FOCUS

Foundation of
Cannabis Unified Standards

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# CANNABIS LABORATORY STANDARD

FS-4001-1:2016



**Laboratory Reference/Citation:**

## OVERVIEW

FOCUS Standards form the foundation for a rigorous, comprehensive quality and safety system that provides 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 laboratory operations to meet safety and quality requirements.

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

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

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

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## FS-4001-0100 Quality Management System

1) Quality Management System
    a) The laboratory shall implement a lab management system (LMS) to ensure the lab performs to established standards and procedures.
    b) The LMS must provide systems, methods, tools and training to ensure that staff follow standard operating procedures at all times, and ensure all structures, equipment, control systems and lab processes continuously operate as designed and specified.
    c) The LMS shall require continuous assessment, corrective action for nonconformances, accurate and detailed documentation, and open sharing and use of quality data within the operation.
    d) To remain current with quality control requirements and individual responsibilities, all staff must have documented training in the LMS and receive refresher training annually or when the operation changes the system.
2) Document Control
    a) The operation must have procedures to control documents related to production, product quality, worker safety and work operations that include:
        i. Approval of documents prior to issue
        ii. Review and revision as required including re-approval
        iii. Documented changes and current revision status
        iv. Ensuring documents remain legible and readily identifiable
        v. Ensuring correct versions of relevant documents are available at points of use
        vi. 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
3) 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.
4) Procedures and Training
    a) Management shall ensure that work processes are documented using standard operating procedures.
    b) Managers shall ensure workers receive appropriate training and refresher training to perform assigned responsibilities.
    c) Workers must have full access to current procedures and training materials.

## FS-4001-0200 General Operations

1) Management Capability
    a) 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.

b) Managers must possess the qualifications (training, experience and credentials) required to effectively execute the quality, safety, procedural, workforce and compliance requirements assigned to them.

c) Management shall:

i. Provide evidence that all managers have completed management training and instruction in the organization's standard operating procedures and record keeping related to GAP and/or GMP including worker/staff management, safety, sanitation, regulatory compliance and maintenance, and other defined topics critical to the organization's efficient and safe operation.

ii. Implement and maintain robust programs as defined in the FOCUS Standard to ensure business viability and continuity, and environmental sustainability.

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

### 2) Organizational Structure

a) Management shall maintain an organization chart that documents the organization structure, reporting relationships and decision-making paths.

b) Management shall maintain current job documentation including job descriptions, qualifications, responsibilities, training requirements, compensation processes and evaluation methods.

### 3) Regulatory Compliance

a) Management shall ensure the operation remains compliant with all applicable federal, state/provincial, county and local regulations related to cannabis business operations.

b) The operation must provide appropriate training and retain compliance records for review.

c) The operation must regularly monitor regulatory changes, make appropriate revisions to procedures and update worker training.

### 4) Business Assessments

a) The operation shall conduct periodic assessments of the business to expose and mitigate anomalies and vulnerabilities.

b) The operation must document assessments and the corrective action taken, and retain assessment and audit reports permanently for authorized review.

c) Business Operations Assessments – conduct an annual self-assessment that:

i. Reviews the business climate and adjusts strategies (legal, regulatory, legislative, investment, competition, products, community, etc.)

ii. Analyzes markets and customer preferences

iii. Analyzes product supply chain (relationships with suppliers, distributors, wholesalers and others)

iv. Analyzes critical business risks and mitigation plans

v. Reviews business locations

vi. Reviews and improves core business processes

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

d) Financial Assessments – conduct an annual self-assessment of:

i. Financial results against auditable, valid business plans as reported to regulators

ii. Performance to budget

iii. Payables/receivables, cash management and bank transactions

iv. Contracts, agreements and partnerships

v. Projections and data for future business requirements

e) Third-Party Audits – conduct assessments as required by company policy:
    i. Business finances and operations
    ii. Partnerships, joint ventures, contracts and agreements
    iii. Use certified, impartial auditors

5) Operational Controls
    a) 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).
    b) 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).

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

7) Licenses and Permits
    a) The operation must have appropriate permits and licenses to operate compliantly, including:
        i. Business license or operating permit
        ii. Tax license (if required)
        iii. Zoning permit or variance
        iv. Building, signage and alarm permits
        v. Safety permits (fire, environmental)
        vi. Health permit

8) Business Insurance
    a) The operation must have valid insurance policies in place:
        i. Liability: protection from lawsuits, negligence
        ii. Property: loss/damage to location, contents
        iii. Casualty: loss/damage to the business
        iv. Business interruption/continuation

9) Business Certifications
    a) The operation should identify any business certifications it has achieved and related benefits or activities:
        i. LEED – green buildings
        ii. ISO 9000 or similar quality or professional certifications
        iii. WEBNC/woman-owned business
        iv. Minority-owned business
        v. Native American-owned business
        vi. Veteran-owned business

### 10) Advertising Methods

a) 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).

b) The operation must not make unsubstantiated medical claims and must provide an accurate representation of the level of medical expertise available.

c) No advertising shall be targeted at minors.

   i. No use of cartoons or graphics targeted at minors.

   ii. No imitation of popular consumer product labeling or graphics.

   iii. For web/mobile devices, operation should use "over 21" qualifying questions to enter site/application and provide easy opt-out features.

d) 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.

### 11) 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

### 12) Crisis Management Plan

a) The operation must have a documented Crisis Management Plan that management reviews and updates annually.

b) At a minimum, the Crisis Management Plan must document the following:

   i. 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

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

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

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

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

   vi. Document management and protection plan

   vii. Financial and legal considerations

   viii. Media relations plan and contacts

### 13) Crisis Plan Training and Testing

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

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

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

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

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

ii. Crisis plan test reports, including corrective actions, must be approved by senior management.
iii. Test reports must be retained for two years.

## FS-4001-0300 Employment

1) Goal Setting
   a) Business leaders should set, maintain and communicate ongoing goals that are aligned to the business plan, strategy and mission.
   b) Workers should set and maintain goals based on position responsibilities, projects and related manager goals.
   c) Managers and workers should review goals monthly or more and update as required; managers should retain goal plans to support performance evaluations.
2) Fair Labor Standards
   a) The business operates with fair labor standards and has evidence that it:
      i. 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.
      ii. Pays overtime rates if overtime is required
      iii. Bases all pay deductions on a formula documented in work contract
      iv. Complies with child labor laws
3) Workplace Discrimination
   a) The operation must display an Equal Opportunity Employment Commission poster or equivalent that indicates the illegality of discrimination and provides processes to report violations.
   b) 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.
4) Work Contracts
   a) The operation must have work contracts for all workers on file.
   b) The contracts must specify:
      i. Terms and schedule for payment of wages
      ii. Job title and job description
      iii. Terms for dismissal from job
      iv. Terms of dispute resolution between worker and employer
      v. Weekly maximum hours worked before overtime is calculated
      vi. Details of any vacation time paid, mandatory overtime, sick leave or other compensated time off, if provided
      vii. Background checks required; bonding if required
5) Workers' Compensation

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

6) Worker Data

a) 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.

b) Worker data must be retained for at least two years after termination date or as required by local regulations.

7) Background Checks

a) The operation must complete a criminal background check on all workers, including management and contract workers, using a bonded, certified or authorized service.

i. Workers must pre-authorize the background check in writing or using e-signature.

ii. Background reports must be kept confidential except as required for procedural decisions.

iii. Reports must be stored in a secure filing system or computer records management system; retain for two years after worker termination.

b) The operation must establish criteria for hiring/not hiring before conducting a background check and it must document all rejections.

c) 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.

d) Theft, embezzlement or felony drug convictions should prevent employment; all employment restrictions should be clearly documented on the operation's pre-employment information.

e) 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.

f) Background checks must comply with federal, state and local employment and privacy laws.

8) Staff Qualifications

a) Lab must establish minimum qualifications (education, skills, knowledge, training, certifications and experience) for all staff positions.

b) Lab must collect, verify and retain records of each staff member's qualifications and work experience.

i. Records include resume/CV, degrees, certificates, interview notes, professional references, publications, online presence, background checks and workplace observation.

ii. Verification includes checking professional references, verifying college degrees and validating professional certificates.

iii. Retain records for two years past termination date or as required by records management procedure.

c) Operation manuals and technical specifications related to quality control must be present and their use evident.

d) The lab must conduct background checks on new hires and on existing staff as required by procedures or circumstances to verify qualifications.

e) Laboratory Supervisors – Technical supervisors should have at least a four-year undergraduate degree in chemistry, biology or microbiology and at least three years employment in an analytical laboratory with experience analyzing samples and interpreting data.

f) Lab Analysis Technicians – Technicians performing analysis and interpretation should have a four-year degree in chemistry, biology or microbiology and at least two years of applicable, documented testing experience in an analytical laboratory.

g) Lab Sample Technicians – Technicians performing sampling functions should have at least one year of documented experience in a working analytical laboratory.

h) Contractors must be held to the same standards as lab staff for testing, technical tasks and reporting. Subcontractors require the same qualifications as staff and must complete equivalent training to perform testing and laboratory services.

## FS-4001-0400 Training

### 1) Training Manager

a) 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.

b) The training manager must have a working knowledge of the facility processes and procedures.

### 2) Worker Training Program

a) Management shall ensure all workers receive adequate training to complete assigned responsibilities safely and effectively prior to beginning the work.

b) Managers shall reinforce comprehension by observing behaviors in the workplace and providing timely feedback.

c) The operation must maintain a documented training program that ensures all staff are trained on the following at a minimum:

i. Company policies and procedures
ii. Emergency procedures
iii. Government laws and regulations
iv. Hazardous materials
v. Industry policies and standards
vi. Laboratory methods, operations and quality control
vii. Managing and handling cannabis samples
viii. Required record keeping
ix. Regulatory inspections
x. Safe, quality service delivery
xi. Sanitation and cleaning procedures
xii. Security and interaction with law enforcement
xiii. Sexual harassment
xiv. Specific job training
xv. Worker health and safety

d) The operation must have a designated training coordinator.

e) The operation must maintain training records for all workers for two years.

### 3) Comprehensive Training Materials

a) Training materials must provide adequate quality, safety and operational detail for all work responsibilities and cover all topics listed in the training program.

b) Training materials must be available to workers.

4) Quality and Technical Trainings

a) The lab must provide adequate quality and technical training for assigned scientific, technical and laboratory responsibilities including periodic training in the lab management system.

b) Training should include tests and calibrations for test requirements, in-house calibrations and documentation methods.

c) Staff must demonstrate consistent proficiency in precision, accuracy, specificity, reportable ranges, blanks and unknown challenge samples (proficiency samples or internally generated quality controls).

d) Training must be current with testing methods and technology.

e) Training logs should include participants, trainer, dates and content.

5) Security Training

a) 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.

b) 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.

c) The security manager should observe and interview all workers monthly to ensure they understand and follow company security policies and procedures.

6) Regulatory and Law Enforcement Interaction

a) The operation must provide training to management and all workers to prepare them for interaction with regulatory and law enforcement agencies.

b) Training must include preparation for scheduled and unscheduled regulatory inspections and potential actions that might be taken by law enforcement affecting business operations.

c) Training should cover regulatory policies and federal laws as they apply to employees and the operation of the business.

7) Hygiene Training

a) All workers, management and staff must participate in a documented workplace hygiene-training course to ensure product protection.

b) All new workers must receive training in product handling, sanitation responsibilities, cleanliness standards and reporting requirements prior to working.

c) All workers, including management, must participate in documented refresher training on hygiene practices annually at a minimum.

d) Managers must ensure workers demonstrate expected practices.

8) Proficiency Reviews

a) Lab managers must periodically review the competence each staff member's lab practices including test accuracy, records accuracy and protection and retention of data.

b) Staff members performing new tests or procedures must perform proficiency tests, and results must be reviewed to validate and improve staff performance.

c) Lab must record how often each worker performs each test and the validity and acceptability of the data according to the laboratory's quality control requirements.

d) Lab must retain documentation on staff test validity and take corrective actions.

e) Proficiency test completion and documentation can be used to reduce the frequency of practice reviews; procedures must provide appropriate specifications.

f) All proficiency review records must be retained for two years.

9) Ongoing Training Program

a) The laboratory manager and quality manager must conduct, at a minimum, annual reviews of training activity and requirements.

b) Reviews should prompt managers and the training coordinator to improve processes and practices that affect skills and training.

c) Managers must conduct reviews when the lab introduces new equipment or test procedures into the system.

d) Based on findings, managers must update training programs and individual training plans and deliver revised training to affected workers.

## FS-4001-0500 Recordkeeping

1) Records Management

a) 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:

i. Records Inventory List – A master list of records and control requirements

ii. Destruction process – Retention time and destruction/deletion methods

iii. HIPAA compliance – Patient records control and destruction requirements

b) The operation must manage all digital files according to procedures including:

i. System access controls

ii. User controls and tracking (viewing, printing, editing and deleting)

iii. Standard file labeling and organized storage hierarchy

iv. Data encryption

v. File deletion schedules and processes including deletion of data on obsolete computers and data storage devices

vi. Data backup: cloud storage, digital storage service, offsite storage of backup hard drives

vii. Automatic file backup

viii. Long-term protection and file integrity

c) The operation must manage all physical files according to procedures including:

i. Restricted storage areas

ii. Lockable filing systems

iii. Sign in/sign out procedures for file review/removal

iv. Organized filing systems

v. Physical records are filed in a timely manner

vi. Destruction schedules and processes

vii. Crisis protection

viii. Long-term storage/environmental controls

d) 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.

e) Management must conduct a self-assessment of the records process at least every 90 days, document the assessment and complete any corrective action.

f) Records management procedures must comply with applicable federal, state and local regulations.

### 2) Records Inventory List

a) The operation must list all records used or received by the business on a Records Inventory List.

i. 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):

i. Accounting ledgers and reports
ii. Tax returns, tax correspondence and supporting information
iii. Payroll and wages
iv. Contracts and agreements
v. Corporate organization, bylaws, organization charts
vi. Insurance
vii. Intellectual property
viii. Legal files, court documents, attorney files
ix. Public filings
x. Security records
xi. Logins and electronic permissions
xii. Electronic mail
xiii. Employment and worker files
xiv. Training records and program documentation
xv. Safety and health (OSHA, worker's comp, medical, SDS)
xvi. Audit reports, inspection reports and self-assessments
xvii. Quality control procedures, logs and records
xviii. Vendor records
xix. Customer information
xx. Inventory records
xxi. Product test data and test lab reports
xxii. Test method documentation
xxiii. Sample management and control records
xxiv. Sales transactions
xxv. Maintenance logs for facilities and equipment

xxvi. Calibration, maintenance and repair logs
xxvii. Sanitation logs

3) Security of Records

a) All electronic records must be stored in a system that is secure, password-protected and limits data access to those who need it.
   i. Data should be encrypted if feasible.
   ii. A secure offsite backup/storage system must be in place.

b) 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.

4) Standard Report Format

a) The lab shall establish a standard reporting format for testing and ensure all test reports are accurate, complete and legible. For each test performed, the test report should contain:
   i. Calculations and formulas
   ii. Customer name or code
   iii. Equipment and calibration
   iv. Environmental factors
   v. Interferences
   vi. Principles of the test method
   vii. Procedures
   viii. Quality assessment
   ix. Sample requirements
   x. Reference standards
   xi. Test authorization
   xii. Test date
   xiii. Test materials used
   xiv. Test method number or identifier
   xv. Test method release date and current version number
   xvi. Test results and analysis
   xvii. Test technician name or code

5) Error and Complaints Process

The lab must implement a comprehensive error and complaints policy that covers report correction procedures, reporting to clients and corrective actions taken. Process should include methods to manage client relations if incorrect or compromised data has been included in reports.

6) Report Control and Retention

a) Procedures must control report distribution and access by department, function, area, position, customer or other criteria.

b) Lab manager shall audit the report control process periodically and implement corrective action as required. Audits and corrective actions must be documented and retained.

c) The lab must have a functional, offsite back-up system for all electronic data that could include encrypted cloud storage, hard drives stored in a secure location offsite or active service with a qualified data security and storage supplier.

d) The lab must retain all test documentation for three years.

## FS-4001-0600 Facility Management

1) Facility Maintenance Plan
    a) 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.
    b) Records must show the type of maintenance completed, mechanic or technician name and date work was completed.
    c) Lockout/tagout training is required for any workers who perform maintenance or repairs on electrical equipment.
2) Environmental Controls
    a) The lab must maintain appropriate environmental controls such as lighting, ventilation, air quality (viable and non-viable airborne contaminants), temperature, pressure and humidity in all areas used for product testing, sample handling and storage.
    b) The lab must set environmental control parameters and document them in the lab management system.
    c) The lab shall periodically monitor and record conditions in testing and storage areas and take corrective action as required.
    d) The lab shall retain records of environmental monitoring and corrective action for two years.
3) Grounds Maintenance
    a) 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.
        i. Procedures should list the frequencies for specific maintenance.
        ii. Workers operating hazardous or loud equipment must wear appropriate PPE including eye and hearing protection.
        iii. Logs of maintenance should be available for review.
4) Ventilation and Exhaust Fans
    a) Ventilation equipment and fans must maintain safe air quality and vent and/or filter any noxious odors or dangerous airborne contaminants.
        i. Air quality standards must meet worker safety requirements and product quality and safety specifications (see FS-4001-0600(2) Environmental Controls).
    b) Ventilation system must be tested annually (or more frequently as required by conditions) for contaminants and sanitized as required.
    c) All fan guards and coils (cooling units, production equipment and general ventilation) must be clean and free of dust, grease or other collected contaminates.
    d) Walls or ceilings around fans or ventilators must be free of dust build-up or foreign matter.
    e) Vents, filters and fans must be cleaned or replaced periodically.
5) Hazardous Materials
    a) All hazardous materials and cleaning supplies must be identified, marked, segregated, controlled and stored according to written procedures, government regulations and product labeling.
    b) Separate, lockable storage must be in place for all hazardous substances.
        i. Accurate inventory of storage contents must be documented and maintained.
        ii. Storage areas must display required warning signage in appropriate languages.

c) 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.

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

i. Cleanup equipment and materials must be available; waste must be disposed of according to FS-4001-2200 Waste Management.

ii. 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

6) Cleanability

Facility 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.

7) Conservation Plan

a) The operation must develop a conservation plan to reduce consumption of all resources including water, energy, materials and supplies.

b) The operation should conduct an annual energy audit of all energy sources and consumption for key operations or equipment.

c) The operation should implement methods to conserve energy and use or increase use of renewable sources when applicable.

d) The operation must implement waste reduction, recycling and reuse methods.

## FS-4001-0700 Signage

1) Signage

a) Signage for Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), worker safety and hygiene must be posted in all appropriate work areas.

b) Signage must require:

i. Hand washing

ii. Use of personal protective equipment

iii. General cleanliness practices

c) Signs must be presented in languages appropriate for workers, contractors and visitors.

d) Applicable graphic signs also may be used.

2) Safety Signage

a) 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.

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

## FS-4001-0800 Security

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

2) CPTED Approach
    a) 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.
    b) 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.

3) Security Program
    a) 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.
    b) The security program must include:
        i. Company security mission and purpose
        ii. Security roles and responsibilities
        iii. Confidentiality and information security
        iv. Security systems – access, alarms and video surveillance
        v. Cash revenue management
        vi. Record keeping and reporting
        vii. Employee policies and disciplinary action
        viii. Dynamic entry, intrusion, theft, loss and diversion
        ix. Facility access, worker ingress/egress
        x. Inventory control – seed to sale
        xi. Safety policy
        xii. Emergency policies and procedures

4) Security Risk Assessment
    a) An annual Security Risk Assessment must review all threats (crime) and hazards (natural/man-made events) to assets (staff, public, product, currency, materials, information).
    b) Security program must include specific action plans to mitigate all risks including:
        i. Exteriors/perimeter
        ii. Doors, windows and other openings
        iii. Interior areas of site or building
        iv. Property and equipment
        v. General security processes/protocol

vi. Alarm systems
vii. Security employees and contractors
viii. Cash management procedures
ix. Worker procedures
x. Worker and background checks
xi. Opening and closing the facility
xii. Managing and removing trash
xiii. Working with vendors
xiv. Working with contractors
xv. Threats from neighbors
xvi. Training and monitoring employees
xvii. General management practices
xviii. Managing security emergencies
xix. Plans for dynamic entry or intentional threats

c) Retain annual Security Risk Assessment documentation for at least two years.

5) Security Qualifications

a) 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.

b) Security managers must have documented security training and demonstrated security experience that qualifies them to competently oversee all security responsibilities.

c) The operation must have an organization chart that identifies security titles and responsibilities.

6) 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.

7) Physical Barriers

a) The operation must apply methods to prevent unauthorized access to buildings, production areas and products, shipping/receiving, storage and parking areas.

b) Prevention methods include fencing, locked gates, secure doors, window protection, automatic access systems and other physical barriers and reinforcements.

c) Security barriers must comply with local security, fire safety and zoning regulations and GMP.

8) Grounds and External Areas

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

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

b) Workers should be trained on safe ingress/egress processes.

9) Door Locks

a) Sturdy commercial-grade locks must be installed on all doors and gates.

b) External doors must have deadbolt locks and comply with local fire and building code regulations.

c) Key distribution must be controlled, monitored and documented.

d) 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.

e) Biometric entry systems must be monitored, controlled and documented.

f) Procedures must ensure keys, locks, codes and biometrics are changed immediately as required by personnel access privilege changes or breaches.

g) Keypad locks (used solo without key card or biometrics) are not permitted for restricted areas or external entry.

### 10) Facility Access Controls

a) 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.

   i. Workers must wear visible identification badges.

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

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

### 11) Restricted Area Access Controls

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

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

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

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

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

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

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

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

### 12) Visitor Access Controls

a) 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.

b) All visitors must be escorted by an authorized person at all times while in controlled areas of the facility.

c) Visitors should wear a visible identification badge while on the premises.

d) Visitor log shall be retained for two years.

### 13) Cash Management

a) The operation must provide documented cash management training to workers including:

   i. Managing cash transactions with customers and suppliers

   ii. Point of sales equipment

   iii. Money counting and money handling

iv. Currency security
v. Counterfeit detection and processing
vi. Video monitoring
vii. Cash drawer management

b) Managers shall review and observe cash management procedures weekly at a minimum and take corrective action on all nonconformances.

c) The operation must document detailed procedures to ensure safe daily opening, closing and transfers of cash to bank or secure location; managers must observe workers regularly to ensure compliance.

d) The operation must train all workers who manage cash or accounting responsibilities on money laundering laws and reporting requirements as required by state and local laws.

## FS-4001-0900 Surveillance System

### 1) Video Monitoring

a) The operation must install video monitoring equipment that satisfies all local regulations pertaining to monitoring of cannabis facilities.

b) 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.

c) Date and time must be embedded on every frame of all surveillance recordings without obscuring any useable areas of the image.

d) An automatic battery backup system must be installed to support a minimum of one hour of recording time.

e) 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.

### 2) Video Recording Security

a) 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.

b) Digital video files must be password protected and reviewed only by authorized personnel.

### 3) Video Quality and Coverages

a) 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.

b) 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.

c) Equipment specifications must be based on operational requirements but no less than HD quality (1920 x 1080 – 2.1 megapixel).

i. 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.

ii. Internal Areas: Medium resolution HD; IR required for grow rooms.

d) Video camera coverage must include:
    i. All secure and restricted access areas
    ii. All point of sale areas
    iii. All points of entry to or exit from secure and restricted access areas
    iv. All points of entry to or exit from the registered facility

4) Continuous Video Monitoring
    a) 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.
    b) Adequate internal and external signage is posted stating "Premises under video surveillance."
    c) 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.

5) Video Retention
    a) 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.
    b) All surveillance recordings must be retained for a minimum of 45 days and in a format that can be easily accessed for viewing.
    c) Access must be password protected and limited to authorized personnel.

6) Video System Maintenance
    a) 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.
    b) Security manager must ensure camera domes/lenses are unobstructed, properly targeted and kept clean.

## FS-4001-1000 Alarm System

1) Facility Alarm System
    a) The operation must be continuously monitored by a building-wide alarm system.
    b) Alarm must be linked to security, management and police as required by Security Risk Assessment.
    c) Alarm should have dual pass-through communication capability.
    d) Redundant phone and Internet lines must be installed and operational.
    e) System delivers automatic power outage notification – automatic check every 5 minutes.
    f) Alarm system includes fire and smoke detection, monitoring and notification of fire department and facility personnel.
    g) 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.

2) Alarm Monitoring
    a) Alarms must be monitored 24/7 by bonded, accredited or certified professional security company.
    b) Alarm triggers and breaches require a 2-minute response time or less and a clearing code process validated via phone by authorized representatives.

c) Monitoring includes fire and smoke detection and notification of fire department and company managers.

d) Automatic alarm is activated for all power outages – automatic check every 5 minutes; monitoring company provides immediate outage notification to authorized managers.

3) 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.

4) Panic Buttons

a) 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.

b) Establish a code word for emergencies to alert fellow workers to an active emergency.

5) Alarm System Maintenance

a) 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.

b) Security manager must ensure alarm sensors and triggers are functional and alarm system is operational 24/7.

## FS-4001-1100 Health and Safety

1) Health and Safety

a) Management shall develop and maintain a safe and healthy work environment for all workers, contractors and visitors.

b) The health and safety program shall be documented and include annual training and periodic assessment for all workers.

2) 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.

3) 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.

4) Worker Cleanliness

a) Workers must practice personal cleanliness including:

i. Outer garments such as smocks, aprons and lab coats must be clean and appropriate for the assigned tasks.

ii. Nails must be trimmed and clean.

iii. 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.

5) Hand Sanitation

a) 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.

b) Disposable protective gloves must be in stock and available.

c) Gloves must be discarded when damaged and after using toilets, eating or contacting a foreign substance.

6) Wounds and Infections

a) 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.

b) Workers with observable or reportable infections must be excused from work according to the organization's procedures.

c) Management must evaluate all situations and take corrective action when any communicable disease is observed and document the corrective action taken.

d) Facility must have similar procedures to manage patients, customers or suppliers that enter or attempt to enter the facility with signs of infectious illness.

e) The operation can establish procedures to cover wounds with bandages and/or gloves to eliminate contamination risk.

7) Protective Clothing

a) Workers who handle open samples or test materials must wear:

i. Aprons
ii. Gloves
iii. Masks
iv. Hair nets
v. Beard nets (if beard can be grasped with fingers – longer than 3 mm)
vi. Lab coats

b) Protective clothing must be issued to all affected workers and must be clean and in good condition (not frayed, torn or stained).

c) Shoes must be appropriate for the position; open-sole or open-toed shoes must not be worn in controlled areas of the lab.

8) Prohibited Items

a) Procedures must prohibit workers from wearing false eyelashes, false nails, magnetic jewelry or other items that can detach during production.

b) 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.

c) Gloves must be used to cover nail polish; other cosmetics may be restricted by procedures.

9) Eating and Drinking

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

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

### 10) Smoking and Tobacco Products

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

### 11) 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.

### 12) Violence and Weapons

a) 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.

b) 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.

### 13) Health and Safety Risk Assessment

a) 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.

b) 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.

c) 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.

d) Risk assessment must document risk mitigation in the injury and illness prevention plan and they must be reviewed annually.

e) If required by state regulations, the operation must retain signed consent forms for workers who apply any chemicals.

### 14) Health and Safety Procedures and Training

a) 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.

b) Injury and Illness Prevention Plan must be documented and implemented.

c) All workers shall participate in health and safety training and ongoing training updates; training completion shall be documented and repeated for all workers annually.

d) Safety training must include OSHA-based electrical safety, slip/trip/fall protection, ergonomics, personal protective equipment and workplace violence.

e) 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.

f) The operation shall install and maintain protective devices and systems such as shields, guards, barriers, detectors, warning alarms, automatic shut offs and access controls.

g) 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.

h) Vacuum, high pressure, heating and freezing equipment must include appropriate procedures, safety controls, signage and training.

i) The lab must provide safety procedures and training for the selection, use, handling, cleaning and storage of glassware.

j) Lighted exit signs must be installed as required by OSHA standards.

k) Safety data sheets for all chemicals must be on file and available to workers.

### 15) Personal Protective Equipment

a) 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.

b) PPE must be assigned to workers in proper working order and may include glasses, goggles, ear protection, gloves, masks, respirators, aprons, boots, etc.

c) If respirators are required:

   i. Written respirator protection usage and training plan must be on file.

   ii. All workers must undergo a medical exam.

   iii. Operation must train workers.

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

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

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

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

Reference 29 CFR 1910.132 – Personal Protective Equipment

### 16) Accident and Emergency Procedures

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

b) 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.

c) 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.

d) 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.

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

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

17) First Aid

a) The operation must ensure there is always at least one person on premises with documented first aid training.
    i. Operations with more than 50 workers must have one trained person present for every 50 workers onsite.
b) The operation must maintain well-stocked first aid kits that are checked and restocked monthly; kits should include blood spill kit.

18) Domestic Animals

a) 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.
b) Animals must not be transported in the same vehicle as the operation's finished cannabis products or packaging designated for sale or transfer.
c) Domestic animals are discouraged in all areas of a cannabis facility including office areas; any exceptions must be documented by policy.
d) 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) Drinking Water

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

20) Eyewash Stations

a) 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.
b) 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.

21) Changing Areas

a) If the operation requires gowns and other protective clothing in testing areas:
    i. Workers must have a clean, organized location for gowning and changing clothes.
    ii. The operation shall provide lockers for storage of personal clothes, jewelry and other items.
    iii. The operation must provide enough clean protective clothing to support procedural requirements (each entry, each shift, weekly, etc.).

iv. The operation must provide training for gowning processes (e.g., put on booties before gloves to prevent shoe dirt contamination on gloves).

## FS-4001-1200 Sanitation

1) General Cleanliness

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

2) Master Sanitation Schedule

a) 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.

i. Areas include all processing, packing, product storage and waste areas, and offices, restrooms, break areas and public/patient areas.

ii. Equipment and support items include anything used in the production process or located in production areas.

b) Facility shall keep a log of the area/equipment cleaned, cleaning performed, date cleaned and worker performing the cleaning.

3) Sanitation Procedures and Training

a) The operation must maintain sanitary conditions at all times.

b) Operation must have written sanitation and cleaning procedures for all equipment and areas.

c) All workers must receive formal sanitation training.

d) Procedures and training must cover the following at a minimum:

i. Worker responsible for cleaning

ii. Item/area to be cleaned

iii. Specific cleaning methods

iv. Tools, utensils and cleaning products used

v. Frequency of cleaning

vi. 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

4) Cleaning Equipment and Supplies

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

b) Cleaning and sanitation equipment and supplies must be stored in a designated area separate from samples, test materials, test equipment, packaging or sample storage areas.

c) 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.

d) Equipment must be stored separately from personal clothing.

e) 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.
    i. Acceptable cleaning products could include: diluted bleach; diluted ammonia; 70% ethanol; 70% isopropanol; food-grade detergent, etc.
    ii. The operation should use "green" (environmentally friendly) cleaning products when practical and select the least-hazardous chemical to meet the requirement.
f) Workers must receive documented training on the use of cleaning equipment and supplies and must wear personal protective equipment (see FS-4001-1100(15) Personal Protective Equipment).

5) Cleaning Equipment Identification

a) Cleaning equipment and supplies must be color-coded or boldly marked to prevent contamination or accidental use.
b) Separate cleaning equipment should be assigned to separate physical areas or functions:
    i. Production
    ii. Maintenance
    iii. Storage
    iv. Office
    v. Restroom/toilet
    vi. Outdoor

6) Sanitation Logs

a) The operation must maintain accurate, current sanitation logs that cover all areas of the facility and all equipment.
b) The logs should identify:
    i. What was cleaned
    ii. Who cleaned it
    iii. When it was cleaned
c) The logs should be easily accessible and retained for two years.

7) 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.

8) Product Protection During Cleaning

Test materials and test samples must be removed from the area during cleaning.

9) Toilet and Hand Washing Facilities

a) The operation must provide clean, modern toilets with hand-washing sinks and maintain them in a clean and sanitized condition.
    i. A worker must be designated to clean and stock the facilities.
    ii. Supplies such as soap, toilet tissue, paper towels and sanitizer must be well stocked.
    iii. Records of scheduled cleaning and restocking must be on file.
b) 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.
c) Toilet facilities should have self-closing doors.

d) Surfaces should be smooth, light-colored and easily cleanable.
e) The number of facilities provided for each gender should be based on the number of workers, patients or customers of that gender – separate facilities required if more than 20.
f) Hands-free hand washing units are preferable.
g) Signage must be in place to remind workers to wash/sanitize hands.

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

10) Secondary Hand Sanitation Stations

a) Secondary hand sanitation stations should be conveniently located in traffic zones.
b) 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.
c) Premixed restocking solution should include details of ingredients and strength.

Ware Washing Sink

a) The operation must install a stainless steel sink with at least three compartments for manually washing, rinsing and sanitizing lab equipment and utensils.
b) Compartments should accommodate immersion of the largest equipment and utensils by 50 percent.
c) Each compartment shall be supplied with adequate hot and cold potable running water; faucet necks must reach all compartments.
d) The lab must provide drain boards, utensil racks or tables large enough to hold all items before cleaning and after sanitizing.
e) Adequate equipment should be available to air-dry washed utensils and equipment, if required.
f) Automatic ware-washing equipment requires water temperature, pressure, chemicals and equipment that meet applicable ANSI standards or equivalent.
    i. Ware-washing sink is still required with automatic washing equipment.

## FS-4001-1300 Pest Control

1) Pest Management Plan

a) The lab must have a documented plan for pest and disease management that discourages pest populations and conditions for growth.
    i. Active pest control measures (traps, pest service, etc.)
    ii. Monitoring every three months (minimum) by a qualified third-party provider
    iii. Pest control measures in storage areas
    iv. Monthly inspections for pest contaminants
    v. Records of any pest activity, dates discovered and remedies pursued
b) Pest control devices (traps, light traps, etc.) must be placed to prevent contamination of samples, test materials, packaging, equipment or tools.
c) All equipment and materials must be stored to discourage the harborage of pests such as insects, rodents or birds.
d) Pest control records must be retained for two years.

2) Pest Contaminant Inspections

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

i. Product or product ingredients
ii. Packaging supplies
iii. Growing, processing and storage areas
iv. Equipment, equipment accessories and utensils
v. Office or non-production support areas
vi. Dining and break areas
vii. External areas except for normally occurring pest debris (i.e., insects concentrated around light fixtures and natural bird and insect activity)

3) Pest Control Devices

a) All pest control devices must be in working order (e.g., for sticky traps, glue must still be sticky, not covered with dust).
   i. All devices must be marked, numbered and coded.
   ii. Regular device monitoring must reference trap numbers and locations.

b) 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.
   i. 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.
   ii. Interior traps must be placed to prevent easy movement or accidental damage.
   iii. Traps should not draw pests into areas where product is stored or exposed.
   iv. 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.
   v. Exterior traps must be weighted or attached to ground to prevent movement.

c) 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.

4) Storage Areas

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

## FS-4001-1400 Laboratory Methods

1) Laboratory Methods

a) Procedures must define how the lab will meet a testing requirement within acceptable standards including:
   i. Objectives
   ii. Scope (type of material)
   iii. Definitions
   iv. Apparatus and instrumentation
   v. Method summary
   vi. Reagents and materials
   vii. Sample preparation

viii. Instrument conditions
ix. Calibration
x. Calculations
xi. Quality control
1. Statistical methods used
2. Data acquisition system operation
3. Assignment of uncertainty
4. Interferences/limitations
5. Approaches to address background corrections

b) Hazards and precautions
c) Report format and test forms

### 2) Process Procedures

a) Laboratory processes must be controlled by written procedures that include:
i. Environmental, safety, health and hygiene
ii. Purchasing, inventory control and materials management
iii. Sample receiving and transportation processes
iv. Sample handling, chain-of-custody and documentation procedures
v. Sample storage, stability and protection
vi. Sample preparation
vii. Sample analysis and reporting
viii. Quantification, preparation and handling of reference standards
ix. Post-analysis sample handling
x. Control and stability of standards, reagents and water quality
xi. Cleaning and safe handling of glassware
xii. Waste minimization and disposal
xiii. Process notebooks and logbooks

### 3) Pre-Test Inspections

a) Workers shall inspect lab areas, equipment, materials and personnel, and review current logs and reports to verify quality system readiness prior to each testing process. Inspections shall ensure:
i. Testing areas are decontaminated, cleaned and sanitized
ii. Test equipment is decontaminated, cleaned and sanitized
iii. Storage areas are decontaminated, cleaned and sanitized
iv. Test area is prepared for safe start – PPE, safety equipment, first aid, signage, etc.
v. Personnel are in position and meet GLP and procedural requirements
vi. Previous inspection nonconformances have been corrected
vii. Water source is prepared and meets water quality requirements
viii. All process and sub-process steps were reviewed and verified
ix. Required materials, equipment and quality control logs/forms are in position

b) Completed checklists should be retained for one year after the test.

4) Data Protocols

a) The lab must have data protocols to ensure that test data is accurately collected, documented, input into the lab management system and reviewed by at least two qualified staff members including:

i. Calculations that quantify cannabinoid content in various matrices.

ii. Determination of the range for reporting:

iii. Limit of Detection (LOD)

iv. Limit of Quantification (LOQ)

v. Standard format for Certificates of Analysis (COA) – proper units (ISO), numerical values, method references, date of receipt, date of report and signature of lab supervisor or lab director.

vi. Validation that the value reported in the certificate of analysis is within the range and limitations of the analytical method.

vii. Results for qualitative results below the LOQ but above the LOD must be reported as "trace" or with a non-specific (numerical) designation.

viii. The methodology applied must provide the specificity for the degree of quantitation reported. Final reports must report the quantity of significant figures appropriate for the analytical data.

ix. The lab must document the use of appropriate controls (positive and negative controls including appropriate "matrix blank" and "spiked matrix" controls) with documentation for each calibration run.

5) Chemical Assay Procedures

a) The lab must document assay procedures, including the use of appropriate reference standards, for any quantitative measurements that apply to the test method.

b) Lab must document appropriate reference standards used to create a calibration curve with each analysis.

c) Test should demonstrate calibration curve R2 value of no less than 0.995 with a minimum of six points that all bracket the concentrations expected for the sample.

d) Lab must retain documentation that demonstrates regular proficiency testing for three years past the test date.

6) Quality Control Samples

a) The lab shall retain reference materials, control samples and calibration curves for three years or as required by procedures.

i. Reference materials must be primary reference materials obtained from reputable sources with purity certified by the supplier.

b) Secondary or "working" standards may be used if calibrated to primary reference standards.

c) Control charts (x-bar charts) should be kept for control samples and reviewed periodically to validate that the method is in control.

d) If a customer refutes a test result, the lab should run a control sample parallel to a sample re-run. Proper statistical analysis should always be performed to ensure validity.

e) Outliers in data sets should be statistically or rationally determined.

7) Lab Method Comparison

a) The lab may conduct periodic testing of the same sample at multiple labs to determine, to a preliminary extent, the consistency in laboratory results.

i. If authenticated reference materials are used, the precision of a single method may be estimated by testing the same sample at multiple laboratories. However, inter-laboratory precision (reproducibility) is assured only with collaborative studies using the same method and reference materials.

b) Accuracy can only be conclusively determined by testing reference materials that are independently certified to contain a known concentration of analyte.

### 8) Sample Handling Procedures

a) The lab must implement and maintain detailed procedures for managing samples including:

i. Traceability – demonstrated control of chain-of-custody tracking upon receipt of sample including all staff handling the sample.

ii. Sampling method – identify the sample collection for a complete test batch including:

1. Homogenization
2. Weighing
3. Labeling
4. Sample identifier (source, lot)
5. Date and tracking

iii. Condition of the sample – inspect the sample for foreign matter and decomposition

iv. Test methods fit the intended purpose and are based on compendia, published peer-reviewed methods or single laboratory validation (AOAC Appendix K)

v. Failed-inspection tracking and reporting

vi. Disposal of used/unused samples documentation

vii. Sample preparation, extraction and dilution procedures for:

1. Plant material (flower)
2. Edibles (solid and liquid)
3. Topicals
4. Concentrates

b) The lab should document procedures and obtain equipment that allows authorized lab workers to collect samples at a cultivation or processing site (third-party sample collection) if required by customer or regulatory test procedures. Workers must be trained on collection procedures.

c) The lab sampling technicians and lab analysis technicians must meet the qualifications specified in 7.D Staff Qualifications before performing testing or analysis.

### 9) Sample Control and Destruction

a) All samples that contain cannabis or cannabis-derived products must be controlled by a written policy.

b) Workers responsible for sample handling or testing must receive training in sample handling and management procedures.

c) Samples must be marked, stored and retained as required by the laboratory's sample retention policy.

d) Used or excess sample material must be destroyed in a manner that prevents unauthorized use (see 16.D Cannabis Waste Disposal).

e) Samples must be sealed with tamper-evident tape and only broken and opened by an authorized person.

f) Samples must be retained for at least three months; samples related to an ongoing investigation, claim or lawsuit must not be destroyed.

## FS-4001-1500 Water Quality and Use

1) 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.

2) Water Quality Analysis

a) The lab must conduct water analysis annually at minimum, more frequently if required by water conditions, and retain records according to procedures.
   i. Tests must include biological, physical and chemical contamination.
   ii. Test results must be analyzed and corrective action taken for any water quality issues that could adversely affect lab performance.

b) The operation uses laboratories performing water analyses certified to ISO 17025 level or equivalent standard.

## FS-4001-1600 Equipment Management

1) Equipment Management

a) All laboratory equipment must be documented on a Master Equipment List that identifies each piece of equipment used in the testing process including test systems, computing and measuring equipment, appliances, devices, materials, vessels, wares, utensils and tools. The Master Equipment List should include the following as applicable:
   i. Name/description, serial number, supplier and supplier contact
   ii. Date received, installed and activated, condition at receipt and current location
   iii. Maintenance and calibration requirements and work performed
   iv. Relocation, sale or disposal of equipment
   v. History of equipment malfunction, mishandling, damage or recall

b) The lab must maintain all laboratory equipment to manufacturer's specifications to ensure it is available for use and continually meets operational requirements.
   i. Maintenance procedures must define maintenance requirements, preventative maintenance, frequency of maintenance, manufacturer's specifications and instructions, calibration requirements and relevant equipment performance history.
   ii. The lab shall ensure equipment maintenance is performed as scheduled by qualified workers or third-party service providers.
   iii. 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.
   iv. Manuals, technical sheets and safety instructions should be accessible for all listed equipment and used to support maintenance, calibration, sanitation and training plans.

c) Equipment surfaces that make contact with samples and test 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.

i. Equipment surfaces must not show any flaking paint, corrosion, oil, grease, food residue or other unhygienic materials.
ii. All non-contact equipment surfaces, including any supporting equipment in the work area that may contaminate the testing process, must be clean at all times to prevent potential contamination.

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

2) Equipment Design

a) Equipment must be constructed of materials appropriate for the intended purpose, preclude contamination of products and promote sanitation.
b) The following types of equipment and materials are not recommended:
i. Corrosive metals (iron, unfinished steel)
ii. Brittle plastic
iii. Porous materials
iv. Materials that are difficult to clean or likely to harbor filth
c) Equipment must be made of easily cleanable materials with non-porous, smooth surfaces, tight weld seams, non-toxic materials and no wood surfaces.
d) Equipment should be designed with no unreachable areas to allow access for cleaning and maintenance.

3) Equipment Calibration

a) The lab shall implement equipment calibration procedures that define the frequency of testing, test methods, accepted range of variation, corrective actions required for nonconformances and required records and logs.
b) The lab shall regularly calibrate and maintain all instruments, scales, thermometers, meters, analytical balances, pipettes, measuring devices, containers, timers, environmental control systems and other variable equipment as required by procedures.
i. Procedures must document the frequency of inspections and require prompt repair or recalibration of all variable equipment list on the Master Equipment List.
ii. The operation must record calibration results in the Master Equipment List and document the corrective actions taken when calibration tests exceed the acceptable range of variation.
iii. The quality manager shall approve the calibration schedule.
iv. Scheduled calibrations must be performed in addition to routine calibrations performed prior to each use of the equipment.
v. All equipment must meet state calibration requirements.
c) A label must be affixed to each piece of calibrated equipment that identifies:
i. Date when the equipment was last inspected or calibrated
ii. Date when the next calibration is due
d) Calibration records must be complete and accurate.
i. Technicians must record calibration results using the international metric system.
ii. Calibration records must be retained for two years or to the date of the first testing the lab performed with the equipment, whichever is longer.

4) Equipment Verification

a) Before introducing any piece of equipment into service, the quality manager must determine and document the service, maintenance, calibration and inspection schedules.

b) The quality manager must approve the equipment's technical specifications to ensure the equipment meets lab safety and engineering requirements and is compatible with the lab management system.

c) New equipment and related specifications must be added to the Master Equipment List and the equipment's operations manual should be added to the operations manual files.

5) Critical Equipment Installation

a) All building infrastructure systems, utility connections, equipment installations and support systems must be installed and operated to ensure safe, quality laboratory operations. Safe, quality operation includes:

i. Electrical:

1. Outlets are adequate, unobstructed, single use with no multi-plug adaptors.
2. No extension cords are in use.
3. Ground fault circuit interrupters are located near wet/water use areas.

ii. Plumbing:

1. Separate sinks are provided and used for work and personal use.
2. Sinks show adequate drainage.
3. The operation provides hot and cold running water.

iii. Ventilation:

1. Areas where solvent is used, stored or processed are well ventilated.
2. The lab has a vented hood for any microbiological analysis.
3. The lab has a Class II Type A biosafety cabinet as required by lab methods.

iv. Vacuum:

1. Appropriate utilities and traps are installed to prevent contamination.
2. Accessible, well-marked emergency shut off controls are located inside and outside of the laboratory.

## FS-4001-1700 Quality Control

1) Cross Contamination Prevention

a) All lab processes must be designed and organized to prevent contamination of samples, test materials, equipment, wares and utensils.

i. Test processes must ensure clear physical separation of test samples, test materials, reference materials and equipment.

ii. Gloves must be used and discarded between test processes and sample handling.

iii. Equipment, tools, wares and utensils must be cleaned between operations and daily at a minimum.

iv. All areas must be clean, organized and free from debris.

v. Adequate workspace must be available to limit the risk of test interference and sample corruption.

2) Quality Management Responsibility

a) The lab's organization chart and job descriptions must identify the staff members responsible for managing quality control and define the hierarchy for quality-related decisions.

i. Quality managers must have appropriate education, credentials and experience to meet the technical, quality and management requirements of the position.

3) Lab Risk Assessment

a) The lab must conduct an initial and annual Lab Risk Assessment to identify all potential quality risks to laboratory processes and services.

b) Risks and mitigation plans must be documented in the lab management system, procedures and quality control checklists.

c) The lab should document corrective and preventative actions taken and track results.

d) The risk assessment must be approved by the quality manager.

4) Quality Status and Updates

a) The quality manager shall regularly communicate quality measurement data to staff and ensure data is available for staff review (daily recommended, weekly at a minimum).

b) Quality nonconformances must be documented; corrective action must be taken and communicated to staff as soon as practical. Procedures and training must be revised accordingly.

c) Documented quality control procedures must be readily available and consistently applied by workers; managers shall ensure workers follow procedures.

d) Workers must receive training and annual refresher training on quality control procedures.

5) Quality Control Checklists

a) The lab should use quality control checklists or similar tools to verify and document method validity.

b) If control checks are outside of specifications, document corrective actions taken; calibrate and mark related test equipment.

c) Supporting documentation such as checklists, corrective action logs and calibration records must be retained for three years.

6) Out-of-Specification Procedure

a) Laboratories must have a documented out-of-specification (OOS) investigation and corrective action procedure.

i. Lab policy shall authorize every worker to notify the quality manager of any suspected quality, tolerance, specification or procedural nonconformances.

ii. Every nonconformance shall be managed and documented according to established corrective action procedures.

iii. The procedure must require an automatic retest in the event of refuted results.

1. If the retest result is different than the original result, the lab report must include disclosure of the original result, the final result and any corrective actions taken.

b) The OOS procedure must include a periodic review of all test methods, equipment calibration procedures and technical performance requirements; corrective action must be documented and completed as required.

7) Corrective Action Process

a) The lab must implement and maintain a robust corrective action process that ensures all nonconformances are documented and corrected as rapidly as possible.

b) Procedures must define how nonconformances and required corrective actions are communicated to appropriate staff in a timely manner.

c) Documentation should identify how corrective actions prevented recurrence.

d) The lab must maintain accurate, accessible corrective action records.

## FS-4001-1800 Test Methods

1) Test Methods

a) The lab must fully document all laboratory test methods used for each test.

i. For chemical tests, the lab should perform a single laboratory validation of methodology AOAC Appendix K to quantify levels of THC, THC-A, CBD, CBD-A, CBN that make up "total cannabinoids" content. Cannabinoids should be tested by high performance liquid chromatography (HPLC).

ii. Terpenes analysis is typically performed using gas chromatography (GC). Other cannabinoids, if quantified, must undergo validation AOAC Appendix K.

b) For chemical tests, the lab must demonstrate method validity, including the following:

i. Linearity of a 6-point calibration curve using control samples containing authentic reference materials certified for purity (R2>0.995)

ii. Accuracy: Recovery of certified reference materials (5 consecutive determinations of the same sample between 90 and 110% of certified value)

iii. Precision: Repeatability over time of control samples within a relative standard deviation appropriate for the expected concentration of analyte (Typically, 97-102% for a sample containing >1% by weight of an analyte like THC)

c) Control Samples – lab must test control samples at the beginning of each day and with each batch to verify calibration of the instrument.

d) The lab must verify analytical range of the instrumentation, and document Limit of Quantification (LOQ) and Limit of Detection (LOD).

e) Matrix extensions are required for each type of product tested; review recovery data for the following:

i. Flower and plant material

ii. Solvent-based concentrate (non-ethanol)

iii. CO2 concentrate

iv. Concentrate made with food-grade ethanol

v. Concentrate made with food-grade glycerin or propylene glycol

vi. Infused liquids (aqueous)

vii. Infused solids (cookies, etc.)

viii. Infused topical preparations

ix. Other oils, butter or fats

f) The lab must verify and document:

i. Identity, origin and purity of all reference materials and control samples

ii. Periodic blank samples to ensure no carryover

iii. Periodic testing of control samples

iv. All applicable daily and periodic monitoring of sample preparation, instruments and proficiency of technicians

2) Test Method Validation

a) Test methods must be scientifically valid, meet the purpose of the test, and be precise and accurate to the extent required to replicate results.

i. All test methods should be based on compendia or published methods. In absence of reference to compendia or published methods, AOAC Appendix K must be published in

full. Complete test methods must be available upon request by clients, regulators and the general public.

ii. All test reports must list compendial and/or published method references. Evidence may include references to peer-reviewed articles, industry publications, technical or scientific journals, or be supported by single laboratory validation AOAC Appendix K.

iii. Proprietary test methods are permitted only if the lab completes full method validation according to AOAC Appendix K; validation data must be documented and retained for as long as the test is used plus three years.

iv. All test methods must produce data in a format that meets scientific and regulatory requirements.

### 3) Active Tests

a) Cannabis is typically tested for contaminants, physical characteristics and potency. Labs must maintain a list of all active tests they perform. Labs may receive requests to test cannabis or cannabis products for the following (acceptable method principles listed in parentheses):

i. Potency and cannabinoids – THC, CBD, CBN, CBG, CBC, THC-V, CBD-V, CBG-A, THC-A and CBD-A (HPLC)

ii. Residual solvents (GC-FID or GC-MS)

iii. Pesticides (LC-MS-MS) and fertilizers

iv. Heavy metals (ICP, ICP-MS)

v. Micro-organisms – molds, mildew, bacteria, Salmonella, E. coli, Staphylococcus, Listeria, Clostridium, Bacillus thuringiensis (Bt) (<USP 20> or <USP 21>)

vi. Mycotoxins, aflatoxins and ochratoxins (HPLC-MS, ELISA)

vii. Bacterial endotoxins (ELISA, Lipopolysaccharide enzymatic)

viii. Terpenes (GC-FID, GC-MS)

ix. Homogeneity (visual, microscopy, sampling with other methods)

x. Moisture content (Karl Fischer, water activity)

xi. Botanical identity (visual, TLC, HPLC, GC)

xii. Foreign matter (visual)

xiii. Visual appearance (macroscopy/microscopy)

xiv. Organolepsis

xv. Cytotoxicity (cell proliferation on normal and cancer cells)

xvi. Genetically modified organisms (PCR)

xvii. Gluten (ELISA/enzymatic)

xviii. Food allergens (ELISA/enzymatic)

xix. Pthalates/endocrine disruptors (GC, LC)

xx. Polyacrylonitrile (PAN)

xxi. Polycyclic Aromatic Hydrocarbons (PAHs)

xxii. PCB, benzopyrenes, environmental toxins (as appropriate)

xxiii. Performance-enhancing drugs (as appropriate)

xxiv. Gamma irradiation (as appropriate)

xxv. Ethylene oxide (as appropriate)

xxvi. Nutritional content (as appropriate)

4) Test Method Tracking

a) Lab must have a system in place that tracks the technician responsible for each test. Records should list all workers involved in the tests.

b) Tracking can include requiring a worker code on all documents, an access code to use equipment or another documented method.

c) If operationally feasible, the tests should be assigned and completed without revealing the manufacturer to ensure impartiality.

5) Polymerase Change Reaction Testing

a) If PCR method is used for microbiology, lab must have procedures in place that ensure the operation and calibration meet recognized international standards (weekly standards curve updates to check for degradation of primer/probes).

b) PCR machines should be able to determine strain lineage and determine quantities of fungus, yeast, mold or bacteria in a sample.

c) All microbiological methods must be based on compendial methods such as those found in the U.S. Pharmacopeia or commonly used for food safety testing.

## FS-4001-1900 Laboratory Operations

1) Service Quality

a) Management shall ensure laboratory services meet all quality methods, specifications and requirements.

b) Management shall:

i. Implement a lab management system that ensures all facilities, equipment, processes and people operate to produce safe, quality services and accurate documentation.

ii. Conduct and document an annual assessment of the quality program and lab management system; record updates to the program and corrective action taken.

iii. Designate managers responsible for quality management that have the skills, time allotment and defined job descriptions to perform the requirements of the positions.

2) Computer Functionality

a) The lab computer system must:

i. Support sample tracking

ii. Support analytical equipment software

iii. Be compatible with commercial and laboratory-developed software

iv. Contain security systems to protect software and data

v. Limit manual data input and maximize data input automation and sharing

1. Automatically inputs weight and measures
2. Automatically inputs test equipment results
3. Automatically enters or shares data from other forms or databases

vi. Include software acceptance testing when installed, after software updates or changes, and periodically during use, as appropriate

1. Testing may consist of performing manual calculations, verifying against another validated software product or analysis against standards.

vii. Document the version and manufacturer of the software

1. Lab may accept commercially available software as supplied by the vendor

2. Lab may perform acceptance testing for vendor-supplied instrument control and data analysis software
3. For laboratory-developed software:
    a. Retain copy of the original program code
    b. Document all changes with full description and authorization for the change
    c. Retain test data that validates changes

## FS-4001-2000 Packaging

1) Sustainable Packaging
    a) 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.
    b) Packaging specifications must define sustainability parameters.
    c) Operation must retain supplier sustainability certifications for review.

## FS-4001-2100 Product Storage

1) Product Storage
    a) Cannabis samples must be stored in a controlled environment to protect sample integrity and prevent degradation. Operation must implement written procedures to control areas.
    b) The operation shall protect samples and sensitive test support materials from biological contamination, dust, electromagnetic disturbances, humidity, electrical supply, temperature and sound/vibration levels, as appropriate to maintain sample integrity.
    c) Operation must maintain environmental controls such as humidity, temperature and air pressure within established parameters to protect stored samples.
    d) Storage area access must be controlled and restricted to authorized personnel; access logs or automatic access monitoring must be used.
    e) Quarantined material must be physically segregated and clearly marked.
    f) All storage areas must be organized (appropriate shelving, drawers and labeling), well illuminated, clean, well ventilated and free from condensation, dust, dirt, chemicals or other contaminants; all contents including packaging must be clean and free of all contaminants.
    g) Cleaning schedules and logs must be current and retained for review; samples and test support materials must be protected during cleaning.
    h) Only products associated with laboratory testing and sampling can be stored in designated controlled storage areas.
    i) Controlled storage areas should be constructed of non-porous, easy-to-clean surfaces.
    j) Safe, effective pest control methods must be used and periodically evaluated.

## FS-4001-2200 Waste Management

1) Cannabis Waste Disposal
    a) Cannabis waste must be rendered unusable and unrecognizable prior to leaving the facility.

b) 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:
    i. Food waste
    ii. Cardboard waste
    iii. Paper waste
    iv. Compost activators
    v. Soil or soil mix
c) Other waste processing methods are acceptable if justified and documented.
d) Cannabis waste (weight, plant ID, lot code, etc.) must be recorded in the inventory system.

2) Waste Container Control

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

3) Minimize Landfill Waste

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

## FS-4001-2300 Receiving

1) Supplier Qualification

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

2) Incoming Goods Inspection

a) 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):
    i. Correct item
    ii. Correct quantity and/or weight (use calibrated scale)
    iii. Meets quality specifications
    iv. Signs of decay or degradation
    v. Foreign materials contamination
    vi. Odor
    vii. Physical damage
    viii. Improper packaging or mislabeling
    ix. Product safety
    x. Security issues

b) Document all nonconformances and the corrective action taken.

3) Incoming Sample Inspection

a) A qualified staff member must inspect all incoming cannabis samples for correct documentation, packaging integrity and chain-of-custody controls.

b) The inspector shall document incoming inspection results and report any nonconformances to the lab supervisor.

c) The inspector shall record all incoming samples in the lab receiving and tracking system.

d) New samples must be labeled and promptly moved to the appropriate controlled staging or storage area to maintain chain-of-custody control and sample integrity.

## FS-4001-2400 Transfers and Transport

1) Transport Manager

a) The operation must designate a qualified person to manage the company's product transport program including:

i. Product and document control

ii. Verification and training of transport agents

iii. Vehicle security, vehicle inspections and sanitation requirements

iv. Route management

v. Risk assessments

b) Managers must assess transportation security and transport agent compliance quarterly at a minimum. Nonconformances must be documented and corrective action completed.

2) Transport Security Procedures

a) The operation must have written procedures that protect all aspects of the transportation of cannabis samples.

b) Procedures are required for each physical location the company operates and must include:

i. Departure

ii. In transit

iii. Arrival requirements for all legs of the route regardless of destination

c) 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.

d) 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.

e) 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.

f) Procedures must align with all state and local laws and must be implemented as specified.

NOTE: If the lab does not provide cannabis sample pickup/delivery service for customers, the lab should process incoming samples according to incoming sample inspection procedures.

3) Transport Agents

a) Transport agents are the only workers authorized to transport cannabis and cannabis products and must be listed on documentation for each route they drive.

b) 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.

c) 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).

d) Transport agents must obey all traffic laws; management shall assess each agent's safe driving performance periodically.

e) Transport agents must file a security incident report for any threat, accident or unusual event experienced during the transportation process.

### 4) Transport Agent Credentials

a) All company transport agents must have valid state and/or local registration documents that clearly identify the person as an approved cannabis transport agent.

b) All transport agents must have a valid driver's license; a copy must be on file.

c) The operation must obtain a current driving record for all new transport agents and annually for all transport agents.

d) Procedures must require existing transport agents to report all moving violations and motor vehicle accidents (not just work-related) to their manager.

e) 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.

### 5) Delivery Route Process

a) The operation must document date, time and delivery route of all shipments of cannabis and cannabis products.

b) Transport agents must carry the manifest with copies for the origin site and destination locations.

c) Transport manager must inspect incoming and outgoing product transport vehicles Transport procedures.

d) Delivery times and routes should be changed on a routine basis to safeguard deliveries; limit authorized delivery windows to daylight hours.

e) When practical, transport agents should call ahead to ensure readiness at destination.

f) 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.

g) Delivery and receiving areas, doors, parking and physical access should be separate from worker or customer entrances and exits.

### 6) Shipment Invoice

a) The shipment invoice, manifest or bill of lading must include at a minimum:

i. Name, location and registration number of origin facility

ii. Date of invoice

iii. Name, location and registration number of destination

iv. Total product quantity delivered to each location if more than one with detailed bill of lading for each location

v. Date and time of departure

vi. Date an estimated time of arrival

vii. Delivery route

viii. Vehicle manufacturer, model and license plate number

b) Invoices must be protected as confidential information.

7) Transport Packaging

a) Transport agents must use an approved, sanitary container sealed with tamper-evident tape or equivalent control.

b) Traceability information must be clearly marked on the outside of the container.

c) Packages inside of sealed containers (if applicable) must be closed to protect contents and sealed if required by product specification.

8) Transport Vehicle Controls

a) 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.

b) The operation must segregate an area of the vehicle for secure, sanitary cannabis storage during transport.

c) 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.

d) The operation should install active GPS or security tracking on vehicles.

e) Vehicle glove box should contain an "accident and emergency packet" that contains all required information in case of collision or other emergency.

f) 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.

9) Vehicle Inspections

a) The operation must inspect all transport vehicles and maintain a log that records:

i. Product security
ii. Mechanical operation
iii. Condition/damage
iv. Vehicle cleanliness
v. Fuel status
vi. Temperature control
vii. Inspector/inspection date

b) Vehicles must have shipping manifest and trip/route plan on file.

10) 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.

## FS-4001-2500 Social Sustainability

1) Community Relations

a) The operation should conduct a community impact study that explores cooperative strategies for minimizing negative impacts and highlighting positive impacts.

b) The operation should contribute to the community through employee volunteerism, community outreach programs, education programs, charitable donations (cash and in-kind) and other methods.

c) 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) 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.

## 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.
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- **Good Manufacturing Practices (GMP) or (cGMP)**
    - Current Good Manufacturing Practices (GMP) or (cGMP) ensure that products are consistently produced according to quality standards. The term Good Production Practices (GPP) may also be used.
- **HACCP**
    - Hazard Analysis and Critical Control Points Plan – A detailed, systematic, documented approach that identifies, evaluates and controls quality hazards for each product-related process used by

an operation. HACCP may be applied to GAP or GMP requirements. FOCUS Standards use the terms Hazard Control Plan and HACCP Plan interchangeably.

- **Hazard Control Plan**
  - A detailed, systematic, documented approach that identifies, evaluates and controls quality hazards for each product-related process used by an operation. Hazard Control Plans and HACCP may be applied to GAP or GMP requirements. FOCUS Standards use Hazard Control Plan interchangeably with HACCP Plan.
- **Health and Safety Program**
  - A comprehensive health and safety program includes physical safety, safely designed work processes, safe tools and equipment, facility and environmental safety, regular safety assessments, worker engagement and ongoing safety training.
- **Infused Products**
  - A food product, tincture or salve that contains concentrated or cannabis-derived cannabinoids.
- **Injury and Illness Prevention Plan**
  - An ongoing intervention method to reduce the number and severity of workplace-related injuries and illnesses. Program components include management leadership, worker participation, hazard identification, hazard prevention and control, training and evaluation of results.
- **Lab Management System (LMS)**
  - Business, operational, quality and data processes and systems that ensure the lab operates according to policies and procedures.
- **Limit of Detection (LOD)**
  - The lowest signal that can be measured by a given testing method.
- **Limit of Quantification (LOQ)**
  - The lowest possible concentration that can provide quantitative results by a given method.
- **LMS**
  - Lab Management System – Business, operational, quality and data processes and systems that ensure the lab operates according to policies and procedures.
- **Master Equipment List**
  - A Master Equipment List identifies each piece of equipment used in the production process including machinery, test systems, computing and measuring equipment, appliances, devices, vessels, wares, utensils and tools.
- **Master Sanitation Schedule**
  - A Master Sanitation Schedule identifies each area, piece of equipment and support item to be cleaned; the frequency of cleaning; and workers responsible for cleaning.
- **Medical Dispensary**
  - A facility, operation or company licensed to dispense medical cannabis to qualified patients according to state and local laws.
- **Must vs. Should**
  - The terms *must* and *shall* are used interchangeably to indicate requirements to the FOCUS Standard; the terms *should, could, may* and *can* are used where flexibility is allowed or the standard is offering examples or guidance rather than directing specific requirements.
- **Patient**
  - A person registered and/or qualified by a state, municipality or agency and authorized to purchase or receive medical cannabis from an authorized provider.
- **Personal Protective Equipment**
  - Personal Protective Equipment (PPE) is worn to minimize exposure to hazards that cause workplace injuries and illnesses due to processes, environmental conditions, chemicals, radiation, mechanical irritants, airborne contaminants or other risks capable of causing injury or impairment to any part of the body through absorption, inhalation, sound or physical contact. Personal protective equipment may include gloves, safety glasses and shoes, earplugs or muffs, hard hats, respirators, coveralls, kneepads, vests and full body suits.

- **Pesticides**
    - Classified and controlled by the Environmental Protection Agency and state and local agencies, pesticides are defined as:
        - Any substance or mixture of substances intended to prevent, destroy, repel or mitigate any pest, fungus, disease or weed. Fungicides and herbicides are included under the definition of pesticides.
        - Any substance or mixture of substances intended for use as a plant regulator, defoliant or desiccant.
        - Any nitrogen stabilizer or fertilizer additive that is not itself a source of nutrients.
- **Plant Protection Products (PPP)**
    - Non-pesticide agricultural inputs cultivators use to protect and maximize cultivation outputs. PPP may include fertilizers or growth regulators.
- **Plant Regulator**
    - A substance that physiologically accelerates or retards the rate of growth or plant maturation or otherwise alters a plant's behaviors, or affects products derived from the plant. Plant regulators are generally considered Plant Protection Products (PPP).
- **PPE**
    - Personal Protective Equipment (PPE) is worn to minimize exposure to hazards that cause workplace injuries and illnesses due to processes, environmental conditions, chemicals, radiation, mechanical irritants, airborne contaminants or other risks capable of causing injury or impairment to any part of the body through absorption, inhalation, sound or physical contact. Personal protective equipment may include gloves, safety glasses and shoes, earplugs or muffs, hard hats, respirators, coveralls, kneepads, vests and full body suits.
- **PPP**
    - Plant Protection Products – Non-pesticide agricultural inputs cultivators use to protect and maximize cultivation outputs. PPP may include fertilizers or growth regulators.
- **Product Recall Program**
    - A Product Recall Program defines the methods for removing or correcting products that violate laws, present a risk of injury or gross deception, or are otherwise defective. Recalls are voluntary but can be requested by regulatory agencies; mandated recalls are reserved for urgent situations or when a firm is not achieving recall responsibilities. Recalls require the prime manufacturer (may include wholesalers, suppliers, distributors and retailers) to analyze the hazard, notify the supply chain and issue product return procedures. Recall does not include market withdrawal or a stock recovery, which is accomplished through normal stock rotation practices, routine equipment adjustments and repairs, etc. Almost all recalls are conducted on a voluntary basis by the manufacturer.
- **QMS**
    - Quality Management System – Business and operational processes and systems implemented to ensure GAP and GMP; they include organizational structure, policies, procedures, processes, systems, controls and resources needed to ensure quality products and services.
- **Quality Management System**
    - Business and operational processes and systems implemented to ensure GAP and GMP; they include organizational structure, policies, procedures, processes, systems, controls and resources needed to ensure quality products and services.
- **Quarantine**
    - Material or products physically isolated from production, marked and controlled until formally authorized for release.
- **Raw Materials**
    - A substance in its natural, modified or semi-processed state used as an input to a production process for subsequent modification or transformation into a finished good.

- **Rejected**
  - Material, work-in-process or finished goods that do not meet product quality specifications. Rejected material is dispositioned as “rework” or “dispose.”
- **Residue Testing**
  - A validated analytical procedure that detects, identifies and measures the presence of chemical substances, their metabolites or degradation products in or on raw or processed agricultural products.
- **Retail Store**
  - A facility, operation or company licensed to sell cannabis to qualified adults according to state and local laws.
- **Safety Data Sheets (SDS)**
  - A standardized form that contains detailed information about possible health and safety hazards of a product and how to safely use, store, transport, handle and dispose of a product. Under the Federal Hazardous Substances Act, suppliers must provide SDSs for all hazardous material as a condition of sale, and employers must make them available to workers in multiple formats for review.
- **Security Risk Assessment**
  - A Security Risk Assessment reviews all threats (crime) and hazards (natural/man-made events) to assets (staff, public, product, currency, materials and information) and is used to develop the operation’s security program.
- **Strain**
  - Plant varieties (cultivars) selectively bred to produce distinct, desirable traits and effects of Cannabis sativa. The traits and effects include differentiated products or can be cultivation traits such as fast flowering, pest resistance or high yield. There is no standard for cannabis strain naming and cultivators have cultivated and named hundreds of cannabis strains.
- **Traceability**
  - Ability to trace the inputs, history, application or location of an entity by means of recorded identifications.
- **Water Use Plan**
  - A Water Use Plan documents an operation’s plans and procedures for water sourcing, storage, use, discharge and testing. It defines the frequency for water testing and analysis and procedures to ensure tests are conducted as scheduled and incorporates local water regulations.
- **Work-in-Process**
  - Material dispersed from inventory and released into the manufacturing process that has not been fully processed into a finished good.
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## List of Resources

- 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 with Disabilities Act (ADA)
- AOAC International – Appendix K: Guidelines for Dietary Supplements and Botanicals, Part I. AOAC Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals
- Association of Public Health Laboratories (APHL) – Guidance for State Medical Cannabis Testing Programs
- Cannabis Safety Institute – Microbiological Safety Testing of Cannabis
- Code of Federal Regulations – 21 CFR 7.40 – Food and Drugs – Recall Policy
- Code of Federal Regulations – 21 CFR 111 – Food and Drugs – Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements
- Code of Federal Regulations – 21 CFR 117 – Food and Drugs – Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- Code of Federal Regulations – 21 CFR 211 – Food and Drugs – Current Good Manufacturing Practice for Finished Pharmaceuticals
- Code of Federal Regulations – 29 CFR 1910.132 – Labor – Occupational Safety and Health Standards – Personal Protective Equipment
- Domestic Fair Trade Association (DFTA)
- Fair Trade USA
- Food and Agriculture Organization (FAO) – World Health Organization (WHO) – Codex Alimentarius – International Food Standards
- ISO 17025:2005 General Requirements for the Competence of Testing and Calibration Laboratories
- ISO 22000:2005 Food Safety Management Systems -- Requirements for any Organization in the Food Chain
- ISO 22005:2007 Traceability in the Feed and Food Chain -- General Principles and Basic Requirements for System Design and Implementation
- ISO 9000:2015 Quality Management Systems – Fundamentals and Vocabulary
- ISO 9001:2008 Quality Management Systems – Requirements
- The National Institute for Occupational Safety and Health (NIOSH)
- U.S. Composting Council (USCC)
- U.S. Department of Agriculture (USDA) – Food Safety Inspection Service (FSIS) Compliance Guidelines – Allergens and Ingredients of Public Health Concern: Identification Prevention and Control, and Declaration through Labeling
- U.S. Department of Labor (DOL) – Occupational Safety and Health Administration (OSHA)
- U.S. Food & Drug Administration (FDA) – Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA)
- U.S. Food & Drug Administration (FDA) – Pesticide Analytical Manual (PAM)
- U.S. Pharmacopeial Convention (USP) – General Chapter <467> Residual Solvents/Organic Volatile Impurities
- U.S. Pharmacopeial Convention (USP) – General Chapter <561> Articles of Botanical Origin
- U.S. Pharmacopeial Convention (USP) – General Chapter <2750> Manufacturing Practices for Dietary Supplements
- World Health Organization (WHO) – Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants