process.
3. Technicians/mechanics shall record calibration test results and the corrective actions taken when test results exceed the acceptable range of variation.
4. Equipment must meet state calibration requirements and show appropriate stickers or tags that list calibration service and due dates.
5. Calibration records must be retained for at least two years.

8.D Product Containers

1. Buckets, bins, trays, tubs, racks, sinks, etc., used to process or store product or ingredients must be food grade and kept clean and sanitized at all times; cleaning must be logged and logs retained for two years.
2. Operation must use approved food-grade containers and food-grade liners. Retain documentation of food-grade certification for two years.
3. Products and ingredients must be stored in a manner that keeps them clean and uncontaminated (e.g., covered, stowed or segregated).
4. Single-use containers for microbiologically sensitive products are prohibited from reuse.
5. Containers must be the proper size for the task.

8.E Utensils and Tools

1. All utensils, hand tools and other items regularly used in production must be stored clean and in a manner that prevents contamination (e.g., dedicated areas).
2. Tools used for repairing or adjusting equipment in production and storage areas must be clean, free of corrosion and in good working order.

9. Propagation Material

9.A Strain Identity

To maintain strain identity, integrity and traceability, suppliers must provide the strain name on a signed certificate of analysis or supplier letterhead with a high-resolution image of the inflorescence of the parent materials.

9.B Detailed Strain Information

1. Cultivator must maintain records that detail all strains under cultivation.
    a. Details should include: typical THC, THC-A, CBD, CBD-A and CBN levels; pertinent terpenoid and flavonoid profiles, visual description of strain; and plant or seed source.
    b. Methods to determine strain identity may include one or more of the following: DNA testing, chemical fingerprints (e.g., terpenes) using gas chromatography, other chromatography methods that can reliably distinguish among different strains, biological activity (e.g., enzyme activity), physical and morphological characteristics determined macroscopically or microscopically.

9.C Seeds

Cultivator must have records of seed acquisitions that include variety/strain, source, quantity of seeds obtained and date of purchase.

9.D Treatments to Plant Materials

1. Growing operation must keep detailed records on applications of inputs (e.g., rooting hormones or fungicide) made to cuttings, mother plants, seeds, etc., and methods of application.
    a. Records must indicate the name of materials used, quantity applied, date of application and the applicator (worker).

9.E Genetically Modified Organisms

Cultivator must document or attest that all plant materials grown are not themselves GMOs and have not been treated with organisms that are genetically modified using transgenic techniques. (e.g., transgenically modified varieties of Bacillus Thuringensus used as fungicide).

10. Soil and Growing Mediums

10.A Soil Analysis or Composition Profile

1. The operation must maintain soil analysis documentation that records the soil or soil medium's primary mineral components, soil types and/or components.
2. If used, the operation must document details and components of non-soil-based growing mediums.

3. For commercial or packaged soil or soil mixes, manufacturer labels can be used for analysis if they identify specific test results (testing recommended for major acquisitions or when using new suppliers); labels and specifications must be retained for two years.

4. The operation must have non-commercial soil compositions tested by a third party when mixed or purchased. The test results and any related soil analysis must be retained for two years.

10.B Heavy Metal Analysis

1. The operation must ensure heavy metal contaminants in soil and growing mediums are within test plan limits by reviewing soil test results and related analysis reports.

2. The operation must take corrective action for contaminants above limits established by the product test plan and document the actions.

3. Commercial soil or soil mixture packaging and labeling should identify heavy metal content, which can be used for analysis (metals testing recommended for major acquisitions or when using new suppliers).

4. If soil flushing is used to remove heavy metals, flushing procedures must be documented and flushing dates must be recorded.

5. For outdoor grows, soil must be tested prior to initial planting and annually for the presence of heavy metals. If documented agricultural inputs do not contain metals, and the water supply is tested annually and meets heavy metals tolerances, the operation may not require annual soil testing. Supporting documentation must be retained for evaluation.

6. Soil contaminant levels must meet federal, state and local requirements.

10.C Analysis for Organic Amendments

Cultivator must retain certificates of analysis for all organic or certified organic materials such as animal-manure-based components that may include materials approved by Organic Materials Review Institute (OMRI); Oregon Tilth; California Certified Organic Farmers (CCOF); or other recognized certifying organization.

10.D Sustainable Sourcing

Cultivator should provide evidence that the substrate materials (e.g., coir, peat moss, rockwool, etc.) come from a sustainable source. Evidence could include certifications from third-party certification organizations, guarantees from producers or second-party audits or investigations.

10.E Use or Reuse of Soil

1. Cultivator must have a documented policy that details how soil and soil mixes are used and/or reused for production. Policy should define soil usability term and soil disposal process.

2. Records must track current batches of soil in use and their location in the operation

11. Irrigation and Water Use

11.A Water Use Plan

The operation must document a Water Use Plan that identifies water sourcing, storage, use, discharge and testing procedures; it must define the frequency for water testing and analysis, ensure tests are conducted as scheduled and incorporate local water regulations

11.B Water Use Risk Assessment

1. The operation must complete a water use risk assessment at start up and every five years at a minimum or when any material change (substantive enough to require changes to standard operating procedures) is made to the Water Use Plan. Retain assessment documents for two years. The risk assessment should document:
    a. Water sources
    b. Irrigation methods and timing
    c. Siltation
    d. Pollution from nutrients, agrochemicals and other chemicals
    e. Fuels, lubricants, solvents
    f. Contaminated run-off
    g. Livestock, human sewage, waste water
    h. Inflow, outflow, flood risk
    i. Risk of untreated water contamination
    j. Alternate water sources
    k. Potential environmental damage or pollution from water sourcing or discharge

11.C Water Source

1. All irrigation and production water must come from sustainable, legal sources.
2. The operation should assess use and recharge rates for irrigation water sources to determine the sustainability of the source.
    a. Use the best available information and data for analysis.
    b. Develop alternate water source plans as applicable.
3. If the operation uses water diversion, it must obtain local water board or similar municipal or association approval and document legal usage.
4. Water well records including drilling dates, depth and servicing must be retained if applicable.

11.D Water Quality Analysis

1. The operation must analyze water quality at the frequency defined in the Water Use Plan (annual testing recommended unless conditions require more) and retain records for at least two years.
    a. Tests must include biological, physical and chemical contamination.
    b. The operation should use test analysis data to improve water quality and the irrigation process.
2. The operation must use laboratories performing water analyses certified to ISO 17025 level or equivalent standard.

11.E Irrigation Records

1. The operation must evaluate irrigation system efficiency on a regular basis to ensure the following:
    a. Automatic irrigation systems are operating properly and are maintained

b. Pumps are in good working order and operating efficiently

c. There are no leaks or defective valves

d. Subsurface drips are used where suitable

e. Automated irrigation control systems are used when practical and operate as programmed

f. Irrigation schedules are altered for hot, windy or wet conditions (outdoor/greenhouse only)

11.G Leak Detection

1. The operation must complete a detailed system-wide irrigation review and leak detection assessment every year at a minimum.

   a. Repair all leaks, structural issues, deteriorated pipe and fittings.

   b. Perform field surveys and monitor water consumption for unusual usage increases.

   c. Implement appropriate leak detection methods such as flow monitoring and regular data review from meters and submeters to detect and promptly correct any leaks along the system.

   d. Document all repairs and improvements to the system in production records.

11.H Humidity Control

1. The operation shall use humidity control equipment properly sized for the area.
2. The operation should use an atmospheric controller or humidistat to maintain humidity within parameters.
3. The operation should use humidity control equipment in conjunction with ventilation system and exhaust fans.
4. The operation must prevent water pooling by controlling water collection and discharge methods and effectively exhausting humid air.
5. Do not locate water catchment systems in humidity controlled spaces.

11.I Drought Management

1. The operation should have written procedures to manage water requirements during periods of drought or forced water restriction.

   a. Procedures should include drought management plan.

2. Drought management must comply with state and local regulations.

11.J Environmental System Flush

Operation must have a written policy that details how irrigation systems are regularly flushed, and any waste, salt or nutrient build-up must be reused or disposed according to waste management procedures. The operation must ensure flush methods do not pose a threat to people or the environment.

11.K Rainwater Harvesting

1. If rainwater harvesting is used, the operation shall document objectives, procedures and quality controls for water collection, storage and use. Procedures should document the use of earthworks (swales, contours and drainage design that maximize water retention and minimize run-off). Applies to greenhouse and outdoor cultivation only.
2. Water catchment systems must be covered by procedures and facilitate adequate recharge capability. Applies to greenhouse and outdoor cultivation only.

12. Pest Control

12.A Pest Management Plan

1. The operation must develop and implement an integrated pest management (IPM) plan to protect plants from pests and disease, discourage pest populations, prevent disease and promote conditions for healthy growth.

    a. Plan must incorporate product safety and quality controls to minimize risks to products, people and the environment.

    b. Plan shall document risks to plants, remedies (chemical, organic, mechanical, process), workers responsible for tasks, worker training, IPM documentation and worker safety.

    c. Operation must document the pest management plan requirements, dates of service, records of pest activity, dates discovered and remedies pursued. Documentation shall be retained for two years.

2. EPA-approved worker protection safety training and certification are required for all workers mixing, handling or applying pesticides and hazardous inputs or who work in areas where inputs have been applied.

3. The operation must maintain accurate, current documentation for all agricultural inputs.

4. The operation integrates appropriate non-chemical methods (see 12.D Non-Chemical Pest Controls) into the production system.

5. Pest management plan should include monitoring every three months (at a minimum) by a qualified third party provider.

6. An exterior perimeter space of 24 inches should be maintained clear of plants, structures or decorations to facilitate the positioning of exterior pest traps and to discourage pest harborage areas.

7. All equipment and materials must be stored to discourage the harborage of pests such as insects, rodents or birds.

12.B Pest Contaminant Inspections

1. Entire facility should be free of pest contaminants such as whole or parts of insects, rodents, birds, reptiles or mammals, feces, hair and other pest waste to the maximum extent practical.

2. The operation shall inspect the following for evidence of any pest debris at least monthly:

    a. Product or product ingredients

    b. Packaging supplies

    c. Growing, processing and storage areas

    d. Equipment, equipment accessories and utensils

    e. Office or non-production support areas

    f. Dining and break areas

    g. External areas except for normally occurring pest debris (i.e., insects concentrated around light fixtures and natural bird and insect activity)

12.C Pest Control Devices

1. All pest control devices must be in working order (e.g., for sticky traps, glue must still be sticky, not covered with dust).

a. All devices must be marked, numbered and coded.

b. Regular device monitoring must reference trap numbers and locations.

2. Pest control devices (traps, light traps, etc.) must be placed to prevent contamination of raw materials, work-in-process, finished goods, packaging, production equipment or tools.

   a. Interior traps (tin cats, etc.) should be located every 25 to 30 feet or as recommended by service provider based on site layout and process flow.

   b. Interior traps must be placed to prevent easy movement or accidental damage.

   c. Traps should not draw pests into areas where product is stored or exposed.

   d. Exterior traps should be located at least every 30 to 50 feet depending on site and within 6 feet of all exterior doors on both sides of entrance.

   e. Exterior traps must be weighted or attached to ground to prevent movement.

3. Baited traps (baited with poison) can only be used outside of the facility and shall never be used in cultivation, production, product handling, processing or storage areas.

12.D Non-Chemical Pest Controls

Operation must show evidence of the use of some form of plant care that does not involve the application of pesticides (e.g., removal of diseased, damaged or moldy plant material; use of "bait" plants to attract pests; and monitoring airflow and humidity to control mold, mildew or other microorganisms, etc.).

12.E Domestic Animals

1. No animals or pets are permitted in production areas or areas that contain raw materials, work-in-process, finished goods or stored products, production equipment, product containers or packaging.

2. Animals must not be transported in the same vehicle as the operation's finished cannabis products or packaging designated for sale or transfer.

3. Domestic animals are discouraged in all areas of a cannabis facility including office areas; any exceptions must be documented by policy.

4. If a worker requires a service animal to perform job functions and company policy allows service animals, actions taken to protect products from potential contamination must be documented in the worker's file and retained for two years.

13. Agricultural Inputs

13.A Using Agricultural Inputs

1. The operation's pest management plan and production records must document the operation's decisions to use pesticides, fertilizers and other agricultural inputs in the cultivation process.

   a. Plan should document the rationale for specific nutrients, growth acceleration and protection methods and materials.

   b. Results must be documented and should be analyzed to improve plant health and meet cultivation goals.

2. Application procedures must document methods to protect workers, products and the environment from all hazardous substances and conditions.

3. All inputs must be handled, stored, applied and disposed according to manufacturer's label

specifications and in accordance with federal, state and local laws and regulations.

4. Cultivator should develop and document specific input plans for outdoor, greenhouse and indoor cultivation as required.
5. Manufacturer's labels for all agricultural inputs used must be retained for at least two years after harvest date.

13.B Worker Safety and Training

1. The EPA's Worker Protection Standard (WPS) applies to all workers who work with pesticides or in areas treated with pesticides. The WPS provides the specific requirements for training, labeling, worker resources, entry control, notification, personal protective equipment, decontamination and emergency assistance.
    a. The operation must train and certify workers to the EPA's WPS if they mix, store, apply or handle pesticides or other hazardous materials; training must be completed prior to performing the work.
    b. The operation must provide workers who handle or apply agricultural inputs with personal protective equipment (PPE).
    c. Workers must use PPE as directed by product Safety Data Sheets (SDS) and according to 5.E Personal Protective Equipment.

13.C Pre-Harvest Intervals

1. The operation must have a written policy controlling the application of agricultural inputs prior to harvest date, called the pre-harvest interval date (PHI).
2. The policy must identify the PHI for each input based on GAP principles, product safety and manufacturer specifications.
3. Application records must list the PHI of each material used as stated on the label, and plants must not be harvested prior to the PHI specified release date.

13.D Inputs Inventory

1. The operation must maintain an accurate inventory list of all agricultural inputs, supplier documentation and Safety Data Sheets (SDS) for each applicable product.
    a. Products should be listed by EPA registration number when applicable.
    b. Operation shall not use unapproved chemicals or ingredients and must review the EPA-approved and state-approved pesticide lists when selecting agricultural inputs.
    c. Records must document the complete trade name (including formulation) and active ingredient or beneficial organism with scientific name.
    d. Inventory records should include supplier, date purchased and quantities and dates dispersed/mixed.
    e. All inputs must be stored in properly labeled, closed containers separate from any inputs used for production or processing.
    f. Inputs with expired shelf life must be removed from inventory and disposed according to waste management procedures.
    g. A physical inventory must be conducted every three months at a minimum.

13.E Plant Treatment Records

1. Workers must record the application of all agricultural inputs including pesticides, fungicides, herbicides

and fertilizers.

2. The operation must record:
    a. Date and time of each application
    b. Worker applying the input
    c. Amount applied – total volume or weight for each separate application
    d. Method of application (e.g., irrigation system, soil amendment, fogger, backpack sprayer, etc.)
    e. Specific location of application within the cultivation/grow area
    f. Number of plants treated
    g. Reason for application
    h. Strain/variety
    i. Production tracking number (batch/lot) of the treated plants
    j. Climate/weather conditions (if outdoor/greenhouse)
3. If the operation's test lab indicates the presence of inputs residue, enter the test results into the production records for the appropriate batch/lot.
4. List content of NPK, micronutrients and additives in application records.
5. For fertilizers or other inputs, document the rationale for product selection and how results will be measured and evaluated for potential integration into cultivation methods.
    a. Prohibited fertilizers include those that may cause harm to public health, such as sewage sludge and uncontrolled industrial wastes

13.F Application Site

1. The operation must control each site where pesticides or plant protection products are applied; records must reference the name of the greenhouse, section, grow house or grow room where crop was treated.
2. Application areas must be clearly marked by signage or verbal warnings provided to all workers.
3. Workers must not access any treated area for at least four hours or as specified on product warning labeling; closed areas must be ventilated and air contamination levels must be under product label limits prior to entry.

13.G Measuring Equipment

1. The operation must maintain equipment and containers so that they can accurately and safely measure and mix agricultural inputs.
2. Measuring equipment must be properly maintained and calibrated as defined in the Master Equipment List.
3. Records of annual calibration and equipment assessment must be retained.

13.H Inputs Storage

1. All inputs must be stored in a clean, secure dry area.
    a. The area must be sufficiently illuminated to ensure safe handling, have adequate passive or active ventilation systems, be constructed of fireproof materials and be physically segregated from production areas and finished plant products.

b. Stack dry inputs above liquid inputs (if product labels allow proximity storage).

c. Store inputs at least 6 inches off the floor and 18 inches from the ceiling.

2. Inputs storage area must be lockable (keys or combination held by authorized personnel).

3. Area must be locked during non-production hours or as appropriate to ensure security and control.

13.I Spill Control

1. Inputs storage and mix areas must be equipped with a container of absorbent material such as sand or oil dry, a floor brush and dustpan and plastic bags to be used in the case of spillage of hazardous materials.

2. A sign must be posted to indicate the location and handling of cleanup materials.

3. Workers must be trained on spill cleanup procedures.

13.J Used Containers

1. The operation must have written procedures that identify how used inputs containers are handled, stored and disposed.

2. The operation must have evidence that all used containers are disposed through approved methods such as municipal recycling or by an approved waste disposal company.

   a. Retain receipts for disposal or contracts

   b. Install specially designated barrels and signage

3. Input containers must not be reused to store other inputs.

13.K Composting

1. If composting is used, the operation must document and follow composting procedures to maximize compost input value and prevent contamination of work areas, equipment, products and people.

2. Decomposing compost temperature must be maintained to eliminate pathogenic disease and pests, ideally between 131°F and 170°F for at least 15 days.

3. The operation must test finished compost at a certified laboratory to detect hazardous microbial organisms, pathogens and metals as required by the Pest Management Plan, Product Test Plan and production procedures.

   a. The operation should test, analyze and document nutrient values (NPK, etc.) to the extent practical to support GAP and production goals; any test requirements must be specified in production procedures.

4. The operation must protect in-process and finished compost from contamination.

5. Workers must document compost source ingredients and processing and monitoring activity in production records.

6. Workers must document compost applications and the results of compost use in production records.

   a. Usage records could include benefits to plants, reduction in chemicals, application and handling improvements, review of risks and negative effects, and corrective/preventative actions taken.

7. The operation shall not use human, dog or cat biological waste, industrial waste or sludge, or sewage in compost.

   Reference U.S. Composting Council

13.L CO2-Enriched Environment

1. The operation must install a CO2 monitor with alarm in all closed areas where CO2 is released or burned. Monitors must include real-time reports of CO2 levels.
2. Worker must turn off CO2 supply and/or burners 30 minutes prior to anyone entering the CO2-enriched room.
3. Entry door must display sign: “Warning: Oxygen-Depleted Environment – Ventilate Before Entering”
4. The operation should develop and implement a safer alternative to CO2 enrichment to reduce health and safety risks.

13.M Plant Growth Regulators

The operation must have a written policy attesting that plant growth regulators are not used in later-stage cultivation of cannabis and if used at all, are used only as a rooting compound for plant cuttings.

13.N Pesticide Phase Out

1. If pesticides are used, the cultivator should document an annual phase-out progress report that details the reduction and phase out of pesticides.
2. Production records should indicate if the cultivator is using the least hazardous inputs practical to achieve objectives.
3. Pesticides known to cause acute, chronic or ecotoxic risks to workers must be phased out as soon as practical

14. Environmental Sustainability

14.A Sustainability Plan

1. The operation must develop a written environmental Sustainability Plan that details energy efficiency, water reduction, land reclamation, enhancement of biological communities and reuse of resources, and demonstrates progress toward sustainable operations.
    a. Complete and document an environmental impact assessment that identifies positive and negative environmental impacts and possible remediation actions.
    b. Develop and implement a biodiversity plan for the production site and surrounding area including a map of biodiversity areas and plans to support and protect all rare and endangered species or habitats.
    c. Integrate energy audits and energy reduction plans.
    d. Review Water Use Plan and integrate water reduction and reuse plans.
    e. Integrate carbon footprint reduction plans.
2. The operation should update the Sustainability Plan annually and document progress toward objectives and new sustainability plans.

14.B Carbon Footprint Reduction

1. The operation must document actions and plans to reduce its carbon footprint including greenhouse gases, other energy-related emissions, water pumping, transportation (commutes, deliveries, errands) and lighting.
    a. Operation must conduct an energy audit that identifies energy sources and energy consumption per amount of crop produced and/or surface area of crop production.

b. Energy audit must be updated annually and retained for use and review.

2. Set a baseline carbon footprint for current production year and provide a plan (goals, methods, changes) that will reduce the carbon footprint over two production years.

   a. Reduction plans must detail specific improvements, changes, investment, timelines, etc.

   b. As operations grow, producer should calculate new carbon footprint baseline and develop new reduction goals.

14.C Lighting Efficiency

1. The operation should implement energy efficient lighting systems and processes:

   a. Maximize use of natural light using solar tubes, skylights, window light or greenhouses.

   b. Use timing controllers and motion detectors in offices and non-production workspaces.

   c. For grid-connected indoor grows, minimize use of lighting during peak times as defined by the electric utility.

14.D HVAC Efficiency

1. The operation should integrate energy-efficient heating, ventilation and air conditioning (HVAC) systems for indoor and greenhouse operations including the use of automatic climate controllers, evaporative coolers, shade structures and piggy-back (AC/evaporative) systems.

2. The operation should periodically calibrate cooling systems and clean ventilation systems as required by the Master Equipment List.

14.E Minimization of Energy Intensity

1. The operation should show evidence of a minimization of energy intensity per unit of product by tracking the amount of energy required in the production process and/or increasing the output while maintaining the same level of energy input.

   Evidence could include in-tandem tracking of production yields and energy use over several production cycles.

14.F Use of Renewable Power

The operation should show evidence of efforts to increase the share of renewable energy in the energy mix used for production. Opportunities include renewable fuels or buying “green power” (e.g., wind and solar energy, hydropower, geothermal, biomass, tidal power, anaerobic digestion, etc.).

14.G Efficient Use of Equipment

The operation should install efficient processing equipment; shut down idle equipment to avoid “standby” energy loads; maintain equipment on schedule; conduct prompt repairs; and train workers on efficiency methods and behaviors.

14.H Use of Petroleum Generators

Use of diesel or gasoline generators for crop production is prohibited unless the cultivator can demonstrate that generator use has no adverse impact on air, soil or water quality. For off-grid operations, generator back up for power supply is allowed based on balance of domestic and production power usage.

14.I Eliminate CO2 Enrichment

Limit or eliminate the open release of CO2 gas and the use of open flame burners to produce a CO2-enriched environment.

15. Harvest Practices

15.A Pre-Operation Inspections

1. Workers shall inspect work areas, equipment and materials, confirm personnel are prepared, and review current logs and reports to verify quality system readiness prior to each production run or cycle. Inspections shall ensure:
    a. Processing areas are decontaminated, cleaned and sanitized
    b. Equipment is decontaminated, cleaned and sanitized
    c. Storage areas are decontaminated, cleaned and sanitized
    d. Production line is prepared for safe start – PPE, safety equipment, first aid, signage, etc.
    e. Personnel are in position and meet GMP and procedural requirements
    f. Previous inspection nonconformances have been corrected
    g. Water source is prepared and meets Water Use Plan requirements
    h. All process and sub-process steps were reviewed and verified
    i. Required materials, equipment and quality control logs/forms are in position
2. Completed checklists must be retained for one year after production or harvest.

15.B Harvest Procedures

1. The operation must have written pre-harvest, harvest and post-harvest handling procedures and evidence that workers have received specific task-related training.
2. Procedures and training should cover methods to mitigate all risks identified in the Production Hazard Analysis.
3. The operation's Hazard Control Plan or equivalent product control procedure must cover all cultivation processes from pre-harvest to finished goods.

15.C Cross Contamination Prevention

1. All processes must be designed and organized to prevent contamination of products.
    a. Gloves must be used and discarded between each product handling.
    b. Areas must be clean, neat and free from debris.
    c. Tools must be cleaned between operations and daily at a minimum.
    d. Production processes must ensure clear physical separation of raw materials from work-in-process and finished goods.
    e. Adequate workspace must be available for all activities and processes.

15.D Handling and Packing Areas

1. All areas for product handling must be clean and organized appropriately for the planned tasks to prevent contamination of the product or product packaging.
2. Only authorized people, materials, equipment and products are allowed in the packing area – no extraneous foot traffic or storage unrelated to packing tasks allowed.

3. Workers must follow documented cleaning procedures; cleaning logs must document who sanitized product handling areas and when.

15.E Drying

1. Areas used for bulk drying of plants or plant material must be separated from other production areas.
    a. Areas must have adequate airflow, ventilation and other environmental controls, such as temperature and humidity, to protect the product.
    b. Plants must not be dried on the floor and should not be dried on surfaces that slow or prevent proper drying.

15.F Trimming

1. Manual and automated tools used for trimming of plant materials must be adequately cleaned and in good repair.
    a. Tools are ergonomically designed to lessen stress on workers and to ensure safe operation.
    b. All final product trimmings are disposed according to procedures or used for secondary purpose (extraction). All product and waste must be accounted for in harvest yields and recorded in inventory records.

15.G Final Curing – Post Harvest Treatments

1. The operation must have a designated space for the curing of product that is separate from other areas of the facility.
2. Procedures must be implemented to properly separate all varieties, strains or batches while curing. All stored product shows evidence of product tracking, coding and traceability recording.
3. Any post harvest treatments (e.g., fumigants) must be recorded as plant protection product applications.
4. Air filters or scrubbers must be installed as appropriate to control odors.

15.H Final Quality Control

1. The operation must have written quality acceptance criteria for harvested products and finished goods. Workers must be trained to ensure harvested or final product meets quality criteria.
2. All materials must be clearly marked with current production status including quarantine, work-in-process, pending approval for production, pending release for sale, or rejected.
    a. All materials pending approval must be physically segregated and clearly marked to prevent commingling with approved or unapproved materials or products.

15.I Post-Harvest Biological Decontamination

1. At the end of a harvest cycle, the operation should decontaminate greenhouses, growing rooms, processing areas and storage areas for biological contaminants to the extent practical.
    a. The operation must clean and sanitize all equipment and surfaces and allow the area to ventilate.
    b. The operation should make any mechanical improvements and conduct required maintenance.
    c. When complete, the operation must conduct environmental testing and take corrective action to ensure the area is prepared for the next crop cycle as defined in the production plan.
2. The operation must document the decontamination process (date, workers, tasks completed, chemicals used, issues discovered, etc.) and retain the records for two years.

16. Product Testing

16.A Product Testing Plan

1. The operation must ensure all products sold or transferred are free from contaminants and adulterants as specified in the product testing plan and/or product specification.
2. The operation must develop a testing plan that addresses all risks to products.
    a. Testing must be done on all batches and final products.
    b. All test reports must reference the corresponding batch.
    c. Test results must match batch/lot and date produced.
    d. Test results must be provided with all final products.
    e. Supplier-provided test results must be from a certified lab and must be checked for accuracy.
    f. Test results must be retained for all raw cannabis and cannabis-derived products for three years.
3. The producer must review test lab report to ensure:
    a. Testing laboratory is certified to ISO 17025, FOCUS Standard or equivalent
    b. Test report lists batch/lot number that matches product tested
    c. The report is complete:
        1) Date
        2) Methodology performed and method reference
        3) Lab technician(s) signature or code
        4) Complete data provided
        5) Equipment protocol data provided (equipment and methods)
4. All test standards are subject to federal, state and local laws and regulations.

16.B Sampling Procedures

1. The operation must apply a documented procedure for collection of sample product material for laboratory analysis.
2. Procedures must adhere to the designated testing facility criteria and established industry standards.
3. The sampling log must define the batch or lot size, production date, lot-received date, container type, how samples are obtained and who performed the sampling.
4. The operation must demonstrate that samples were sufficiently homogenous and are representative of the product sold.
5. Samples must be retrieved, stored and transported in original, clean packaging that is clearly marked and packaged in a way that preserves the composition of the sample.
6. Samples must be sealed with tamper-evident tape and not be broken except by an authorized person.
7. Records of sampling, laboratory data and chain-of-custody documents must be kept on file for review for three years from test date.

8. If testing procedures require a third-party lab worker to obtain test samples at the production site, the operation shall document procedures, train workers and lab staff, and provide the equipment necessary to facilitate an onsite sample collection.

16.C Test Lab Standards

1. The operation must use a testing laboratory that meets ISO 17025 or equivalent, the FOCUS Laboratory Standard or relevant state cannabis test lab standard; if such a lab is not available, operation must maintain documentation to validate the laboratory methods that were used.
2. The operation must retain valid certification documents for all testing labs used.

16.D Allowable Thresholds

1. The operation must establish documented thresholds for the presence of biological, chemical and physical contaminants.
2. Thresholds must adhere to established federal, state or local regulatory standards and FOCUS standards, but can be more stringent.
3. Threshold levels should be stated in commonly understood units such as parts per million (PPM or ppm) or colony-forming unit (CFU or cfu).

16.E Microbiological Testing

1. All products must be tested for aerobic plate count.
2. Product test results must validate that less than one colony forming unit (CFU) per gram of tested material is present for E. coli or Salmonella species or the product shall be rejected.
3. Products must be tested for the presence of yeast and molds.
4. Test reports must include method reference.

16.F Metals

1. Testing for heavy metals must include but is not limited to lead, arsenic, cadmium and mercury.
2. Test results must meet federal, state and local regulations and limits – if these are not available or applicable, the following apply:
    a. Lead – max limit < 6 ppm
    b. Arsenic – max limit < 10 ppm
    c. Cadmium – max limit < 4.1 ppm
    d. Mercury – max limit < 2.0 ppm

16.G Pesticide Residue

1. The operation must test all product batches for any pesticides used in the cultivation process; results for residue must be within limits specified in federal, state and local regulations – where not specified, 0.1 ppm or a positive result at the Limit of Detection (equipment's lowest possible detection amount) will be considered to exceed safe residue limits.
2. Pesticide residue testing must analyze samples for the presence of chlorinated hydrocarbons, organophosphates, carbamates and pyrethroids, neonicotinoids, acaracides, fungicides and bactericides to the maximum extent practical.
    a. The operation's test plan, including tests for pesticides not used in the cultivation process, must meet all federal, state and local regulations.

b. If local laboratories cannot provide the level of testing specified, labs should test for pesticides to the maximum extent of their technical capabilities.

16.H Potency and Cannabinoid Profile

The operation must test products for cannabinoid profiles and provide results for levels of THC, THC-A, CBD, CBD-A, CBN and terpenoid profile as applicable to the product specification.

16.I Contaminants and Filth

1. The operation must inspect all products for contaminants and filth.
    a. Contaminants include any biological or chemical agent, foreign matter, or other substances not intentionally added to products that may compromise food safety or suitability.
2. The operation must document allowable thresholds for physical contaminants as part of the product test plan.
    a. Inspection requirements must be included in the operation's product test plan for third party testing.
3. Inspection records must indicate a continual process of physical inspection has taken place for all batches.

16.J Test Results Analysis

1. All products with pending tests must be segregated in containers, marked "quarantined" and held in a secure location until test results are received. Containers must include batch/lot code for tracking.
2. The operation shall designate a qualified staff member to review each test result against the product specification. If the product meets all specifications, the staff member shall release the batch of product to the next step in the process.
3. Products that do not meet specifications must be rejected and quarantined.
4. All quarantined batches/lots held for testing, releases to production or rework, and final disposition must be documented in inventory records.
5. The operation shall document and retain all test results and certificates of analysis for three years.

16.K Batch Monitoring

1. If required by the operation's test plan, the operation must collect and store a control sample of product from each production batch.
2. An organized storage area and reference system should be in place for all samples.
3. All product samples must be kept in storage for a period of one year past expiration date or related quality control date in case of product recall.
4. Any sample involved in a pending claim or legal dispute shall not be destroyed.

16.L Test Records

1. Test logs must list the batch/lot/plant/product test date.
2. The operation must maintain all test logs and test results (lab reports) for a minimum of three years from the date test was performed, including test results received from suppliers.

17. Packaging and Labeling

17.A Packaging and Labeling Specifications

1. The operation must document written procedures for labels and packaging materials including selection of materials, design, inspection, approval, storage, handling and rejection processes.
    a. Each batch of labels or packages must have traceability information that links it to manufacturer.
2. Records must be in place that detail receipt of materials and use.
3. Specific label language and packaging requirements vary by state and locality; check state and local laws and keep procedures current and on file.
4. Packaging specification must identify appropriate work environment controls (e.g., humidity, airflow, dust, temperature) to protect product during handling and packaging.
5. Packaging/labeling training must be provided to the appropriate workers and documented in the training record.

17.B Labeling Protocol

1. The operation's labeling protocol must be documented and should include the following at a minimum and as required by product specification and government regulations:
    a. Name of the business
    b. Product name or identity
    c. Net quantity of contents
    d. Active ingredients (cannabinoid/terpene profiles)
    e. Directions for use
    f. Warnings (see 17.C Warning Labels)
    g. Common allergens
    h. Instructions for appropriate storage
    i. Additives
    j. Inputs used in cultivation process (pesticides, fertilizers)
    k. Statements or information required by state or local regulations
    l. Perishable products must display a "Use By" and/or a "Freeze By" date
    m. Laboratory that performed the testing (or a lab key code)
    n. Date of manufacture using Julian date
    o. Operation must ensure all supplier labeling meets requirements

    Reference 21 CFR 201.60 Subpart C — Labeling Requirements for Over-the-Counter Drugs series

17.C Warning Labels

1. All products and packaging must display the warnings appropriate for the product as defined in the product specification and by applicable government regulations.

2. Warning labels should include the following as required:
    a. This product is infused with cannabis and/or cannabinoids.
    b. This product is intended for use by adults 21 years and older. Keep out of reach of children.
    c. There may be health risks associated with the consumption of this product.
    d. The intoxicating effects of this product may be delayed by two or more hours.
    e. There may be additional health risks associated with the consumption of this product for women who are pregnant, breastfeeding or planning on becoming pregnant.
    f. Do not drive a motor vehicle or operate machinery while using this product.
    g. This product was produced without federal regulatory oversight for health, safety or efficacy.
    h. This product may be habit forming.
    i. This product is unlawful outside the State of (insert appropriate state).
    j. Do not use with (list of contraindications).
    k. Ask a doctor before use if you have (list of conditions or symptoms).
    l. Ask a doctor before use if you use or eat (list of drug/drug or drug/food interaction warnings).
    m. Stop use and ask a medical professional if you experience (list toxicity or other biological reactions).
    n. Other warnings that may apply: allergic reaction, asthma alert, flammability, choking/water soluble gum and sore throat.

17.D Exit Packaging

1. The operation must appropriately package all finished goods to protect product quality and prevent accidental or unauthorized use as defined by packaging specifications.
2. Each exit package must display an accurate, complete label as required by the labeling protocol and product specification.
    a. Labels must be consistent with products offered for sale.
    b. Labels and packages must comply with federal, state and local regulations.

17.E Child Resistant Packaging

1. The operation must ensure every exit package containing cannabis or cannabinoid product is child resistant as defined by the Poison Prevention Packaging Act and 16 CFR 1700 — Poison Prevention Packaging.
2. Packaging must be significantly difficult for children under 5 years of age to open or to obtain a toxic or harmful amount of the substance within a reasonable time; it should also not be difficult for normal adults to reasonably access or use the product properly.
3. For elderly or disabled persons unable to open special packaging, manufacturers may package substances in noncomplying packaging if:
    a. Complying packaging is also supplied
    b. Noncomplying packages are conspicuously labeled to indicate they should not be used in households where children are present.

17.F Tamper Evident Packaging

1. The operation must package a product in a tamper-evident package if the product is physically accessible to consumers prior to a sales transaction.
2. A tamper-evident package has one or more indicators or barriers to entry that, if breached or missing, provide visible evidence of tampering to consumers.

   Reference 21 CFR 211.132 — Tamper-Evident Packaging Requirements for Over-the-Counter (OTC) Human Drug Products

18. Traceability and Recal

18.A Traceability System

1. The operation must have a documented traceability system that tracks products from the production site to the consumer distribution point.
2. The operation must be able to identify products by batch number in the production records.
3. The operation must document supplier inputs and materials used to produce each batch to the maximum extent feasible.

18.B Product Recall Program

1. The operation must have a documented Product Recall Program that includes:
   a. Depth of Distribution – Methods and support resources to rapidly analyze and determine the extent of distribution affected: consumer, retail, wholesale or a combination of channels.
   b. Recall Classification – Procedures that ensure appropriate and rapid assessment and classification of risk level and require the appropriate level and urgency of response (e.g., FDA Class I, II, III).
   c. Supply Chain Notification – Contact and tracking procedures that verify all consignees in the distribution chain, including related product suppliers, are notified and take appropriate action.
   d. Regulatory Notification – Procedures for communication with federal, state and local authorities, including the public health department, within 24 hours (sooner as required).
   e. Public Warning Process – Procedures to assess the need for an alert to the public that a product under recall presents a serious hazard to health. These warnings are reserved for urgent situations and typically involve collaboration with the FDA.
   f. Recall Coordinator – A worker with the skills, training, job description and authority to effectively execute the requirements of the position including coordinating team training and mock tests and managing documentation and corrective action.
   g. Recall Team – Workers, suppliers, third-party professionals and others trained to respond as required by procedures.
   h. Call List – A contact list that defines the priority of contact for all recall team members, regulators, suppliers, distributors, retailers and others necessary to effectively execute a product recall.
   i. Product Returns – Communicate the procedure for return of the recalled product from distribution.
   j. Recall Documentation – Procedures that require documentation of all recall incidents and outcomes.
   k. Corrective Action – Requirements to investigate root cause and scope of product problem, complete corrective or preventative actions and improve recall procedures.

18.C Recall Mock Test

1. The operation must conduct a “mock recall” test:
    a. Within the first year of operation
    b. Every two years thereafter
2. Mock recalls should include all steps required in the Product Recall Program.
    a. All associated supplier records, sales information, shipping details, contact lists, etc., should be available for use.
3. Results of the mock recall must be analyzed and corrective action must be taken and documented.
4. Mock recalls should include worker training on recall procedures and the resources needed to complete a successful test.

18.D Complaints Procedure

1. The operation must follow a documented complaints procedure to ensure all complaints are recorded, evaluated and followed up.
2. Procedure must include a defined timeline for response to complaints, persons responsible for complaint procedures and actions taken.
3. Procedure must indicate methods for resolution of complaints, including corrective action required in the production process.
4. The operation shall retain complaints records for two years; do not destroy complaints records related to open litigation or active product recall.

19. Product Storage

19.A Product Storage

1. Cannabis and cannabis-derived products must be stored in a controlled environment to preserve product identity, strength, purity and quality.
2. The operation must implement written procedures to control storage areas and provide specific storage procedures for raw (cured) cannabis and cannabis products.
3. Product storage areas must only be used to store raw cannabis, components of cannabis products, final cannabis products, packaging and labeling related to cannabis products.
4. Workers must record all products added or removed in the inventory system.

19.B Storage Area Access Control

1. All areas where cannabis or cannabis-derived products are stored must be locked and secure with access restricted to authorized personnel.
2. Signage must indicate “Restricted Access – Authorized Personnel Only” or equivalent.
3. The operation should use a sign in/sign out log or automatic RF tracking system; retain access logs for two years.

19.C Quarantined Material Segregation

1. An area must be set aside for quarantined material and products.

2. The area must be marked with clear signage and access marked or limited by physical barriers.
3. Quarantined products and materials shall be labeled and tracked in production records.
4. Quarantined containers must bear distinguishing labels (non-standard color, extra-large bold letters, etc.).
5. Containers must be sealed with tamper-evident seals or packaging that records the worker who sealed the container and the seal date.
6. All quarantined material should be dispositioned within 30 days (unless justified in writing) and recorded in the inventory system.

19.D Storage Area Construction

1. All storage areas should be constructed of easily cleaned materials (non-porous, non-toxic) and with limited unreachable, difficult-to-clean areas.
2. All products must be stored a minimum of 6 inches off the ground.
3. Air filters or scrubbers should be installed and used as appropriate.

19.E Cleaning

1. All storage areas must be clean, well ventilated and free from condensation, sewage, dust, dirt, chemicals or other contaminants.
2. Stored products and packaging should be clean and free from dust, debris and contaminants.
3. Cleaning schedules and logs must be current and retained for review; product must be protected or removed during cleaning.

19.F Pest Control

1. The operation's Integrated Pest Management (IPM) must cover all product storage areas and include:
    a. Requirements for pest control in storage areas
    b. Evidence of active pest control measures (traps, pest service, etc.)
    c. Documentation of service in pest service logs

20. Receiving and Transport

20.A Product Transfers

1. If allowed by state and local laws and regulations, a licensed operation may transfer (sell/purchase) cannabis or cannabis plants to another licensed cannabis operation.
    a. Both operations must document the transaction using a transfer manifest.
    b. Material must be tested and analyzed for product quality prior to use per testing procedures.
    c. Receiving agent must enter all product transfers into the inventory control system.
    d. The operation must retain records of all product transfers for two years.
2. Cannabis transfers must have this information documented, as applicable:
    a. Name and address of seller and buyer

b. Transfer manifest authorizing the transfer

c. Unique product code or SKU

d. Supplier batch, lot or control number

e. Weight in metric units (all usable cannabis)

f. Number of immature plants received

g. Date of manufacture or processing

h. Date the cannabis/plants were received

i. Amount of finished products received including, as applicable, the weight in metric units or the number of units

j. Strain identification; traceability; certificates of strain analysis or similar documentation

k. Product test data from a certified laboratory

l. Certificate of Analysis – product specifications

m. Harvest specifications including chemicals added during cultivation

n. Transferring agent's registration card and expiration date

o. Transfer and transportation subject to all requirements in 6.4 Transport Security

20.B Supplier Qualification

1. Suppliers must be evaluated, qualified and selected based on specified criteria.
2. The operation must periodically assess supplier performance to ensure that qualified suppliers continue to provide acceptable materials and services.
3. The operation must document supplier nonconformance and corrective action taken and retain for two years.

20.C Incoming Goods Inspection

1. The operation must have a documented inspection process for all incoming goods that documents all nonconformances to specifications. The inspection process must identify inspection parameters and sampling procedures. Goods must be inspected for (as applicable to the product):

   a. Correct item

   b. Correct quantity and/or weight (use calibrated scale)

   c. Meets quality specifications

   d. Signs of decay or degradation

   e. Foreign materials contamination

   f. Odor

   g. Physical damage

   h. Improper packaging or mislabeling

   i. Product safety

   j. Security issues

2. Document all nonconformances and the corrective action taken.

20.D Vehicle Inspections

1. The operation must inspect all transport vehicles and maintain a log that records:
    a. Product security
    b. Mechanical operation
    c. Condition/damage
    d. Vehicle cleanliness
    e. Fuel status
    f. Temperature control
    g. Inspector/inspection date
2. Vehicles must have shipping manifest and trip/route plan on file.

20.E Sealed Trailers and Trucks

1. Outbound transport trailer and truck doors should be fitted with seals and/or commercial grade locks to maintain security.
2. Seal numbers should be recorded if seals are used. Retain seal bands if necessary.
3. Only authorized personnel can break incoming trailer seals.

20.F Contract Carriers

If used, an operation must have a written contract with the carrier service that details the methods of transport, security measures and other information relevant to the quality and security of the final product

21. Facility Maintenance

21.A Facility Maintenance Plan

1. The operation must have a documented plan for the upkeep of all operational elements of the physical facility including mechanical equipment, utilities, structure integrity, water drainage and external signage.
2. Records must show the type of maintenance completed, mechanic or technician name and date work was completed.
3. Lockout/tagout training is required for any workers who perform maintenance or repairs on electrical equipment.

21.B Plumbing Contamination

Sewer and water pipes must be placed to avoid possible contamination of product or equipment in the event of a leak or dripping condensation. Preventative measures should be documented and implemented as applicable.

21.C Ventilation and Exhaust Fans

1. Ventilation equipment and fans must maintain safe air quality and vent and/or filter any noxious odors or dangerous airborne contaminants.

a. Air quality standards must meet worker safety requirements and product quality specifications (see 7.D Environmental Controls).

2. Ventilation system must be tested annually (or more frequently as required by conditions) for contaminants and sanitized as required.

3. All fan guards and coils (cooling units, production equipment and general ventilation) must be clean and free of dust, grease or other collected contaminates.

4. Walls or ceilings around fans or ventilators must be free of dust build-up or foreign matter.

5. Vents, filters and fans must be cleaned or replaced periodically.

21.D Foot Disinfectant Dips

1. If required by quality procedures and used, foot dips must contain a USDA approved food-grade sanitizer at a determined concentration – common chemicals are iodine (20-25 ppm), chlorine (2-25 ppm free chlorine) and quaternary ammonium (150-200 ppm).

2. Foot dips should be regularly checked to ensure their effectiveness with corrective actions recorded (e.g., dip solution replenishment and anti-microbial additions).

21.E Grounds Maintenance

1. Written procedure must detail maintenance requirements for the external grounds, building exteriors, signage, parking areas, lighting, storage and trash areas, trash collection, litter clean up and general appearance.

   a. Procedures should list the frequencies for specific maintenance.

   b. Workers operating hazardous or loud equipment must wear appropriate PPE including eye and hearing protection.

   c. Logs of maintenance should be available for review.

21.F Hazardous Materials

1. All hazardous materials and cleaning supplies must be identified, marked, segregated, controlled and stored according to written procedures, government regulations and product labeling.

2. Separate, lockable storage must be in place for all hazardous substances.

   a. Accurate inventory of storage contents must be documented and maintained.

   b. Storage areas must display required warning signage in appropriate languages.

3. All hazardous chemical containers and secondary containers must display labels that meet OSHA and GHS (Globally Harmonized System) specifications including pictograms, signal word, hazard and precautionary statements, the product identifier and supplier identification.

4. If food-grade chemicals, including lubricants, greases, etc., are used in product/packing contact areas, chemicals must be handled according to procedures and segregated from non-food-grade items at all times to eliminate misuse.

5. Non-food-grade chemicals must be clearly marked and segregated from product production areas.

6. The operation must train workers that handle chemicals in liquid and chemical spill clean up as defined by manufacturer's label and the safety data sheet, and as appropriate for the materials and risks.

   a. Cleanup equipment and materials must be available; waste must be disposed of according to 24. Waste Management.

b. If hazardous spill cleanup involves worker exposure or a reasonable possibility of exposure to hazards, the operation must contact local government hazardous materials first responders immediately.

Reference 29 CFR 1910.120 – Hazardous Waste Operations and Emergency Response

22. Sanitation and Cleaning

22.A Sanitation Procedures and Training

1. The operation must maintain sanitary conditions at all times.
2. Operation must have written sanitation and cleaning procedures for all equipment and areas.
3. All workers must receive formal sanitation training.
4. Procedures and training must cover the following at a minimum:
   a. Worker responsible for cleaning
   b. Item/area to be cleaned
   c. Specific cleaning methods
   d. Tools, utensils and cleaning products used
   e. Frequency of cleaning
   f. Safety, PPE and chemical controls:
      1) Dilution and mix hazards
      2) Application procedures
      3) Labeling, containers and storage
      4) Personal protective equipment
      5) Spill clean up
      6) First aid

22.B Master Sanitation Schedule

1. Facility must maintain a Master Sanitation Schedule that identifies each area, each piece of equipment and each support item to be cleaned and frequency of cleaning.
   a. Areas include all processing, packing, product storage and waste areas, and offices, restrooms, break areas and public/patient areas.
   b. Equipment and support items include anything used in the production process or located in production areas.
2. Facility shall keep a log of the area/equipment cleaned, cleaning performed, date cleaned and worker performing the cleaning.

22.C Cleaning Equipment and Supplies

1. All necessary cleaning equipment and consumable supplies must be readily available and their use promoted.

2. Cleaning and sanitation equipment and supplies must be stored in a designated area separate from raw materials, production, packaging or product storage areas. Equipment must be stored separately from personal clothing.

3. Equipment must be clean and should be replaced when worn. Absorbent equipment such as brushes, mops, towels, sponges and other easily contaminated items must be sanitized before each use or replaced.

4. The operation should develop a list of acceptable cleaning products to meet each sanitation requirement. List should document cleaning requirement, product, product sources, mixing, application and storage directions.

    a. Acceptable cleaning products could include: diluted bleach; diluted ammonia; 70% ethanol; 70% isopropanol; food-grade detergent, etc.

    b. Operation should use "green" (environmentally friendly) cleaning products when practical and select the least-hazardous chemical to meet the requirement.

5. Workers must receive documented training on the use of cleaning equipment and supplies and must wear personal protective equipment (see 5. Health and Safety).

22.D Cleaning Equipment Identification

1. Cleaning equipment and supplies must be color-coded or boldly marked to prevent contamination or accidental use.

2. Separate cleaning equipment should be assigned to separate physical areas or functions:

    a. Production

    b. Maintenance

    c. Storage

    d. Office

    e. Restroom/toilet

    f. Outdoor

22.E General Cleanliness

All areas identified under the cleaning procedure must be kept clean, organized and well maintained.

22.F Sanitation Logs

1. The operation must maintain accurate, current sanitation logs that cover all areas of the facility and all equipment.

2. The logs should identify:

    a. What was cleaned

    b. Who cleaned it

    c. When it was cleaned

3. The logs should be easily accessible and retained for two years.

22.G Floor Drain Cleaning

The operation shall clean floor drains on a regular schedule and maintain a log that indicates when they were cleaned and the worker performing the cleaning.

22.H Swab Testing

The operation must conduct periodic environmental testing (swab testing, air impaction or equivalent methods), document test results and the corrective actions taken if results show evidence of biological contamination.

22.I Product Protection During Cleaning

Raw materials, work-in-process, finished goods and packaging materials must be removed from the area during cleaning. “Cleaning” includes cleaning production lines between product runs, sanitizing equipment surfaces and general cleaning of fixtures, floors, walls, tables, doors, etc., in the work area.

23. Sanitary Facilities

23.A Toilet and Hand Washing Facilities

1. The operation must provide clean, modern toilets with hand-washing sinks and maintain them in a clean and sanitized condition.
    a. A worker must be designated to clean and stock the facilities.
    b. Supplies such as soap, toilet tissue, paper towels and sanitizer must be well stocked.
    c. Records of scheduled cleaning and restocking must be on file.
2. Toilet facilities should be in an area separate from all processing areas or far enough away so as not to pose a risk to processing. Doors should not open directly into production or storage areas.
3. Toilet facilities should have self-closing doors.
4. Surfaces should be smooth, light-colored and easily cleanable.
5. The number of facilities provided for each gender should be based on the number of workers of that gender – separate facilities required if more than 20.
6. Hands-free hand washing units are preferable.
7. Signage must be in place to remind workers to wash/sanitize hands.

    Reference 29 CFR 1910.141(c)(1)(i) — Sanitation: Toilet Facilities

23.B Secondary Hand Sanitation Stations

1. Secondary hand sanitation stations should be conveniently located in traffic zones.
2. Records of regular restocking and strength testing (e.g., chlorine: 2-25 ppm free chlorine; and quaternary ammonium: 150-400 ppm or naturally based equivalent) should be retained.
3. Premixed restocking solution should include details of ingredients and strength.

23.C Ware-Washing Sink

1. The operation must install a stainless steel sink with at least three compartments for manually washing, rinsing and sanitizing equipment, wares and utensils.
2. Compartments should accommodate immersion of the largest equipment and utensils by 50 percent.
3. Each compartment shall be supplied with adequate hot and cold potable running water; faucet necks must reach all compartments.

4. The operation must provide drain boards, utensil racks or tables large enough to hold all items before cleaning and after sanitizing.
5. Adequate equipment should be available to air-dry washed utensils and equipment, if required.
6. Automatic ware-washing equipment requires water temperature, pressure, chemicals and equipment that meet applicable ANSI standards or equivalent.
    a. Ware-washing sink is still required with automatic washing equipment.

23.D Drinking Water

1. Adequate potable water must be available to ensure clean, safe water for production, sanitation and worker consumption.
2. Hands-free drinking fountains are preferred and if used must be sanitized according to Master Sanitation Schedule.
3. Icemakers must be listed on the Master Sanitation Schedule and are sanitized according to manufacturer's specifications.
4. Documented water analysis or municipal certificate of analysis must be on file for review.
5. Any non-potable water sources must be marked with a 12-x-12-inch warning sign in appropriate languages.

23.E Changing Area

1. If the operation requires protective gowns and other protective clothing in production areas:
    a. Workers must have a clean, organized location for gowning and changing clothes.
    b. The operation shall provide lockers for storage of personal clothes, jewelry and other items.
    c. The operation must provide enough clean protective clothing to support procedural requirements (each entry, each shift, weekly, etc.).
    d. The operation must provide training for gowning processes (e.g., put on booties before gloves to prevent shoe dirt contamination on gloves).

24. Waste Management

24.A Waste Management Plan

1. The operation must conduct an assessment to document risks associated with waste management including waste reduction, pollution control, recycling and reuse.
2. The operation must document and follow a Waste Management Plan that addresses risks and contains policies and procedures to control pollution and safely handle, reduce, store and dispose of waste and recyclables.

24.B Hazardous Materials Disposal

1. The operation must document and maintain an accurate inventory of all hazardous materials used in the operation. Hazardous materials may include product waste, containers, piping and other contaminated equipment.
2. The operation must dispose of chemical, dangerous or hazardous waste in compliance with federal, state and local laws and regulations.

24.C Minimize Landfill Waste

The operation should recycle/compost organic waste from plant material, soil, biodegradable consumable products, etc., when practical; recycle office paper, plastic, cardboard, containers, etc.

24.D Sustainable Packaging

1. The operation should integrate sustainable packaging to the maximum extent practical including packaging reuse, use of recycled source materials, packaging designed for composting or recycling, and labels integrated into packaging or printed using environmentally safe materials.
2. Packaging specifications must define sustainability parameters.
3. Operation must retain supplier sustainability certifications for review.

24.E Cannabis Waste Disposal

1. Cannabis waste must be rendered unusable and unrecognizable prior to leaving the facility.
2. The operation can accomplish this by grinding and incorporating the cannabis waste with non-consumable, solid wastes listed below so that the resulting mixture is at least 50 percent non-cannabis waste:
    a. Food waste
    b. Cardboard waste
    c. Paper waste
    d. Compost activators
    e. Soil or soil mix
3. Other waste processing methods are acceptable if justified and documented.
4. Cannabis waste (weight, plant ID, lot code, etc.) must be recorded in the inventory system.

24.F Waste Container Control

1. All inside and external areas where waste collection containers are located must be well maintained and clean.
2. If required by security procedures, external waste containers must be locked.
3. Waste must be removed daily or more often if necessary to prevent overflowing containers.
4. All waste canisters, dumpsters, etc., should be equipped with easily closable lids.

Glossary

Agricultural Inputs

Any material, compound, substance or formula added to the cultivation process to control pests and disease, promote healthy growth or improve the harvested product to meet cultivation goals. Agricultural inputs include:

Fertilizers: Substances that provide essential nutrients for plant growth, such as nitrogen, phosphorus or potassium. Generally used to promote or enhance growth characteristics. Fertilizers may be derived from raw plant material, composts and other organic matter.

Pesticides: Classified and controlled by the Environmental Protection Agency and state and local agencies, pesticides are defined as:

- Any substance or mixture of substances intended to prevent, destroy, repel, or mitigate any pest, fungus, disease or weed. Fungicides and herbicides are included under the definition of pesticides.

- Any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant.

- Any nitrogen stabilizer or fertilizer additive that is not itself a source of nutrients.

Plant Protection Products (PPP): Non-pesticide agricultural inputs cultivators use to protect and maximize cultivation outputs. PPP may include fertilizers or growth regulators.

Cannabis-Infused Product

A topical, inhalable or ingestible product that contains active cannabis or cannabis concentrate as a regular ingredient incorporated through homogenization or topical application.

CCP

Critical Control Point – A point in a production process where failure to follow or meet a standard procedure or process step could cause harm to products, customers and the business; the operation documents each critical control point in the Hazard Control Plan along with the critical limits for each CCP.

cGMP

Current Good Manufacturing Practices (cGMP) ensure that products are consistently produced according to quality standards. The term Good Production Practices (GPP) may also be used.

CL

Critical Limits – The maximum and/or minimum parameters allowed by each critical control point to ensure product quality. Critical limits are based on existing standards, scientific research, regulations, GMP, production data and results, and equivalent verifiable sources.

Concentrate

Any type of cannabis product that is refined from aboveground plant components into a more purified and potent form. A concentrate can refer to any form of hash, rosin, kief or forms of hash oil (shatter, wax).

Contaminants

Any biological or chemical agent, foreign matter or other substances not intentionally added to products that may compromise product quality, safety or suitability.

Contaminants include insects or insect parts, feathers, fingernails, cosmetics, jewelry, hair, feces, mold, decomposition or visible growth, visible adulterants, lubricants, glass shards from glassware or lighting, metal shavings from equipment, staples, plastic, wood splinters, stones, sand and foreign plant parts.

Crisis Management Plan

Crisis Management Plans document procedures to prepare for, manage and recover from events that could interrupt business operations including natural disasters, fire, flood, chemical spill, loss of key staff, sabotage, vandalism, terrorism, theft, robbery, workplace violence, seizure of assets or property, product contamination and product recall.

Critical Control Points

Designated points in a production process where failure to follow or meet a standard procedure or process

step could cause harm to products, customers and the business; the operation documents each critical control point in the Hazard Control Plan along with the critical limits for each CCP.

Critical Limits

The maximum and/or minimum parameters allowed by each critical control point to ensure product quality. Critical limits are based on existing standards, scientific research, regulations, GMP, production data and results, and equivalent verifiable sources.

Crop Cycle

The time from initial planting to harvest of a discrete group of plants cultivated in the same area, using the same methods and using the same agricultural inputs.

Curing

Removing sufficient moisture from the plant to prepare it for processing or finishing, ensure shelf stability and minimize microbiological growth.

Exit Package

Packaging and labeling that encloses a final consumer product when it is sold or dispensed to a customer.

Extraction

Process of extracting cannabis compounds into a concentrated substance using solvents such as water, ethanol or CO2, or physical separation such as sieving or friction to remove trichomes.

Finished Goods

Materials or products that have received final increments of value through manufacturing or processing operations, and are released for storage, delivery, sale or use.

GAP

Good Agricultural Practices – A set of operational practices that verify agricultural products are produced, packed, handled and stored as safely as possible to minimize risks of food safety hazards.

GHS

Globally Harmonized System of Classification and Labelling of Chemicals

GLP

Good Laboratory Practice (GLP) principles provide a scientific and quality framework to plan, perform, monitor, record, report and archive laboratory studies and tests. ISO 17025 is the general benchmark for GLP.

GMP

Current Good Manufacturing Practices (GMP) or (cGMP) ensure that products are consistently produced according to quality standards. The term Good Production Practices (GPP) may also be used.

Good Agricultural Practices (GAP)

A set of operational practices that verify agricultural products are produced, packed, handled and stored as safely as possible to minimize risks of food safety hazards.

Good Laboratory Practices (GLP)

Good Laboratory Practice (GLP) principles provide a scientific and quality framework to plan, perform, monitor, record, report and archive laboratory studies and tests. ISO 17025 is the general benchmark for GLP.

Good Manufacturing Practices (GMP) or (cGMP)

Current Good Manufacturing Practices (GMP) or (cGMP) ensure that products are consistently produced according to quality standards. The term Good Production Practices (GPP) may also be used.

HACCP

Hazard Analysis and Critical Control Points Plan – A detailed, systematic, documented approach that identifies, evaluates and controls quality hazards for each product-related process used by an operation. HACCP may be applied to GAP or GMP requirements. FOCUS Standards use the terms Hazard Control Plan and HACCP Plan interchangeably.

Hazard Control Plan

A detailed, systematic, documented approach that identifies, evaluates and controls quality hazards for each product-related process used by an operation. Hazard Control Plans and HACCP may be applied to GAP or GMP requirements. FOCUS Standards use Hazard Control Plan interchangeably with HACCP Plan.

Health and Safety Program

A comprehensive health and safety program includes physical safety, safely designed work processes, safe tools and equipment, facility and environmental safety, regular safety assessments, worker engagement and ongoing safety training.

Infused Products

A food product, tincture or salve that contains concentrated or cannabis-derived cannabinoids.

Injury and Illness Prevention Plan

An ongoing intervention method to reduce the number and severity of workplace-related injuries and illnesses. Program components include management leadership, worker participation, hazard identification, hazard prevention and control, training and evaluation of results.

Lab Management System (LMS)

Business, operational, quality and data processes and systems that ensure the lab operates according to policies and procedures.

Limit of Detection (LOD)

The lowest signal that can be measured by a given testing method.

Limit of Quantification (LOQ)

The lowest possible concentration that can provide quantitative results by a given method.

LMS

Lab Management System – Business, operational, quality and data processes and systems that ensure the lab operates according to policies and procedures.

Master Equipment List

A Master Equipment List identifies each piece of equipment used in the production process including machinery, test systems, computing and measuring equipment, appliances, devices, vessels, wares, utensils and tools.

Master Sanitation Schedule

A Master Sanitation Schedule identifies each area, piece of equipment and support item to be cleaned; the frequency of cleaning; and workers responsible for cleaning.

Medical Dispensary

A facility, operation or company licensed to dispense medical cannabis to qualified patients according to state and local laws.

Must vs. Should

The terms must and shall are used interchangeably to indicate requirements to the FOCUS Standard; the terms should, could, may and can are used where flexibility is allowed or the standard is offering examples or guidance rather than directing specific requirements.

Patient

A person registered and/or qualified by a state, municipality or agency and authorized to purchase or receive medical cannabis from an authorized provider.

Personal Protective Equipment

Personal Protective Equipment (PPE) is worn to minimize exposure to hazards that cause workplace injuries and illnesses due to processes, environmental conditions, chemicals, radiation, mechanical irritants, airborne contaminants or other risks capable of causing injury or impairment to any part of the body through absorption, inhalation, sound or physical contact. Personal protective equipment may include gloves, safety glasses and shoes, earplugs or muffs, hard hats, respirators, coveralls, kneepads, vests and full body suits.

Pesticides

Classified and controlled by the Environmental Protection Agency and state and local agencies, pesticides are defined as:

- Any substance or mixture of substances intended to prevent, destroy, repel or mitigate any pest, fungus, disease or weed. Fungicides and herbicides are included under the definition of pesticides.
- Any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant.
- Any nitrogen stabilizer or fertilizer additive that is not itself a source of nutrients.

Plant Protection Products (PPP)

Non-pesticide agricultural inputs cultivators use to protect and maximize cultivation outputs. PPP may include fertilizers or growth regulators.

Plant Regulator

A substance that physiologically accelerates or retards the rate of growth or plant maturation or otherwise alters a plant's behaviors, or affects products derived from the plant. Plant regulators are generally considered Plant Protection Products (PPP).

PPE

Personal Protective Equipment (PPE) is worn to minimize exposure to hazards that cause workplace injuries and illnesses due to processes, environmental conditions, chemicals, radiation, mechanical irritants, airborne contaminants or other risks capable of causing injury or impairment to any part of the body through absorption, inhalation, sound or physical contact. Personal protective equipment may include gloves, safety glasses and shoes, earplugs or muffs, hard hats, respirators, coveralls, kneepads, vests and full body suits.

PPP

Plant Protection Products – Non-pesticide agricultural inputs cultivators use to protect and maximize cultivation outputs. PPP may include fertilizers or growth regulators.

Product Recall Program

A Product Recall Program defines the methods for removing or correcting products that violate laws, present a risk of injury or gross deception, or are otherwise defective. Recalls are voluntary but can be requested by regulatory agencies; mandated recalls are reserved for urgent situations or when a firm is not achieving recall responsibilities. Recalls require the prime manufacturer (may include wholesalers, suppliers, distributors and retailers) to analyze the hazard, notify the supply chain and issue product return procedures. Recall does not include market withdrawal or a stock recovery, which is accomplished through normal stock rotation practices, routine equipment adjustments and repairs, etc. Almost all recalls are conducted on a voluntary basis by the manufacturer.

QMS

Quality Management System – Business and operational processes and systems implemented to ensure GAP and GMP; they include organizational structure, policies, procedures, processes, systems, controls and resources needed to ensure quality products and services.

Quality Management System

Business and operational processes and systems implemented to ensure GAP and GMP; they include organizational structure, policies, procedures, processes, systems, controls and resources needed to ensure quality products and services.

Quarantine

Material or products physically isolated from production, marked and controlled until formally authorized for release.

Raw Materials

A substance in its natural, modified or semi-processed state used as an input to a production process for subsequent modification or transformation into a finished good.

Rejected

Material, work-in-process or finished goods that do not meet product quality specifications. Rejected material is dispositioned as “rework” or “dispose.”

Residue Testing

A validated analytical procedure that detects, identifies and measures the presence of chemical substances, their metabolites or degradation products in or on raw or processed agricultural products.

Retail Store

A facility, operation or company licensed to sell cannabis to qualified adults according to state and local laws.

Safety Data Sheets (SDS)

A standardized form that contains detailed information about possible health and safety hazards of a product and how to safely use, store, transport, handle and dispose of a product. Under the Federal Hazardous Substances Act, suppliers must provide SDSs for all hazardous material as a condition of sale, and employers must make them available to workers in multiple formats for review.

Security Risk Assessment

A Security Risk Assessment reviews all threats (crime) and hazards (natural/man-made events) to assets (staff, public, product, currency, materials and information) and is used to develop the operation’s security program.

Strain

Plant varieties (cultivars) selectively bred to produce distinct, desirable traits and effects of Cannabis sativa. The traits and effects include differentiated products or can be cultivation traits such as fast flowering, pest resistance or high yield. There is no standard for cannabis strain naming and cultivators have cultivated and named hundreds of cannabis strains.

Traceability

Ability to trace the inputs, history, application or location of an entity by means of recorded identifications.

Water Use Plan

A Water Use Plan documents an operation's plans and procedures for water sourcing, storage, use, discharge and testing. It defines the frequency for water testing and analysis and procedures to ensure tests are conducted as scheduled and incorporates local water regulations.

Work-in-Process

Material dispersed from inventory and released into the manufacturing process that has not been fully processed into a finished good.

List of Resources

American Association for Laboratory Accreditation (A2LA) – Cannabis Testing Laboratory Accreditation

American Herbal Pharmacopoeia (AHP) – Cannabis Inflorescence Standards of Identity, Analysis and Quality

American Herbal Products Association (AHPA) – Recommendations for Regulators – Cannabis Operations

American National Standards Institute (ANSI)

Americans for Safe Access (ASA) – Patient Focused Certification

Americans with Disabilities Act (ADA)

AOAC International – Appendix K: Guidelines for Dietary Supplements and Botanicals, Part I. AOAC Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals

Association of Public Health Laboratories (APHL) – Guidance for State Medical Cannabis Testing Programs

Cannabis Safety Institute – Microbiological Safety Testing of Cannabis

Code of Federal Regulations – 21 CFR 7.40 – Food and Drugs – Recall Policy

Code of Federal Regulations – 21 CFR 111 – Food and Drugs – Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements

Code of Federal Regulations – 21 CFR 117 – Food and Drugs – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

Code of Federal Regulations – 21 CFR 211 – Food and Drugs – Current Good Manufacturing Practice for Finished Pharmaceuticals

Code of Federal Regulations – 29 CFR 1910.132 – Labor – Occupational Safety and Health Standards – Personal Protective Equipment

Domestic Fair Trade Association (DFTA)

Fair Trade USA

Food and Agriculture Organization (FAO) – World Health Organization (WHO) – Codex Alimentarius – International Food Standards

ISO 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories

ISO 22000:2005 Food Safety Management Systems -- Requirements for any Organization in the Food Chain

ISO 22005:2007 Traceability in the Feed and Food Chain -- General Principles and Basic Requirements for System Design and Implementation

ISO 9000:2015 Quality Management Systems – Fundamentals and Vocabulary

ISO 9001:2008 Quality Management Systems – Requirements

The National Institute for Occupational Safety and Health (NIOSH)

U.S. Composting Council (USCC)

U.S. Department of Agriculture (USDA) – Food Safety Inspection Service (FSIS) Compliance Guidelines – Allergens and Ingredients of Public Health Concern: Identification Prevention and Control, and Declaration through Labeling

U.S. Department of Labor (DOL) – Occupational Safety and Health Administration (OSHA)

U.S. Food & Drug Administration (FDA) – Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)

U.S. Food & Drug Administration (FDA) – Pesticide Analytical Manual (PAM)

U.S. Pharmacopeial Convention (USP) – General Chapter <467> Residual Solvents/Organic Volatile Impurities

U.S. Pharmacopeial Convention (USP) – General Chapter <561> Articles of Botanical Origin

U.S. Pharmacopeial Convention (USP) – General Chapter <2750> Manufacturing Practices for Dietary Supplements

World Health Organization (WHO) – Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants