FOCUS

Foundation of
Cannabis Unified Standards

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Manufacturing Standard

Manufacturing Reference/Citation:

Foundation of Cannabis Unified Standards. FS-2001-1:2016. *Cannabis Manufacturing.* 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 extraction operations and cannabis-infused products producers 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 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 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

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. Security and interaction with law enforcement
n. Sexual harassment
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 Food Safety Training

1. The operation must provide formal food handling training to managers and all workers involved in the production and handling of concentrates.

a. Training must be certified for food safety (such as ServSafe™ or equivalent) and include workplace hygiene.

2. Operation must deliver training specific to each position to promote product quality.
3. Training shall include documented cleaning and sanitation procedures for workers responsible for those tasks.
4. Training materials must be comprehensive and available for review by workers and auditors.
5. Training documentation must include instructor name (or source for e-learning), worker name, topic and date completed.
6. All workers, including management, must participate in documented refresher training on hygiene practices annually at a minimum.

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 Product Quality Expertise

1. Designated product quality manager must have documented training and experience sufficient to adequately oversee the program. Expertise includes documented:
    a. GMP
    b. ServSafe™
    c. HACCP courses and certifications
    d. Job history and responsibilities
    e. Demonstrated working knowledge
    f. Advanced education, related degrees
    g. Professional references
    h. Related credentials or certificates

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 17.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 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 production areas or processing facilities.

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 GMP Signage

1. Signage supporting Good Manufacturing Practices (GMP), 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. If glassware is used in production, the operation must provide safety procedures and training for the selection, use, handling, cleaning and storage of glassware.
9. Vacuum, high pressure, heating and freezing equipment must include appropriate procedures, safety controls, signage and training.
10. Lighted exit signs must be installed as required by OSHA standards.
11. Safety data sheets for all chemicals must be on file and available to workers.

Extraction only

12. A qualified engineer, chemist, industrial hygienist or equivalently certified professional shall train managers and all production workers on safe extraction equipment operation, hazardous material handling, working with heat and pressure and equipment safety procedures.

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 cleanup; 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.

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 Hazard Control Plan – HACCP

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.C 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 CCP 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.D Critical Control Points

1. The operation must identify critical control points (CCPs) in a CCP Responsibilities Chart to monitor potential hazards identified in the Production Hazard Analysis.
2. Critical control points must be located at all potentially hazardous points in the production flow to detect defects and prevent nonconforming product from receiving further processing.
    a. CCPs must include detailed monitoring procedures.
    b. Procedures must define inspection frequencies.

c. Forms and reporting methods must be issued.

3. Qualified workers must set critical limits (maximum or minimum parameters and tolerances) for each critical control point.

   a. Product quality manager should use product specifications, process and equipment specifications, production history, standards, regulations, scientific research or other data-substantiated resources to set critical limits.

   b. Critical limits must help workers identify and reduce production risks to an acceptable, safe level.

   c. Source data and justification for critical limits must be documented and retained.

4. The HACCP coordinator must ensure all required CCPs are included in the control process and assigned to workers for monitoring.

7.E CCP Assignments

1. The operation must assign workers to monitor, record and manage corrective actions for each critical control point.

   a. Worker responsibilities must be documented on a HACCP CCP Responsibilities Chart.

   b. Workers must be trained in HACCP principles and on critical control point monitoring, critical limit detection, data recording and reporting procedures.

   c. Workers must know the critical control points and control limits in their areas of responsibility.

   d. Workers must know the appropriate actions to take if product tolerances exceed control limits.

7.F CCP Forms Readiness

1. The operation must design and publish forms and logs to record the control point monitoring data in production records.

2. Critical control point records must match the critical control points defined in the Hazard Control Plan CCP Responsibilities Chart.

3. Required documents include:

   a. CCP Responsibilities Chart

   b. Critical Control Logs

   c. Corrective Action Reports

4. All documents must list a revision date.

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 must establish specifications for all steps in the manufacturing process where control

is required to ensure specifications are met for the identity, purity, strength, composition, formulation or specific recipe of the cannabis-derived product.

Such specifications could include:

a. Weight or fill of units

b. Weight or fill variation of units

c. Hardness or friability of tablets, food products, etc.

d. Disintegration time of unit dosages

e. Clarity, viscosity, specific gravity, total dissolved solids or pH of solutions

f. Loss on drying, moisture content or solvent residue

g. Time, temperature and pressure

h. Microbiological characteristics

i. Organoleptic characteristics

(see 7.J Product Specifications)

7.I Product Classification and Control

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.”

   j. Quality characteristics

7.J 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 (operation and batch/lot), contents and dosage recommendations if applicable

h. Potential risks associated with the product and materials used (see 13.C Warning Labels)

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

7.K 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.L Control of Allergens

1. If allergens are used in any product or product component, the operation must implement written procedures to control the purchase, storage, handling and integration of allergens; workers must be trained and demonstrate required controls.

2. The operation must document and maintain a current and complete list of all potential allergens and sensitizing chemicals used.

   a. Major allergens recognized by the USDA and Codex include proteins from peanuts, tree nuts, crustacean shellfish, fish, dairy, egg, soy and wheat.

   b. The allergen list should define where and how the allergen is used in the production process.

3. Allergens and allergen-containing materials must be handled and stored using methods that avoid cross-contaminating all other materials, raw materials or work-in-process with allergens.

4. All allergens must be clearly labeled; all allergen-containing products must be labeled as required by the FDA Food Allergen Labeling and Consumer Protection Act of 2004.

5. The operation shall maintain a documented allergen validation process to verify sanitary conditions including testing methods such as enzyme-linked immunosorbent assays (ELISA), adenosine triphosphate (ATP) swabs or equivalent methods.

7.M 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 should be retained for one year after the production run.

7.N 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, critical control point records, control limit 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 HACCP 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.O 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.P Nonconformance to Process

1. Workers must document all nonconformances to critical limits in a Critical Control Points Log.
2. All nonconformances must be reported to the HACCP coordinator or quality manager immediately.
3. Workers must document corrective actions taken to return the process within critical limits, and any preventative actions taken in a Corrective Action Report.
    a. Workers must record the disposition of potentially affected product (rework or disposal).
4. HACCP coordinator or quality manager must review all Corrective Action Reports and take additional actions as required.

7.Q 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 21.D Cannabis Waste Disposal)

7.R 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 15.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 person 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.S Corrective Action Reports

1. Workers must document product and process failures in production records using a Corrective Action Report or other authorized HACCP form.
2. Failure documentation must include a detailed description of the situation (date, time, 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 with critical control limits.

7.T CCP Records Verification

1. A HACCP-trained coordinator must verify that CCP monitoring records are current, accurate and include required corrective action reports.
2. The HACCP coordinator must develop a schedule and assign a worker to verify each CCP.
3. The coordinator should verify all CCPs every 30 days at a minimum, more frequently as required.
4. Production records must document that assigned workers conduct CCP monitoring as specified.
5. The quality manager or supervisor must review and approve all CCP records daily for completion and accuracy.
6. Workers must immediately notify the HACCP coordinator and/or quality manager of any nonconformance.

7.U Revising the Hazard Control Plan

1. When changes are made to the production process (equipment, ingredients, actions), the operation must review the Hazard Control Plan (HACCP Plan) and coordinate updates through the HACCP coordinator; the coordinator will update the plan according to document control procedures.
2. Evidence of plan review and changes, review of production hazard analysis, CCP decisions and CCP records must be marked with revision date and be retained.
3. If new training is required, training materials and records must be on file.
4. If required by local municipality, updates must include an approval from the municipality.

7.V Assessing the Hazard Control Plan

1. The operation must conduct a self-assessment of the HACCP program annually at a minimum.
2. Self-assessments must validate the process flow, hazard analysis and HACCP chart.
3. The operation must document:
    a. Changes to the program
    b. Training delivered to workers
    c. Any changes to CCPs

7.W CCP Records Management

1. HACCP coordinator serves as the records manager for the HACCP process. This includes managing the master documents and templates, maintaining accurate and current tracking documents, ensuring the

latest document revisions are in circulation and serving as a master archivist for CCP records.

2. All HACCP records should be stored in a secure area limited to authorized personnel. Computer-based records should be protected by segregation and passwords.
3. HACCP records must be backed up weekly and stored in a remote, secure location.
4. HACCP records must be accessible and well organized. Three-ring binders, paper file system or electronic system are acceptable.
5. All HACCP CCP records should be retained in a secure location for a minimum of one year, regardless of the production item's shelf life.
6. The operation complies with state and local records retention requirements.
7. Records involved in an open legal or regulatory action shall not be destroyed or altered.

8. Production Operations

8.A 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.

8.B Cleanability of Facility

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.

8.C Cross Contamination Prevention

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

8.D 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.E 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 21. 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

9. Production Equipment

9.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.

9.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 product controls and safety 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

9.C Equipment Calibration

1. The operation must calibrate all variable equipment listed on the Master Equipment List.

   a. Variable equipment includes scales, measuring devices, thermostats, thermometers, probes, timers, ovens, water heaters 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.

9.D Independent Thermometers

The operation must provide thermometers independent from equipment's built-in thermostat/probes so workers can periodically verify temperatures (between calibrations) or use if thermostat/probes malfunction or lose calibration.

9.E 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.

9.F Cooling Coils

1. All coils in coolers and freezers must be clean with no build-up of dust, mold or other airborne contaminants.
    a. Cleaning procedures must define cleaning schedule for all cooling or freezing units and associated equipment and be included in the Master Sanitation Schedule.

9.G Utensils, Wares and Tools

1. All utensils, wares and other items regularly used in production must be cleaned (heat and chemical sanitation) according to HACCP plan specifications. When not in use, utensils and wares must be stored in dedicated areas to prevent contamination.
2. Tools that are used for repairing or adjusting equipment in the production and storage areas must be clean, free of corrosion and in good working order.

10. Water Use and Quality

10.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.

10.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. Pollution from chemicals, lubricants and solvents

b. Inflow, outflow, flood risk

c. Risk of untreated water contamination

d. Alternate water sources

e. Potential environmental damage or pollution from water sourcing or discharge

10.C 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. Analysis should be used to improve water quality as required.

2. The operation uses laboratory performing water analyses certified to ISO 17025 level or equivalent standard.

11. Extraction Operations

11.A Quality and Safety Controls

1. This section provides quality standards for cannabis concentrate extraction using several methods.

   Extraction includes processes that refine aboveground cannabis plant components into a more purified and potent form and can be generally divided into three methods: hydrocarbon solvents (such as butane), non-hydrocarbon solvents (water, alcohol/ethanol, CO2) and dry sieves (screens and filters).

   a. The operation must have written safety and quality control procedures designed to maximize safety and minimize potential product contamination.

   b. The operation shall ensure products are continually produced to established standards and specifications.

   c. All workers must have documented training in the QMS and tasks specific to quality control and safety procedures.

11.B Equipment Installation and Training

1. The operation must show evidence that a qualified technician or manufacturer's representative installed the extraction equipment.

2. All production workers must receive training in operations, safety and maintenance from a qualified professional such as a chemist, certified engineer, industrial hygienist or other authorized technical or safety representative.

3. The operation must install and maintain a standby power source and automatic switch-over controls for all smoke and gas alarms, detection meters, ventilation systems, lighting and other emergency systems in case of a power outage.

4. The operation must retain installation and training documentation for the life of the equipment.

11.C Production Training

1. The operation must deliver a comprehensive training process to all production workers to ensure their

proficiency to safely operate equipment. Training documentation should provide step-by-step instructions for each method used to produce a cannabis concentrate.

2. Documentation must include the following topics at a minimum:
    a. All standard operating procedures for each method of concentrate production
    b. Concentrate manufacturer's quality control procedures
    c. Emergency procedures for the facility
    d. Appropriate use of any necessary safety or sanitary equipment
    e. Hazards presented by all solvents used within the operation as described in the safety data sheet for each solvent
    f. Clear instructions on the safe use of all equipment involved in each process (in accordance with manufacturer's instructions, where applicable)
    g. Any additional periodic cleaning to meet applicable sanitary rules

11.D Emergency Procedures

1. The operation must establish written emergency evacuation procedures in case of a fire, explosion, chemical spill or other emergency.
2. Workers must be trained in emergency procedures with annual refresher training at a minimum.
3. Evacuation drills should be conducted quarterly, the results documented and corrective actions implemented and documented.
4. Emergency signage must be posted.

11.E Food-Grade Chemicals

The operation must ensure all components such as propylene glycol or glycerin used in the production of a food-based cannabis concentrate are certified food grade with written documentation.

11.1 Water-Based Extraction

11.1A Water Quality

1. Procedures must specify that only potable drinking water or ice made from potable drinking water is used in the production of a water-based cannabis concentrate.
2. Documented water analysis or other proof of potability is required.

11.2 CO2-Based Extraction

11.2A CO2 Monitoring

1. If CO2 is used as solvent, a certified industrial hygienist or engineer must install a CO2 monitoring and alarm system in the work area where cannabis concentrates are produced or CO2 is stored.
2. Monitors must include real-time reports of CO2 levels and must activate as required by state regulations and OSHA (alarm activates at 5000 ppm for 8-hour time-weighted average; see OSHA Method ID-209 and the OSHA Technical Manual for guidance).

3. CO_2 should be recovered to the maximum extent possible.
4. Install proper ventilation (air change 6X per hour unless specified by certified installer) including at floor level.
5. Ensure actions taken are in accordance with the system's specifications and with applicable laws and regulations.

11.2B Use of Dry Ice

1. The operation must ensure that any room where dry ice is stored or used to process cannabis into concentrate is well ventilated to prevent against the accumulation of dangerous levels of CO_2.
2. Operation must install a CO_2 monitor with alarm in all closed areas where CO_2 extraction is performed. Monitors must include real-time reports of CO_2 levels.
3. All equipment and PPE used shall be suitable for use and material handling at extremely cold temperatures.

11.3 Ethanol or Alcohol-Based Extraction

11.3A Food-Grade Ethanol

1. If the producer produces cannabis concentrate using ethanol or alcohol, the criteria applicable to solvent-based extraction applies.
    a. Ethanol must be food grade or at least 190-proof pure; isopropanol alcohol is not recommended.

11.4 Solvent-Based Extraction

11.4A Solvent Safety

1. If a flammable or volatile hydrocarbon solvent is used to process cannabis concentrate, the operation must use a certified industrial hygienist or engineer to:
    a. Install solvent extraction equipment in a room separate from other production areas
    b. Establish maximum amount of flammable solvents or materials authorized for storage within the licensed premises
    c. Install Division-1 Class-1 electrical equipment (or state-authorized equivalent) in production area and solvent storage area in accordance with applicable regulations to control ignition and spark sources
    d. Install proper ventilation (air change 6X per hour unless certified installer provides specifications) including at floor level
    e. Install a gas monitoring system as required by local regulations
    f. Install fire suppression system as required by local fire code
    g. Ensure all workers receive safety training on equipment, materials and risks such as explosion, fire, gas release, evacuation, etc. Document all training participation; repeat for new hires and existing workers periodically
    h. Ensure use of ground straps/grounded workstations and non-static clothing

i. Ensure proper control of solvent gas release during open cycle of extractor with the use of an exhaust hood and hand-held leak detector

j. Establish procedures for safe handling of compressed gas cylinders

k. Ensure all support equipment meets spark/ignition requirements and is UL certified or equivalent

l. Establish/maintain occupancy levels

2. Engineer/hygienist assessment and installation information must be on file.

11.4B Solvent Recovery

1. All equipment must be professional grade and the system must perform closed-loop extraction that is capable of recovering the solvent.
2. The extraction system should be constructed of materials that meet ASME, ASTM or equivalent standards.
3. Pumps used to assist with recovery of a flammable solvent must not produce any ignition source (e.g., pneumatic, compressed-air-driven piston pump).
4. For extraction units plumbed to permanent water supply, operation must ensure water temperature remains between 60°F and 100°F and is flushed weekly.
5. Self-contained units must be visually inspected weekly and flushing-fluid changed according to manufacturer instructions.
6. Solvent should be collected and stored in medical-grade containers when practical to maintain purity.
7. Solvent containers must be replaced or safely purged, cleaned and sanitized periodically.

11.4C Food-Grade Solvents

1. The operation must ensure that all solvents used in the extraction process are the highest purity practical; at a minimum, food-grade solvent must be used.
2. A current copy of safety data sheets and a receipt of purchase for all solvents used or to be used in an extraction process must be kept on file.
3. For all solvents used, operation must retain a certificate of analysis (COA) from the original manufacturer with purity and impurity limits and results.

    a. Operation must retain certificates for two years.

11.4D Waste Solvent Disposal

1. The operation must safely handle, store and dispose of all flammable solvents, flammable materials, chemicals and waste in accordance with all applicable laws and regulations.
2. Solvent should be removed from waste material to the maximum extent possible before disposal.
3. Disposal process records must be retained for two years.

12. Product Testing

12.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. A qualified worker must review all test lab reports 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.

12.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.

12.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.

12.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).

12.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.

12.F Solvent and Chemical Residue

1. Cannabis concentrates and infused products must be tested for the following solvents to the maximum extent practical:
    a. Acetone < 1 ppm
    b. Benzene < 0 ppm
    c. Butanes/ Heptanes/ < 50 ppm
    d. Hexane < 10 ppm
    e. Polyacrylonitrile (PAN) < 1 ppm
    f. Polycyclic Aromatic Hydrocarbons (PAHs) < 1 ppm
    g. Toluene < 1 ppm
    h. Total Xylenes < 1ppm
    i. Solvent-extracted products made with Class 3 or other solvents must not exceed 0.5% residual solvent by weight or 50 parts per million (ppm) per one gram of solvent-based product.
    j. The product must test at or below 50 ppm total.
2. Test results must meet federal, state and local regulations and limits – if these are not available or applicable, the limits specified above apply.
    a. Test reports must provide specific data for all listed and detected solvents.
    b. The test report should list the solvents that were not or could not be tested.
    c. If the test equipment's Limit of Detection (lowest possible detection limit) is above the specified limit for a solvent, the equipment's LOD amount will be considered sufficient to exceed safe contamination limits.

3. Tolerance levels may be revised based on accepted technical publications.
4. Additional substances may be added to the required list as necessary to protect the quality and safety of products.
5. If local laboratories cannot provide the level of testing specified, labs should test for solvents to the maximum extent of their technical capabilities.

12.G 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
3. If the cannabis concentrate used to make an infused product was tested for metals and test results indicate the batch/lot was within established limits, then the infused product should not require additional testing for metals.

12.H Pesticide Residue

1. The operation must test all product batches for pesticides; 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 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.

12.I 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.

12.J 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.

12.K Stability Testing

1. The operation must complete stability/shelf life testing and assessment on perishable products that have an established expiration date or products with the potential for substantial breakdown of quality and/or safety over time.
2. Test results and analysis must be retained.

12.L 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.

12.M 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.

12.N 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 qualified suppliers.

13. Packaging and Labeling

13.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.

13.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 13.C Warning Labels)
    g. Common allergens
    h. Instructions for appropriate storage
    i. Additives
    j. Solvents used in concentrate production
    k. Inputs used in cultivation process (pesticides, fertilizers)
    l. Carrier agents used in topicals or concentrates
    m. Statements or information required by state or local regulations
    n. Perishable products must display a "Use By" and/or a "Freeze By" date
    a. Shelf life or expiration period on the label of an infused product must be supported by appropriate data and an expiration tracking form
    o. Laboratory that performed the testing (or a lab keycode)
    p. Date of manufacture using Julian date
    q. Operation must ensure all supplier labeling meets requirements

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

13.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.

13.D Cannabis-Infused Product Labels

1. For all cannabis-infused products, the operation should follow FDA Food Labeling Guide to maximum extent possible by using a consumable products "facts box" that includes:

   a. Name of food

   b. Net quantity or weight of contents

   c. Ingredients list

   d. Cannabis ingredients

   e. Cannabinoid and/or terpenoid content

   f. Food allergen information

   g. Nutrition labeling

   h. Total calories and fat calories

   i. Total fat, saturated fat and trans fat

   j. Cholesterol

   k. Sodium

   l. Total carbohydrates

   m. Dietary fiber

   n. Sugars

   o. Protein

   p. Vitamins

   q. Food Claims: nutrient content, health, qualified health and structure/function claims must comply with FDA Food Labeling Guide.

   r. List daily values for children under 4, infants, pregnant and lactating women if applicable.

2. Edible cannabis infused products must display warning labeling on the outside of the packaging including "WARNING: MEDICINAL/ADULT USE PRODUCT – KEEP OUT OF REACH OF CHILDREN" in bold capital letters, in a font size larger than the font size of the other printing on the label.

13.E 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.

13.F 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.

13.G 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

14. Traceability and Recall

14.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.

14.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.

14.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.

14.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.

15. Product Storage

15.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, concentrates and cannabis-infused 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.

15.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.

15.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.

15.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.

15.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.

15.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

16. Receiving and Transport

16. A Product Transfers

1. If allowed by state and local laws and regulations, a licensed operation may transfer (sell/purchase) usable 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. 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

16.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.

16.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 complete corrective action.

16.D Raw Material Inspection

1. The operation must follow a written procedure for the inspection of all raw materials and packaging to ensure materials meet product specifications.
    a. Incoming inspection logs and raw material inventory report must be on file for review.
    b. All raw materials must be entered into the inventory list when received and when released to production.
    c. The operation must have quality certifications, letters of guarantee or similar documentation for all raw materials, ingredients, cannabis extracts, etc., used in the process.
    d. Documentation must be retained for two years.

16.E 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.

16.F 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 seals.

16.G 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

17. Facility Maintenance

17.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.

17.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.

17.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 8.A 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.

17.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).

17.E Conservation Plan

1. The operation must develop a conservation plan to reduce consumption of all resources including water, energy, materials and supplies.
2. The operation must conduct an annual energy audit of all energy sources and consumption for key operations or equipment.
3. The operation should implement methods to conserve energy and use or increase use of renewable sources when applicable.
4. The operation must implement waste reduction, recycling and reuse methods.

17.F 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.

18. Pest Control

18.A Pest Management Plan

1. The operation must develop and implement a pest management plan to protect products, production areas, storage areas, packaging, equipment and supplies from pests and disease, discourage pest populations and prevent disease.
    a. Plan must incorporate product safety and quality controls to meet product specifications and minimize risks to products, people and the environment.
    b. 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. On building exteriors, a 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.
3. All equipment and materials must be stored to discourage the harborage of pests such as insects, rodents or birds.
4. If processing operation is physically co-located with a cultivation the operation, operation should take additional precautions to create effective pest and disease barriers to prevent cross-contamination of the operations.

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

18.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)

18.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 production, product handling, processing or storage areas.

18.D 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.

19. Sanitation and Cleaning

19.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

19.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.

19.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. The 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).

19.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

19.E General Cleanliness

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

19.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.

19.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.

19.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.

19.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.

20. Sanitary Facilities

20.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

20.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.

20.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 leaning 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.

20.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.

20.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).

21. Waste Management

21.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.

21.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.

21.C 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.

21.D Cannabis Waste Disposal

1. Cannabis and cannabis-infused product 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. Ensure any cannabis waste containing flammable solvents is dried safely and processed according to the waste management plan.
4. Other waste processing methods are acceptable if justified and documented.
5. Cannabis waste (weight, plant ID, lot code, etc.) must be recorded in the inventory system.

21.E 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.

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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

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. 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