

The Cannabis Health & Safety Organization

FOCUS Standards

Requirements Summary 2020

Important

This document contains the high level requirements for all FOCUS Standards. It is provided as a courtesy to AFDO members.

Full copies of the FOCUS Standards are available to local, state and federal regulators. Please note that FOCUS Standards are copyright protected. Any use of, or reference to, the standards or their content must be appropriately cited. Please email your request to info@focusstandards.org.

If you have questions or would like more information about FOCUS services, please contact us using the aforementioned email or visit www.focusstandards.org



The Cannabis Health & Safety Organization

Cultivation Standard

FOCUS Cultivation Standard Requirements Summary

Management Summary

Requirements related to management's responsibilities, training, and qualifications overall to ensure product quality, health and safety, security, procedures, training, and regulatory compliance throughout the operation.

Business Practices

Requirements related to the operation's business practices including goal setting, internal and external business assessments, certifications, licensing and permitting, insurance, accounting, operational controls, fair labor practices, record keeping, inventory, advertising methods and crisis management.

Training

Requirements related to the operation's employee and management training including corporate policies and procedures, GAP, GMP, handling, sanitation, agricultural expertise, emergency and crisis management, laws and regulations, quality control, hazardous materials, hygiene, quality control, food safety, product quality, testing, regulatory inspections, record keeping, sanitation and cleaning, security, interaction with law enforcement, sexual harassment, violations and enforcement, specific job requirements and worker health and safety.

Worker Practices

Requirements related to the operation's worker practices including cleanliness and attire, hand sanitation, wounds and infections, protective clothing, prohibited items, eating and drinking, smoking and tobacco products, control of drug use, violence and weapons, and GMP, GAP signage.

Health & Safety

Requirements related to the operation's health and safety program including physical safety, safely designed processes, safe tools and equipment, health and safety risk assessments, safety procedures, training, PPE, safety signage, accident and emergency procedures, first aid, eye wash stations, and protections from UV light exposure.

Security

Requirements related to the operation's security program including mission, purpose, roles and responsibilities, qualifications, training, risk assessments, incident reporting, background checks, confidentiality and information security, record keeping and reporting, cash management, inventory control, safety policy, CPTED approach, physical barriers, grounds and external areas, door locks, facility access controls, restricted areas, visitor access, product controls, theft and loss prevention, alarm systems, alarm monitoring, motion detectors, panic .buttons, and video surveillance. Also includes requirements for transport security including procedures, policies, qualifications, training, documentation, credentials, routes, shipments, invoices, packaging, and vehicle controls.

Product Quality

Requirements related to the operation's Quality Management System including systems, methods, tools, and training, land or site assessment, buildings and facilities, environmental controls including appropriate lighting, ventilation, air quality, temperature, pressure, and humidity in all areas used for packaging, weighing, trimming, preparation, modification, processing, and storage. A hazard control plan (HACCP) is also required including, hazard analysis, critical control points, production hazard analysis, production flow charts, production classification and control, product specifications, control of contaminants, production records, yield analysis and reconciliation, product rejection process, quarantined materials or products, corrective action plans, and cannabis inventory.

Production Equipment

Requirements related to operation's equipment management including record keeping, design, calibration, surfaces, thermometers, product containers, cooling coils, utensils and tools.

Propagation Material

Requirements related to operation's ability to maintain strain identity, integrity and traceability including seeds, treatment of plant materials, and genetically modified organisms.

Soil & Growing Mediums

Requirements related to the operation's soil and growing mediums including soil analysis, composition profile, heavy metal analysis, sustainable sourcing, analysis for organic amendments, and use/ reuse of soil.

Irrigation & Water Use

Requirements related to the operation's extraction water use plan including water sourcing, discharge, testing procedures, risk assessment, storage, use, quality analysis, irrigation records, irrigation system efficiency, leak detection, humidity control, drought management, environmental system flush, and rainwater harvesting.

Pest Control

Requirements related to the operation's pest management plan including how to protect plants from pests and disease, discourage pest populations, prevent disease and promote health growing conditions. Also required are pest contamination inspections, pest control devices, non-chemical pest controls, and domestic animals.

Agricultural Inputs

Requirements related to the operation's use of pesticides, fertilizers, and other agricultural inputs used in the cultivation process. Also included are requirements for worker safety and training, pre-harvest intervals, inputs, plant treatment records, application, measuring equipment, storage, spill control, used containers, composting, CO2 enriched environment, plant growth regulators, and pesticide phase out.

Environmental Sustainability

Requirements related to the operation's sustainability plan including energy efficiency, water reduction, land reclamation, enhancement of biological communities, and reuse of resources. Also included are requirements for carbon footprint reduction, lighting efficiency, HVAC efficiency, minimization of energy intensity, use of renewable power, efficient use of equipment, use of petroleum generators, and elimination of CO2 enrichment.

Harvest Practices

Requirements related to the operation's harvest practices including pre-operation inspections, harvest procedures, cross contamination prevention, handling and packaging areas, drying, trimming, final curing, post-harvest treatments, final quality control, and biological decontamination.

Product Testing

Requirements related to the operation's product testing plan to ensure all products sold or transferred are free from contaminants and adulterants including sampling procedures, testing lab standards, allowable thresholds, microbiological testing, heave metals, pesticide residue, potency and cannabinoid profile, contaminants and filth, test results analysis, batch monitoring and test records.

Packaging & Labeling

Requirements related to the operation's packaging and labeling policies including material selection, design, inspection, approval, storage, handling and rejection process. Also included are specific requirements for product information, warning labels, exit packaging, child resistant packaging, and tamper evident packaging.

Traceability & Recall

Requirements related to the operation's traceability and recall policy and procedures including the overall traceability system, recall program, mock recall, and compliance procedures.

Product Storage

Requirements related to the operation's storage policies and procedures to assure cannabis and cannabis derived products are maintained in a controlled environment to preserve product identity, strength, purity, and quality, including product storage, storage access controls, quarantined materials segregation, storage area construction, cleaning and pest control.

Receiving & Transport

Requirements related to the operation's policies and procedures including product transfers, supplier qualifications, incoming goods inspections, raw material inspections, vehicle inspections, record keeping, sealed trucks and trailers, and contract carriers.

Facility Maintenance

Requirements related to the operation's Facilities Maintenance Plan including plumbing contamination, ventilation and exhaust fans, foot disinfectant dips, grounds maintenance, and hazardous materials.

Sanitation & Cleaning

Requirements related to the operation's ability to maintain sanitary conditions at all times including sanitation procedures and training, master sanitation schedule, cleaning equipment and supplies, cleaning equipment identification, general cleanliness, sanitation logs, floor drain cleaning, swab testing, and product protection during cleaning.

Sanitary Facilities

Requirements related to the operation's facilities including toilet and handwashing facilities, secondary hand sanitation stations, ware-washing sink, drinking water, and changing areas.

Waste Management

Requirements related to the operation's waste management plan including policies and procedures, hazardous materials disposal, minimize landfill waste, sustainable packaging, cannabis waste disposal, and waste container controls.



The Cannabis Health & Safety Organization

Laboratory Standard

FOCUS Laboratory Standard Requirements Summary

Management Summary

Requirements related to management's responsibilities, training, and qualifications overall to ensure product quality, health and safety, security, procedures, training, and regulatory compliance throughout the operation.

Business Practices

Requirements related to the operation's business practices including goal setting, internal and external business assessments, certifications, licensing and permitting, insurance, accounting, operational controls, document control, fair labor practices, workplace discrimination, work contracts, community relations, advertising methods, ADA compliance, certifications, crisis management, and emergency procedures.

Training

Requirements related to the operation's ability to ensure all staff members receive adequate training to complete assigned responsibilities safety and effectively prior to beginning work. Specific requirements include company policies and procedures, emergency procedures, laws and regulations, hazardous materials, laboratory methods, operations, and quality control, management and handling of cannabis samples, record keeping requirements, regulatory inspections, safe, quality service delivery, sanitation and cleaning procedures, security, interaction with law enforcement, sexual harassment, specific job training, and worker health and safety training. Also included are specific requirements for quality and technical training, proficiency reviews, hygiene training, and ongoing training plan.

Staff Practices

Requirements related to the operation's staff practices including personal cleanliness and attire, hand sanitation, wounds and infections, protective clothing, prohibited items, eating and drinking, smoking and tobacco products, control of drug use, violence and weapons, and GLP/GMP signage.

Health & Safety

Requirements related to the operation's ability to develop, implement and maintain a comprehensive health and safety program that includes physical safety, safely designed processes, safe tools and equipment, facility and environmental safety, risk assessments, safety procedures, training, PPE, safety signage, first aid, eye wash stations, and emergency procedures.

Security

Requirements related to the operation's ability to develop, implement, and maintain a security program that protects business assets, facilities, products, workers, visitors and the community from risks and threats. Specific requirements include roles and responsibilities, confidentiality and information security, security systems, access, alarms, and video surveillance, record keeping and reporting, employee policies and disciplinary actions, dynamic entry, intrusion, theft, loss and diversion control, facility access, worker ingress/egress, safety policy, emergency policies and procedures, CPTED approach, risk assessments, security qualifications, security training, records security, incident reporting, background checks, physical barriers, grounds and external areas, door locks, facility access controls, restricted area controls, visitor access, cash management, facility alarm systems, alarm monitoring, motion detectors, and video recording, quality, coverage, surveillance, monitoring and retention. Also includes requirements for transport security including procedures, policies, qualifications, training, documentation, credentials, routes, shipments, invoices, packaging, and vehicle controls.

Quality Control

Requirements related to the operation's ability to develop, implement, and maintain a laboratory management system (LMS) to ensure that the laboratory performs to established standards and procedures. Specific requirements include quality management responsibilities, risk assessments, staff qualifications, quality status and updates, environmental controls, computer functionality, quality control checklists, out of specifications procedures, corrective action processes, cross contamination prevention and water quality analysis.

Laboratory Methods

Requirements related to the operation's ability to develop, implement, and maintain laboratory procedures to meet testing requirements within acceptable standards including objective, scope or type of material, definitions, apparatus and instrumentation, method summary, reagents and materials, sample preparation, instrument conditions, calibration, calculations, quality control including statistical methods used, data acquisition system operations, assignment of uncertainty, interferences and limitation, approaches to address background corrections, hazards and precautions, report format and test forms, processing procedures, pretest inspections, data protocols, chemical assay procedures, quality control samples, lab method comparison, sample handling procedures, sample control and destruction, and storage controls.

Testing Methods

Requirements related to the operation's ability to document and maintain all laboratory test methods used for each test including chemical tests, terpenes analysis, method validation, active tests, instruments analytical range, test method tracking, and polymerase chain reaction testing.

Data & Records Management

Requirements related to the operation's ability to develop, implement and maintain a record management system that follows established procedures to ensure the organized storage, retention, and protection of all records and supporting data including a records inventory list, destruction process, HIPPA compliance, system access controls, user controls and tracking, file labeling and storage hierarchy, data backup, long term protection of file integrity, restricted storage areas, lockable filing systems, sign-in/out procedures for file review and removal, destruction processes and schedule, crisis management and environmental controls. Additional specific requirements include a records inventory list, standard reporting format, error and complaints process, and report control and retention.

Laboratory Equipment

Requirements related to operation's equipment management including record keeping, design, critical installation, calibration, surfaces, thermometers, product containers, utensils and tools.

Receiving & Transport

Requirements related to the operation's packaging and labeling policies and procedures including selection Requirements related to the operation's policies and procedures including supplier qualifications, incoming sample inspections, incoming goods inspections, vehicle inspections, and contract carriers.

Facility Maintenance

Requirements related to the operation's Facilities Maintenance Plan including ventilation and exhaust fans, pest control, conservation plan, grounds maintenance, hazardous materials, and domestic animals.

Sanitation & Cleaning

Requirements related to the laboratory's ability to maintain sanitary conditions at all times including sanitation procedures and training, master sanitation schedule, cleaning equipment and supplies, cleaning equipment identification, general cleanliness, sanitation logs, swab testing, and product protection during cleaning.

Sanitary Facilities

Requirements related to the laboratory's facilities including toilet and handwashing facilities, secondary hand sanitation stations, ware-washing sink, drinking water, and changing areas.

Waste Management

Requirements related to the laboratory's waste management plan including policies and procedures, risk assessments, hazardous materials disposal, sustainable packaging, cannabis waste disposal, and waste container controls.





The Cannabis Health & Safety Organization

Manufacturing Standard

FOCUS Manufacturing Standard Requirements Summary

Management Summary

Requirements related to management's responsibilities, training, and qualifications overall to ensure product quality, health and safety, security, procedures, training, and regulatory compliance throughout the operation.

Business Practices

Requirements related to goal setting, internal and external business assessments, certifications, licensing and permitting, insurance, accounting, operational controls, fair labor practices, recordkeeping, inventory, advertising and crisis management.

Training

Requirements related to employee and management training including corporate policies and procedures, emergency and crisis management, laws and regulations, quality control, hazardous materials, hygiene, food safety, product quality, testing, regulatory inspections, record keeping, sanitation and cleaning, security, interaction with law enforcement, sexual harassment, violations and enforcement, specific job requirements and worker health and safety.

Worker Practices

Requirements related to worker cleanliness and attire, hand sanitation, wounds and infections, protective clothing, prohibited items, eating and drinking, smoking and tobacco products, control of drug use, violence and weapons, and signage.

Health & Safety

Requirements related to the operations health and safety program include risk assessments, safety procedures, training, PPE, signage, visitors, accident and emergency procedures, first aid, and eye wash stations.

Security

Requirements related to the operations security program including roles and responsibilities, qualifications, training, risk assessments, incident reporting, background checks, confidentiality and information security, recordkeeping and reporting, cash management, inventory control, safety policy, CPTED approach, physical barriers, grounds and external areas, door locks, facility access controls, restricted areas, visitor access, product controls, theft and loss prevention, alarm systems, alarm monitoring, motion detectors, panic buttons, and video surveillance. Also includes requirements for transport security including procedures, policies, qualifications, training, documentation, credentials, routes, shipments, invoices, packaging, and vehicle controls.

Product Quality

Requirements related to the operations Quality Management System include hazard control plans (HACCP), hazard analysis, critical control points, roles and responsibilities, forms, production flow charts, manufacturing process, product classification and control, product specifications, control of contaminants, control of allergens, pre-operation inspections, production records, yield analysis and reconciliation, nonconformances, product rejection, corrective action records, and quarantined materials or products.

Production Operations

Requirements related to the operations ability to maintain appropriate environmental controls including lighting, ventilation, air quality, temperature, pressure, and humidity in all areas used for packaging, weighing, trimming, preparation, modification, processing and storage. Requirements related to the cleanability of the facility, cross contamination prevention, inventory, hazardous materials and disposal.

Production Equipment

Requirements related to equipment management, record keeping, design, calibration, thermometers, product containers, cooling coils, utensils, wares and tools.

Water Use & Quality

Requirements related to the operation's Water Use Plan including a water use, systems, risk assessments, and quality analysis.

Extraction Operations

Requirements related to the operation's extraction processes including equipment installation and training, production training, emergency procedures, food grade chemicals, water-based extraction, CO2-based extraction, CO2 monitoring, use of dry ice, ethanol or alcohol based extraction, solvent safety and recovery, food grade solvents, and solvent disposal and waste procedures.

Product Testing

Requirements related to the operation's product testing policies and procedures including a product testing plan, sampling procedures, laboratory requirements, allowable thresholds, microbiological testing, solvent and chemical residue, heavy metals, pesticide residue, potency and cannabinoid profile, contaminants and filth, stability testing, analyzing test results, batch monitoring, test records and document retention.

Packaging & Labeling

Requirements related to the operation's packaging and labeling policies and procedures including the labeling protocol, warning labels, infused product labels, exit packaging, child resistant packaging, and tamper evident packaging.

Traceability & Recall

Requirements related to the operation's traceability and recall policy and procedures including the overall traceability system, recall program, mock recall, and compliance procedures.

Product Storage

Requirements related to the operation's storage policies and procedures including product storage, storage access controls, quarantined materials segregation, storage area construction, cleaning and pest control.

Receiving & Transport

Requirements related to the operation's policies and procedures including product transfers, supplier qualifications, incoming goods inspections, raw material inspections, vehicle inspections, sealed trucks and trailers, and contract carriers.

Facility Maintenance

Requirements related to the operation's policies and procedures related to facility maintenance including a facility maintenance plan, plumbing contamination, ventilation and exhaust fans, foot disinfectant dips, conservation plan, and grounds maintenance.

Pest Control

Requirements related to the operation's pest management plan including pest contamination inspections, pest control devices and domestic animals.

Sanitation & Cleaning

Requirements related to the operation's policies and procedures for sanitation and cleaning including a master sanitation schedule, cleaning equipment and supplies, equipment identification, general cleanliness, sanitation logs, floor drain cleaning, swab testing, and product protection during cleaning.

Waste Management

Requirements related to the operation's waste management policies and procedures including a waste management plan, hazardous materials disposal, sustainable packaging, cannabis waste disposal, and waste container controls.





The Cannabis Health & Safety Organization

Retail Standard

FOCUS Retail Standard Requirements Summary

Management Summary

Requirements related to management's responsibilities, training, and qualifications overall to ensure product quality, health and safety, security, procedures, training, and regulatory compliance throughout the operation.

Business Practices

Requirements related to the operation's business practices including goal setting, internal and external business assessments, certifications, licensing and permitting, insurance, accounting, operational controls, fair labor practices, record keeping, inventory, advertising methods and crisis management.

Training

Requirements related to the operation's ability to adequately train employees to complete assigned responsibilities safely and effectively prior to beginning work. Including requirements for cash management, policies and procedures, customer and patient care, laws and regulations, hazardous materials, HIPAA, hygiene and food safety, ID verification, packaging and labeling, equipment and facility maintenance, product quality, product specifications, testing, uses and consumption methods, regulatory inspections, sanitation and cleaning, security and interaction with law enforcement, sexual harassment, violations and enforcement, and worker health and safety.

Worker Practices

Requirements related to the operation's employee hygiene and cleanliness including clothing and outer garments, shoes, wounds and infection, protective clothing, prohibited items, eating and drinking, smoking and tobacco, control of drug use, violence and weapons, and GMP signage.

Health & Safety

Requirements related to the operation's ability to develop and maintain a comprehensive health and safety program that protects fall workers, patients, customers, contractors, and visitors. Specific requirements include physical safety, safely designed processes, safe tools and equipment PPE, signage, accident and emergency procedures, first aid, facility and environmental safety, safety assessments, worker engagement and ongoing safety training.

Security

Requirements related to the operation's ability to develop, document, implement, and maintain a security plan that protects the businesses assets, facilities, products, workers, visitors and the community from risks and threats. Specific requirements include roles and responsibilities, confidentiality and information security, security system access, alarms and video surveillance, cash management, record keeping and reporting, employee policies and disciplinary actions, dynamic entry, intrusion, theft, loss and diversion, facility access, worker ingress/egress, inventory control, safety and emergency policies and procedures, CPTED approach, risk assessments, security qualification, training, records security, incident reporting, background checks, physical barriers, grounds and external areas, door locks, access controls, restricted area access, visitor access, product control, theft/loss plan, alarm monitoring, motion detection, panic buttons, alarm system maintenance, video system maintenance, monitoring, retention, transport security, transport agent credentialing, delivery route process, shipments, invoices, transport packaging, and vehicle controls.

Product Quality

Requirements related to the operation's ability to develop, implement, and maintain a comprehensive quality management system to ensure that products meet established standards and specifications. Specific requirements include a hazard control plan, critical control points, product hazard analysis, flow charts, product classification and control, product specifications, rejection process, quarantined products and materials, environmental controls, pre-operation inspections, cross contamination prevention, cleanability of

the facility, equipment design, maintenance, and calibration, and inventory control.

Facility Operations

Requirements related to the business' operational policies and procedures including the preclusion of minors from entering the facility, customer capacity and flow, infectious diseases and open wounds, service animals, maintenance plan, ventilation and exhaust fans, conservation plan, grounds maintenance, and hazardous materials.

Product Transactions

Requirements related to the operation's ability to train employees to provide information that aligns with product specifications including product strains, types, consumption methods, potential effects and side effects, dosing, strength and consumption quantities, manufacturing processes, extraction methods, solvents, additives, homogenization, dosing and perishability, testing, certificate of analysis, appropriate medical information sharing, consumer protections, and warnings. Also included are selling procedures, medical cannabis information, cash management and product transfers.

Records Management

Requirements related to the operation's ability to develop, implement, and maintain a records management system to ensure the organized storage, retention, and protection of all records and supporting data. Specific requirements include a records management plan, records inventory list, and patient records.

Product Testing

Requirements related to the operation's ability to develop, implement, and maintain a testing plan including policies and procedures to ensure that all products sold or transferred are free from contaminants and adulterants as specified in the product specifications. Also includes specific requirements for sampling, testing labs, allowable thresholds, microbiological testing, solvents and chemical residue, heavy metals, pesticide residue, potency and cannabinoid profile, contaminants and filth, test results analysis, and batch monitoring.

Packaging & Labeling

Requirements related to the operation's packaging and labeling policies and procedures including selection of materials, design, inspection, approval, storage, handling, and rejection process. Also includes specific requirements around labeling protocols, warning labels, infused product labels, exit packaging, child resistant packaging, and tamper evident packaging.

Traceability & Withdrawal

Requirements related to the operation's ability to develop, implement and maintain a documented traceability system that tracks products from the production site to the consumer or patient distribution point. Specific requirements include a recall program, mock recalls, and compliant handling procedures.

Product Storage

Requirements related to the operation's ability to assure cannabis and cannabis products are stored in a controlled environment at all times to preserve product identity, strength, purity, and quality. Specific requirements include storage area access controls, quarantined materials segregation, storage area construction, cleaning, and pest control.

Receiving & Transport

Requirements related to the operation's receiving and transport policies and procedures including a supplier qualification plan, incoming goods inspection, vehicle inspections, sealed trucks and trailers, and contract carriers.

Pest Control

Requirements related to the operation's ability to develop, implement, and maintain a pest management plan to protect products, production areas, storage areas, packaging, equipment and supplies from pests, disease, discourage pest populations and prevent disease. Specific requirements include pest contaminant inspections, pest control devices, and domestic animals.

Sanitation & Cleaning

Requirements related to the operation's ability to maintain sanitary conditions at all times including sanitation procedures and training, master sanitation schedule, cleaning equipment and supplies, cleaning equipment identification, general cleanliness, sanitation logs, flood drain cleaning, swab testing, and product protection during cleaning.

Sanitary Facilities

Requirements related to the operation's facilities including toilet and handwashing facilities, secondary hand sanitation stations, and drinking water.

Waste Management

Requirements related to the operation's waste management plan including policies and procedures, hazardous materials disposal, minimize landfill waste, sustainable packaging, cannabis waste disposal, and waste container controls.