

Seneca Nation Licensed Hemp Producer: Compliance Audit and Inspection Procedures



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1. SCOPE

- A. **Purpose** – This practice identifies the minimum requirements for the planning, conduct, and reporting of compliance audits of a hemp business. It provides information on terms, procedures, and responsibilities. It applies to seed farming (breeding), growing of hemp plants, harvesting (pre-harvest and post-harvest) of hemp plants, and packaging of raw hemp inflorescences without further processing (e.g. Whole Flower, pre-rolls, etc.).
- B. **Intent** – The intent is to provide specific instruction needed to develop reliable audit and inspection programs and procedures that are used to conduct audits and inspections that produce credible, consistent, and objective evidence and findings related to compliance with one or more standards, regulations, policies, best practices, or quality specifications.
- C. **Disclaimer** -- Compliance with this document does not excuse failure to comply with any other applicable laws or regulations. If needed, contact your immediate supervisor for any situation not addressed in this document.

2. DEFINITIONS

Action plan – means a plan to correct negative audit findings and close compliance gaps.

Adulteration – means to make imperfect by adding extraneous, improper, or inferior ingredients.

Allergen – means substances that cause an exaggerated immune response in some people and that may result in a runny nose, watery and/or itchy eyes, a rash, wheezing, serious illness or (occasionally) death.

Audit – *see Compliance audit.*

Audit authority – means the Hemp Compliance Administrator (HCA) or its designee.

Audit criteria – means the set of requirements that are applicable to the objective and scope of an audit.

Audit data – means data collected during an audit to support the audit findings.

Audit finding – means a statement of the audited entity's conformity/ nonconformity of each question or criteria at the time of the audit.

Audit objective(s) – means broad statement(s) of what the audit intends to accomplish.

Audit plan – means documentation that describes the objective, scope, specific responsibilities, schedule, logistics, deliverables, completion requirements and other plan details for a particular audit.

Audit program – means an auditing body’s procedures, protocols, methods, and techniques for conducting an audit.

Audit program supplier – means an entity that develops and provides a program of audit procedures and protocols that can be used repeatedly by auditing bodies to conduct consistent and reliable audits.

Audit protocol – means standard methods for the collection of audit data.

Audit report – means a written summary that provides the context or objectives of the audit, relevant background information, the audit findings, and objective audit data that provides evidence to support the findings.

Audit scope – means a description of what is to be audited.

Audit team – one or more auditors responsible for conducting an audit. The audit team may be supported by technical experts and auditors-in-training.

Audited entity – means a facility, organization, or part thereof, that is the subject of an audit.

Auditing body – means the Hemp Compliance Administrator or Seneca Nation Cannabis Department designee that plans and conducts an audit, and provides the audit report.

Auditor – means a person qualified to conduct an audit. A member of an audit team.

Authority having jurisdiction – means the Seneca Nation Hemp Production Ordinance and accompanying rules and other documents to support the program, as administered by the HCA or its designee.

Calibration – means the adjustment of an instrument for accuracy relative to an established standard.

Certificate of analysis – means a document containing test results that are provided to the customer by the supplier to demonstrate that hemp meets the defined test or at least provides results of requested tests.

Contamination – means a condition that can affect a product that has been exposed to and faced introduction of foreign matter, including filth, a poisonous substance or pests, disease-causing microorganisms or parasites, or toxins.

Control point – means any step in the process at which a hazard can be controlled, reduced, or eliminated.

Cross-contamination – means a situation that occurs when microorganisms, allergens, chemicals, or other hazards that are carried by utensil, hands, towels or other items are transferred from one product, raw material, or surface to another.

Compliance audit – means a comprehensive, systematic, documented, and objective assessment of an audited entity to evaluate and report objective evidence of compliance relative to predefined audit criteria.

Compliance gap – means a condition that does not meet the requirements of one or more applicable standards, regulations, policies, best practices, or quality specifications.

Documents – means written policies, processes, procedures, plans, standards, specifications, and other written information that governs the conduct of a business. Documentation also includes records.

Foreign matter – means any substance or object that does not naturally or normally belong in a product.

Hazard – means a biological, chemical, or physical agent that is reasonably likely to cause illness or injury in the absence of a control.

Hemp operation – means a person, group of persons, or business entity that cultivates, processes, manufactures, tests, distributes, stores, markets, sales, or otherwise handles hemp, or products containing cannabis/hemp.

Independence – means a condition characterized by organizational standing where an auditor is free to conduct an audit without being controlled or influenced by others.

Integrated Pest Management (IPM) – means an effective and environmentally sensitive approach to pest management that relies on a combination of common-sense practices. The information in combination with available pest control methods are used to manage pest damage by the most economical means and with the least possible hazard to the people, property, and environment.

Lead auditor – means an auditor designated to lead and manage the audit.

Mitigation Strategies – means the controls to remove, or reduce to an acceptable level, an identified risk, vulnerability, or threat.

Objective evidence – means information collected that someone when reviewing an audit report can inspect and evaluate for themselves.

Objectivity – means a condition characterized by the absence of bias, influences, and conflicts of interest that affect or have the potential to compromise audit findings.

Open audit issue – means a potentially negative audit finding that cannot be verified or resolved without additional time and information.

Period under review – means the time interval over which conditions at the audited entity are evaluated against audit criteria.

Personal Protective Equipment – means protective clothing, helmets, goggles, or other garments or equipment designed to protect the wearer’s body from injury or infection. The hazards addressed by protective equipment include physical, electrical, heat, chemicals, biohazards, and airborne particulate matter.

Pest – means any objectionable insect or other animal including but not limited to birds, rodents, flies, mites, and larvae.

Pest harborage – means any condition or structural defect that provides a place for pests to live and reproduce.

Physical inspection – means first-hand observation and assessment of the audited entity conditions.

Potable water – means water suitable for drinking, free from pollutants and harmful organisms, and conforms to local legal requirements.

Raw material – commodities, parts or substances that are assembled or processed to form a final product.

Records – means an audited entity’s documentation and other forms of recorded information.

Risk – means the likelihood of an occurrence and the size of the consequences of an adverse event.

Risk analysis – the likelihood of an occurrence and the size of the consequences of an adverse event.

Risk assessment – means the process of identifying a hazard and characterizing the risk presented by that hazard in qualitative or quantitative terms.

Root cause – means the underlying cause(s) of a problem.

Standard Operating Procedure (SOP) – means a set of step-by-step instructions compiled by a site to help employees carry out operations.

Supplier – means a person or organization that provides a product or service.

Threat assessment – means a risk assessment designed to examine a location’s processes for potential product security or other security risks.

Traceability – means the identification of any suspect raw material of finished product and its initial shipment location.

Validation – means the confirmation of plausibility for a specific intended use or application through the provision of objective evidence that specified requirements have been fulfilled.

Verification – means the confirmation of truthfulness through the provision of objective evidence that specified requirements have been fulfilled.

Vulnerability assessment – means a risk assessment designed to examine processes and the supply chain for potential fraud.

Working papers – means paper, electronic documentation, or both developed or collected by the auditing body and its auditors relating to an audit.

3. AUDIT PROCESS OVERVIEW

A. An audit involves a minimum of three activities:

1. **Audit Preparation**

- a. Prior to conducting an audit, the HCA or its designee, coordinates, organizes, and communicates the activities for conducting an effective and efficient audit.

2. **Conducting the Audit**

- a. The audit is conducted per plan by the audit team member(s) to assess the operation by collecting objective evidence, working papers, and audit findings. The audit activities can occur remotely, during an on-site visit, or both as specified by the audit plan.

3. **Reporting Findings**

- a. The audit findings, objective evidence, and working papers are organized to produce a clear and concise audit report. Depending on the objectives and scope, the audit report is shared with the HCA or its designated auditing authority, audited entity, or others as defined in the Ordinance, Rules, and other policies thereof. Reporting the audit findings occurs after conducting the audit is completed; however, preparatory reporting may occur earlier in the process.

B. Follow-up Audit

In most cases the objective of an audit is to identify and execute corrective/ preventative actions to address compliance gaps and reduce various risks. A follow-up audit can be conducted to verify that such actions have resolved compliance gaps.

4. MANAGEMENT RESPONSIBILITY

A. Organizational Structure

The Licensee shall have an organizational chart showing the reporting structure of the company. The organizational chart shall clearly document what personnel are responsible for safety and quality. The location shall:

1. Ensure there are documented job descriptions for all personnel involved in operational safety and quality.
2. Identify personnel responsible for operational safety and Quality Management Systems; and have documented back-up personnel.
3. Ensure personnel have training or experience to substantiate qualifications to manage such systems.

5. DOCUMENT CONTROL AND RECORD-KEEPING

A. Document Control

The Licensee shall have a procedure in place to manage documents that are part of safety, quality management systems, or compliance. The document control procedures shall include:

1. A master list of all controlled documents.
2. A method for the identification of the most current version.
3. The process for the authorization of amendments for changes to any documents.

B. Record-Keeping

The Licensee shall have a procedure in place to maintain legible records for a time period that meets legal requirements. Records may also be in the form of pictures, videos, or other forms of media. Records shall be readily accessible and be stored securely to prevent damage, theft, or unwanted changes. Records that are stored electronically shall be limited to authorized personnel unless otherwise specified by the Licensee. Records shall be backed up to prevent loss.

6. HEMP CULTIVATION OPERATIONS

A. Safety Practices and Quality Management Systems

Licensee shall have a system in-place that promotes the production of safe and quality hemp within the bounds of applicable law(s) and regulation(s). The system may be in an electronic format and/or hard copy. At minimum the system shall:

1. Be implemented and readily available to all relevant staff.

2. Include all Standard Operating Procedures (SOPs), any pre-requisite programs, forms, logs, diagrams, placards, and other supporting documentation.
3. Include a copy of relevant regulations and other supporting documentation to support and implement regulatory compliance.
4. Be maintained and updated as necessary.

B. Safety, Quality, and Regulatory Compliance Policy

The Licensee shall have a documented operational safety, quality, and regulatory compliance policy that states the Licensee's commitment and be communicated to all applicable staff.

C. Harvesting and Packaging Practices

The location shall have a system in place to ensure that all personnel involved in harvesting do not negatively affect the safety or quality of the product. The location shall have in place a documented procedure for personnel harvesting practices. The procedure shall include:

1. The methods used for the inspection of harvested products and how the location removes any physical hazards.
2. The methods for the exclusion of damaged, decayed, or adulterated product from being harvested.
3. How the location ensures that product that comes in contact with the ground is excluded from harvesting unless it is being used for extraction.
4. What measures are in place to ensure harvesting equipment or tools are kept clean and do not pose a risk to the safety or quality of the product.
5. How the location ensures the application of agricultural inputs does not negatively affect the product safety or quality.
6. Measures are taken to mitigate cross-contamination of cannabis plants from agricultural inputs, cleaning agents, personnel, or other factors that could potentially cross-contaminate products.

D. Personnel Packing Practices

The location shall have a system in place to ensure that all personnel involved in packaging do not negatively affect the safety or quality of the product. The location shall have in place a documented procedure for personnel packaging practices. The procedures

shall include a provision for packaging materials, equipment, and/or tools to ensure they are inspected before use and are free from contamination or exposure to the ground.

E. Allergen Management

The Licensee shall have in place a documented procedure for the control of unintended allergenic materials. The procedure shall include:

1. A risk assessment of unintended allergen cross-contamination from suppliers, employees, and visitors.
2. How the location addresses unintended allergens from entering the harvesting, packing, or storage operation areas.

F. Foreign Matter

A. Foreign Matter Control

The location shall exclude all wood, glass, brittle plastic, ceramics, or other similar materials from areas where raw product is handled, where possible. The location shall keep all pallets clean and in good repair. The location shall have in place a documented procedure for the control of foreign matter. The procedure shall include:

1. An inspection process to ensure the facility, equipment and tools remain in good repair as not cause a potential foreign matter contamination.
2. Provision for the protection of the damage, breakage or deterioration of wood, glass, brittle plastic, ceramic or other similar objects that cannot be removed from the harvesting or field packaging area and how the location monitors the objects.
3. Methods for how the location controls the use of metal cutting instruments used in harvesting and field packaging operations.

B. Foreign Matter Detection

The location shall conduct a risk assessment to determine If the use of foreign matter detection equipment is necessary. If the location uses foreign matter detection equipment during field packaging it shall be fit for its purpose and effectively remove or detect foreign matter. The location shall have in place a documented procedure for the detection of foreign matter, appropriate to the location's risks. The procedure shall include:

1. How the location plans to detect foreign matter.
2. The methods used to monitor and verify foreign matter detection.

3. Provision for the inspection and investigation of foreign matter that is removed by detection devices.
4. The calibration of foreign matter detecting equipment.

C. Managing Foreign Matter Contamination

The location shall have in place a documented procedure for the management of foreign matter contamination. The procedure shall include:

1. The methods used to quarantine and inspect the area of the foreign matter contamination.
2. The methods used to remove and clean the foreign matter contamination.
3. The methods used and responsibility for deciding if the potentially affected product is usable or to be disposed of.

G. Environmental Monitoring

The location shall have in place a documented procedure for environmental monitoring for any area where raw hemp, hemp flower, or hemp biomass is being packaged. The procedure shall include:

1. Person(s) responsible for the environmental monitoring program.
2. A risk assessment that outlines the methods, frequency, and limits that are used for sampling.
3. Trending of environmental records.

H. Volunteer Cannabis Monitoring (Outdoor Production)

The location shall have in place a documented procedure for volunteer cannabis monitoring and disposal. The procedure shall include:

1. Person(s) responsible for the volunteer cannabis monitoring program.
2. A risk assessment that outlines methods and frequency of the monitoring program.
3. The process of notifying the HCA and record-keeping.
4. The methods of disposal pursuant to the Ordinance.

I. Internal Audits

The location shall conduct internal audits to verify the effectiveness of the entire hemp operations at least annually. The location shall have in place a documented procedure for conducting internal audits. The procedure shall include:

1. Person(s) responsible for conducting internal audits and how the location ensures staff carrying out internal audits are competent and qualified.
2. Methods and frequency of internal audits.
3. How the location communicates audit results and corrective actions to relevant staff.
4. Trending of audit records and corrective actions.

J. Storage and Distribution

A. Stock Management

The location shall have a system in place to ensure that raw materials, agricultural inputs, and other products are utilized to ensure effective stock rotation.

B. Dry Storage

The location shall have an area to store dry products that are suitable for its purpose and constructed to protect the product from contamination. The location shall ensure that packaging material is stored separately from raw materials, including agricultural inputs, and other substances in accordance with their safety data sheets.

K. Unloading, Loading, and Shipping Practices

The location shall have in place a documented procedure for unloading, loading, and shipping practices. The procedure shall include:

1. The inspection process before unloading or loading.
2. The methods used to ensure minimal exposure of the product to detrimental conditions.
3. The methods used to ensure the prevention of cross-contamination and that the product maintains its integrity throughout the unloading, loading, and shipping process.
4. The methods used to ensure the load is secure from tampering or external elements.

L. Construction and Layout of Buildings and Fields

A. Fields

The location shall have in place a documented risk assessment of the location's land and adjacent lands to ensure they do not pose a risk to hemp and operational safety or quality. The risk assessment shall include:

1. The history of land use of the location and adjacent lands.
2. The topography or other natural factors that may impact hemp and operational safety or quality.
3. Control measures implemented for any known risks associated with the land.
4. Methods for a re-evaluation of risk assessments, at a minimum, annually.

B. Greenhouses and Other Indoor Facilities – Exterior

The location's indoor facilities shall be located so that they do not interfere with hemp and operational safety or quality and follow all local laws and regulations. The location shall ensure:

1. The location's construction is maintained and in good repair.
2. The location's grounds and surrounding area are maintained and free from debris, standing water, and excessive dust.
3. The location shall maintain all vegetation growth around the exterior of the facility to ensure there is no harborage of pests.
4. Roadways, loading and unloading areas under the location's control are maintained and free from debris.

C. Greenhouses and Other Indoor Facilities – Interior

The location shall be suitable for the intended purpose and mitigate opportunities for cross-contamination between and during operations. The location shall ensure:

1. All floors, walls, doors, windows, ceilings, drains and other building fixtures are constructed to not pose a risk to operational safety or quality, are designed to be easily cleanable, are maintained and in good repair.
2. Light fixtures and skylights are constructed to not pose a risk to safety or quality operations, are of appropriate intensity, are maintained and in good repair.
3. Windows, light fixtures, and skylights that could pose a risk to product safety and quality are shatterproof or protected against breakage.
4. Adequate ventilation and extraction to prevent condensation or excessive dust is provided.

5. All external openings are effectively sealed when closed and prevent dust and pests from entering the building.

M. Equipment

The location's equipment shall be suitable for its intended purpose. The location shall ensure all equipment is designed not to pose a risk to operational safety or quality, easily cleanable, maintained, and in good repair. The location shall:

1. Ensure all vehicles used for harvesting are maintained and in good repair as to not let lubricant, oil, or other foreign matter to contaminate the hemp.
2. Ensure equipment is stored separate from raw materials, agricultural inputs, and is protected from unintentional contamination.
3. Ensure vehicles used for transportation of product are used for vehicles intended purpose and is maintained and in good repair.
4. Clearly identify all equipment used for non-harvesting practices.
5. Ensure all hoses are stored on racks and off the floor.
6. Have all tools used for cleaning be color-coded or labeled as to its purpose.

N. Maintenance

The location shall ensure that the building and equipment are maintained as to not pose a threat to operational safety or quality. The location shall have in place a documented procedure for the maintenance of the building and equipment. The procedure shall include:

1. A master preventative maintenance schedule.
2. How the location documents unplanned maintenance.
3. Process for maintenance staff for alerting the appropriate supervisor when repairs pose a threat to product safety or quality.
4. Process for ensuring that product safety or quality is not jeopardized during maintenance.
5. Process for ensuring that any product contamination hazards (tools, lubricants, debris, etc.) are completely removed from the area being maintenance before the commencement of operations.

6. A provision for how the location controls and monitors temporary repairs, so as not to pose a risk to operational safety or quality and ensures that temporary repairs do not become permanent.

O. Calibration

The location shall ensure all equipment used to measure factors that affect safety, quality, or compliance are calibrated appropriately. The location shall:

1. Identify all equipment being calibrated with the valid calibration due date.
2. Calibrate equipment against national or international standards and according to regulatory requirements and manufacturer's recommendations.
3. Protect calibrated equipment against damage and unauthorized adjustment.

P. Water Safety and Quality

A. Water Safety and Quality Management

The location shall have a documented water management plan to ensure operational safety, quality, and regulatory compliance. The water management plan shall include:

1. A current detailed description of the flow of water used on-site including how the water is sourced and stored.
2. How water systems intended to carry wastewater are separated from water systems delivering agricultural water.
3. A risk assessment of the location's water system to determine the frequency of water testing and cleaning.
4. Microbiological and chemical analysis of the onsite water supply at a frequency decided by the location's water system risk assessment conducted by an accredited International Organization for Standardization (ISO) 17025 laboratory.
5. Methods the location uses to monitor the water systems effectiveness to product safety and quality.
6. How the location ensures all treated water complies with safety and quality specifications and regulatory requirements.
7. How the location ensures all water used for washing, treating, cleaning, and handwashing are from a verified potable source and in compliance with regulatory requirements.
8. Methods used to prevent backflow or back-siphonage.

9. Methods for which water drainage does not negatively affect the product.

Q. Air Safety and Quality

Air Safety and Quality Management

Greenhouses and other indoor facilities shall test ambient air, at minimum, annually. The location shall ensure all air or other gases that come in contact with the product or packaging process is filtered and monitored at an appropriate frequency to ensure it does not pose a risk to product safety or quality. The location shall ensure that appropriate measures are taken for odor elimination.

R. Agriculture Inputs

A. Soil Amendments, Fertilizer, and Grow Mediums

The location shall have a documented procedure in place for soil amendments, fertilizer, and grow media management. The procedure shall:

1. Ensure no untreated manure or other untreated natural fertilizers are used.
2. Evaluate all soil amendments, fertilizers, or grow media for any potential hazards.
3. Outline the methods used to treat manure and other untreated organic soil amendments.
4. Outline the verification process of treated manure and other organic soil amendments.
5. Ensure all applications of soil amendments, fertilizers, and grow media meet safety and quality specifications and regulatory compliance.
6. Outline how the location records and tracks the usage of soil amendments, fertilizers, and grow medias.
7. Ensure that inorganic and organic soil amendments, fertilizers, and grow media are stored separately and in a manner that does not pose a risk to product safety or quality.

B. Agriculture Chemicals

The location shall have a documented procedure in place for agricultural chemical management. The procedure shall ensure:

1. All agricultural chemicals are authorized for the cultivation of hemp by local regulatory authority.

2. All agricultural chemicals are used according to the manufacturer's requirements.
3. Agricultural chemical residues do not exceed regulatory requirements.
4. Employees or contractors who apply agricultural chemicals are qualified and trained in the proper application the specific agricultural chemical being applied
5. All documentation of agricultural chemicals are maintained and meet regulatory requirements and include the date of application, the chemical used, which hemp plants were sprayed, and the concentration

S. Waste Management

A. Standard Waste Disposal

The location shall ensure all standard waste is removed regularly to prevent accumulation and the attraction of pests. The location shall ensure the designated waste areas and containers are:

1. Clearly identified.
2. Clean and maintained regularly.
3. Kept sealed or closed when possible.
4. Removed or emptied regularly.

B. Hemp Waste Disposal

The location shall ensure all hemp waste is disposed of according to regulatory requirements and does not accumulate. The location shall ensure all hemp waste and waste areas are:

1. Clearly identified and labeled according to regulatory requirements.
2. Cleaned and maintained regularly.
3. Kept sealed and restricted to authorized personnel.
4. Removed regularly and according to regulatory requirements.

T. Pest and Animal Prevention

A. Pest and Animal Control Program

The location shall effectively prevent pest and animal infestations. The presence of pest and animal infestations on location shall be identified and eliminated so that they do not pose a risk to product safety or quality. The location shall have in place a documented pest and animal control program that is reviewed annually, at a minimum. The program shall:

1. Clearly define the responsibilities of the location and/or contractors involved in the development, implementation, and maintenance of the pest and animal control program.

2. Include a trap and bait station map that identifies the type, location and number of the trap or bait stations used.
3. Ensure that traps, bait stations, insect light traps, and pheromone traps are located as to not pose a risk to product safety or quality.
4. Include a list of regulatory compliant pesticides used with their Safety Data Sheets (SDS).
5. Include the frequency of the monitoring of pest and animal traps or bait stations.
6. Include how the location records and trends the sighting of pests and animals and how the location effectively handles recommendations from pest and animal control personnel.
7. Describe what to do when staff come in contact with a trap or bait stations contents.

B. Pest and Animal Control Personnel

The location shall ensure that all personnel, either location staff or external contractors, involved with the application of pesticides do not pose a threat to product safety or quality. Pest and animal control personnel shall:

1. Be trained and qualified to conduct pest and animal control activities and meet regulatory compliance.
2. Be licensed and approved by the relevant authorities.
3. Only use regulatory compliant pesticides.
4. Provide a documented report of findings and pesticides used during the inspection.

U. Cleaning and Sanitation

Cleaning and Sanitation Program

The location shall ensure the building and equipment are maintained cleanly and hygienically, as to not pose a risk to operational safety or quality. Cleaning operations should not pose a potential risk to safety or quality. Suitable cleaning areas should be provided for the cleaning of equipment and tools. Storage for clean equipment and tools should be separate from dirty equipment and tools. The location shall have in place a written cleaning and sanitation program. The program shall include:

1. What is to be cleaned.
2. Method for cleaning, including what cleaning chemicals and materials are to be used.
3. The frequency of cleaning based on risk.
4. Person(s) responsible for cleaning.

5. Person(s) responsible for cleaning verification and what method is used to verify cleanliness.

V. Chemical Controls

Chemical Control and Storage

The location shall control and store all chemicals in compliance with regulatory requirements. The location shall:

1. Have a chemical approval procedure and list of approved chemicals specific to that location's operations.
2. Store all chemicals to ensure that they do not pose a risk to product safety or quality.
3. Store food-grade chemicals separately from non-food grade chemicals.
4. Store chemicals in their original container or clearly labeled secondary containers.
5. Ensure that chemical storage areas are adequately ventilated, have appropriate signage identifying the area, and be restricted to authorized personnel only.
6. Ensure that chemical storage areas include the appropriate protective clothing, first aid equipment, and a list of approved chemicals with their respective Safety Data Sheets (SDS).
7. Dispose of all chemicals in accordance with regulatory compliance.

W. Personnel Hygiene and Welfare

A. Hand Washing

The location shall ensure personnel are effectively washing their hands at appropriate frequencies. The location shall ensure:

1. All personnel have clean hands and that hands are washed after handling something that could pose a threat to operational safety or quality.
2. Hand washing stations are easily accessible.
3. Hand washing stations have a potable water supply, are at the appropriate temperature, and are installed with a hands-free soap dispenser and paper towel dispenser.
4. Signage instructing personnel to wash their hands is prominently displayed near hand washing stations in a language understood by all staff.

B. Personnel Health Control

The location shall have a procedure in place to ensure employees are not a vector for the transmission of diseases to products. The location shall:

1. Inform all employees of the signs and symptoms of infectious diseases which would prevent them from working with products.
2. Have a system in place for all employees to report symptoms to senior management.
3. Ensure employees with exposed cuts, sores or lesions do not handle product.
4. Ensure minor exposed cuts are covered with bandages and disposable gloves.
5. Ensure areas, where the spillage of bodily fluids (blood, vomit, etc.) occurs, are adequately quarantined, cleaned, and sanitized, and released by authorized personnel.

C. Personnel Hygiene Practices

The location shall have a procedure in place to ensure that personnel practices do not negatively affect product safety or quality. The procedure shall ensure:

1. Smoking, chewing tobacco, eating, and drinking are only conducted in permitted areas away from growing, harvesting, or packaging areas (drinking water is permitted as long as it does not pose a risk to operational safety or quality).
2. Personnel do not wear false fingernails, fingernail polish, or false eyelashes.
3. Personnel fingernails are kept short and clean.
4. Personnel do not wear excessive perfume or aftershave.

D. Clothing, Jewelry, and Personnel Belongings

The location shall have in place procedures to ensure that personnel clothing, jewelry, and other personnel belongings do not pose a risk to product safety or quality. The location shall ensure:

1. That there are a sufficient number of protective clothing items for each employee.
2. Protective clothing is suitable to prevent contamination of the hemp and operations.
3. Racks are provided at staff amenities entrances and exits to ensure there is no contamination of clothing.
4. That all protective clothing (unless disposable) is effectively cleaned, either by an approved contractor or in house/policy, at a frequency that minimizes risk to product safety and quality.

5. That dirty and clean protective clothing is adequately separated, and clean clothes are protected from contamination.
6. Gloves are replaced or cleaned at a frequency that does not pose a risk to product safety or quality.
7. No jewelry, except for a plain wedding band or medical alert bracelet, shall be worn.

X. Employee Facilities

The location shall ensure employee facilities are sufficient to accommodate all personnel, are clean and maintained, and are designed to minimize the potential risk of product safety and quality. The location shall ensure:

1. Restrooms are easily accessible to personnel and are designed to not pose a risk to operational safety or quality.
2. Changing facilities are provided for all personnel and provide an area for employees to store personal items and outside clothing.
3. Lunch facilities are separated from harvesting and packaging areas and provide an area for employees to store their food in a clean and hygienic manner.

Y. Visitors

The location shall have a system in place to ensure no visitor poses a threat to operational safety or quality. Visitors shall:

1. Not be allowed to enter growing, harvesting or field packaging areas if they are showing signs of illness.
2. Wear suitable clothing and footwear.
3. Remove all jewelry and other loose objects. (Exceptions may be made for wedding bands, upon entity's discretion, applying mitigation measures, and/or assuming any risks).
4. Practice good personal hygiene and handwashing practices.

Z. Training

Training of Personnel

The location shall have in place a documented training program to ensure that all personnel, including temporary employees and contractors, are adequately trained before commencing work. The training program shall include:

1. A training matrix indicating what each employee has been trained on.
2. A provision for refresher training completed at least annually.

7. RECORD MANAGEMENT

Audit and Inspection related program documentation is retained by the HCA in a secure manner. Only authorized personnel may access the program's audit and inspection records. The content of all records, whether audit or inspection data or working papers, shall be considered confidential to the entity to which the content or data belongs unless otherwise specified in the audit plan. Audit records are retained by the HCA for three (3) years from the date of audit and/or inspection.

8. ROLES AND RESPONSIBILITIES

A. Audit Authority Responsibilities – the audit authority shall:

1. Determine the need for and initiate an audit;
2. Specify or approve the audit objectives;
3. Select the auditing body; and
4. Support the audit process.

B. Auditing Body Responsibilities – the auditing body shall:

1. Provide or acquire a valid audit program;
2. Provide qualified auditors;
3. Select a lead auditor;
4. Coordinate with the audit authority;
5. Provide quality assurance and quality control of their audit procedures, auditor qualifications, auditor effectiveness, and audit reports;
6. Provide support for the management and accountability of the audit working papers, collected data, audit findings, and audit reports; and
7. Disclose to the audit authority issues that compromise the auditing body, or audit team objectivity.

C. Lead Auditor Responsibilities – the lead auditor shall:

1. Ensure the audit process is efficient and effective;
2. Develop or lead the effort to develop the audit plan and coordinate with the audit authority as needed to meet the audit objectives;
3. Gather appropriate background information from the audited entity to support audit preparation and planning;
4. Communicate with the audited entity and manage audit plan issues. For example: schedule, logistics, access, availability, audit team needs, and health and safety precautions;
5. Assemble and manage a qualified audit team as needed;
6. Serve as the primary point of communication between the audit team and others;
7. Coordinate to prevent and resolve problems that could affect audit quality and timeliness;

8. Ensure the audit is conducted in accordance with this practice;
9. Notify the audit authority of conditions that may prevent audit completion in accordance with this practice;
10. Prepare an audit report; and
11. Communicate in writing with the audited entity regarding audit report status and issues. For example: initial findings, responses to findings, negative findings resolved during the audit, action plans that are in place, open audit issues, findings that lack objective evidence.

D. Auditor Responsibilities – the auditor shall:

1. Support the lead auditor in completing an audit (where applicable);
2. Understand the audit plan and their individual area of responsibility;
3. Follow lead auditor direction;
4. Review audit criteria and any protocols to be used, and establish a personal work plan for assigned areas of responsibility;
5. Collect sufficient relevant audit data and document data sources to support audit findings;
6. Maintain audit data and documentation in a secure manner;
7. Organize the working papers, document the audit findings and objective evidence, and prepare the audit report(s) or manage efforts to accomplish such; and
8. Disclose issues to the auditing body that may compromise objectivity.

E. Audited Entity Responsibilities – the audited entity shall:

1. Ensure that the audit is supported, including cooperating with the auditors to ensure that audit objectives are met;
2. Provide the auditing body with requested background information in a timely manner;
3. Ensure audit team is safe, timely, and has complete access;
4. Inform audit team of relevant health and safety requirements and practices;
5. Provide audit team, for the duration of the audit, with secure and reasonable support needs;
6. Provide the audit team with facility escorts knowledgeable of audited entity operations, to accompany auditors on physical inspections;
7. Assist auditor in identifying pertinent personnel and in scheduling interviews;
8. Ensure audit team access to documents needed to develop audit findings;
9. Ensure that the facilities, documents, records, methods, and operations audited accurately represent normal conditions as well as known abnormal conditions;
10. Inform audit team of abnormal conditions;
11. Evaluate and retain audit reports and determine appropriate follow-up activities;
12. Take measures to ensure that the audit team is provided with accurate and complete answers to questions;
13. Promptly notify the audit team if there is disagreement with an audit finding; and
14. If requested, provide comments on draft audit findings.

F. Auditor Qualifications and Staffing

1. Competence:
 - a. An auditor shall conduct an audit with the care, diligence, skill, and judgment expected of a professional auditor in similar circumstances.
 - b. An auditor shall have a working knowledge of the provisions of this practice and audit criteria relevant to her or his area of audit responsibility.

2. Objectivity:
 - a. Auditors shall disclose actual or potential issues compromising objectivity.
 - b. The auditing body shall disclose actual or potential issues compromising objectivity.

3. Independence:
 - a. An auditor should be independent of the audited entity. As applied to internal audits, this would require that the auditor does not have direct responsibility for the compliance of the operation under review.

4. Audit Team Staffing:
 - a. The audit team shall collectively be able to implement the audit plan. The following shall be considered in assembling an audit team:
 - i. Knowledge of audited entity operations;
 - ii. Knowledge of audit criteria;
 - iii. Experience in auditing;
 - iv. Workload;
 - v. Communication, language, technical, or other skills needed;
 - vi. Knowledge of this practice;
 - vii. Ability to remain objective;
 - viii. Ability to manage confidential business information; and
 - ix. Other audit authority requirements.

9. AUDIT PROCESS CHART

Audited Entity
Audit Preparation: <ul style="list-style-type: none">➤ Have the most current standard on-file➤ Designate an employee (and backup) to manage systems/programs to be audited➤ Conduct an Internal audit or receive an external mock audit against applicable standard➤ Correct any non-conformances from internal/mock audit
Audit Planning: <ul style="list-style-type: none">➤ Ensure all appropriate personnel are present the day of onsite audit (where applicable)
Onsite Evaluation: <ul style="list-style-type: none">➤ Opening meeting➤ Facility/ Operations inspection and/or audit➤ Documentation review➤ Conduct mock recall➤ Closing meeting
Post Audit: <ul style="list-style-type: none">➤ Follow-up audit (where applicable)➤ Close-out non-conformances within thirty (30) days from onsite evaluation➤ HCA reviews corrective actions, supporting evidence, and root cause analysis➤ If all corrective actions are satisfactory, a letter will be issued by the HCA within five (5) Seneca Nation Business Days to the Licensee. Letter shall be kept on-file by both parties for three (3) years.