

DEPARTMENT OF PUBLIC HEALTH
AND HUMAN SERVICES

CHAPTER 107

MARIJUANA REGISTRY

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Subchapter 1

General Requirements

37.107.101 DEFINITIONS (REPEALED) (History: 50-46-210, MCA; IMP, 50-46-103, 50-46-210, MCA; NEW, 2009 MAR p. 322, Eff. 3/13/09; REP, 2011 MAR p. 2047, Eff. 9/23/11.)

37.107.102 PURPOSE (1) The purpose of these rules is to establish requirements for implementing the Montana Medical Marijuana Act. These rules outline requirements for registered cardholders, providers, marijuana-infused product providers, dispensaries, chemical manufacturing endorsements, marijuana quality assurance testing, testing laboratories, and inventory tracking system. (History: 50-46-344, MCA; IMP, 50-46-301, 50-46-303, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.103 REGISTRATION AND APPLICATION PROCESS (REPEALED) (History: 50-46-210, MCA; IMP, 50-46-103, 50-46-210, MCA; NEW, 2009 MAR p. 322, Eff. 3/13/09; REP, 2011 MAR p. 2047, Eff. 9/23/11.)

37.107.104 INVALIDATION OR REVOCATION OF REGISTRY IDENTIFICATION CARD (REPEALED) (History: 50-46-210, MCA; IMP, 50-46-103, 50-46-210, MCA; NEW, 2009 MAR p. 322, Eff. 3/13/09; REP, 2011 MAR p. 2047, Eff. 9/23/11.)

37.107.105 PROOF OF MONTANA RESIDENCY (1) If an applicant does not have a valid Montana driver license or Montana identification card, the applicant must submit documentation that shows the applicant is a resident of Montana, such as a current lease agreement or current utility bill that has the applicant's name and address.

(2) Montana residency must be maintained by registered cardholders and licensees. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-311, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

Rule 37.107.106 reserved

37.107.107 FEES (REPEALED) (History: 50-46-210, MCA; IMP, 50-46-103, 50-46-210, MCA; NEW, 2009 MAR p. 322, Eff. 3/13/09; AMD, 2009 MAR p. 2028, Eff. 10/30/09; REP, 2011 MAR p. 2047, Eff. 9/23/11.)

Rule 37.107.108 reserved

37.107.109 REPLACING LOST OR STOLEN REGISTRY IDENTIFICATION CARDS (REPEALED) (History: 50-46-210, MCA; IMP, 50-46-103, 50-46-210, MCA; NEW, 2009 MAR p. 322, Eff. 3/13/09; REP, 2011 MAR p. 2047, Eff. 9/23/11.)

37.107.110 DEFINITIONS

- (1) "Applicant" means a person applying to become a provider, marijuana-infused products provider (MIPP), or registered cardholder.
- (2) "Authorized employee" means:
 - (a) an employee of the department who has received written authorization from the Department of Public Health and Human Services director or the director's designee to obtain individual names and other identifying information from the marijuana registry;
 - (b) an employee of a state or local law enforcement agency who is authorized to obtain marijuana registry information through the Montana Criminal Justice Information Network (CJIN)/marijuana registry interface; or
 - (c) an employee of a state or local government agency, including a state or local law enforcement agency, who has received authorization to obtain marijuana registry information.
- (3) "Batch" means:
 - (a) a quantity of usable marijuana from a harvest lot; or
 - (b) a quantity of cannabinoid concentrate or extract or cannabinoid product from a process lot.
- (4) "CBD" means cannabidiol.
- (5) "CBDA" means cannabidiolic acid.
- (6) "Child resistant" means designed or constructed to be significantly difficult for children under five years of age to open and not difficult for adults to use properly. The standard for child-resistant packaging is set by the federal consumer product safety commission (CPSC) and the testing procedures found in 16 CFR 1700.20 (2012).
- (7) "Cultivate" means to grow, propagate, clone, or harvest marijuana for use by registered cardholders.
- (8) "Department" means the Department of Public Health and Human Services.
- (9) "Exit package" means a sealed container or package provided at the retail point of sale, in which any marijuana item already within a container is placed.
- (10) "Fee" means the mandatory fees required by the department.
- (11) "Financial interest" means any interest or ownership in the business or entity.
- (12) "Fingerprint card" means an FD-258 fingerprint card utilized to facilitate a Federal Bureau of Investigation (FBI) fingerprint and background check.
- (13) "Food-Grade" means the processing and packaging has been done with clean equipment and can be safely eaten.
- (14) "Harvest lot" means a specifically identified quantity of marijuana that is cultivated utilizing the same growing practices, harvested within a 72 hour period at the same location, and cured under uniform conditions. A harvest lot may contain multiple strains.

(15) "ISO" means International Organization for Standardization.

(16) "Landlord permission form" means a completed, signed, and notarized form which gives a registered cardholder, applicant, or licensee who is renting or leasing the property where marijuana will be cultivated and manufactured for medical purposes, permission to do so, by the property owner. The form must be provided by the department.

(17) "Licensee" means any person licensed by the department.

(18) "Limited access area" means a building, room, or other contiguous area upon the registered premises where marijuana is grown, cultivated, stored, weighed, packaged, sold, or processed for sale, under the control of the licensee.

(19) "Manufacture" means the act of preparing and processing usable marijuana into a marijuana-infused product. A marijuana-infused product must be labeled as to indicate that it contains marijuana.

(20) "Marijuana items" means:

- (a) marijuana;
- (b) usable marijuana;
- (c) dried leaves and flowers of the marijuana plant;
- (d) marijuana derivatives, concentrates, extracts, resins, infused products, edible products, ointments, tinctures, suppositories, topicals; and
- (e) other marijuana-related products.

(21) "Physician statement" means a written statement by a Montana licensed physician on department forms certifying the registered cardholder applicant's debilitating condition. Physician statement forms include:

- (a) Physician Statement for Debilitating Condition; or
- (b) Physician Statement for Minors.

(22) "Process lot" means:

- (a) any amount of cannabinoid concentrate or extract of the same type and processed at the same time using the same extraction methods, standard operating procedures, and test batches from the same or different harvest lots; or
- (b) any amount of cannabinoid products of the same type and processed at the same time using the same ingredients, standard operating procedures, and test batches from the same or different harvest lots or process lots of cannabinoid concentrate or extract.

(23) "Proof of residency" means a readable photocopy of a current Montana driver's license or Montana state-issued identification card.

(24) "Registered premises" means the premises specified in an application for a license that is owned or in possession of the licensee and within which the licensee is authorized to cultivate, manufacture, dispense, store, transport, or test medical marijuana.

(25) "Registry" means the department's confidential record identifying registered cardholders.

(26) "Test Batch" means a portion of a harvest or process lot that has been submitted for quality assurance testing.

(27) "THC" means tetrahydrocannabinol.

(28) "THCA" means tetrahydrocannabinolic acid. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-307, 50-46-308, 50-46-310, 50-46-318, 50-46-344, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11; AMD, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.111 REGISTERED CARDHOLDER APPLICATION PROCESS

- (1) An applicant must be a resident of the State of Montana under 1-1-215, MCA.
- (2) All applications must be completed on forms provided by the department.
- (3) A complete application must include the required fee, statements, and forms required in the application packet to be accepted and processed by the department.
- (4) The registry identification card expires one year from the date of issuance with the exception of the following:
- (a) the physician statement provides a written certification for a shorter period of time; or
 - (b) a registered cardholder changes provider or marijuana-infused products provider.
- (5) Renewal applications must be submitted within 30 calendar days prior to the expiration date of the license.
- (6) The department will approve or deny an application within 30 calendar days of receiving a complete application.
- (7) A registered cardholder may not purchase, grow, or possess marijuana items prior to the effective date of the registration card.

(8) Any denial under this part is subject to judicial review.

(9) A custodial parent or legal guardian may submit an application for a minor under 50-46-307, MCA.

(10) An applicant must designate either a licensed provider or licensed marijuana-infused products provider, unless the registered cardholder intends to cultivate or manufacture marijuana for their own use under 50-46-303, MCA. If the registered cardholder intends to cultivate or manufacture marijuana for their own use, a landlord permission form must also be submitted if applicable. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-307, 50-46-310, 50-46-344, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11; AMD, 2018 MAR p. 321, Eff. 4/10/18.)

Rule 37.107.112 reserved

37.107.113 MINOR APPLICATION PROCESS (REPEALED) (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-307, 50-46-344, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11; REP, 2018 MAR p. 321, Eff. 4/10/18.)

Rule 37.107.114 reserved

37.107.115 LICENSE AND ENDORSEMENT APPLICATION PROCESS

(1) An applicant must be a resident of the State of Montana under 1-1-215, MCA.

(2) All applications must be completed on forms provided by the department.

(3) A complete application must include the required fee, statements, forms, diagrams, operation plans, and other applicable documents required in the application packet to be accepted and processed by the department.

(4) Applicants include, but are not limited to:

(a) any individual or legal entity who holds or controls an interest, ownership, or partnership in the business or entity;

(b) all directors; and

(c) principal officers of corporate applicants.

(5) The license will expire one year from the date of issuance.

(6) Renewal applications must be submitted at least 30 calendar days prior to the expiration date of the license.

(7) The department will approve or deny an application within 30 calendar days of receiving a complete application.

(8) Prior to approving an application, the department may contact any applicant or individual listed on the application and request additional supporting documentation or information.

(9) Prior to issuing a license or endorsement, the department will inspect the proposed premises to determine if the applicant complies with these rules and Montana statute.

(10) If a licensee fails to submit a renewal application prior to the license or endorsement expiration date, the licensee may not continue to operate.

(11) If a renewal application is received within 30 days of expiration, the department may process the application.

(12) The department will not consider renewal applications received more than 30 days after the license or endorsement expiration date.

(13) An applicant or licensee may request a chemical manufacturing endorsement or dispensary license upon submission of an initial application or at any time following licensure.

(14) Chemical manufacturing endorsements and dispensary licenses issued under this rule will expire the same date of the provider license or marijuana-infused product provider license.

(15) A licensee:

(a) may not operate until on or after the effective date of the license; and

(b) must display proof of licensure in a prominent place on the registered premises.

(16) A license or endorsement may not be sold or transferred.

(17) Any denial under this part is subject to judicial review. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-309, 50-46-344, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11; AMD, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.116 CHEMICAL MANUFACTURING ENDORSEMENTS

(REPEALED) (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-312, 50-46-319, 50-46-328, 50-46-329, 50-46-344, MCA; NEW, 2017 MAR p. 1911, Eff. 10/28/17; REP, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.117 FEES (1) An applicant must submit to the department the following fees with the initial application and renewal application:

- (a) registered cardholder application fee of \$30;
- (b) provider or marijuana-infused product provider with:
 - (i) ten or fewer registered cardholders, an application fee of \$1,000;
 - (ii) 11 to 49 registered cardholders, an application fee of \$2,500;
 - (iii) 50 or more registered cardholders, an application fee of \$5,000.
- (c) a combined provider and marijuana-infused product provider with more than 10 registered cardholders, an application fee of \$5000;
- (d) dispensary license application fee of \$500;
- (e) chemical manufacturing endorsement application fee of \$500;
- (f) testing laboratory application fee of \$2000;
- (g) marijuana employee permit fee of \$10 for each individual licensee employee listed on application and any subsequent hires; or
- (h) a caretaker relative, caretaker custodial parent, or legal guardian provider fee of \$100.

(2) All fees must be submitted with the application and must be made payable to the Department of Public Health and Human Services. Cash is not accepted.

(3) Fees are nonrefundable regardless of final application status. (History: 50-46-344, MCA; IMP, 50-46-344, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11; AMD, 2012 MAR p. 1061, Eff. 5/25/12; AMD, 2016 MAR p. 1166, Eff. 7/9/16; AMD, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.118 MARIJUANA AND MARIJUANA-INFUSED PRODUCTS
PROVIDER LICENSEE REQUIREMENTS

(1) A licensee must clearly identify all limited access areas at a registered premises.

(2) All licensee employees must wear a department-issued identification badge.

(3) A licensee must maintain a daily log of all visitor activity on a registered premises. The log must contain the visitor's first and last name and date of visit.

(4) Visitors must be accompanied by a licensee or licensee employee at all times.

(5) A licensee must post signs inside the registered premises in a conspicuous location that read:

(a) "No Minors Permitted on This Premises Except When Accompanied By An Adult"; and

(b) "No On-Site Consumption of Marijuana except by registered cardholders".

(6) A licensee may have up to 50 square feet of canopy space per registered cardholder:

(a) square footage of canopy space is measured horizontally starting from the outermost point of the furthest mature flowering plant in a designated growing space and continuing around the outside of all mature flowering plants located within the designated growing space;

(b) a licensee may designate multiple grow areas at a registered premises but those spaces must be separated by a physical boundary such as an interior wall or by at least eight feet of open space;

(c) total canopy size is calculated by multiplying 50 square feet of canopy by the number of registered cardholders; and

(d) a licensee must not exceed the total canopy allowed by the department for cultivation of marijuana.

(7) A licensee is responsible for the security of all marijuana items on a registered premises, in transit, and under the supervision of any licensee or licensee employee until the marijuana item is sold.

(8) A licensee must have a written security plan maintained on the registered premises that safeguards against theft, diversion, or tampering of marijuana items both on the registered premises and during transit.

(9) Commercial grade, nonresidential door locks must be installed on every external door and gate of a registered premises.

(10) A licensee must ensure general sanitary requirements are met on a registered premises to include:

- (a) hand-washing facilities;
- (b) proper and timely removal of all litter and waste; and
- (c) toilet facilities that are maintained in a sanitary condition and good repair.

(11) A licensee must establish written standard operating procedures to produce marijuana and maintain them on the registered premises. The standard operating procedures must include:

- (a) when and how all pesticides or other chemicals are to be applied during the production process;
- (b) water usage and waste water disposal;
- (c) the waste disposal plan; and
- (d) any other written procedures as required by the department.

(12) If a licensee makes a material change to its standard operating procedures it must document the change and revise its standard operating procedures accordingly.

(13) A licensee must use a standardized scale whenever marijuana items are:

- (a) packaged for sale by weight;
- (b) bought and sold by weight; and
- (c) weighed for entry into the inventory tracking system.

(14) A licensee must maintain the following records in either paper or electronic form on the registered premises for at least three years:

- (a) financial records that clearly reflect all financial transactions; and
- (b) all licensee employee training and payroll records.

(15) A licensee must establish written emergency procedures to be followed in case of a fire, chemical spill, or other emergency at all registered premises.

(16) In addition to other records required by these rules, a licensee must maintain on the registered premises:

- (a) the material safety data sheet for all pesticides, fertilizers, or other agricultural chemicals used in the production of marijuana;
- (b) the original label or a copy thereof for all pesticides, fertilizers, or other agricultural chemicals used in the production of marijuana; and
- (c) a log of all pesticides, fertilizers, or other agricultural chemicals used in the production of marijuana.

(17) The licensee must maintain documentation of meeting all local jurisdiction requirements such as licensing, fire, health, and safety.

(18) A licensee may not:

(a) give marijuana items as a prize, premium or consideration for a lottery, contest, game of chance or game of skill, or competition of any kind;

(b) sell or transfer to a registered cardholder any marijuana item through a drive-up window; or

(c) treat or otherwise alter usable marijuana, consisting of dried leaves and flowers, with the intent of altering the color, appearance, weight, or smell. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-312, 50-46-319, 50-46-326, 50-46-328, 50-46-329, 50-46-330, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.119 FINGERPRINT AND BACKGROUND CHECK REQUIREMENTS

(1) A fingerprint background check by the Montana Department of Justice and Federal Bureau of Investigation is required for the following:

(a) all individuals listed on the application; and

(b) a parent or guardian of a minor serving as the minor's provider.

(2) Two fingerprint cards must be completed by a trained individual within a certified fingerprinting agency and submitted to the department.

(3) If an adequate set of fingerprints cannot be obtained, a federal name-based background check can be conducted but may take up to 90 days to complete.

(4) Fingerprint background checks are required with the initial application and annual renewal applications.

(5) Results of background checks must be received prior to approval of any application.

(6) If the certified fingerprinting agency charges a fee for fingerprinting, the applicant is responsible for the fee. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-344, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11; AMD, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.120 MARIJUANA EMPLOYEE PERMIT (1) A marijuana employee permit is required for any employee of a licensee prior to working.

(2) The marijuana employee permit must always be carried when performing work on behalf of a licensee.

(3) The department will issue providers two department-issued volunteer badges to be used for no more than 300 hours per volunteer per year. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-311, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.121 INCOMPLETE APPLICATION, RENEWAL, OR CHANGE REQUESTS (REPEALED) (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-344, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11; REP, 2018 MAR p. 321, Eff. 4/10/18.)

Rule 37.107.122 reserved

37.107.123 PROPERTY RESTRICTIONS (REPEALED) (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-344, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11; REP, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.124 TRANSPORTATION AND DELIVERY OF MARIJUANA ITEMS

(1) Marijuana items may only be transported between a registered premises, licensed testing laboratories, or a registered cardholder's home by a licensee or licensee employee.

(2) A printed transport manifest must accompany every transport of marijuana items. The manifest must contain the following information:

- (a) registered premises address and license number of departure location;
- (b) address and license number or cardholder number of receiving location;
- (c) product name, quantities (by weight or unit), and unique identification numbers of each marijuana item to be transported;
- (d) date and time of departure;
- (e) date and time of arrival;
- (f) delivery vehicle make, model, and license plate number; and
- (g) name and signature of each licensee or licensee employee accompanying the transport.

(3) The transport manifest may not be voided or changed after departing from the originating registered premises.

(4) A copy of the transport manifest must be given to each location receiving the inventory described in the transport manifest.

(5) A registered premises is prohibited from receiving any marijuana items from transit without a valid transport manifest.

(6) The receiving location must ensure that the marijuana items received are as described in the transport manifest and must record receipt of the inventory.

(7) The receiving location must document any differences between the quantity specified in the transport manifest and the quantities received.

(8) Any vehicle transporting marijuana items must be capable of:

- (a) keeping marijuana items in transit shielded from public view;
- (b) securing (locking) the marijuana items during transportation; and
- (c) being temperature controlled if perishable marijuana items are being transported.

(9) A licensee must contact the department within 24 hours if a vehicle transporting marijuana items is involved in an accident that involves product loss.

(10) Copies of the transport manifest and delivery receipts must be presented to law enforcement officers or authorized department employees if requested. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-311, 50-46-319, 50-46-326, 50-46-329, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.125 REPLACING LOST OR STOLEN REGISTRY IDENTIFICATION CARDS (REPEALED) (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-344, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11; REP, 2018 MAR p. 321, Eff. 4/10/18.)

Rule 37.107.126 reserved

37.107.127 DENIAL OF REGISTRY IDENTIFICATION CARD APPLICATION OR REVOCATION OF REGISTRY IDENTIFICATION CARD (1) The department, after written notice to the applicant or registered cardholder, may deny or revoke an application or registry identification card if:

- (a) the applicant did not provide the information required in the application;
- (b) the department determines the information provided in the application was inaccurate, misleading or falsified;
- (c) the applicant did not submit the required fee with the application;
- (d) the applicant or registered cardholder does not have or no longer has a debilitating medical condition as defined in 50-46-302, MCA;
- (e) the applicant is not a resident of the State of Montana;
- (f) the applicant is in the custody of or under supervision of the Department of Corrections or youth court;
- (g) the applicant or registered cardholder has been convicted of driving under the influence of alcohol or drugs under 50-46-320, MCA;
- (h) the applicant or registered cardholder is found to be in violation of 50-46-330, MCA;
- (i) the department is notified in writing by a landlord revoking permission under 50-46-307, MCA;
- (j) the applicant or registered cardholder did not report changes to the department in accordance with ARM 37.107.415;
- (k) the registry identification card has been found to be altered or manipulated in any way; or
- (l) any violations otherwise under Title 50, chapter 46, part 3, MCA have occurred.

(2) Any denial or revocation under this part is subject to judicial review. (History: 50-46-344, MCA; IMP, Section 35, Ch. 419, L. 2011, 45-9-203, 50-46-303, 50-46-308, 50-46-320, 50-46-344, 61-11-101, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11; AMD, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.128 LEGAL PROTECTIONS - ALLOWABLE AMOUNTS (1) A registered cardholder who has not named a provider may possess up to 1 ounce of usable marijuana. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-312, 50-46-319, 50-46-328, 50-46-329, 50-46-344, MCA; NEW, 2017 MAR p. 1911, Eff. 10/28/17; AMD, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.129 NOTIFICATION TO LOCAL LAW ENFORCEMENT (REPEALED) (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-344, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11; REP, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.130 DENIAL OR REVOCATION OF APPLICATION, LICENSE, OR ENDORSEMENT (1) The department, after written notice to the applicant or licensee, may deny or revoke an application, license, or endorsement if:

- (a) the applicant did not provide the information required in the application;
- (b) the department determines the information provided in the application was inaccurate, misleading, or falsified;
- (c) the applicant did not submit the required fee with application;
- (d) the applicant is not a resident of the State of Montana as defined in 1-1-215, MCA;
- (e) the department is notified in writing by a landlord revoking permission under 50-46-308, MCA;
- (f) the applicant or licensee is found to be in violation of 50-46-308, 50-46-311, and 50-46-312, MCA;
- (g) a provider or marijuana-infused product provider has been convicted of driving under the influence of alcohol or drugs under 50-46-320, MCA;
- (h) a provider or marijuana-infused product provider is found to be in violation of 50-46-320(8), MCA;
- (i) the applicant or licensee is found to be in violation of 50-46-330, MCA;
- (j) the applicant or licensee did not report changes to the department in accordance with ARM 37.107.415;
- (k) the licensee is no longer named as a provider or marijuana-infused product provider by a registered cardholder;
- (l) the applicant is not in substantial compliance with any other licensing requirements established by this chapter; or
- (m) the applicant or licensee is found to be in violation of any provision under Title 50, chapter 46, part 3, MCA.

(2) Any denial or revocation under this part is subject to judicial review.

(3) A person whose application has been denied or a current licensee whose license has been revoked may not reapply for at least six months from the date of denial or revocation. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-312, 50-46-329, 50-46-330, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.131 HEALTH CARE FACILITY PROCEDURES (1) A residential health care facility must develop a policy regarding the use of marijuana within the facility.

(2) Should the facility choose to allow the use of marijuana by residents, the policy and procedures must cover, at a minimum:

- (a) compliance with the Montana Clean Air Act;
- (b) methods the facility will allow for the resident use of marijuana;
- (c) physical security of the marijuana; and
- (d) resident confidentiality.

(3) A policy addressing delivery of hospice services related to the use of marijuana for resident or patient use must be developed. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-320, 50-46-344, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11.)

37.107.132 TESTING LABORATORIES (REPEALED) (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-311, 50-46-312, 50-46-328, 50-46-329, 50-46-344, MCA; NEW, 2017 MAR p. 1911, Eff. 10/28/17; REP, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.133 COMPLAINT HOTLINE (REPEALED) (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-342, 50-46-344, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11; REP, 2018 MAR p. 321, Eff. 4/10/18.)

Rule 37.107.134 reserved

37.107.135 DISCLOSURE OF CONFIDENTIAL MARIJUANA REGISTRY INFORMATION (REPEALED) (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-344, MCA; NEW, 2011 MAR p. 2047, Eff. 9/23/11; REP, 2018 MAR p. 321, Eff. 4/10/18.)

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Subchapter 2

Marijuana-Infused Products, Concentrates,
and Extracts; Inventory Tracking

Rules 37.107.201 to 37.107.203 reserved

37.107.204 PRODUCING MARIJUANA-INFUSED PRODUCTS,
CONCENTRATES, AND EXTRACTS (1) To produce marijuana-infused products or
engage in chemical manufacturing, a licensee must:

- (a) ensure the registered premises and equipment are maintained in a clean and sanitary condition for product preparation purposes;
 - (b) use equipment, counters, and surfaces for processing that are food grade, do not react adversely with any solvent being used, reduce the potential for development of microbials, molds and fungi, and can be easily cleaned;
 - (c) maintain detailed instructions for making each infused product, concentrate, or extract;
 - (d) conduct necessary safety checks prior to commencing processing; and
 - (e) create written detailed operating procedures for:
 - (i) cleaning all equipment, counters, and surfaces thoroughly;
 - (ii) proper handling and storage of any solvent, gas, or other chemical used in processing or on the registered premises;
 - (iii) proper disposal of any waste produced during processing;
 - (iv) training licensee employees on how to use the system and handle and store the solvents and gases safely; and
 - (v) any other written procedures required by the department.
- (2) A licensee with a chemical manufacturing endorsement must:
- (a) only use hydrocarbon-based solvents that are at least 99 percent pure, except when using solvents outlined in (3);
 - (b) only use nonhydrocarbon-based solvents that are food grade;
 - (c) work in an environment with proper ventilation, controlling all sources of ignition where a flammable atmosphere is or may be present;
 - (d) use only potable water and ice made from potable water in processing;
 - (e) process in a fully enclosed room;
 - (f) use a professional grade closed loop extraction system designed to recover the solvents;
 - (g) have equipment and facilities used in processing approved for use by the local fire code official;
 - (h) have an emergency eye-wash station in any room in which chemical manufacturing is occurring;
 - (i) have all applicable material safety data sheets readily available; and
 - (j) establish written emergency procedures to be followed in case of a fire, chemical spill, or other emergencies at all registered premises.

- (3) A licensee with a chemical manufacturing endorsement may use:
- (a) a mechanical extraction process;
 - (b) a chemical extraction process using a nonhydrocarbon-based or other solvent, such as water, vegetable glycerin, vegetable oils, animal fats, isopropyl alcohol or ethanol; or
 - (c) a chemical extraction process using the solvent carbon dioxide, provided that the process:
 - (i) does not involve the use of heat over 180 degrees fahrenheit; and
 - (ii) uses a professional grade closed-loop carbon dioxide gas extraction system where every vessel is rated to a minimum of six hundred pounds per square inch.
- (4) A licensee with a chemical manufacturing endorsement may not use:
- (a) class I solvents;
 - (b) pressurized canned flammable fuel intended for use in camp stoves, handheld torch devices, refillable cigarette lighters, and similar products; or
 - (c) denatured alcohol.
- (5) A licensee may not treat or otherwise alter a marijuana item with any noncannabinoid additive that would increase potency, toxicity, or addictive potential that would create an unsafe combination with other psychoactive substances.
- (6) All licensees using solvent-based or solvent-free extraction processes authorized under this rule must obtain a chemical manufacturing endorsement. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-312, 50-46-328, 50-46-329, 50-46-330, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.205 INVENTORY TRACKING SYSTEM USER REQUIREMENTS

- (1) A licensee must have a department inventory tracking system account activated and functional prior to operating or exercising any privileges of the license and must maintain an active account while licensed.
- (2) Additional licensees or licensee employees may be authorized to obtain inventory tracking system user accounts.
- (3) To obtain and maintain an inventory tracking system user account, a licensee or licensee employee must successfully complete all required department inventory tracking system training.
- (4) An individual entering data into the inventory tracking system may only use that individual's inventory tracking system account.
- (5) A licensee must ensure:
 - (a) all inventory tracking system users are up to date on inventory tracking system user training requirements; and
 - (b) any data that is entered into the inventory tracking system in error is corrected.
- (6) A licensee and any designated inventory tracking system user must enter data into the inventory tracking system that accounts for all inventory tracking activities.
- (7) A licensee is accountable for all actions inventory tracking system users take while logged into the inventory tracking system.
- (8) A licensee is responsible for the accuracy of all information entered into the inventory tracking system.
- (9) Nothing in this rule prohibits a licensee from using secondary separate software applications to collect information to be used by the business including secondary inventory tracking or point of sale systems.

(10) If a licensee uses a separate software application that links to the inventory tracking system it must get approval from the inventory tracking system vendor contracting with the department and the software application must:

(a) accurately transfer all relevant inventory tracking system data to and from the inventory tracking system; and

(b) preserve original inventory tracking system data when transferred to and from a secondary application.

(11) If a licensee loses access to the inventory tracking system, the licensee must keep and maintain comprehensive records detailing all tracking inventory activities that were conducted during the loss of access.

(12) Once access is restored, all inventory tracking activities that occurred during the loss of access must be entered into the inventory tracking system.

(13) A licensee must document when access to the inventory tracking system was lost and when it was restored.

(14) All compliance notifications from the inventory tracking system must be resolved in a timely fashion. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-311, 50-46-319, 50-46-326, 50-46-329, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.206 INVENTORY TRACKING AND RECONCILIATION (1) A licensee must use the department's selected inventory tracking system as the primary inventory and record keeping system.

(2) Each individual marijuana plant that reaches a height of twelve inches must be issued a unique identification number in the inventory tracking system, which follows the plant through all phases of production and final sale to a registered cardholder.

(3) All marijuana items, test batches, harvest lots, and process lots must be issued a unique identification number in the inventory tracking system.

(4) Unique identification numbers cannot be reused.

(5) Each marijuana plant, marijuana item, test batch, harvest lot, and process lot that has been issued a unique identification number must have a physical tag placed on it with the unique identification number.

(6) The tag must be legible and placed in a position that can be clearly read and must be kept free from dirt and debris.

(7) Licensees must use unique identification tags provided by the department.

(8) All on-premises and in-transit marijuana item inventories must be reconciled in the inventory tracking system at the close of business each day.

(9) For each marijuana sale or transfer to a registered cardholder, the following must be recorded in the inventory tracking system at the close of business each day:

- (a) the amount;
- (b) the price before tax; and
- (c) the date of the sale or transfer to a registered cardholder.

(10) Licensees must record in the inventory tracking system:

- (a) wet weight of all harvested marijuana plants immediately after harvest;
- (b) information for marijuana items by unit count;
- (c) weight per unit of a product;
- (d) weight and disposal of post-harvest waste materials;
- (e) theft or loss of marijuana items; and
- (f) other information as may be required by the department.

(11) These requirements do not apply to marijuana items held by a laboratory licensee that are undergoing analytical testing, so long as the marijuana items do not leave the laboratory's licensed premises and are reconciled on the same day that the quality assurance testing concludes.

(12) All samples taken for quality assurance testing must be recorded in the inventory tracking system.

(13) Licensed testing laboratories must record all testing results in the inventory tracking system.

(14) All transport manifests must be generated by the inventory tracking system and contain all the information required by these rules.

(15) A receiving location must document in the inventory tracking system any marijuana items received, and any differences between the quantity specified in the transport manifest and the quantities received. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-311, 50-46-319, 50-46-326, 50-46-329, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

Subchapter 3
Testing Laboratories

Rules 37.107.301 through 37.107.304 reserved

37.107.305 MARIJUANA TESTING LABORATORY LICENSEE REQUIREMENTS (1) A licensed marijuana testing laboratory may:

(a) obtain samples of marijuana items from licensees for testing as provided in these rules;

(b) transport and dispose of samples as provided in these rules; and

(c) perform testing on marijuana items in a manner consistent with the laboratory's accreditation.

(2) A licensed laboratory may return a marijuana item obtained for purposes of testing to the licensee. The return of such marijuana items must be documented.

(3) A laboratory must document the following:

(a) receipt of samples for testing;

(b) size of the sample;

(c) licensee from whom the sample was obtained;

(d) date the sample was collected;

(e) tests performed on samples;

(f) date testing was performed;

(g) results of all testing performed; and

(h) disposition of any testing sample material.

(4) A licensee must clearly identify all limited access areas at the premises.

(5) All licensee employees must wear a badge or clothing that easily identifies the individual as an employee.

(6) A licensee must maintain a daily log of all visitor activity to a limited access area on a registered premises. The log must contain the first and last name the date they visited.

(7) Visitors must be accompanied by a licensee or licensee employee at all times.

(8) A licensee is responsible for the security of all marijuana items on the premises, in transit, and under the supervision of any licensee or licensee employee.

(9) A licensee must have a written security plan maintained on the premises that adequately safeguards against theft, diversion, or tampering of marijuana items both on the premises and during transit.

(10) Commercial grade, nonresidential door locks must be installed on every external door, and gate if applicable, of premises.

(11) A licensee must ensure general sanitary requirements are met on the premises to include:

- (a) adequate and convenient hand-washing facilities;
- (b) proper and timely removal of all litter and waste;
- (c) adequate and readily accessible toilet facilities that are maintained in a sanitary condition and good repair;
- (d) prohibiting a licensee or licensee employee with a communicable disease, open or draining skin lesions, or any illness accompanied by diarrhea or vomiting from working on a premises until the condition is corrected if the individual has a reasonable possibility of contacting marijuana items; and
- (e) assurance that the licensee or licensee employees wash hands thoroughly before starting work, prior to having contact with a marijuana item, and at any other time when the hands may have become soiled or contaminated.

(12) A licensee must establish written standard operating procedures for each test being conducted and maintain them on the premises.

(13) A licensee must maintain the following records for at least three years. Records may be kept in either paper or electronic form on the premises:

- (a) financial records that clearly reflect all financial transactions;
- (b) testing documentation; and
- (c) all licensee employee training and payroll records.

(14) A licensee must establish written emergency procedures to be followed in case of a fire, chemical spill, or other emergency at all premises. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-311, 50-46-312, 50-46-326, 50-46-328, 50-46-329, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.306 MARIJUANA TESTING LABORATORIES ACCREDITATION

(1) A laboratory licensee must be ISO 17025 accredited.

(2) An applicant, after providing written evidence of pending ISO 17025 accreditation:

(a) may submit an application for licensure pending the accreditation approval; and

(b) is eligible for a provisional license not to exceed six months.

(3) A licensed laboratory must maintain accreditation at all times.

(4) If a laboratory's accreditation lapses or is revoked, the laboratory may not perform any activities until it is reinstated. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-311, 50-46-312, MCA; NEW 2018 MAR p. 321, Eff. 4/10/18.)

Subchapter 4
Quality Assurance Compliance

37.107.401 LABELING OF MARIJUANA ITEMS (1) Prior to marijuana items being sold or transferred to a registered cardholder the container holding the usable marijuana items must have a label that has the following information:

- (a) licensee business or trade name and licensee registration number;
- (b) date of harvest of marijuana or date the marijuana item was manufactured;
- (c) name of strain or marijuana item (common or usual name);
- (d) net weight or volume in U.S. customary and metric units;
- (e) concentration by weight or volume of THC, THCA, CBD, and CBDA; and
- (f) unique identification number.

(2) Labels must include a consumer warning that states:

- (a) "For use by Montana Medical Marijuana Program registered cardholders only. Keep out of reach of children.";
- (b) "It is illegal to drive a motor vehicle while under the influence of marijuana."; and
- (c) "This product is not approved by the U.S. Food and Drug Administration (FDA) to treat, cure, or prevent any disease."

(3) If the marijuana item has passed required testing, the licensee must include on the label: "This Product Has Been Tested and Meets the Quality Assurance Requirements of the State of Montana."

(4) Licensees with ten or fewer registered cardholders who are not required to submit marijuana items for testing and have not submitted marijuana items for testing must include on the label: "This Product Has Not Been Tested for compliance with Quality Assurance Requirements of the State of Montana."

(5) Additional labeling requirements for marijuana topicals, ointments, suppositories, and other marijuana products not intended to be administered orally must include:

- (a) "DO NOT EAT" in bold capital letters; and
- (b) a list of ingredients in descending order or predominance by weight or volume used to process the product.

(6) Additional labeling requirements for edible marijuana products and tinctures must include:

- (a) "BE CAUTIOUS" in bold capital letters, followed by "This product can take up to two hours or more to take effect";
- (b) if the marijuana item is perishable, a statement that the marijuana item must be refrigerated or kept frozen;
- (c) list of potential major food allergens;
- (d) a "contains" statement to summarize the major food allergen information at the end of or immediately adjacent to the ingredient list; or
- (e) a statement of the appropriate major food allergen in parenthesis within the ingredient list after the common or usual name of the ingredient derived from that major food allergen.

(7) Additional labeling requirements for marijuana concentrates and extracts must include:

- (a) "DO NOT EAT" in bold capital letters;
- (b) extraction method and solvent.

(8) Labels required by these rules must:

- (a) be placed on the container and on any packaging, that is used to display marijuana items for sale or transfer to a registered cardholder;
- (b) be in no smaller than eight point Times New Roman, Helvetica, or Arial font;

- (c) be in English; and
- (d) be unobstructed and conspicuous.

(9) Marijuana items may have one or more labels affixed to the container or packaging if necessary.

(10) Licensees may use a peel-back or accordion label with the required information if the peel-back or accordion label can be easily identified by a registered cardholder as containing important information.

(11) A label may not:

- (a) contain any untruthful or misleading statements; or
- (b) be attractive to minors. For the purpose of this rule, "attractive to minors" means packaging, labeling and marketing that features:
 - (i) cartoons;
 - (ii) designs, brands, or names that resemble a non-cannabis consumer product of the type that is typically marketed to minors;
 - (iii) symbols or celebrities that are commonly used to market products to minors;
 - (iv) images of minors; or
 - (v) words that refer to products that are commonly associated with minors or marketed by minors.

(12) If a marijuana item is placed in a package that is being reused, the old label or labels must be removed and it must have a new label or labels.

(13) Exit packaging must contain a label that reads: "Keep out of the reach of children." (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-326, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.402 PACKAGING FOR SALE TO CONSUMER (1) Containers or packaging for usable marijuana items must protect the product from contamination and must not impart any toxic or deleterious substance to the product.

(2) Marijuana items for final sale to a consumer must be:

(a) packaged in a container that is child-resistant as defined in ARM 37.107.110; and

(b) labeled in accordance with ARM 37.107.401. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-326, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.405 QUALITY ASSURANCE TESTING SAMPLE REQUIREMENTS

(1) A licensee must separate each harvest lot of usable marijuana into no larger than five-pound test batches.

(2) A licensee must separate each process lot of a marijuana-infused product into no larger than 5,000 unit-of-sale test batches.

(3) A process lot is considered a test batch for marijuana concentrates and extracts.

(4) Usable marijuana consisting of dried leaves and flowers may only be sampled after it is cured.

(5) Sufficient sample increments must be taken for analysis of all required tests and the quality control performed by the testing laboratory for these tests.

(6) A licensee must provide a laboratory the following documentation at the time of testing:

(a) the unique identification number;

(b) licensee business or trade name and licensee registration number;

(c) the date the sample was collected;

(d) the weight of the sample; and

(e) whether the tests being requested are:

(i) compliance tests;

(ii) quality control or research and development tests;

(iii) being re-sampled because of a failed test; or

(iv) being retested after undergoing remediation or sterilization.

(7) Following samples being taken from a harvest or process lot, a licensee must label each test batch with:

(a) the name and accreditation number of the laboratory responsible for the testing;

(b) the sample unique identification numbers supplied by the laboratory personnel;

(c) the date the samples were taken; and

(d) in bold capital letters, no smaller than 12-point font, "PRODUCT NOT TESTED."

(8) The licensee must store and secure the test batch in a manner that prevents the product from being tampered with or sold or transferred to a registered cardholder prior to test results being reported.

(9) If the marijuana item is being resampled after a failed test the licensee must provide the secondary laboratory with documentation of the failed test.

(10) A licensee may only order tests for marijuana items the licensee has produced or processed. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-311, 50-46-326, 50-46-329, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

Rule 37.107.406 reserved

37.107.407 QUALITY ASSURANCE TESTING REQUIREMENTS

- (1) Except as provided in (10), a licensee must submit for testing every test batch from a harvest lot of marijuana and process lots of marijuana-infused product, extracts, and concentrates intended for use by a registered cardholder prior to selling or transferring the marijuana item to a registered cardholder.
- (2) Usable marijuana lots consisting of dried leaves and flowers must be tested for the following:
 - (a) cannabinoid profile;
 - (b) moisture analysis;
 - (c) foreign matter screening;
 - (d) microbiological screening; and
 - (e) pesticides screening.
- (3) Marijuana concentrate and extract lots must be tested for the following:
 - (a) cannabinoid profile;
 - (b) microbiological screening;
 - (c) residual solvents screening; and
 - (d) pesticides screening.
- (4) Marijuana-infused products must be tested for the following:
 - (a) cannabinoid profile.
- (5) The cannabinoid profile for each sample must include:
 - (a) THCA;
 - (b) THC;
 - (c) Total THC;
 - (d) CBDA;
 - (e) CBD; and
 - (f) Total CBD.
- (6) The sample and related lot or test batch fail quality assurance testing for moisture analysis if the results exceed the following limits:
 - (a) moisture content no more than twelve percent.
- (7) The sample and related lot or test batch fail quality assurance testing for foreign matter screening if the results exceed the following limits:
 - (a) five percent of stems 3mm or more in diameter; and
 - (b) two percent of seeds or other foreign matter.
- (8) The sample and related lot or test batch fail quality assurance testing for microbiological screening if the results exceed the following limits:
 - (a) Salmonella: 10 CFU/g;
 - (b) E. Coli: 10 CFU/g;
 - (c) Total of Aflatoxin B1, B2, G1, G2: 20 µg/kg; and
 - (d) Ochratoxin A: 20 µg/kg of substance.

(9) A sample and related lot or test batch fail quality assurance testing for residual solvents if the results exceed the limits provided in the table below.

Residual Solvents	
Solvent*	ppm
Acetone	5,000
Benzene	2
Butanes	5,000
Cyclohexane	3,880
Chloroform	2
Dichloromethane	600
Ethyl acetate	5,000
Heptanes	5,000
Hexanes	290
Isopropanol (2-propanol)	5,000
Methanol	3,000
Pentanes	5,000
Propane	5,000
Toluene	890
Xylene**	2,170

* And isomers thereof.

** Usually 60% m-xylene, 14% p-xylene, 9% o-xylene with 17% ethyl benzene.

(10) Heavy metals will be tested at random. A sample and related lot or test batch fail quality assurance testing for heavy metals if the results exceed the limits provided in the table below.

Heavy Metals		
	Limits; Unprocessed/Dry Flower	Limits; Extract
Inorganic arsenic	2.0 µg/g	10 µg/g
Cadmium	0.82 µg/g	4.1 µg/g
Lead	1.2 µg/g	6.0 µg/g
Mercury	0.4 µg/g	2.0 µg/g

(11) A sample and related lot or test batch fail quality assurance testing for pesticides if the results exceed the limits provided in the table below.

Pesticides			
Analyte	Chemical Abstract Services (CAS) Registry Number	Action Level ppm; Unprocessed/Dry Flower	Action Level ppm; Extract
Abamectin	71751-41-2	0.5	2.5
Acequinocyl	57960-19-7	2	10
Bifenazate	149877-41-8	0.2	1
Bifenthrin	82657-04-3	0.2	1
Chloromequat chloride	999-81-5	1	5
Cyfluthrin	68359-37-5	1	5
Daminozide	1596-84-5	1	5
Etoxazole	153233-91-1	0.2	1
Fenoxycarb	72490-01-8	0.2	1
Imazalil	35554-44-0	0.2	1
Imidacloprid	138261-41-3	0.4	2
Myclobutanil	88671-89-0	0.2	0.6
Paclobutrazol	76738-62-0	0.4	2
Pyrethrins†	8003-34-7	1	5
Spinosad	168316-95-8	0.2	1
Spiromesifen	283594-90-1	0.2	1
Spirotetramat	203313-25-1	0.2	1
Trifloxystrobin	141517-21-7	0.2	1

† Pyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1 and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-14-2 respectively). (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-311, 50-46-326, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

Rules 37.107.408 and 37.107.409 reserved

37.107.410 FAILED TEST SAMPLES (1) If a sample fails any initial test, the laboratory that did the testing must reanalyze the sample.

(2) A licensee must request a reanalysis within seven calendar days of receiving notice from the laboratory of any failed testing.

(3) The reanalysis must be completed by the laboratory within 30 days of receiving the request from the licensee.

(4) If the sample passes reanalysis, a second laboratory must sample the test batch and confirm the results for the test batch to pass testing.

(5) The licensee is responsible for the costs of reanalysis.

(6) A licensee is not permitted to sell or transfer to a registered cardholder, marijuana items that have failed a test.

(7) Failed harvests, lots, or test batches may be remediated so long as the remediation method does not impart any toxic or deleterious substance to the usable marijuana, marijuana concentrates, or marijuana-infused product.

(8) Remediation methods used on the marijuana item must be disclosed to the department.

(9) No remediated harvests, lots, or test batches may be sold until the completion and successful passage of quality assurance testing as required in these rules and Montana statute.

(10) If a sample fails and cannot be remediated or sterilized the test batch must be destroyed.

(11) A licensee must document all sampling, testing, sterilization, remediation and destruction that are a result of failing a test under these rules. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-311, 50-46-326, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

Rules 37.107.411 and 37.107.412 reserved

37.107.413 WASTE MANAGEMENT (1) A licensee must store, manage, and dispose of solid and liquid waste generated during marijuana production and processing in accordance with applicable state and local laws and regulations.

(2) A licensee must store marijuana waste in a secured waste receptacle in the possession of and under the control of the licensee.

(3) The allowable method to render marijuana plant waste unusable is by grinding and incorporating the marijuana plant waste with other ground materials so the resulting mixture is at least fifty percent nonmarijuana waste by volume. Material used to grind with the marijuana falls into two categories: compostable waste and noncompostable waste.

(a) Compostable mixed waste is marijuana waste to be disposed as compost feedstock or in another organic waste method, such as an anaerobic digester, mixed with food waste, yard waste, or vegetable based grease or oils.

(b) Noncompostable mixed waste is marijuana waste to be disposed in a landfill or another disposal method, such as an incinerator, mixed with paper waste, cardboard waste, plastic waste, or soil.

- (4) Waste that must be rendered unusable prior to disposal includes:
 - (a) marijuana plant waste, including roots, stalks, leaves, and stems that have not been processed with solvent;
 - (b) waste solvents used in the marijuana process;
 - (c) spent solvents, laboratory waste, and excess marijuana from any quality assurance testing; and
 - (d) marijuana items that ultimately fail to meet testing requirements.
- (5) A licensee must maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of marijuana to include:
 - (a) what was disposed;
 - (b) quantity by weight or volume;
 - (c) date disposed;
 - (d) disposal method;
 - (e) reason for the disposal;
 - (f) identity of who disposed the waste; and
 - (g) record of the destination of marijuana waste rendered unusable.
- (6) A licensee must provide a minimum of 72 hours' notice in the inventory tracking system prior to rendering the marijuana item unusable and disposing of it. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-311, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

- 37.107.415 REPORTING REQUIREMENTS (1) A registered cardholder must notify the department within ten calendar days of any changes in the following:
- (a) cardholder's name or address;
 - (b) referral physician;
 - (c) provider or marijuana-infused products provider; or
 - (d) change in the status of the cardholder's debilitating medical condition.
- (2) A registered cardholder that is their own provider, must notify the department ten calendar days prior to the change in location of plants or seedlings.
- (3) A registered cardholder must report to the department within ten calendar days any lost or stolen registry identification card.
- (4) A licensee must notify the department within 30 calendar days of any changes in the following:
- (a) anyone identified as an applicant;
 - (b) temporary closure of longer than 30 days; and
 - (c) permanent closure of the business.
- (5) A licensee who wishes to change the location of a registered premises must submit a completed application for the new premises including all required forms, documents, and fees.

(6) A licensee who intends to make any material or substantial changes to the registered premises must submit the changes to the department for approval prior to making any such changes. Material or substantial changes include:

(a) any increase or decrease in the total physical size or capacity of the registered premises;

(b) alterations to public ingress or egress of limited access areas;

(c) any changes to the security plan.

(7) A licensee must notify the department as soon as reasonably practical but in no case more than 24 hours following the theft of marijuana items or money from the registered premises. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-307, 50-46-308, 50-46-311, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.420 MARIJUANA ITEM RECALLS (1) The department may require a licensee to recall any marijuana item that the licensee has sold or transferred to a registered cardholder that poses a risk to public health and safety.

(2) A recall may be based on evidence that a usable marijuana item is contaminated or otherwise unfit for human use, consumption, or application.

(3) If the department determines that a recall is required, the licensee must notify the registered cardholder or cardholders to whom the marijuana item was sold and destroy the recalled product. (History: 50-46-344, MCA; IMP, 50-46-326, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

37.107.425 INSPECTIONS (1) The department may conduct inspections to determine compliance with these rules and Montana statutes. To include:

- (a) an initial application inspection;
- (b) annual renewal inspections;
- (c) unannounced inspections; and
- (d) complaint inspections.

(2) A licensee or licensee employee must cooperate with the department during an inspection.

(3) A licensee or licensee employee may not:

- (a) refuse to admit a department regulatory surveyor from entering a registered premises to conduct an inspection; or
- (b) ask the regulatory surveyor to leave until the surveyor has had an opportunity to fully conduct an inspection.

(4) If a licensee or licensee employee fails to permit the department to conduct an inspection, the department may deny, suspend, or revoke their license or endorsement.

(5) If during an inspection the department determines the applicant is not in compliance with applicable licensing requirements or Montana statute, the department will notify the applicant of the specific deficiencies or errors.

(6) The department will not issue a license or renew a license until all required or corrected information has been received. (History: 50-46-344, MCA; IMP, 50-46-303, 50-46-308, 50-46-311, 50-46-312, 50-46-319, 50-46-328, 50-46-329, MCA; NEW, 2018 MAR p. 321, Eff. 4/10/18.)

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