

64-4.010 Inspection of Ongoing Operations.

An approved Dispensing Organization must maintain compliance with the criteria demonstrated for selection and approval as a Dispensing Organization. As such, an approved Dispensing Organization must meet the requirements set forth in Section 381.986(5)(b), Florida Statutes at all times. Failure to meet any requirement of Section 381.986(5)(b) is grounds for revocation of Approval by the department

A Dispensing Organization is bound by the representations made in the application it submitted to the department for approval. Material changes to the Dispensing Organization's operations, including significant alterations in buildouts, the use of alternative locations not described in the application, or expansion to new facilities not included in the application must be approved by the department

(1) Cultivation

(a) Technical Ability

1. Standard Operating Procedures

a. A Low-THC Cannabis cultivation Facility must have written standard operating procedures for cultivating Low-THC Cannabis.

b. A copy of all standard operating procedures must be maintained on the Approved Premises of the Dispensing Organization's Cultivation Facility.

c. If a Dispensing Organization makes a Material Change to its standard Low-THC cultivation process, it must document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Approved premises

2. Training:

a. A Dispensing Organization must have a comprehensive training manual that provides step-by-step instructions for cultivating Low-THC Cannabis. The training manual must include, but need not be limited to, the following topics:

1. The Cultivation Facility's quality control procedures;

2. The emergency procedures for that Cultivation Facility;

3. The appropriate use of any necessary safety or sanitary equipment;

4. The hazards presented by potentially harmful chemicals within the Approved Premises;

5. Clear instructions on the safe use of all equipment involved in cultivation; and

6. Any additional periodic cleaning required to comply with all applicable sanitary rules.

b. Provide adequate training to every Owner, Manager, or Employee prior to that individual undertaking any step in the process of cultivating Low-THC Cannabis.

1. Adequate training must include providing a copy of the training manual for that Approved Premises.

2. The individual training an Owner, Manager, or Employee must sign and date a document attesting that all required aspects of training were conducted and that he or she is confident that the Owner, Manager, or Employee can safely produce a Low-THC Cannabis.

3. The Owner, Manager, or Employee that received the training must sign and date a document attesting that he or she can safely implement all standard operating procedures, quality control procedures, and emergency procedures, and use all safety, sanitary and other equipment.

4. The Dispensing Organization must maintain clear and comprehensive records of the name of every individual who engaged in any step related to the cultivation of Low-THC Cannabis and the step that individual performed.

(b) Infrastructure

1. A Dispensing Organization utilizing vehicles that will be used to transport product among cultivating, cultivation, and dispensing facilities, or deliver products to patients, must demonstrate the following:

a. That each vehicle used for Dispensing Organization operations is owned or leased by the Dispensing Organization;

b. That vehicles are in good working order. Dispensing Organizations must maintain service records and maintenance logs for each vehicle in its fleet;

c. That vehicles transporting Low-THC Cannabis or Low-THC Derivative Products maintain adequate climate control to prevent spoilage; and

d. That vehicles are secure, and that Low-THC Cannabis and Low-THC Cannabis Derivative products are transported in a locked container or compartment.

2. A Dispensing Organization must be able to demonstrate the following:
 - a. That staff transporting Low-THC Cannabis or Low-THC Cannabis Derivative Products have sufficient communication equipment to contact Dispensing Organization personnel at all times; and
 - b. That the organization has viable facility communication systems to allow for communication to staff in the event of an emergency.
3. A Dispensing Organization must make reasonable efforts to mitigate odor within an approved cultivation facility.
4. A Dispensing Organization must adopt standard operating procedures for the use of cultivation back-up systems in case of emergency. Back-up equipment must be in good working order, and the Dispensing Organization must keep related maintenance logs and service records.

(c) Premises, Resources, Personnel

1. A Dispensing Organization must maintain the place and manner of any approved cultivation facility consistent with its representations to the department. Material changes to an approved facility must be approved by the Department.
2. A Dispensing Organization must ensure compliance with local building codes, zoning, sanitation, and waste disposal regulations.
3. A Dispensing Organization must maintain a list of all employees.
4. A Dispensing Organization shall take all reasonable measures and precautions to ensure the following:
 - a. That any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for Low-THC Cannabis shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected;
 - b. That hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Cultivation Facility, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices
 - c. That all persons working in direct contact with cultivation of Low-THC Cannabis shall conform to hygienic practices while on duty, including but not limited to:
 1. Maintaining adequate personal cleanliness;
 2. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the cultivation of Low-THC Cannabis;
 3. Refraining from having direct contact with Low-THC Cannabis if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected;
 - d. That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for the cultivation of Low-THC Cannabis;
 - e. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Low-THC Cannabis is grown, trimmed, dried, or stored;
 - f. That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept in good repair;
 - g. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;
 - h. That the Approved Premises provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;
 - i. That all contact surfaces, including utensils and equipment used for the cultivation, drying, trimming, or storage of Low-THC Cannabis, shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained;
 - j. That any potentially toxic chemicals used within the cultivation facility shall be identified, held, stored and disposed of in a manner that protects against contamination of Low-THC Cannabis, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance;
 - k. That all operations in the cultivation, inspecting, transporting, segregating, preparing, packaging, and storing of Low-THC Cannabis shall be conducted in accordance with adequate sanitation principles; and

1. That storage and transportation of Low-THC Cannabis and Derivative Products shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container;

5. A Cultivation Facility that engages in the cultivation of Low-THC Cannabis must:

a. Adopt standard operating procedures related to the safe use of herbicides, pesticides, and any other chemicals used in cultivation;

b. Adopt standard operating procedures related to an integrated pest management program, including protocols for the quarantine and destruction of contaminated plants; and

c. Ensure that the facility has a functioning ventilation and exhaust system sufficient to ensure a safe environment.

(d) Accountability

1. A Cultivation Facility that engages in the cultivation of Low-THC Cannabis must:

a. Ensure that all external doors, as well as doors to sensitive areas within the facility are securely locked;

b. Ensure that the facility is equipped with an alarm system sufficient to monitor for unauthorized ingress or egress;

c. Ensure 24-hour video surveillance of the cultivation facility. Surveillance footage must be stored by the Dispensing Organization and made available to the Department by request; and

d. Ensure the safe and secure storage of any Low-THC Cannabis. All safes, vaults, and storage rooms must be in good working order, with sufficient climate controls to prevent spoilage.

2. A Dispensing Organization must adopt a diversion plan that is clearly communicated to all Owners, Managers, and Employees. The diversion plan shall be included in the Dispensing Organization's training manual.

3. A Dispensing Organization must utilize an inventory tracking system for Low-THC Cannabis and derivative products, and ensure that employees are adequately trained to use the system. The Dispensing Organization must maintain staff training records related to the inventory tracking system.

4. A Dispensing Organization must adopt standard operating procedures for record keeping including, but not limited to, records required by Section 381.986, Florida Statutes and this Chapter.

5. A Dispensing Organization must adopt standard operating procedures for waste disposal that:

a. Ensures that all Low-THC Cannabis and derivative products are rendered unusable;

b. Adheres to federal, state and local laws, rules, and regulations regarding waste disposal; and

c. Prevents diversion.

6. A Dispensing Organization must reserve two samples of Low-THC Cannabis from each cultivation batch, and make those samples available to the Department for testing.

7. A Dispensing Organization must adopt step-by-step plans for the recall of any Derivative Products that have a reasonable probability of causing adverse health consequences based on a testing result, bad patient reaction, or other reason.

(2) Processing

(a) Technical Ability

1. Standard Operating Procedures

a. A Low-THC Cannabis Cultivation Facility must have written standard operating procedures for cultivating Low-THC Cannabis.

b. A copy of all standard operating procedures must be maintained on the Approved Premises of the Dispensing Organization's Processing Facility.

c. If a Dispensing Organization makes a Material Change to its standard Low-THC cultivation process, it must document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Approved premises

2. Training

a. A Dispensing Organization must have a comprehensive training manual that provides step-by-step instructions for each method used to process Low-THC Cannabis in its Processing Facilities. The training manual must include, but need not be limited to, the following topics:

1. All standard operating procedures for each method of concentrate production used at that Approved Premises;

2. The Dispensing Organization's quality control procedures;

3. The emergency procedures for that Approved Premises;

4. The appropriate use of any necessary safety or sanitary equipment;

5. The hazards presented by all solvents used within the Approved Premises;
6. Clear instructions on the safe use of all equipment involved in each process and in accordance with Dispensing Organization's instructions, where applicable; and
7. Any additional periodic cleaning required to comply with all applicable sanitary rules.

b. Provide adequate training to every Owner, Manager, or Employee prior to that individual undertaking any step in processing Low-THC Cannabis

1. Adequate training must include providing a copy of the training manual for that Approved Premises
2. The individual training an Owner, Manager, or Employee must sign and date a document attesting that all required aspects of training were conducted and that he or she is confident that the Owner, Manager, or Employee can safely process Low-THC Cannabis.
3. The Owner, Manager, or Employee that received the training must sign and date a document attesting that he or she can safely implement all standard operating procedures, quality control procedures, and emergency procedures, operate all closed-loop extraction systems, use all safety, sanitary and other equipment and understands all hazards presented by the solvents to be used within the Approved Premises and any additional period cleaning required to maintain compliance with all applicable sanitary rules.
4. The Dispensing Organization must maintain clear and comprehensive records of the name of every individual who engaged in any step related to the processing of Low-THC Cannabis and the step that individual performed.

(b) Infrastructure

1. A Dispensing Organization utilizing vehicles that will be used to transport product among cultivating, processing, and dispensing facilities, or deliver products to patients, must demonstrate the following:
 - a. That each vehicle used for that Dispensing Organization operations is owned or leased by the Dispensing Organization;
 - b. That vehicles are in good working order. Dispensing Organizations must maintain service records and maintenance logs for each vehicle in its fleet;
 - c. That vehicles transporting Low-THC Cannabis or Derivative Products maintain adequate climate control to prevent spoilage.
 - d. That vehicles are secure, and that Low-THC Cannabis and Derivative Products are transported in a locked container or compartment.
2. A Dispensing Organization must be able to demonstrate to the following:
 - a. That staff transporting Low-THC Cannabis or Derivative Products have sufficient communication equipment to contact Dispensing Organization personnel at all times.
 - b. That the organization has viable facility communication systems to allow for communication to staff in the event of an emergency.
3. A Dispensing Organization must make reasonable efforts to mitigate odor.
4. A Dispensing Organization must maintain standard operating procedures for the use of back-up systems in case of emergency. Back-up equipment must be in good working order, and the Dispensing Organization must keep related maintenance logs and service records.

(c) Premises, Resources, Personnel

1. A Dispensing Organization must maintain the place and manner of any approved processing facility consistent with its representations to the department. Material changes to an approved facility must be approved by the Department.
2. A Dispensing Organization must ensure compliance with local building codes, zoning, sanitation, and waste disposal regulations.
3. A Dispensing Organization must maintain a list of all employees.
4. A Dispensing Organization shall take all reasonable measures and precautions to ensure the following:
 - a. That any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for Low-THC Cannabis or Derivative Products shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected
 - b. That hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Approved Premises and/or in Derivative Products preparation areas and where good

sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices

c. That all persons working in direct contact with preparation of Low-THC Cannabis or Derivative Products shall conform to hygienic practices while on duty, including but not limited to:

1. Maintaining adequate personal cleanliness;

2. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the processing of a Low-THC Cannabis and at any other time when the hands may have become soiled or contaminated; and

3. Refraining from having direct contact with preparation of Low-THC Cannabis or Derivative Products if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

d. That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for processing of Low-THC Cannabis.

e. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Low-THC Cannabis or Derivative Products are exposed;

f. That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;

g. That there is adequate safety-type lighting in all areas where Low-THC Cannabis or Derivative Products are processed or stored, and where equipment or utensils are cleaned;

h. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;

i. That the Approved Premises provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;

j. That all contact surfaces, including utensils and equipment used for the processing of Low-THC Cannabis, Low-THC Cannabis Concentrate or Derivative Products, shall be cleaned and sanitized as frequently as necessary to protect against contamination. Equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained.

k. That toxic cleaning compounds, sanitizing agents, solvents used in the production of Derivative Products, and other chemicals, shall be identified, held, stored and disposed of in a manner that protects against contamination of Low-THC or Derivative Products, and in a manner that is in accordance with any applicable local, state, or federal law, rule, regulation or ordinance;

l. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Low-THC Cannabis or Derivative Products shall be conducted in accordance with adequate sanitation principles;

m. That Low-THC Cannabis or Derivative Products that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms; and

n. That storage and transport of finished Derivative Products shall be under conditions that will protect products against physical, chemical, and microbial contamination, as well as against deterioration of any container.

5. A Processing Facility that engages in the processing of Low-THC Cannabis, must:

a. Ensure that the space in which any Derivative Product is to be produced is a fully enclosed room and clearly designated on the current diagram of the Approved Premises provided to the Department.

b. Ensure standard operating procedures related to its Processing Operations for the use of analytical lab equipment.

c. Ensure that the standard operating procedure for each method used to produce Derivative Products on its Premises includes, but need not be limited to, step-by-step instructions on how to safely and appropriately:

1. Conduct all necessary safety checks prior to commencing production;

2. Prepare Low-THC Cannabis for processing;

3. Extract cannabinoids and other essential components of Low-THC Cannabis;

4. Purge any solvent or other unwanted components from a Low-THC Cannabis Concentrate,

5. Clean all equipment, counters and surfaces thoroughly; and

6. Dispose of any waste produced during the processing of Low-THC Cannabis in accordance with all applicable local, state and federal laws, rules and regulations.

7. Establish written and documentable quality control procedures designed to maximize safety for Owners, Managers, and Employees and minimize potential product contamination.

8. Establish written emergency procedures to be followed in case of a fire, chemical spill or other emergency.

d. Ensure the supply of potable and hot water shall be sufficient for the operations intended by the Dispensing Organization. Private water supplies shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the Facility's needs.

e. Ensure the safe packaging and proper labeling of all derivative products.

f. Ensure computer systems that are HIPAA compliant.

g. Ensure that the facility has a functioning ventilation and exhaust system sufficient to ensure a safe environment.

(d) Accountability

1. A Processing Facility that engages in the processing of Low-THC Cannabis Derivative Products must:

a. Ensure that all external doors, as well as doors to sensitive areas within the facility, are securely locked;

b. Ensure that the facility is equipped with an alarm system sufficient to monitor for unauthorized ingress or egress;

c. Ensure 24-hour video surveillance of the Processing facility. Surveillance footage must be stored by the Dispensing Organization and made available to the Department by request; and

d. Ensure the safe and secure storage of any Low-THC Cannabis or Low-THC Cannabis Derivative Product. All safes, vaults, and storage rooms must be in good working order, with sufficient climate controls to prevent spoilage.

2. A Dispensing Organization must adopt a diversion plan that is clearly communicated to all Owners, Managers, and Employees. The diversion plan shall be included in the Dispensing Organization's training manual.

3. A Dispensing Organization must utilize an inventory tracking system for Low-THC Cannabis and derivative products, and ensure that employees are adequately trained to use the system. The Dispensing Organization must maintain staff training records related to the inventory tracking system.

4. A Dispensing Organization must adopt standard operating procedures for record keeping including, but not limited to, records required by Section 381.986, Florida Statutes and this Chapter.

5. A Dispensing Organization must adopt standard operating procedures for waste disposal that:

a. Ensure that all Low-THC Cannabis and derivative products are rendered unusable;

b. Adheres to federal, state and local laws, rules, and regulations regarding waste disposal; and

c. Prevents diversion.

6. A Dispensing Organization must reserve two samples of Low-THC Cannabis from each Processing batch, and make those samples available to the Department for testing.

7. A Dispensing Organization must adopt step-by-step plans for the recall of any Derivative Products that have a reasonable probability of causing adverse health consequences based on a testing result, bad patient reaction, or other reason.

(4) Dispensing

(a) Technical Ability

1. Standard Operating Procedures

a. A Low-THC Cannabis cultivation Facility must have written standard operating procedures for dispensing Low-THC Cannabis.

b. A copy of all standard operating procedures must be maintained on the Approved Premises of the Dispensing Organization's Dispensing Facilities.

c. If a Dispensing Organization makes a Material Change to its standard Low-THC cultivation process, it must document the change and revise its standard operating procedures accordingly. Records detailing the Material Change must be maintained on the relevant Approved premises

2. Training

a. A Dispensing Organization must have a comprehensive training manual that provides step-by-step instructions for dispensing Low-THC Cannabis. The training manual must include, but need not be limited to, the following topics:

1. The Dispensing Organization's quality control procedures;

2. The emergency procedures for that Dispensing Facility;

3. The appropriate use of any necessary safety or sanitary equipment;
 4. Clear instructions on the safe use of all equipment, where applicable; and
 5. Any additional periodic cleaning required to comply with all applicable sanitary rules.
- b. Provide adequate training to every Owner, Manager, or Employee prior to that individual undertaking part of operations at the Dispensing Organization:
1. Adequate training must include providing a copy of the training manual for that Authorized Facility
 2. The individual training an Owner, Manager, or Employee must sign and date a document attesting that all required aspects of training were conducted and that he or she is confident that the Owner, Manager, or Employee can safely take part in Dispensing operations.
 3. The Owner, Manager, or Employee receiving the training must sign and date a document attesting that he or she can safely implement all standard operating procedures, quality control procedures, and emergency procedures, and use all safety.
 4. The Dispensing Organization must maintain clear and comprehensive records of the name of every individual who engaged in any step related to the dispensing of Low-THC Cannabis and the step that individual performed.
- (b) Infrastructure
1. A Dispensing Organization utilizing vehicles that will be used to transport product among cultivating, processing, and dispensing facilities, or deliver to patients, must demonstrate the following:
 - a. That each vehicle used for Dispensing Organization operations is owned or leased by the Dispensing Organization;
 - b. That vehicles are in good working order. Dispensing Organizations must maintain service records and maintenance logs for each vehicle in its fleet;
 - c. That vehicles transporting Low-THC Cannabis or Low-THC Cannabis Derivative Products maintain adequate climate control to prevent spoilage; and
 - d. That vehicles are secure, and that Low-THC Cannabis and Derivative Products are transported in a locked container or compartment.
 2. A Dispensing Organization must be able to demonstrate to the following:
 - a. That staff transporting Low-THC Cannabis or Low-THC Cannabis Derivative Products have sufficient communication equipment to contact Dispensing Organization personnel at all times; and
 - b. That the organization has viable facility communication systems to allow for communication to staff in the event of an emergency.
 3. A Dispensing Organization must make reasonable efforts to mitigate odor within an approved cultivation facility
 4. A Dispensing Organization must maintain standard operating procedures for the use of back-up systems in case of emergency. Back-up equipment must be in good working order, and the Dispensing Organization must keep related maintenance logs and service records.
- (c) Premises, Resources, Personnel
1. A Dispensing Organization must maintain the place and manner of any approved Dispensing Facility consistent with its representations to the department. Material changes to an approved facility must be approved by the Department.
 2. A Dispensing Organization must ensure compliance with local building codes, zoning, sanitation, and waste disposal regulations.
 3. A Dispensing Organization must maintain a list of all employees.
 4. A Dispensing Organization shall take all reasonable measures and precautions to ensure the following:
 - a. That any person who, by medical examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation or storage surfaces for Low-THC Cannabis or Derivative Products shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected
 - b. That hand-washing facilities shall be adequate and convenient and be furnished with running water at a suitable temperature. Hand-washing facilities shall be located in the Approved Premises and/or in Derivative Products preparation areas and where good sanitary practices require employees to wash and/or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices
 - c. That all persons working in direct contact with preparation of Low-THC Cannabis or Derivative Products shall conform to hygienic practices while on duty, including but not limited to:

1. Maintaining adequate personal cleanliness;
2. Washing hands thoroughly in an adequate hand-washing area(s) before starting work, prior to engaging in the dispensing of Derivative Products and at any other time when the hands may have become soiled or contaminated; and
3. Refraining from having direct contact with preparation of Low-THC Cannabis or Derivative Products if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.
- d. That there is sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for cultivation, processing, or dispensing of Low-THC Cannabis.
- e. That litter and waste are properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Low-THC Cannabis or Derivative Products are exposed;
- f. That floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and kept clean and kept in good repair;
- g. That there is adequate safety-type lighting in all areas where Low-THC Cannabis or Derivative Products are processed or stored and where equipment or utensils are cleaned;
- h. That any buildings, fixtures, and other facilities are maintained in a sanitary condition;
- i. That the Approved Premises provides adequate screening or other protection against the entry of pests. Rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;
- j. That all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of Derivative Products shall be conducted in accordance with adequate sanitation principles;
- k. That Derivative Products that can support the rapid growth of undesirable microorganisms shall be held in a manner that prevents the growth of these microorganisms; and
 1. That storage and transport of Derivative Products shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container.
5. Safe Operation: A Dispensing Facility, must:
 - a. Ensure computer systems that are HIPAA compliant.
 - b. Ensure the safe packaging and proper labeling of all derivative products.
 - c. Ensure that the facility has a functioning ventilation and exhaust system sufficient to ensure a safe environment.
- (d) Accountability
 1. A Dispensing Facility that engages in the Dispensing of Low-THC Derivative Products, must:
 - a. Ensure that external doors are securely locked when not in operation. During regular business hours, ensure that all points of ingress and egress are secure, and that doors to sensitive areas are locked.
 - b. Ensure that the facility is equipped with an alarm system sufficient to monitor for unauthorized ingress or egress;
 - c. Ensure 24-hour video surveillance of the Dispensing facility. Surveillance footage must be stored by the Dispensing Organization and made available to the Department upon request; and
 - d. Ensure the safe and secure storage of any Low-THC Cannabis or derivative product. All safes, vaults, and storage rooms must be in good working order, with sufficient climate controls to prevent spoilage
 2. Diversion: A Dispensing Organization must adopt a diversion plan that is clearly communicated to all Owners, Managers, and Employees. The diversion plan shall be included in the Dispensing Organization's training manual, and must be signed by each employee.
 3. Inventory Tracking: A Dispensing Organization must utilize an inventory tracking system for Low-THC Cannabis and derivative products, and ensure that employees are adequately trained to use the system. The Dispensing Organization must maintain staff training records related to the inventory tracking system.
 4. Record Keeping Policies and Procedures: A Dispensing Organization must adopt standard operating procedures for record keeping including, but not limited to, records required by Section 381.986, Florida Statutes and this Chapter.
 5. Compassionate Use Registry: A Dispensing Organization must adopt standard operating procedures related to the use of the Compassionate Use Registry. Records for employee training on the registry must be maintained by the Dispensing Organization.
 6. Waste Disposal: A Dispensing Organization must adopt standard operating procedures for waste disposal that:

- a. Ensure that all Low-THC Cannabis and derivative products are rendered unusable;
- b. Adheres to federal, state and local laws, rules, and regulations regarding waste disposal; and
- c. Prevents diversion.

7. Recall Plan: A Dispensing Organization must adopt a step by step plan for the recall of any Derivative Products that have a reasonable probability of causing adverse health consequences based on a testing result, bad patient reaction, or other reason.

(5) Violations: If the department identifies a violation of Section 381.986, F.S., or this chapter during an inspection of a Dispensing Organization facility, the Dispensing Organization shall notify the department in writing, within 20 calendar days after the date of receipt of the written notice of violation, identifying the corrective action taken and the date of the correction. Failure to cure violations within 20 days is grounds for revocation of authorization by the Department.

Rulemaking Authority 381.986(5)(d) FS. Law Implemented 381.986(5)(b) FS. History–New_____.