FOCUS CANNABIS INFUSED PRODUCTS STANDARD

Overview

The FOCUS Standards provide comprehensive cannabis standards for cultivation, extraction, infused products, laboratory, retail, packaging and labeling, security and sustainability.

Scope

This FOCUS Standard provides direction for cannabis infused products operations to meet safety and quality requirements. An operation must integrate the standards as specified to meet FOCUS certification requirements. Management must ensure operations remain compliant with local, state and federal laws and regulations.

Definitions

CANNABIS INFUSED PRODUCT – A topical or ingestible product that contains active cannabis or cannabis concentrate as a regular ingredient incorporated through homogenization or topical application.

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

GOOD MANUFACTURING PRACTICES – 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.

HAZARD ANALYSIS AND CRITICAL CONTROL POINTS (HACCP) PLAN – A detailed, systematic, documented approach that identifies, evaluates and controls safety hazards for each product-related process used by an operation.

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.

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.

MUST VS. SHOULD: This standard is written to direct cannabis operations toward safety and quality certification under the FOCUS Standard; it also informs regulators, legislators and the public on the requirements for safe, quality cannabis procedures. Accordingly, “must” and “shall” are used interchangeably to indicate requirements to the FOCUS Standard; “should” and “could” are used where

flexibility is allowed or the standard is offering examples or guidance rather than directing specific requirements.

QUALITY MANAGEMENT SYSTEM – Business and operational processes and systems implemented to ensure GMP that include organizational structure, policies, procedures, processes, systems, controls and resources needed to ensure quality products and services.

SAFETY DATA SHEET (SDS) – A standard 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.

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.

Resources

- American Association for Laboratory Accreditation – Cannabis Testing Laboratory Accreditation
- American Herbal Pharmacopoeia – Cannabis Inflorescence Standards of Identity, Analysis and Quality Control
- American Herbal Products Association – Recommendations for Regulators – Cannabis Operations
- American National Standards Institute (ANSI)
- Americans for Safe Access – Patient Focused Certification
- Americans with Disabilities Act
- AOAC International – Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals
- Association of Public Health Laboratories – Guidance for State Medical Cannabis Testing Programs
- Cannabis Safety Institute – Microbiological Safety Testing of Cannabis
- FDA Food and Pesticide Analytical Manual (PAM)
- International Standardization Organization (ISO) 17025 - General Requirements for the Competence of Testing and Calibration Laboratories
- ISO 17025 - General Requirements for the Competence of Testing and Calibration Laboratories
- ISO 22000 Food safety management systems – Requirements for any organization in the food chain
- ISO 22005 – Traceability System
- ISO 9000 Quality Management Systems – Fundamentals and vocabulary
- National Institute for Occupational Safety and Health
- Occupational Safety and Health Administration
- USP 561 – Articles of Botanical Origin (United States Pharmacopeial Convention)

- World Health Organization – Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants
- 21 CFR 110/117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food
- 21 CFR 111 Electronic Records with Dietary Supplement GMPs
- 21 CFR 211 Electronic Records with Drug GMPs

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1.0 MANAGEMENT: SUMMARY OF RESPONSIBILITIES

The *Management Summary* section encapsulates core management responsibilities contained in the FOCUS Standards; detailed requirements and specifications for each topic are located in the appropriate sections.

a) MANAGEMENT CAPABILITY: A cannabis-infused products operation must have a defined manager or management team responsible for operating the business according to documented polices and procedures and all applicable laws and regulations. Organization managers must possess the qualifications (training, experience and credentials) required to effectively execute the quality, safety, procedural, workforce and compliance requirements assigned to them. Management shall:

- Provide evidence that all managers have completed management training and instruction in the organization's standard operating procedures and recordkeeping related to GMP including worker/staff management, safety, sanitation, regulatory compliance and maintenance, and other defined topics critical to the organization's efficient and safe operation.
- Implement and maintain robust programs as defined in the FOCUS Standard.
- Engage all stakeholders to contribute to safe, quality products and services.

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

c) SAFE AND HEALTHY WORK ENVIRONMENT: Management shall develop and maintain a safe and healthy work environment for all workers, contractors and visitors. The safety and health program shall be documented and include annual training and periodic assessment for all workers.

d) SECURITY: Management shall rigorously protect the people, products, information, systems and assets associated with business operations from risks and threats. Management shall stay current with evolving security risks, conduct periodic risk assessments and make appropriate improvements to the security program. All workers must receive ongoing training to prepare them for potential threats and emergencies.

e) PROCEDURES AND TRAINING: Management shall ensure that work processes are documented using standard operating procedures and that all workers receive appropriate training and refresher training to perform assigned responsibilities; workers must have full access to current procedures and training materials.

f) REGULATORY COMPLIANCE: Management shall ensure the operation remains compliant with all applicable local, county, state, provincial and federal regulations related to cannabis business operations. Operation must provide appropriate training and retain compliance records for review. Operation must regularly monitor regulatory changes, make appropriate revisions to procedures, and update worker training.

g) ORGANIZATION STRUCTURE: Management shall maintain an organization chart that shows the levels in the organization, defines all positions and responsibilities, and identifies reporting relationships. Job documentation shall

define worker qualifications, training requirements, compensation processes and evaluation methods.

h) SUSTAINABILITY: Management shall ensure business viability and continuity and environmental sustainability. Business requirements include structure, finance, internal controls, compliance, risk management, fair labor practices, community relations and crisis management. Environmental requirements include environmental impact assessments, conservation plans, carbon footprint reduction, water management, energy efficiency and waste reduction.

2.0 TRAINING

a) WORKER TRAINING PROGRAM: Management shall ensure all workers receive adequate training to complete assigned responsibilities safely and effectively prior to beginning the work. Managers shall reinforce comprehension by observing behaviors in the workplace and providing timely feedback. The operation must maintain a documented training program that ensures all workers are trained on the following at a minimum:

- Company policies and procedures
- Industry policies and standards
- Government laws and regulations
- Regulatory inspections
- Security and interaction with law enforcement
- Worker health and safety
- Hazardous materials
- Product safety and quality
- Customers and patients
- Emergency procedures
- Hygiene and food-handling safety
- Product testing
- Cleaning and sanitation procedures
- Required record keeping
- Labeling and packaging
- Violations and enforcement
- Specific job training as required

State-certified cannabis training or apprenticeship certifications may fulfill training requirements for certain training topics.

The training manager shall retain training plans and participation records for two years.

b) FOOD SAFETY TRAINING: Business must provide formal food handling training to managers and all workers involved in the production and handling of products. Training must be certified for food safety (such as ServSafe™ or equivalent) and include workplace hygiene.

- Operation must deliver training specific to each position to promote quality and safety.
- Training shall include documented cleaning and sanitation procedures for workers responsible for those tasks.
- Training materials must be comprehensive and available for review by workers and auditors.
- Training documentation must include instructor name (or source for e-learning), worker name, topic and date completed.

c) HEALTH AND SAFETY TRAINING: All workers must have documented training related to health and safety risks and issues for production processes. Workers must demonstrate processes and methods defined in the training. Training logs must be available for review.

d) QUALITY CONTROL TRAINING: Workers must have periodic and documented training in the operation's quality control procedures. Workers must demonstrate understanding of quality procedures.

e) TRAINING MANAGER: Training manager 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. The training manager must have a working knowledge of the facility processes and procedures.

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

- Training materials must be available to workers.

g) PRODUCT SAFETY AND QUALITY EXPERTISE: Designated product safety and quality manager must have documented training and experience sufficient to adequately oversee the program. Expertise includes documented GMP, ServSafe, HACCP courses and certifications, job history and responsibilities, demonstrated working knowledge, professional references and related credentials or certificates.

h) REGULATORY AND LAW ENFORCEMENT INTERACTION: Business must provide training to management and all workers to prepare them for interaction with government regulatory and law enforcement agencies and personnel.

- Training should include preparation for scheduled and unscheduled regulatory inspections and potential actions that might be taken by law enforcement affecting business operations.
- Training should cover regulatory policies and U.S. federal laws as they apply to employees and the operation of the business.
- Training can be provided internally or contracted to a qualified supplier.
- Training materials must be available for use and review.

3.0 WORKER PRACTICES

The operation will ensure workers adhere to practices that affect product safety and quality. The training manager must ensure these practices are included in required training. Managers shall observe workers to ensure they are demonstrating the practices and take corrective action as required. The operation should require workers to sign worker practices policy.

a) GMP SIGNAGE: Signage supporting Good Manufacturing Practices (GMP), worker safety and hygiene must be posted in all appropriate work areas. Signage must require hand washing, use of personal protective equipment and other hygienic practices. Signs must be presented in languages appropriate for workers, contractors and visitors. Applicable graphic signs also may be used.

b) EMPLOYEE CLEANLINESS: Workers must practice personal cleanliness including outer garments such as smocks; aprons or lab coats; they must be clean and appropriate for the assigned tasks. Nails must be trimmed and clean. 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. If foot dips are required and operational, workers must clean shoes according to procedures (see Foot Dips in *Facility Maintenance* section).

c) HAND SANITATION: All employees must wash hands with sanitizing soap prior to and after all work activities. Disposable protective gloves must be in stock and available; gloves must be discarded when damaged and after using toilets, eating, or contacting a foreign substance.

d) WOUNDS AND INFECTIONS: 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. Workers with observable or reportable infections must be excused from work according to the organization's procedures. Management must evaluate all situations and take corrective action when any communicable disease is observed and document the corrective action taken.

e) PROTECTIVE CLOTHING: Workers who handle open product must wear aprons, gloves, hairnets, beard nets or other protective clothing as outlined in production handling procedures. Beard guards must be worn if beard is long enough to be grasped with fingers (generally longer than 3 mm). Protective clothing must be issued to all affected workers, be clean, not frayed, and in good working order. Shoes must be appropriate for the position; open-sole or open-toed shoes must not be worn in production areas or processing facilities.

f) PROHIBITED ITEMS: A written policy must be in place that prohibits the wearing of false eyelashes, fingernails, magnetic jewelry or other items that can detach during production. Workers can wear jewelry that does not affect job tasks if gloves are worn, or a plain (no jewels) band may be allowed unless worker is

operating machinery or it is prohibited by the site safety policy. Gloves must be used to cover nail polish; other cosmetics may be restricted by procedures.

g) EATING AND DRINKING: Written procedures must prohibit employees from eating, drinking, gum chewing and spitting in product handling areas. Closed containers of clearly marked drinking water kept separate from production materials are acceptable if documented in facility procedures and enforced.

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

4.0 HEALTH AND SAFETY PROGRAM

Management must provide a safe work environment for all workers, contractors and visitors. A comprehensive health and safety program includes physical safety, safely designed work processes, safe tools and equipment, facility and environmental safety, regular safety assessments and ongoing safety training.

a) HEALTH AND SAFETY RISK ASSESSMENT: Operation must complete a risk assessment that examines all risks to worker health and safety throughout the production process.
   - Risk assessment must detail specific risks such as, but not limited to, use of hazardous chemicals, machinery use, dusts, pollen, exposure to toxic materials, flammable materials and fire, electricity, glass breakage, asphyxiation and fall hazards.
   - In conjunction with the security plan, account for worker safety in case of external threat such as robbery or intrusion.
   - Risk assessment must document risk mitigation and injury and illness prevention plans and they must be reviewed annually.
   - If required by state regulations, the operation must retain signed consent forms for workers who apply any chemicals.

b) HEALTH AND SAFETY PROCEDURES AND TRAINING: 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 risk assessment.
   - Injury and Illness Prevention Plan must be documented and implemented.
   - All workers shall participate in health and safety training and ongoing training updates; training completion shall be documented and repeated for all workers annually.
   - Safety training must include OSHA-based electrical safety, slip/trip/fall protection, ergonomics, personal protective equipment and workplace violence.

- 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 or safety program file.
- All necessary safety equipment and guards must be in place, available and operational.
- Operation shall install and maintain portable fire extinguishers as specified by 29 CFR 1910.157. All workers must be trained on fire safety procedures.
- Safety data sheets for all chemicals must be on file and available to workers.

c) PERSONAL PROTECTIVE EQUIPMENT: Workers must wear personal protective equipment (PPE) when required by job, task or work environment. Specifically, PPE is required when handling hazardous materials or cleaning and sanitizing with chemicals.

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

- If respirators are required, written respirator protection usage and training plan must be on file and all workers must undergo a medical exam, be trained and get a fit test for the equipment. Respirators must be serviced and tagged to manufacturer's specifications.
- For reusable PPE equipment, written instructions for cleaning and proper storage must be in place and followed.
- PPE must be stored separately from personal clothing.

d) EYEWASH UNITS: The operation must install an emergency eye wash station in any room where hazardous chemicals are used.
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.

e) SAFETY SIGNAGE: The operation must post signage for all hazardous areas identified in the risk assessment. Information signs must provide clear instructions and general safety information for material handling and equipment operation. Signage must be in languages appropriate for onsite workers, contractors and visitors.

f) ACCIDENT AND EMERGENCY PROCEDURES: The operation must document emergency procedures, train workers and display emergency signage. 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.

- 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.

- 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. Provide copies of safety data sheets to fire department and local OSHA office.
- During operational hours, the facility must have workers onsite that are trained in liquid and chemical spill clean up; appropriate cleanup PPE and supplies must be available.

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

h) HEALTH AND SAFETY MANAGER: The operation must designate a worker to implement and maintain the worker health and safety program, and the worker must have the skills, time allotment and defined job description to perform the requirements of the position.

5.0 PRODUCT QUALITY AND SAFETY

Management must assess the entire operation to ensure all properties, buildings, systems, operations, equipment, work areas and workers are prepared and controlled to produce safe, quality products. Procedures should specify appropriate controls for work areas, worker behaviors, processes and equipment.

a) PRODUCTION SYSTEM: The operation must document product-related processes using flow diagrams, process maps, procedures and checklists etc. to ensure the safe production of safe, quality products that meet product specifications..

- Facility layout must provide physical separation of production processes to ensure product integrity and purity.
- Production flow should separate incoming material, staging, manufacturing, processing, finishing, packaging, inspection and storage functions to the maximum extent practical.

b) PRODUCTION SYSTEM RISK ASSESSMENT: Operation must conduct an initial and annual production risk assessment and monthly to quarterly inspections (defined in QMS) to review all biological, chemical and physical hazards to the production system. The operation will use the assessment results to develop and implement safety and quality control methods for all processes.

Operation uses a Hazard Analysis Critical Control Points (HACCP) plan (used in food production) or similar process to ensure risks for each separate process are identified and mitigated.

Production inspection plan:

- Inspection frequency
- Inspector
- Documented findings
- Corrective actions and due dates

All areas of the facility must be inspected.

HACCP plans and related worker training must be updated when new processes, equipment or other process controls are added or changed.

c) PRODUCT QUALITY MANAGEMENT SYSTEM: Operation must use a quality management system (QMS) with clearly defined product standards.

All workers must have documented training in the QMS and receive refresher training annually or when the operation changes the system to remain familiar with quality control requirements and individual quality responsibilities.

d) PRODUCT CLASSIFICATION – The operation shall classify all materials and products in the production process and control them according to documented procedures:
   - Raw Material – 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.
   - Work-in-Process – Material dispersed from inventory and released into the manufacturing process that has not been fully processed into a finished good.
   - 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.
   - Quarantine – Material or products physically isolated from production, marked and controlled until formally authorized for release.
   - Rejected – Material, work-in-process, or finished goods that do not meet product quality and safety specifications. Rejected material is dispositioned as “rework” or “dispose.”

e) EQUIPMENT MAINTENANCE PLAN: All production equipment must be maintained for safe and efficient operation. All instruments, refrigeration equipment and measurement equipment should be calibrated or tested annually at a minimum. Plan must list the maintenance requirements and dates for all equipment used. Records must show type of maintenance performed, mechanic name and date work was completed.

f) EQUIPMENT CALIBRATION: The operation must calibrate all required equipment and record the results and the corrective actions taken when calibration test exceeds the acceptable range of variation. Documented calibration procedures must define frequency of testing, testing methods, accepted range of variation and corrective actions required. Equipment must meet state calibration requirements and show appropriate stickers or tags.

g) INSPECTION REPORTS: Operation maintains copies of previous product safety and quality-related inspection reports. All documented non-conformances have corresponding corrective action responses (date of response, action taken, and signature). Inspection reports could include local, county or state inspections completed as part of a cannabis-licensing program.

h) PROCESS MONITORING LOGS: Current, accurate logs should record all production process monitoring actions and dates.
   - Records must detail nonconformance and corrective actions taken to return the process within control limits.
   - Records must be retained for the maximum time any of the products are available for sale in the marketplace.
   - The process documents and records are required for trace-back/recall data. Retain for one year unless products are shelf stable for a longer period of time.

i) PRE-OPERATION INSPECTION LOG: Checklists are in place for all areas and process steps. Checklists must be completed before the start of each production run and should include:
   - Examination of equipment to verify cleanliness
   - Cleanliness of storage and production areas
   - Verifying the production line prepared for safe start
   - Ensuring personnel are in position and meet the GMP requirements
   - Corrective actions have been implemented to correct all non-conformances recorded during previous production run or inspection
   - Review of the steps specific to a process or a phase of a process

   Completed checklists should be retained for one year after the production run.

j) DEVIATION LOG: Workers should be encouraged to report any unexpected findings, process failures or other unusual occurrences at any processing steps. Workers must record occurrences in a Deviation Log and report them to Quality Control for analysis and corrective action.

k) DOMESTIC ANIMALS: No animals or pets are permitted in production areas or areas that contain raw material, work-in-process, finished or stored products, production equipment, product containers or packaging. Animals must not be transported in the same vehicle as the operation's finished cannabis products or packaging designated for sale or transfer. Domestic animals are discouraged in all areas of a cannabis facility including office areas; any exceptions should be documented by policy. 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.

6.0 PRODUCT SPECIFICATIONS, PACKAGING AND LABELING

a) PRODUCT SPECIFICATIONS: The operation shall document product specifications for each final product to be sold or transferred. The specification shall specify identity, purity, strength, composition, recipes, and formulations and include:
   - Materials and raw ingredients used
   - Manufacturing processes used to produce products including special processing, additives and sub-processes. Processes identified during the Production System Risk Assessment (see *Production Plan* section) and mapped for HACCP/product control plans can be used throughout the production process to develop control points, processes, procedures, worker aids and training.
   - Unique identifier code for the product (Product code).
   - Intended consumption process, i.e., edible, topical, inhalant, combustible, etc., by the patient/consumer (if known).
   - Expected shelf life, perishability, and special storage requirements.
   - Packaging and labeling specifications including traceability (operation and batch/lot), contents and dosage recommendations if applicable.
   - Potential risks associated with the product and materials used (see Warning Labels below).
   - Intended customers if known (general public, patients, over 21) and use restrictions (allergies, sensitivities or health conditions), etc.

b) BATCH OR LOT RECORDS: Batch record must include the identity of the product, batch or lot number, packaging batch size and pack date. These records must be able to be linked to all prerequisite program records for the facility.

c) PRODUCT BATCH REVIEW: Operation must verify that all product batch or lot numbers meet specifications for identity, purity, strength, and composition, specific recipes, formulations. All reasonable, accepted, scientific methods should be considered, including laboratory testing.

d) BATCH SAMPLING PROCEDURES: Procedures must be in place that detail the sampling of all product batches. Sampling procedures must be specific to each product produced and adequately documented.

e) PRODUCT REJECTION PROCESS: Defined safety and quality criteria must be in place for all products. Workers, quality assurance, and critical control point operators must have documented training in the selection/rejection process. All rejected material must be marked, quarantined and managed according to product procedures. Records of rejected product and product disposition must be retained for two years.

f) PRODUCT MANUFACTURING PROCESSES: Operation must establish specifications for all steps in the manufacturing process where control is required to ensure specifications are met for the identity, purity, strength, composition, formulation or specific recipe of the cannabis-derived product.

Such specifications could include:

- Weight or fill of units
- Weight or fill variation of units
- Hardness or friability of tablets, food products, etc.
- Disintegration time of unit dosages
- Clarity, viscosity, specific gravity, total dissolved solids, or pH of solutions
- Loss on drying, moisture content, or solvent residue
- Time, temperature and pressure
- Microbiological characteristics
- Organoleptic characteristics
- Quality characteristics

(These details may be specified in the HACCP plan for all processes)

g) YIELD CALCULATIONS: Operation must determine and document actual yields at the conclusion of each appropriate control point in the manufacturing process. Yields must be calculated by one person and independently verified by a second person or, if the yield is calculated by automated equipment, one person must verify it.

h) BATCH YIELD RECONCILIATION: Operation must have procedures in place to investigate and document yields that fall outside the established minimum or maximum yield parameters defined in the manufacturing procedures and product specifications. Records of deviations, corrective actions and product disposition must be on file for review.

i) PACKAGING AND LABELING SPECIFICATIONS: Operation must document written procedures on labels and packaging materials including design, inspection, approval, storage, handling and rejection processes.

- Each batch of labels or packages must have traceability information that links it to manufacturer.
- Records must be in place that detail receipt of materials and use.
- Specific label language and packaging requirements vary by locality and state; check local and state laws and keep procedures current and on file.
- Packaging specification must identify appropriate work environment controls (e.g., humidity, airflow, dust, temperature) to protect product during handling and packaging.
- Packaging/labeling training must be provided to the appropriate workers and documented in the training record.

j) LABELING PROTOCOL: The operation's labeling protocol must be documented and should include the following at a minimum and as required by product specification and government regulations:

- Name of the business
- Product name or identity
- Net quantity of contents

- Active ingredients (cannabinoid/terpene profiles)
- Purpose of product
- Directions for use
- Appropriate warnings (see *Warning Labels* below)
- Common allergens
- Instructions for appropriate storage
- Additives
- Solvents used in concentrate production
- Carrier agents used in topicals or concentrates
- Statements or information required by state or local regulations
- Perishable products must display a "Use By" and/or a "Freeze By" date
- Any shelf life or expiration period indicated on the label of an edible product must be supported by appropriate data and an expiration tracking form
- Laboratory that performed the testing (or a lab keycode)
- Date of manufacture using Julian date

Operation must ensure all supplier labeling meets requirements.

Reference 21 CFR 201.60

k) PRODUCT LABELS: Prior to transferring or selling cannabis or cannabis-derived product, the facility must ensure a label is affixed to the package that includes all information required by the labeling protocol and the individual product specifications.

Labels must be consistent with products offered for sale.

Labels and packages must comply with local, state and federal regulations.

l) CANNABIS INFUSED PRODUCT LABELS: Operation should follow FDA Food Labeling Guide to maximum extent possible for all cannabis infused products using a "facts box" for consumable products that includes:

- Name of food
- Net quantity or weight of contents
- Ingredients list
- Cannabis ingredients
- Cannabinoid and/or terpenoid content
- Food allergen information
- Nutrition labeling
- Total calories and fat calories
- Total fat, saturated fat, and trans fat
- Cholesterol
- Sodium
- Total carbohydrates
- Dietary fiber
- Sugars
- Protein

- Vitamin A, vitamin C, calcium, and iron
- Food Claims: nutrient content, health, qualified health and structure/function claims must comply with FDA Food Labeling Guide.
- List daily values for children under 4, infants, pregnant and lactating women if applicable.

Edible cannabis infused products must display warning labeling on the outside of the packaging including:

"WARNING: MEDICINAL/ADULT USE PRODUCT – KEEP OUT OF REACH OF CHILDREN" in bold capital letters, in a font size larger than the font size of the other printing on the label.

m) WARNING LABELS: All products and packaging must display the warnings appropriate for the product as defined in the product specification and by applicable government regulations.

Warning labels should include the following as required:

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

n) EXIT PACKAGING: The operation must ensure that an accurate, complete label is affixed to every exit package before sale. An exit package is the packaging that encloses the final product sold or dispensed. The exit package labeling must include:

- License number of the cannabis seller
- Name of the business that sold the product to the consumer or patient

- Name or identity of the product
- Date of manufacture
- Applicable product warning labeling as specified in *Warning Labels* and the product specification

o) CHILD RESISTANT PACKAGING: Operation must ensure every exit package containing cannabis or cannabinoid product is child resistant as defined by the Poison Prevention Packaging Act and 16 CFR 1700.

Packaging must be significantly difficult for children under 5 years of age to open or to obtain a toxic or harmful amount of the substance within a reasonable time; at the same time, it should also not be difficult for normal adults to reasonably access or use the product properly.

For elderly or disabled persons unable to open special packaging, manufacturers may package substances in noncomplying packaging if:

- Complying packaging is also supplied, and;
- Noncomplying packages are conspicuously labeled to indicate they should not be used in households where children are present.

p) TAMPER EVIDENT PACKAGING: Manufacturer or operation that packages an active cannabis product for retail sale shall package the product in a tamper-evident package if the product is accessible to customers prior to a sales transaction.

A tamper-evident package has one or more indicators or barriers to entry that, if breached or missing, provide visible evidence of tampering to consumers. Reference 21 CFR 211.132

7.0 HACCP PLAN – PROCESS FLOW

The infused products operation must develop, implement and maintain a comprehensive Hazard Analysis and Critical Control Points (HACCP) plan to ensure product safety and quality. HACCP plans require the engagement of the entire workforce and may involve key suppliers and contractors. To develop the plan, the operation creates detailed process flows, assesses all product quality and safety risks, and defines specific control points to diligently and continuously monitor production.

a) HAZARD ANALYSIS AND CRITICAL CONTROL POINTS PLAN: Operation must develop and maintain an ongoing HACCP program. The facility should designate a team of representatives from all functions such as quality control, equipment maintenance, packaging, sanitation, customer service, inventory control, etc.

The facility must designate a team member as coordinator who will oversee program and implement improvements.

If the facility has less than 20 people, one person can collect and implement changes or updates to the HACCP program.

b) HACCP TRAINING: Facility HACCP coordinator, managers and other key workers should be trained in the process in a course accredited by the International HACCP Alliance or similar body.
   - Key workers should complete a minimum of 16 hours of formal training.
   - Designated CCP operators should be specially trained.
   - All other facility employees should receive basic overview on HACCP and the facility's program.

c) PRODUCT SPECIFICATIONS: A product specification provides details and specifications for all aspects of a product and its production and generally includes:
   - Materials and raw ingredients used
   - Manufacturing processes used
   - Shelf life, perishability, and storage
   - Packaging and labeling
   - Potential product risks

   The *Product Specifications, Packaging and Labeling* section provides complete requirements and details for product specifications.

d) PRODUCTION FLOW CHART: Operation must have a process map or flow chart that illustrates each step of the production process. The map must be adequately detailed and include all steps in the process. Each step should show holding times, temperature controls or regimes, special coding, thresholds, and rejection standards and processes.

e) HAZARD ANALYSIS REPORT: Operation must conduct and document a detailed hazard analysis for all process flows. Assess all steps in the process to determine if any potential product safety hazards exist. Identified hazards should include any specific biological, chemical and physical risks. Record the controls for each hazard on a hazard analysis chart. Hazard analysis should indicate if an adequate control step for the potential risk exists later in the process.

f) IDENTIFYING ALL CCPS: Critical Control Points should be developed to control all hazards identified in the hazard analysis. CCPs must provide adequate detail and defined parameters to eliminate or reduce the risk to acceptable “safe” levels. HACCP team should ensure no CCPs were omitted from the control process.

g) CCP CONTROL SPECIFICATIONS: Detailed monitoring requirements and the frequency of inspection must be set and documented for all Critical Control Points.
   - Requirements should include the critical control limits (CCLs) – the maximum and/or minimum parameters of the CCP.
   - All CCPs must have support documentation on how CCLs are scientifically derived and meet relevant legal requirements.

- Procedures must be implemented for each CCP monitoring process and CCP operators must be trained on the procedures.

h) NONCONFORMANCE PROCESS: All nonconformances must be reported to the HACCP coordinator immediately.
   - Worker will document all CCL deviations in a corrective action plan that will detail corrective actions taken to return the process within control limits.
   - Worker will record the disposition of potentially affected product and process modifications taken in the corrective action plan.
   - HACCP coordinator will review the corrective action and take additional actions as required.

i) ASSIGNMENT OF CCP RESPONSIBILITIES: The facility must assign specific responsibilities to monitor, record and manage corrective actions of each CCP. Responsibilities should be clearly indicated on a HACCP CCP responsibilities chart.

j) MANAGER CCP VERIFICATION: A HACCP-trained manager must verify the CCP monitoring records are current, accurate and include any corrective action reports.
   - HACCP team develops a schedule and assigns a verification manager to each CCP.
   - Verification manager should verify all CCPs a minimum of every 30 days, more frequently as required.
   - Documentation should show designated managers are conducting CCP verifications as specified.

k) HACCP FORMS READINESS: Operation must design and publish monitoring records to record the CCP data. CCP records should match CCPs defined in the HACCP Plan. Required documents include HACCP CCP Responsibilities Chart, Corrective Action Logs and Corrective Action Reports. All documents should list a revision date.

l) CCP OPERATOR OBSERVATION: CCP operators should be aware of basic HACCP principles, the CCPs in their areas of responsibility, and for taking appropriate action should they exceed critical control limits.

m) CCP CONFORMANCE TO PROCESS: Records and observation indicate CCP monitoring actions and frequency of monitoring conform to the plan. Critical control limits should match those mentioned on the HACCP plan, and a worker should be assigned to each CCP. Corrective action log and reports should indicate product and process actions taken.

n) CCP SIGN OFF: The CCP operator must sign off on each CCP checkpoint (signatures, initials and electronic signatures acceptable).

o) CORRECTIVE ACTION PLANS: All CCP failures must be documented in the records required in the HACCP plan. Failures must provide detailed description of the

situation (date, time, issue, people involved), corrective actions implemented and preventative actions taken. Records must identify specific effects to the product, how the product was dispositioned, and how the operator returned the process to conformance with critical control limits.

p) DAILY VERIFICATION: CCP records should be reviewed and signed off daily by the quality control supervisor or manager. Confirm with supervisor that all aspects of the monitored activities were actually checked and approved. Workers should notify the HACCP coordinator of any nonconformance immediately. Auditor should note if any other HACCP verification occurs on a daily/regular basis.

q) HACCP PLAN CHANGES: When changes are made to the production process (equipment, ingredients, actions), the team must review the HACCP and recommend updates to the HACCP coordinator; the coordinator will update the plan according to procedure.

   Evidence of plan changes, review of hazard analysis, CCP decisions and CCP records must be on file. If new training is required, training records must be on file. All revisions to the HACCP plan should be dated. If required by local municipality, updates must include an approval from the municipality.

r) HACCP SELF-ASSESSMENTS: Operation must conduct a self-assessment of the HACCP program annually at a minimum. Self-assessments must validate the process flow, hazard analysis and HACCP chart. The operation must document changes to the program, train all workers and implement CCP changes.

s) CCP RECORDS MANAGEMENT: HACCP coordinator or designee serves as the records manager for the HACCP process. This includes managing the master documents and templates, maintaining accurate and current tracking documents, ensuring the latest document revisions are in circulation, and serving as a master archivist for CCP records.
   - All HACCP records should be stored in a secure area limited to authorized personnel. Computer-based records should be protected by segregation and passwords.
   - HACCP records must be backed up weekly and stored in a remote, secure location.
   - HACCP records must be accessible and well organized. Binders, paper file system, or electronic system is acceptable.

t) CCP RECORDS RETENTION: All HACCP CCP records should be retained in a secure location for a minimum of one year regardless of the production item's shelf life.
   - Operation complies with local, state and provincial records retention requirements.
   - Records involved in an open legal or regulatory action shall not be destroyed or altered.

8.0 FOREIGN MATERIALS CONTROL

a) CONTROL OF FOREIGN MATERIALS: Operation must assess production processes for risk of contamination by foreign materials and implement appropriate foreign material controls, which may include metal detectors; traps; visual inspection; sieves; filters; and magnets, designed to prevent, collect or detect foreign materials in raw material, work-in-process and finished products.
   - Foreign materials posing a hazard to product safety may include, but not be limited to: metal shavings or parts from equipment, glass shards from glassware or lighting, wood splinters and staples.
   - Foreign material control systems should be tested to ensure proper operation; document all tests and calibrations and maintain records of control system performance and corrective actions or improvements.
   - Operation must record the discovery of foreign material in production records accompanied by corrective actions.

b) GLASS AND BRITTLE PLASTIC POLICY: Operation must have written procedures in place for the handling of glass and hard plastics. The policy must detail a plan that covers actions taken in case of breakage or if glass or brittle plastic is detected in the production or storage areas of the facility.

c) FOOD GRADE LUBRICANTS: If used in production, food grade lubricants must be stored in a labeled storage area separate from all other non-food grade materials. All food grade materials must have safety data sheets available for review.

9.0 ALLERGENS

a) USE OF ALLERGENS: Operation must have a complete list of all potential allergens and sensitizing chemicals on file (major allergens recognized by the USDA and Codex include proteins from peanuts, tree nuts, dairy, egg, soy, milk and wheat). List should define where/how the allergen is used in the production process.

b) ALLERGEN MANAGEMENT PROCEDURES: Written procedures must be in place that detail how all allergens are purchased, stored, handled and added to products. These must ensure raw materials or work-in-process are not cross-contaminated with allergens.

c) ALLERGEN STORAGE CONTROLS: Allergen materials and allergen-containing materials must be stored using methods that avoid cross-contaminating all other materials. Allergens must be clearly labeled (rotation and lot coding) and should be identified as allergens.

d) PRODUCT LABELING WITH ALLERGENS: All allergen-containing products must be labeled as such as detailed in the FDA Food Allergen Labeling and Protection Act of 2004.

e) ALLERGEN SELF-INSPECTION: An allergen verification program must be in place and documented as part of the written procedures on allergen management.

10.0 OPERATIONAL PROCEDURES

a) PRODUCT INTEGRITY: Operation must record safety and quality risks in the operational plan in addition to CCPs noted in HACCP plan. The operation should monitor factors such as time, temperature and humidity to ensure that mechanical breakdown, delays, temperature deviations, and other factors do not contribute to the degradation or contamination of product.

b) PROCESSING AREA CONTROL: The operation must maintain adequate lighting, ventilation, temperature and humidity controls in all processing areas. Humidity and temperature should be periodically checked and logged in areas where temperature-sensitive products or raw cannabis is processed. Air scrubbers must be used to filter air vented to the outside; facility pest management plan must extend to product storage areas.

c) ROOM STABILIZATION: Processing and storage areas must be decontaminated, cleaned and sanitized for product production and handling before use. Areas must be equipped with cleanable surfaces, protective materials and food grade equipment when required.

d) ADEQUATE WORK SPACE: Adequate workspace is available for all activities and processes. Process flow is designed to eliminate or reduce the risk of product contact with potential contaminants.

e) PRODUCTION LIGHTING: Adequate lighting must be in place in all areas where the product is manufactured, examined, packaged or stored.

f) CLEANABILITY OF FACILITY: 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.

g) SEPARATION OF FUNCTIONS: Facility layout provides physical separation of production processes to ensure product integrity and purity. Production flow is designed to separate incoming material, staging, manufacturing, processing, finishing, packaging, inspection and storage functions to the maximum extent practical. Operation has detailed production process flow diagrams and descriptions of all corresponding documentation (maps, procedures, checklists).

h) CROSS CONTAMINATION PREVENTION: All process steps should be designed and organized to prevent contamination of products.

- Gloves should be used and discarded between each product handling.
- Areas should be clean, neat and free from debris.
- Tools should be cleaned between operations and daily at a minimum.

i) SEGREGATION OF RAW INGREDIENTS: Facility layout must ensure there is clear physical separation of all raw ingredients and materials from work-in-progress and finished products.

j) RAW MATERIAL CERTIFICATION: Operation must have certifications, letters of guarantee or similar documentation for all raw materials, ingredients, cannabis extracts etc. used in the process.

k) RAW MATERIAL INSPECTION: Written procedure for inspection of all raw materials and packaging should be in place. All raw materials must be entered into the inventory list when received. Incoming inspection logs and raw material inventory report should be on file for review.

l) PRODUCT HANDLING: Operation must have a written receiving handling protocol specific to cannabis products and keep records of the following:

- Identity and item code of the item received
- Supplier originating the shipment
- Original source: cultivation, processing or production operation (traceability coding included)
- Supplier's batch, lot, or control number
- Date of receipt
- Delivery method

m) PRODUCT CONTAINER MANAGEMENT: Documented cleaning and sanitizing of all product-holding containers is required.

- Approved food-grade containers and liners must be used. Retain documentation of food-grade certification for all containers, liners etc. on file.
- Single-use containers for microbiologically sensitive products are prohibited from reuse.
- Containers must be the proper size for the task.

n) QUARANTINED PRODUCTS AND MATERIALS: All products or materials that are suspended or removed from the production process for any reason must be placed in a controlled storage area, physically separated from other products and materials, and be marked adequately with signage or coding system to ensure segregation of product.

- Logs of quarantined product or raw materials must identify the reason for the quarantine, the person responsible for disposition, the quarantine date and required resolution date.
- An authorized quality control worker must conduct a material review of each quarantined product batch/lot, provide documented disposition instructions and ensure the products or materials are dispositioned accordingly.
- Quarantined material can be released to work-in-process or finished goods, or be rejected. If rejected, documentation must direct the product or material to rework or destruction with applicable instructions based on the situation.

- For products or material rejected at incoming inspection, findings and corrective actions must be documented and retained for two years.

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

p) HAZARDOUS MATERIALS: All hazardous materials and cleaning supplies must be identified, marked, segregated, controlled and stored according to written procedures, government regulations and product labeling. Separate, lockable storage must be in place for all hazardous substances. Accurate inventory of storage contents must be documented and maintained. Storage areas must display required warning signage in appropriate languages.

- 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.
- If food-grade chemicals, including lubricants, greases, etc., are used in product/packing contact areas, chemicals must be handled according to procedures and segregated from non-food grade items at all times to eliminate misuse.
- Non-food-grade chemicals must be clearly marked and segregated from product production areas.
- The operation must train workers that handle chemicals in liquid and chemical spill clean up as defined by manufacturer's label and the safety data sheet, and as appropriate for the materials and risks. Cleanup equipment and materials must be available; waste must be disposed of according to Waste Management Plan procedures.
- 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

11.0 PRODUCTION EQUIPMENT

a) PRODUCTION EQUIPMENT: All equipment, vessels, wares, utensils and tools used to produce, process or package concentrate products must be maintained in a clean and sanitary condition according to the facility's HACCP and maintenance plans to prevent contamination of the product or any components used in production. Equipment should be constructed of materials designed for the intended purpose, preclude contamination of products and promote sanitation. The following types of equipment and materials are not recommended::

- Corrosive metals (iron, etc.)

- Glass
- Brittle plastic
- Porous materials
- Materials that are difficult to clean or may harbor filth

b) EQUIPMENT MAINTENANCE PLAN: Business must have a documented plan for the upkeep of all equipment used in the production process.
   - Plan must adequately address the maintenance requirements and dates for all equipment used.
   - Records must show the type of maintenance performed; mechanic name and date work was completed.

c) EQUIPMENT FINISH: Processing and packing equipment, and supporting equipment must be free of flaking paint, corrosion, oil, grease and other unhygienic materials.

   Supporting equipment includes racks, tables, bins, pipes, tubing, backsplashes, sinks and exterior housings that may contact product.

d) EQUIPMENT SURFACES: Equipment should be made of materials that can be easily cleaned: non-porous, smooth surfaces, tight weld seams, non-toxic materials and no wood surfaces.
   - Surfaces must be maintained in an acceptable condition for food handling.
   - Equipment should be designed with no unreachable areas to allow access for cleaning and maintenance.

e) TEMPERATURE MONITORING: Thermometers should be separate from the equipment's built-in thermostat system and probes to ensure monitoring if the system goes down and/or the probes malfunction or lose calibration.

f) PRODUCT CONTACT SURFACES: All equipment surfaces that make contact with product must be kept clean at all times and sanitized to avoid contaminating products or production materials. Inspect for oil, grease, food residue, stains and other non-hygienic substances. Includes supporting equipment.

   Dried cannabis must be produced, packaged, labeled and stored using equipment that is designed, constructed, maintained, operated and arranged in a manner that:
   - Permits the effective cleaning of its surfaces
   - Permits it to function in accordance with its intended use
   - Prevents it from contaminating the dried cannabis
   - Precludes it from adding an extraneous substance to the dried cannabis

g) PRODUCT NON-CONTACT SURFACES: All product non-contact equipment surfaces should be kept clean at all times to prevent potential contamination. This includes any surface in work areas where product is present and any supporting equipment in the work area.

h) PRODUCT CONTAINERS: Buckets, bins, trays, tubs, racks, sinks, etc. used to store product or ingredients must be food grade and kept clean at all times. These items should be stored in manner that keeps them clean and uncontaminated e.g. covered, stowed or segregated.

i) COOLING COILS: All coils in coolers and freezers should be clean with no build-up of dust, mold or other airborne contaminants. Cleaning procedures should define cleaning schedule for all cooling or freezing units and associated equipment and be included in the Master Cleaning Schedule.

j) CLEAN UTENSILS AND WARES: All utensils, wares and other items regularly used in production must be cleaned (heat and chemical sanitation) according to HACCP plan specifications. When not in use, utensils and wares must be stored in dedicated areas to prevent contamination. If allergens are used in production, use segregated, color-coded equipment for allergen management.

k) MAINTENANCE TOOLS: Tools that are used for repairing or adjusting equipment in the production and storage areas should be clean, free of corrosion and in good working order.

l) SANITATION EQUIPMENT SEGREGATION: Sanitation equipment storage must be segregated from food and packaging materials to prevent contamination of raw materials, work-in-progress and finished goods. Equipment is stored separately from personal clothing and is cleaned and/or replaced periodically.

m) EXHAUST FANS AND VENTILATORS: All fan guards (cooling units and general ventilation) are clean and free of dust, grease or other collected contaminates. There should be no build-up of dust or other materials on the fan guards or dirt collected on the walls or ceilings around the fans or ventilators. Ventilation system should be checked for contamination and cleaned as required. Fan guards are removed and fan blades are cleaned periodically.

n) EQUIPMENT INSTRUCTIONS: Manuals, technical sheets and safety instructions should be on file for all listed equipment for review and training.

12.0 WATER USE AND QUALITY

a) WATER USE PLAN: Operation must document a plan for water sourcing, storage, discharge, and testing; it must conduct a water quality assessment and incorporate local water regulations.

b) WATER USE RISK ASSESSMENT: Risk assessment should document water sources, pollution and alternate sources and include:

- Pollution from chemicals, lubricants and solvents
- Inflow, outflow, flood risk
- Risk of untreated water contamination
- Alternate water sources
- Potential environmental damage or pollution from water sourcing or discharge.

Risk assessment must be completed at start up and every five years at a minimum or when any material change (substantive enough to require changes to standard operating procedures) is made to the water use plan.

c) WATER QUALITY ANALYSIS: Operation conducts water analysis at the frequency defined in the water use plan and retains records (recommend annually, more if required by conditions). Tests include results for biological, physical and chemical contamination. Operation uses laboratory performing water analyses certified to ISO 17025 level or equivalent standard.

13.0 PRODUCT AND RAW MATERIAL TESTING

a) PRODUCT TESTING PLAN: The operation must ensure all products sold or transferred are free from contaminants and adulterants, and must meet tolerances for substances specified in the product specification.

Operation must develop a testing plan that addresses all risks to products throughout the production process. All final products must be tested and test results must be provided with all final products.

If the operation processes raw cannabis received from another licensed supplier, or uses cannabis concentrate from another licensed supplier, the operation may use product test results provided by the supplier.

The operation must review the test lab report to confirm:

- Testing laboratory certified by state or federal authorities was used
- Test report contains a lot/batch number matching the lot/batch of product tested
- Report is complete: date; methodology performed and method reference; lab technician(s) signature or code; complete data provided; equipment protocol data provided (equipment and methods)

If the operation doubts the authenticity of the lab test report, the operation should retest the product.

All test standards are subject to local, state and federal laws and regulations;

b) SAMPLING PROCEDURES: Operation must apply a documented procedure for collection of sample product material for laboratory analysis.

- Procedures must adhere to the designated testing facility criteria and established industry standards.
- The sampling log must define the lot or batch size, harvest date, lot received date, container type, etc., how samples are obtained and who will perform the sampling.
- Operation must demonstrate that samples were sufficiently homogenous and are representative of the product sold.
- Samples must be retrieved, stored and transported in original, clean packaging that is clearly marked and packaged in a way that preserves the

composition of the sample. Samples must be sealed with tamper-evident tape and not be broken except by the authorized person.

- Testing must be done on all batches.
- Records of sampling, laboratory data and chain-of-custody documents must be kept on file for review for three years from test date.

c) TEST LABORATORY STANDARDS: Operation must use a testing laboratory that meets ISO 17025 or equivalent, the FOCUS Laboratory Standard or an equivalent or relevant state cannabis test lab standard; if such a lab is not available, operation must maintain documentation that validates the laboratory methods that were used for product testing.

- Operation must retain valid certification documents for all testing labs used.

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

e) MICROBIOLOGICAL TESTING: All products must be tested for aerobic plate count. All product test results must show less than one Colony Forming Unit (CFU) per gram of tested material for E. coli, and Salmonella species. Products must be tested for the presence of yeast and molds. Test reports must include method reference and results.

f) RESIDUAL SOLVENTS AND CHEMICALS: Cannabis concentrate products must be tested for the following solvents to the maximum extent practical. Test results must meet local, state and federal regulations and limits – if specifications are not available or applicable, the following limits apply:

- Acetone < 1 ppm
- Benzene < 0 ppm
- Butanes/ Heptanes/ < 50ppm
- Hexane < 10 ppm
- Polyacrylonitrile (PAN) < 1 ppm
- Polycyclic Aromatic Hydrocarbons (PAHs) < 1 ppm
- Toluene < 1 ppm
- Total Xylenes < 1ppm
- Solvent-extracted products made with Class 3 or other solvents must not exceed 0.5% residual solvent by weight or 50 parts per million (ppm) per one gram of solvent-based product. Test reports must provide specific data for all listed and detected solvents.
- Test reports must provide specific data for all listed and detected solvents.
- The product must test at or below 50ppm total.
- Testing must be done on all batches.

- Tolerance levels may be revised based on accepted technical publications.
- Additional substances may be added to the required list as necessary to protect the quality and safety of products.
- If local laboratories cannot provide the level of testing specified, labs should test for solvents to the maximum extent of their technical capabilities. The test report should list the solvents that were not or could not be tested.
- If the test equipment's Limit of Detection (lowest possible detection limit) is above the specified limit for a solvent, the equipment's LOD amount will be considered sufficient to exceed safe contamination limits.
- All test results must reference the corresponding batch of final product.
- Supplier-provided test results from a certified laboratory are acceptable for concentrate provided by a licensed supplier; test results must match batch/lot and date produced.

g) METALS: Heavy metals testing must include but is not limited to lead, arsenic, cadmium, and mercury. Test results must meet local, state and federal regulations and limits – if these are not available or applicable, the following applies:

- Lead- max limit < 6 ppm
- Arsenic- max limit < 10 ppm
- Cadmium- max limit < 4.1 ppm
- Mercury- max limit < 2.0 ppm

Licensed/registered suppliers can provide documented test results with raw material, or tests can be performed for the operation by a certified lab. If raw cannabis or concentrate used to make the infused product was tested for metals and supplier-provided test results indicate the batch/lot is within established limits, then the raw cannabis or concentrate should not require additional testing for metals. Prior testing must be verified for all products.

All test results, including results for the raw cannabis or concentrate, must reference the corresponding batch of final product.

h) PESTICIDE RESIDUE: The operation must test all product batches for any pesticides used in the cultivation process; results for residue must be within limits specified in federal, state and local regulations – where not specified, 0.1 ppm or a positive result at the Limit of Detection (equipment's lowest possible detection amount) will be considered to exceed safe residue limits.

Pesticide residue testing must analyze samples for the presence of chlorinated hydrocarbons, organophosphates, carbamates and pyrethroids, neonicotinoids, acaracides, fungicides and bactericides to the maximum extent practical.

- The operation's test plan, including tests for pesticides not used in the cultivation process, must meet all local, state and federal regulations.

- If local laboratories cannot provide the level of testing specified, labs should test for pesticides to the maximum extent of their technical capabilities.
- Test results must reference the product batch number and must be retained for three years.
- Supplier-provided test results from a certified laboratory are acceptable for concentrate provided by a licensed supplier; test results must match batch/lot and date produced.

i) POTENCY TESTING/CANNABINOID PROFILE: Testing should include comprehensive profiles that detail levels of THC, THC-A, CBD, CBD-A, CBN and terpenoid profile as applicable to the product specification.
   - Test results must be retained for all raw cannabis and cannabis-derived products for three years.
   - Documented results can be from supplier analysis or tests performed for the operation by a certified lab.

j) FILTH AND CONTAMINANTS: The specification must establish and document thresholds for physical contaminants as part of the inspection process.
   - Inspection records must indicate a continual process of physical inspection has taken place for all batches.
   - Records can include supplier certificates of analysis (COA) and specifications in addition to specs/COA and test reports at the production site.

k) STABILITY TESTING: Operation must complete stability/shelf life testing and or assessment on products that have an established "use by" date or have a possibility of substantial breakdown of quality and/or safety over time. Test results and analysis must be on file for review.

l) TEST TRACKING: All product batch/lots must have a unique code or number to facilitate traceability in and out of the facility and for the purposes of linking the proper product testing results to the product.

m) QUARANTINED PRODUCT SEGREGATION: All products with pending tests must be segregated in labeled containers, marked “quarantined” and held in a secure location until test results are received. Only an authorized worker can release quarantined product and the release must be documented.

n) TEST RESULTS ANALYSIS: The operation shall designate a qualified staff member to review each test result against the product specification, and if the product meets all specifications and other requirements, the qualified staff member releases the batch of product to the next step in the process.
   - The product specification identifies all safety and quality requirements (See *Product Specifications, Packaging and Labeling* section) including quality and strain standards that must be met before product is released for sale or consumption.

- Testing should include comprehensive profiles that detail levels of THC, THC-A, CBD, CBD-A, CBN and terpenoid profile as applicable to the product specification.
- Products that do not meet specifications are labeled and segregated and processed as rejected material.
- The operation shall document and retain all test results and certificates of analysis for three years.

o) REJECTED PRODUCT: Operation must establish procedures to control all products that do not meet established quality, strain or safety standards. Rejected product can be either reworked or disposed.

- Rejected product must be labeled and quarantined in a secure location until released for rework or disposal.
- Reworked product must be tracked and retested when required.
- Disposed product must be rendered unusable and must be included in harvest/inventory records.
- All rejected, quarantined product should be dispositioned within 30 days.

p) BATCH MONITORING: A sample of product from each production batch must be collected and stored appropriately per label instructions. An organized storage area and reference system should be in place for all samples.

q) RETAINED SAMPLES: If required by the operation's test plan, the operation shall collect and store a control sample of product from each production batch. An organized storage area and reference system should be in place for all samples.

- All product samples must be kept in storage for a period of one year past expiration date or related quality control date in case of product recall.
- Any sample involved in a pending claim or legal dispute shall not be destroyed.

r) TEST RECORDS: Test logs will list the batch/lot/plant/product test date. The operation will maintain all test logs and test results (lab reports) for a minimum of three years from the date test was performed, including test results received from qualified suppliers.

14.0 PRODUCT TRACEABILITY, RECALL AND WITHDRAWAL

a) TRACEABILITY SYSTEM: The operation must have a documented identification and traceability system that allows product to be traced back to the production site and traced forward to the customer distribution point. The operation must be able to link harvested product by batch number or harvest date to the production records. Operation must document supplier inputs and materials used in product batches to the maximum extent feasible.

Reference ISO 22005 – Traceability System

b) RECALL PROCEDURE: Operation must have a written Product Recall Program that includes a recall coordinator, a 24 hour recall team contact list, a description of

categories (e.g., FDA class 1, class II, class III), and regulatory contacts and procedures to notify FOCUS Standards representatives and regulatory agencies.

In addition, the system must include an action plan that:

- Enables the operation to contact all dispensaries, retail stores and/or customers who have, or likely have obtained the product from the operation.
- Communicates the procedure for return of the recalled product.
- Provides a mechanism to contact the cultivation center or processors that produced the cannabis or cannabis concentrate.
- Provides channels of communication with state and local authorities, including the department of public health, within 24 hours.
- Defines a communication plan as necessary and appropriate.
- Requires the operation to document all recall incidents and outcomes.
- Requires operation to investigate root cause and scope of product problem, complete corrective or preventative actions, and improve recall procedures.

c) RECALL MOCK TEST: A documented "mock recall" must be conducted and documented within the first year of operation and every two years thereafter. These test recalls should include all steps noted in the product recall plan. All associated sales information, shipping details, etc. should be available for review.

Results must be analyzed and corrective action must be taken and documented.

Test process should include worker training on recall procedures, when to initiate a recall notification and resources needed.

d) COMPLAINTS PROCEDURE: Operation must follow a documented complaints procedure to ensure all complaints are recorded, evaluated and followed up.

- Procedure must include a defined timeline for response to complaints, persons responsible for complaint procedures and actions taken.
- Procedure must indicate methods for resolution of complaints, including corrective action required in the production process.
- Complaints files should validate that the complaints procedure is operational and effective.
- Operation shall retain complaint records for two years; do not destroy complaints records related to open litigation or active product recall.

15.0 PRODUCT STORAGE

a) PRODUCT STORAGE: Cannabis and cannabis-derived products must be stored in a controlled environment to preserve product identity, strength, purity and quality. The operation must implement written procedures to control storage areas, and provide specific storage procedures for raw (cured) cannabis, concentrates and cannabis-infused products. Product storage areas in the facility must be limited to raw cannabis, components of cannabis products, final cannabis products, packaging and labeling related to cannabis products. Procedures must require inventory tracking for all products added or removed.

b) STORAGE AREA ACCESS CONTROL: All areas where raw cannabis or cannabis-derived-products are stored must be locked and secure with access restricted to authorized personnel. Signage must indicate “Authorized Personnel Only." Operation should use a sign in/sign out log or automatic RF tracking system; maintain access logs for two years.

c) QUARANTINED MATERIAL SEGREGATION: An area must be set aside for quarantined material and products. The area must be marked with clear signage and access marked or limited by physical barriers. Quarantined containers must bear distinguishing labels (non-standard color, extra-large bold letters, etc.). Containers must be sealed with tamper-evident seals or packaging that records the worker who sealed the container and the seal date. All quarantined material should be dispositioned within 30 days (unless justified in writing) and recorded in the inventory system.

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

e) ENVIRONMENTAL CONTROLS: Operation must install environmental controls as required to protect product including humidity, temperature and air pressure. Operation must set parameters and document environmental factors and direct any deviations to the quality control manager for analysis and correction.
   - Adequate ventilation, air filters and scrubbers should be installed as appropriate to control air quality and odors.
   - Records of environmental monitoring are retained for two years.

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

g) PEST CONTROL: Integrated pest management plan (IPM) must include requirements for pest control in storage areas; active pest control measures (traps, pest service, etc.) are in evidence in storage areas; IPM records include storage area service logs.

16.0 RECEIVING AND TRANSPORT

a) PRODUCT TRANSFERS: If allowed by state and local laws and regulations, a licensed operation may transfer (sell/purchase) usable cannabis or cannabis plants to another licensed cannabis operation.
   - Both operations must document the transaction using a transfer manifest.

- Material must be tested and analyzed for safety and quality prior to use per testing procedures.
- Receiving agent must enter all product transfers into the inventory control system.
- Operation must retain records of all product transfers for two years.

Cannabis transfers must have this information documented, as applicable:

- Name and address of seller and buyer
- Transfer manifest authorizing the transfer
- Unique product code or SKU
- Weight in metric units (all usable cannabis)
- Number of immature plants received
- Date of manufacture or processing
- Amount of finished products received including, as applicable, the weight in metric units, or the number of units
- Strain identification; traceability; certificates of strain analysis or similar documentation
- Product test data from a certified laboratory
- Certificate of Analysis – product specifications
- Harvest specifications including chemicals added during cultivation
- Transferring agent's registration card and expiration date, the date the cannabis/plants were received
- Transfer and transportation subject to all requirements in Transport Security

b) INCOMING VEHICLE INSPECTION: Operation must inspect all incoming product transport vehicles and maintain logs that record the inspection. Log should note cleanliness, load security, temperature, and other appropriate details.

c) INCOMING GOODS INSPECTION: Facility 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):
   - Correct item
   - Correct quantity and/or weight (use calibrated scale)
   - Meets quality specifications
   - Decay or degradation
   - Foreign materials contamination
   - Odor
   - Physical damage
   - Packaging or mislabeling
   - Product safety
   - Security issues

   Document all nonconformances and complete corrective action.

d) CONTRACT CARRIER: 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 safety, quality and security of the final product.

e) OUTGOING VEHICLE INSPECTION: Facility must use a transport checklist to inspect all outgoing transport vehicles and maintain a log that records the inspection.
   - Inspection should include product security, vehicle cleanliness, fuel status, mechanical operation and temperature control.
   - Outgoing vehicle must have shipping manifest and trip/route plan on file.

f) SEALED OR LOCKED TRAILERS OR TRUCKS: Outbound transport trailer or truck doors should be fitted with seals and/or commercial grade locks to maintain security. Seal numbers should be recorded if seals are used. Retain seal bands if necessary. Only authorized personnel can break incoming trailer seals.

17.0 FACILITY MAINTENANCE

a) FACILITY MAINTENANCE PLAN: Business 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.

   Records must show the type of maintenance completed, mechanic or technician name, and date work was completed.

   Lockout/tag out training is required for any workers who perform maintenance or repairs on electrical equipment.

b) PLUMBING CONTAMINATION: Sewer and water pipes are placed to avoid possible contamination of product or equipment in the event of a leak or dripping from condensation. Preventative measures have been implemented and documented as applicable.

c) VENTILATION AND AIR HANDLING: FANS or ventilation equipment must maintain safe air quality and vent and/or filter any noxious odors or dangerous airborne contaminants. Vents, filters and fans must be cleaned periodically.

d) FOOT DISINFECTANT DIPS: If required by quality control plan and used, foot dips must contain a USDA approved food grade sanitizer at a determined concentration – common chemicals are iodine (20-25 ppm), chlorine (2-25 ppm free chlorine) and quaternary ammonium (150-200 ppm).
   - Foot dips should be regularly checked to ensure their effectiveness with corrective actions recorded (e.g. dip solution replenishment and anti-microbial additions)

e) CONSERVATION PLAN: Operation must develop a conservation plan to reduce consumption of all resources including water, energy, materials and supplies. Operation must conduct an annual energy audit of all energy sources and consumption for key operations or equipment. Operation must implement methods to conserve energy and use or increase use of renewable sources when

applicable. Business continually develops and implements waste reduction, recycling and reuse methods.

f) GROUNDS MAINTENANCE PROCEDURE: Written procedures must be implemented that 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.
   - Procedures should list the frequencies for specific maintenance.
   - Workers operating hazardous or loud equipment must wear appropriate PPE including eye and hearing protection.
   - Logs of maintenance should be available for review.

g) PEST-PREVENTATIVE STORAGE: All equipment stored outside should be stored in such a manner as to discourage the harborage of pests e.g., insects, rodents and birds.

h) BUILDING CLEARANCE: A perimeter space of 24 inches should be maintained clear of plants, structures or decorations to facilitate the positioning of exterior pest traps and to discourage pest harborage areas.

18.0 PEST CONTROL PROGRAM

a) PEST AND DISEASE MANAGEMENT PLAN: Operation must have a documented plan for pest and disease management that discourages pest populations and conditions for growth.
   - The plan must incorporate product safety and quality controls to meet product specifications and minimize risks to products, people and the environment.
   - Operation integrates appropriate non-chemical methods (see "Non-Chemical Pest Controls" below) into the production system.
   - Operation can show evidence that the system is in place and functioning.
   - If infused products operation is physically co-located with a cultivation operation, operation should take additional precautions to create effective pest and disease barriers to prevent cross-contamination of the operations.
   - Pest control includes monitoring every three months (at a minimum) by a qualified third party provider.

b) PEST CONTROL DEVICES: All devices must be in working order (for sticky traps, glue must still be sticky, not covered with dust).

   All devices must be marked, numbered and coded so records of regular monitoring can reference trap numbers and locations.

c) TRAP PLACEMENT: Pest control devices (traps, light traps etc.) should be placed in such a manner that they do not pose a threat of contaminating product, packing or raw materials.
   - Traps should not draw pests into areas where product is stored or exposed.
   - Exterior traps should be weighted or attached to prevent movement.

- Interior traps should be placed to prevent movement or damage.

d) TRAP DENSITY: Exterior traps should be located at least every 30-50- feet depending on site and within 6 feet of all exterior doors to both sides of entrance. For interior traps (tin cats etc.) every 25 -30 feet depending on site layout and process flow.

e) USE OF BAITED TRAPS: Baited traps (baited with poison) can only be used outside of the facility, never in product handling, production or storage areas.

f) EVIDENCE OF PEST CONTAMINANTS: 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. Inspect the following for evidence of any pest debris:

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

19.0 SANITATION AND CLEANING

a) SANITATION PROCEDURES AND TRAINING: The operation must maintain sanitary conditions at all times, provide adequate equipment and materials to support sanitation and train workers on sanitation procedures.

Operation must have written sanitation and cleaning procedures for all equipment and areas; all workers must receive formal sanitation training. Procedures and training must cover the following at a minimum:

- Worker responsible for cleaning
- Item/area to be cleaned
- Specific cleaning methods
- Tools, utensils and cleaning products used
- Frequency of cleaning
- Safety, PPE and chemical controls:
  - Dilution and mix hazards
  - Application procedures
  - Labeling, containers and storage
  - Personal protective equipment
  - Spill clean up
  - First Aid

b) MASTER SANITATION SCHEDULE: Operation must have a schedule that identifies each area, each piece of equipment or each support item to be cleaned and how

often. Areas should include all processing, packing, product storage, waste areas, offices, restrooms, break areas and public/patient areas. Operation shall keep a log of cleaning performed.

c) CLEANING EQUIPMENT AND SUPPLIES: All necessary cleaning equipment and consumable supplies should be readily available and their use promoted.
   - Cleaning and sanitation equipment and supplies must be stored in a designated area away from raw materials, production, packaging or product storage areas.
   - 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.
   - Equipment must be stored separately from personal clothing.

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

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

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

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

d) CLEANING EQUIPMENT IDENTIFICATION: Cleaning equipment and supplies must be color-coded or boldly marked to prevent contamination or accidental use. Separate cleaning equipment should be assigned to separate physical areas or functions:
   - Production
   - Maintenance
   - Storage
   - Office
   - Restroom/toilet
   - Outdoor

e) SANITATION LOGS: Operation must have accurate, current sanitation logs that cover the entire area of the facility and equipment. Logs should identify what was cleaned, who cleaned it and when; logs should be easily accessible.

f) FLOOR DRAIN LOG: There must be a log that indicates that floor drains are cleaned on a regular basis, who cleaned it and when.

g) SWAB TESTING: Operation must show documentation of periodic environmental testing (swab testing, air impaction or equivalent methods), test results and corrective actions taken if results show evidence of biological contamination.

h) GENERAL CLEANLINESS: All areas identified under the cleaning procedure must be observed to be clean, organized and well maintained.

i) PRODUCT PROTECTION DURING CLEANING: Raw materials, ingredients, work-in-progress, finished goods and packaging materials must be protected from contamination or removed from the area during cleaning. “Cleaning” includes cleaning production lines between product runs, sanitizing equipment surfaces or components, and general cleaning of the floors, walls tables, doors, etc. in the room or work area.

20.0 SANITARY FACILITIES

a) TOILET AND HAND WASHING FACILITIES: The operation must provide clean, modern toilets with hand-washing sinks and maintain them in a clean and sanitized condition.

- All workers must wash and sanitize their hands before 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.
- Toilet facilities should have self-closing doors.
- Surfaces should be smooth, light-colored and easily cleanable.
- The number of facilities provided for each gender should be based on the number of employee or patients of that gender - separate facilities required if more than 20.
- Hands-free hand washing units are preferable.
- Signage must be in place to remind workers to wash/sanitize hands.

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

b) TOILET FACILITY CLEANLINESS: Supplies such as soap, toilet tissue, paper towels and sanitizer are well stocked. Records of scheduled cleaning and restocking on file. A worker must be designated to clean and stock the facilities.

c) SECONDARY HAND SANITATION STATIONS: Secondary hand sanitation stations should be conveniently located in traffic zones. 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 in place for review. Premixed restocking solution should include details of ingredients and strength.

d) LOCATION OF TOILET FACILITIES: 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 process or storage areas.

e) WARE-WASHING SINK: Operation must install a stainless steel sink with at least three compartments for manually washing, rinsing and sanitizing equipment and utensils.

- Compartments should accommodate immersion of the largest equipment and utensils by 50 percent.
- Each compartment shall be supplied with adequate hot and cold potable running water; faucet necks must reach all compartments.
- Operation must provide drain boards, utensil racks or tables large enough to hold all items before cleaning and after sanitizing.
- Adequate equipment should be available to air-dry washed utensils and equipment, if required.
- Ware-washing sink still required with automatic washing equipment.

Automatic ware-washing equipment requires water temperature, pressure, chemicals and equipment that meet applicable ANSI standards or equivalent.

f) DRINKING WATER: Adequate potable water must be available to ensure clean, safe water for production, sanitation and worker consumption.
- Hands-free drinking fountains are preferred and if used must be sanitized according to master cleaning schedule.
- Icemakers are identified on the cleaning schedule and are sanitized according to manufacturer's specifications.
- Documented water analysis or municipal certificate of analysis must be on file for review.
- Any non-potable water sources must be marked with a 12 x 12-inch warning sign in appropriate languages.

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

21.0 WASTE MANAGEMENT

a) WASTE AND POLLUTION RISK ASSESSMENT: Business must conduct a risk assessment to develop a documented plan that emphasizes waste reduction, pollution control and waste recycling and reuse.

Plan must consider all sources of waste and pollution in the production process including pollution to the environment at large as well as local environment.

b) WASTE MANAGEMENT PLAN: Business must have a documented waste management plan that contains actions taken to reduce and dispose of waste and recycle material. The plan should include procedures for waste handling, recyclables storage and handling, composting wastes, etc.

c) HAZARDOUS MATERIALS DISPOSAL: Operation must document and maintain an accurate inventory of all hazardous materials used in the operation. Operation must dispose of chemical, dangerous or hazardous waste in compliance with federal, state and local laws, regulations and other requirements. Hazardous materials may include certain solvents and other chemicals used in the processing of cannabis concentrate.

d) SUSTAINABLE PACKAGING: Operation can reuse packaging, use recycled sources, design packaging for composting or recycling, or design packaging and other materials from sustainably sourced materials. Labels can be integrated into packaging or printed using environmentally friendly materials. Operation maintains supplier sustainability claims and certifications on file. Packaging specifications must define reuse parameters.

e) CANNABIS AND CANNABIS-INFUSED WASTE DISPOSAL: Cannabis and cannabis-infused product waste must be rendered unusable and unrecognizable prior to leaving the facility. 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:

   - Food waste
   - Cardboard waste
   - Paper waste
   - Compost activators
   - Soil or soil mix

   Ensure any cannabis waste containing flammable solvents is dried safety and processed according to the waste management plan.

   Other methods may be acceptable if justified and documented.

f) WASTE CONTAINER CONTROL: All inside and external areas where waste collection containers are located must be well maintained and clean; if required by security procedures, external waste containers must be locked. Waste must be removed daily or more often if necessary to prevent overflowing containers. All waste canisters, Dumpsters etc. should be equipped with easily closable lids.

22.0 BUSINESS VIABILITY AND SUSTAINABILITY

The management team must establish methods to ensure business viability and continuity, and implement environmental sustainability processes.

a) GOAL SETTING: Business leaders should set and maintain ongoing, clear goals for the business. Goals should be aligned to the strategy and mission. Leaders should communicate goals to all workers. Management shall retain copies of goal plans and results.

b) BUSINESS SELF-ASSESSMENT: Business has evidence it has completed a business self-assessment that:

   - Improves core business processes

- Reviews business climate
- Analyzes core markets and customer preferences
- Reviews business location
- Measures regulatory compliance and issues
- Reviews the investment climate
- Analyzes product supply chain (e.g. relationships with suppliers, operations and others integral to product)
- Exposes and mitigates vulnerabilities
- Contains a completed risk management plan, Strengths-Weaknesses-Opportunities-Threats (SWOT) analysis or other assessment

c) FINANCIAL SELF-ASSESSMENT: Operation conducts and documents, at a minimum, an annual financial self-assessment of business results based on auditable, valid plans as reported to regulators. Operation reviews payables/receivables, budget, cash management, contracts and bank transactions for process gaps and anomalies. Takes corrective action on identified problems.

d) THIRD-PARTY ASSESSMENTS: Business conducts periodic third-party assessments or audits on the operation. Assessment or audit reports on file for review by third-party auditors, who may include a trade group, regulatory representative or contracted auditor.

e) LICENSES AND PERMITS: Business has appropriate permits and licenses to operate compliantly including:

- Business license or operating permit
- Tax license (if required)
- Zoning permit or variance
- Building, signage and alarm permits
- Safety permits (fire, environmental)
- Health permit

f) BUSINESS INSURANCE: The operation has valid insurance policies in place:

- Liability: protection from lawsuits, negligence
- Property: loss/damage to location, contents
- Casualty: loss/damage to the operation
- Business interruption/continuation

g) ACCOUNTING STANDARDS: Business maintains an auditable accounting system or ledger. Management is trained on tax and accounting issues unique to the cannabis business such as IRS 280E. Use of third-party financial service providers (advisors, bankers, accountants) is documented. Business can provide signed affidavit or other proof from accounting firm/accountant certifying use of Generally Accepted Accounting Practices.

h) OPERATIONAL CONTROLS: Business 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).

Periodic assessment of controls should be documented in annual self-assessments and third-party audits or reviews (business and financial).

i) RECORDS MANAGEMENT: Business must have documented policies and procedures to control, protect, retain and destroy records that comply with all applicable regulations depending on record type. Records include:

- Accounting and tax records
- Contracts
- Electronic mail
- Employment
- Insurance
- Intellectual property
- Legal files
- Safety and health (OSHA, worker's compensation, medical)
- Payroll and wages
- Press/media releases
- Public filings
- Sales and marketing
- Corporate structures/bylaws
- Test data, logs and results
- Customer records
- Vendor records
- Inventory records

Management must designate a worker to manage the records process and should conduct a self-audit of the records process at least every 90 days.

Product test data must be retained for 3 years from test date.

j) APPROPRIATE ADVERTISING AND MARKETING METHODS: Business ensures that all advertising/marketing, including websites and social media, are current and accurate and support truth-in-advertising principles.

- Business must not make unsubstantiated medical claims and must provide adequate representation of level of medical expertise (do not inappropriately represent as a medical professional).
- Advertising must comply with local/state advertising regulations for cannabis with no advertising targeted at minors.

Fair Labor Practices

a) COMPLIANCE WITH FAIR LABOR STANDARDS ACT: Business has evidence that it:

- Pays minimum wage or more
- Pays overtime rates if overtime is required

- If piece-rate pay used, maintains an accurate system to ensure rate meets or exceeds the minimum wage
- Bases all pay deductions on a formula documented in work contract.
- Complies with child labor laws

b) WORKPLACE DISCRIMINATION: EEOC poster is displayed indicating illegality of discrimination and processes to report violations:
   - Age
   - Gender
   - Marital status
   - Sexual orientation
   - Race, color, national origin or ancestry
   - Religious or spiritual beliefs
   - Disability or medical condition
   - Sexual harassment

c) WORK CONTRACTS: Operation must have work contracts for all workers on file. The contracts must specify:
   - Weekly maximum hours worked before overtime is calculated
   - Terms and schedule for payment of wages
   - Terms for dismissal from job
   - Terms of dispute resolution between worker and employer
   - Details of any vacation time paid, mandatory overtime, sick leave or other compensated time off, if provided
   - Background checks required; bonding may be required

d) WORKER POLICIES: Business publishes and adheres to a worker policy manual that ensures compliance with all laws and regulations, defines company policies and expectations for all workers.

e) WORKER'S COMPENSATION INSURANCE: Business must maintain state-approved worker's compensation plan for all workers and must demonstrate understanding of worker rights.

f) WORKER DATA: Business must maintain a unified worker data file that is secure, backed up, centrally located and accessible for review. Worker data must be retained for at least two years after termination date or as required by local regulations

g) TRADE OR ADVOCACY GROUPS: Business has documented evidence of membership in a trade or advocacy group that supports progressive and fair labor standards and practices.

Social Sustainability and Community Relations

a) COMMUNITY IMPACT STUDY: Operation must assess potential impacts of its operation on the surrounding community and population. The operation must

show evidence that cooperative strategies for minimizing negative impacts and highlighting positive impacts have been explored.

b) COMMUNITY CONTRIBUTIONS: Operation has documentation of contributions to the community including employee volunteerism, community outreach programs, education programs and charitable donations (cash and in-kind).

b) ADA COMPLIANCE: Operation meets requirements of the Americans with Disabilities Act (ADA) for all U.S. locations (or local equivalent where applicable). Reference ADA.gov

c) BUSINESS CERTIFICATIONS: Operation should identify any business certifications it has achieved such as:

- LEED - green buildings
- ISO9000 or similar quality or professional certifications
- WEBNC/woman-owned business
- Minority-owned business
- Native American-owned business

d) COMMUNITY REPUTATION ASSESSMENT: Operation conducts periodic assessment of business reputation in the community via:

- Input from stakeholders (surveys, comment cards, focus groups)
- Joining/attending local organization groups and meetings
- Media coverage, public relations
- Community awards and recognition

e) CANNABIS INDUSTRY SUPPORT: Operation takes action to support cannabis industry growth and integrity such as membership in cannabis trade or advocacy groups; participation in public outreach and education campaigns; attendance, sponsorship or presentations at industry conferences; participation in award programs; and membership in local networks and cannabis groups.

Crisis Management and Business Continuity

a) CRISIS MANAGEMENT PLAN: The operation must have a documented crisis management plan that management reviews and updates annually. At a minimum, the crisis management plan must document the following:

- Risk assessment - Natural disasters, fire, flood, loss of key staff, sabotage, vandalism, terrorism, theft, robbery, seizure of assets or property, traceability, product contamination and product recall.
- Action Steps - Management actions to restore the business to operation and specific responses for each identified risk.
- Crisis team (core and extended) roles, responsibilities and authorizations.
- Contact list and calling tree. Include key phone numbers for crisis team, staff, emergency authorities, insurance companies, and local regulators and agencies.
- Details of product, equipment and document storage locations.

- Document management and protection plan.
- Financial and legal considerations.
- Media relations plan and contacts.

b) CRISIS TRAINING: All personnel involved in crisis plan have participated in crisis training. Crisis team has current response information and knows how to return the business to operation after an interruption. Team receives updated crisis information and periodic training.

c) CRISIS PLAN TESTING: Management ensures preparedness for crisis events by testing the plan annually. Record of documented crisis plan test is on file for review. Process should test communications, responsibilities, call lists, procedures, scenarios, etc. Crisis plan test must be signed and dated by senior management.

23.0 SECURITY PROGRAM

a) SECURITY PROGRAM: The operation must develop, document, implement and maintain comprehensive security procedures to protect the business assets, facilities, products, workers, visitors and the community from risks and threats.

The operation must have a detailed security program in place that includes:

- Company security mission
- Primary purpose of the security plan
- Security roles and responsibilities
- Confidentiality and information security
- Security systems
- Access systems – keys, pads and cards
- Alarm equipment
- Video equipment
- Cash revenue management
- Record keeping
- Employee policies
- Employee disciplinary action
- Theft, loss, or diversion
- Entrances and doors
- Inventory control - seed to sale
- Safety policy
- Emergency policies and procedures

b) CPTED APPROACH: The operation plans and designs crime prevention mechanisms and methods into the physical and operational environment using Crime Prevention Through Environmental Design (CPTED) or similar security methodology. Operation uses methods such as natural access controls, target hardening, image management, security-based maintenance and formal

surveillance and activity support, such as resident/neighbor engagement, to increase security effectiveness.

c) FACILITY ACCESS CONTROLS: 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.

d) VISITOR SIGN IN: An authorized worker must ensure all visitors sign in and out of the facility (name, organization, date, time, escort) and wear a visible identification badge while on the premises.

e) VISITOR ESCORTS: All visitors must be escorted at all times while in controlled areas of the facility.

f) RESTRICTED AREA ACCESS CONTROLS: Operation has procedures to control access to restricted or protected areas such as areas containing controlled products, hazards, contamination risks or sensitive information; active controls such as locks, keypads, barriers and/or security personnel are in use to restrict access. Restricted access areas have logs or digital records to indicate time, date and ID of person entering and exiting the area.

g) SECURITY ORGANIZATION STRUCTURE: Operation must have an organization chart that identifies security titles and responsibilities. Support documents should identify credentials, training and performance required for security personnel.

Security and Risk Management

a) SECURITY RISK ASSESSMENT: Annual security risk assessment must review all threats (crime) and hazards (natural/man-made events) to assets (staff, public, product, currency, materials, information).

Security program must include specific action plans to mitigate all risks including:

- Exteriors/perimeter
- Doors, windows and other openings
- Interior areas of site or building
- Property and equipment
- General security processes/protocol
- Alarm systems
- Security employees and contractors
- Cash management procedures
- Worker procedures
- Worker and background checks
- Opening and closing the facility
- Managing and removing trash
- Working with vendors
- Working with contractors

- Threats from neighbors
- Training and monitoring employees
- General management practices
- Managing security emergencies
- Plans for dynamic entry or intentional threats

Retain annual security assessment documentation for 4 years.

b) PHYSICAL BARRIERS: Operation applies methods to prevent unauthorized access to production areas including fencing, locked gates, secure doors, window protection and other physical barriers. Security barriers must comply with local security, fire safety and zoning regulations and GMP.

c) GROUNDS AND EXTERNAL AREAS: Security plan must ensure external areas are clear of obstructions, well illuminated and covered by surveillance systems.
   - Include adjacent buildings, neighboring businesses and residential areas, ingress and egress, and exterior signage.
   - Workers should be trained on safe ingress/egress processes.

d) PRODUCTION AREA ACCESS: Operation must have a written policy that details who can access production areas and under what circumstances. The policy must cover access by visitors, subcontractors, regulatory and law enforcement officials.

e) DOOR LOCKS: Sturdy commercial grade locks must be installed on all doors. External doors must have deadbolt locks and comply with local fire and building code regulations.
   - Key distribution must be controlled, monitored and documented.
   - 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.
   - Biometric entry systems are monitored, controlled and documented.
   - Procedures are in place to ensure keys, locks, codes and biometrics are changed immediately as required by personnel access privilege changes or breaches.
   - Managers monitor facility and critical-area access reports on a periodic basis.
   - Keypad locks (used solo) are not permitted for critical areas or external entry.

f) CASH MANAGEMENT: Operation provides documented cash management training to employees including managing cash transactions with customers and suppliers.

g) PRODUCT CONTROL: ALL areas where raw cannabis or cannabis-derived products are stored must be locked and secure. The secure area should limit access to an authorized personnel list – all entries to the product storeroom must be logged.

Ongoing, current inventory records must be maintained inside the storage area. Commercial vault is installed to protect product inventory.

h) PRODUCT CONTROL SIGNAGE: Warning signs that read "Restricted Access Area – Authorized Personnel Only" must be posted in all areas where cannabis or cannabis products are stored and processed. The sign shall be at least 12 x 12 inches, composed of letters at least one-half inch in height.

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

j) THEFT/PRODUCT LOSS PLAN: Operation must implement emergency procedures for securing all product and currency following any instance of diversion, theft or loss of cannabis. Operation manager and/or security manager will conduct a security assessment to determine whether additional safeguards are required; they must update procedures and implement changes.

k) SECURITY AND INCIDENT REPORTING: Operation has implemented 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.

Alarm Systems

a) FACILITY ALARM SYSTEM: Operation is continuously monitored by a building-wide alarm system; a qualified alarm system company monitors alarm status 24/7.
   - Alarm should be linked to security, management and police as required by security risk assessment.
   - Alarm should have dual pass-through communication capability.
   - Redundant phone and Internet lines are installed and operational.
   - System delivers automatic power outage notification – automatic check every five minutes.
   - Alarm includes fire and smoke detection, monitoring and notification of fire department and facility personnel.
   - Pedestrian doors, overhead doors and roof access points must be equipped with door contact sensors connected to an intrusion alarm system.
   - Process is in place to remove access for terminated employees.
   - At least weekly, the security manager or designee shall review entrance access logs to ensure no unauthorized access after hours or off shift.

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

c) 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.

d) BREACH NOTIFICATION: Alarm system should be linked to security monitoring company, management, police and other relevant personnel if a breach is detected.

e) PANIC BUTTONS: 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. Establish a "code word" for emergencies to alert fellow workers to an active emergency.

f) ALARM SYSTEM CONTINUITY AND MAINTENANCE: Operation ensures the alarm system receives preventative maintenance at least annually by a qualified security vendor to ensure operational effectiveness and verify active anti-tampering features to signal any loss of alarm coverage continuity.

Video Surveillance

a) VIDEO MONITORING: Operation must install monitoring equipment that satisfies all local regulations pertaining to monitoring of production areas. Copy of local laws and maintenance logs of all equipment should be on file.

b) VIDEO FAILURE NOTIFICATION: The video monitoring system should be equipped with an automatic failure notification system that promptly notifies management or employees if there is any prolonged surveillance interruption or failure.

c) BATTERY BACKUP FOR VIDEO: An automatic battery backup system should be installed to support a minimum of one hour of recording time.

d) VIDEO RECORDING SECURITY: All video surveillance equipment and recordings should be stored in a locked secure area that is accessible only to management and authorized employees of the facility. Digital video files should be password protected and reviewed only by authorized personnel.

e) VIDEO QUALITY AND COVERAGE: 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.

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.

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

External Areas: High-resolution (2048 x 1536 3.1 megapixel recommended) IP camera with varifocal lens, IP66 rated, with infrared (IR) and wide dynamic range capable of recording in all lighting and weather conditions.

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

Video camera coverage must include:

- All secure and restricted access areas
- All point of sale areas
- All points of entry to or exit from secure and restricted access areas
- All points of entry to or exit from the registered facility

Motion-activated cameras can only be used to reduce or increase frame-per-second recording to manage digital storage volume.

f) CONTINUOUS VIDEO MONITORING: 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.

Adequate internal and external signage is posted stating "premises under video surveillance."

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.

g) VIDEO RETENTION: All surveillance recordings should be retained for a minimum of 45 days and in a format that can be easily accessed for viewing. Access should be password protected and limited to management or designee.

h) TIME AND DATE CODE: Date and time should be embedded on every frame of all surveillance recordings without obscuring any useable areas of the image.

i) VIDEO ARCHIVE INTEGRITY: All video recordings must be stored in a raw uneditable and unedited format that preserves it as a legitimately captured video and guarantees that no alterations of the image have occurred.

j) VIDEO SYSTEM CONTINUITY AND MAINTENANCE: Security manager should schedule video system preventative maintenance at least annually by a qualified vendor to ensure continuity of coverage, check signal loss and operational anti-

tampering features, etc. Security manager should ensure camera domes/lenses are kept clean and free of dust and debris.

Transport Security

a) TRANSPORT SECURITY PROCEDURES: The operation must have written procedures that protect all aspects of the transportation of cannabis and cannabis products. Procedures are required for each physical location the company operates, and must include departure, in-transit and arrival requirements for all legs of the route regardless of destination.
   - Procedures must align with all state and local laws and they must be implemented as specified or be revised.
   - 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.
   - Delivery and receiving areas, doors, parking and physical access should be separate from worker or customer entrances and exits.

b) TRANSPORT COMPLIANCE: 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. Managers must assess transportation security procedures and worker behavior quarterly at a minimum; all corrective action required must be completed and documented.

   The operation shall document compliance actions such as training, policies and procedures, information collection and analysis, certificates of achievement, licenses, notices and regulatory updates, internal and external audits, and incident reports, and retain records for two years.

c) TRANSPORT MANAGER: Operation must designate a qualified person to manage the company's product transport program including:
   - Product and document control
   - Verification and training of transport agents
   - Vehicle security, quality and sanitation activities
   - Route management
   - Risk assessments

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

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

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

f) TRANSPORT AGENT CELLULAR PHONE: Active cellular phones must be available to all employees who physically transport products between facilities. Phones should be programmed with appropriate business numbers. Agent should be trained to dial 911 for emergencies. Private two-way radio system is acceptable.

g) DELIVERY ROUTE PROCESS: Business must document date, time and delivery route of all shipments of cannabis and cannabis products.
   - Transport agents must carry the documents with copies at the origin site and destination locations.
   - Delivery times and routes should be changed on a routine basis to safeguard deliveries; limit authorized delivery windows to daylight hours.
   - Use GPS electronic tracking to monitor all vehicles and their routes.
   - When practical, transportation agents should call ahead to ensure readiness at destination.

h) SHIPMENT INVOICE: Shipment invoice, manifest or bill of lading must include at a minimum:
   - Name, location and registration number of origin facility
   - Date of invoice
   - Name, location and registration number of destination
   - Total product quantity delivered to each location if more than one with detailed bill of lading for each location
   - Date and time of departure
   - Date an estimated time of arrival
   - Delivery route
   - Vehicle, make, mode number and license plate number

- Invoices must be protected as confidential information

i) TRANSPORT PACKAGING: Transporters must use an approved, sanitary container sealed with tamper-evident tape or equivalent control; traceability information must be clearly marked on the outside of the container. Packages inside of sealed containers (if applicable) must be closed to protect contents and sealed if required by product specification.

j) TRANSPORT VEHICLE SAFETY: 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.
   - Transport agents must obey all traffic laws; management shall assess each agent's safe driving performance periodically.
   - The operation must segregate an area of the vehicle for secure, sanitary cannabis storage during transport.
   - Cannabis or cannabis products should not be visible during transport, including when parked.
   - The operation should install active GPS or security tracking on vehicles.
   - Vehicle glove box should contain an "accident and emergency packet" that contains all required information in case of collision or other emergency.

k) TRANSPORT VEHICLE DATA: Bill of lading, manifest or delivery documentation must list vehicle make and license plate number and remain with the shipment at all times.

l) PRODUCT CONCEALMENT: All transport storage areas are hidden from view by tinted glass, barriers or opaque transport containers to prevent visibility of contents by vehicles or pedestrians.

Security Training and Background Checks

a) SECURITY TRAINING: Operation must provide and document training for all workers on security procedures 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) SECURITY TRAINER: 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) SECURITY OBSERVATIONS: The security manager should observe and interview all workers monthly to ensure they understand and follow company security policies and procedures.

d) SECURITY MANAGER: Security managers or designees must have documented security training and demonstrated security experience that qualifies them to competently oversee all security responsibilities.

e) SECURITY PERSONNEL: Business develops qualifications and procedures for onsite security personnel and ensures all security personnel are trained in all company policies including security policy and procedures.

f) CRIMINAL BACKGROUND CHECK: All employees, including management and contract workers, must have documented background checks on file.
   - Business must establish criteria for hiring/not hiring before conducting criminal background check results and document rejections.
   - Criminal background checks must review at least five years history for felony convictions in all 50 U.S. states; international reports may be required depending on candidates and location.
   - Theft, embezzlement or felony drug convictions should prevent employment; all employment rejections based on background checks must be documented; all employment restrictions should be clearly documented on the operation's pre-employment information.
   - 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.