



# Montana Medical Marijuana Program Processing/Manufacturing Facility Checklist

Region # \_\_\_\_\_

## Section 1: General Data

### Inspection Type:

- Announced   
  Un-announced   
  Application   
  Annual   
  Follow-up   
  Complaint driven

### Compliance History:

- Tax Status: \_\_\_\_\_
- Evidence of Electronic Advertising: \_\_\_\_\_
- Complaints Rec'd: \_\_\_\_\_
- Previous Violations: \_\_\_\_\_

Name of Inspector(s): \_\_\_\_\_

Inspector Identification Presented

Other Inspection Participants - Organization(s)/Title(s): \_\_\_\_\_

Inspection Date	Entry/Exit Time	License Number	License Effective/Expiration	Number of Patients	Facility Contact	Facility Phone Number
	/		/			

## Section 2: Licensee Names/Addresses

Name Shown on License: \_\_\_\_\_

Business Name: \_\_\_\_\_

Email Address: \_\_\_\_\_

Mailing Address: \_\_\_\_\_

Physical Address: \_\_\_\_\_

## Section 3: Employees

Rule	Criteria
ARM 37.107.120 (2) Marijuana Employee Permit must be carried when performing work	Number EEs? Permits Carried?
ARM 37.107.120(3) Dept. issued volunteer badges for no more than 300 hours/year	Number volunteers? Hours worked annually?

## Section 4: Other Permits

Rule	Criteria
MCA 50-46-308(5)(d): Providers/MIPs must obtain Dept. of Ag license (MCA 80-7-106) if they sell live plants	List:

## Section 5: Facility Details

Rule	Criteria
MCA 50-46-341: Persons with licenses/reg. cards may not advertise marijuana/products in any medium including electronic media	Any evidence of advertisement?
ARM 37.107.115(15)(b): A licensee must display proof of licensure in a prominent place on the RP	
ARM 37.107.118(17): Documentation meeting all local jurisdiction requirements such as licensing, fire health and safety must be maintained on premises	
MCA 50-46-308 (6)(b): property may not be shared\rented\leased to another provider.	Partner situation? Other?
MCA 50-46-312 (4)(a): Dept. may deny a license if RP is: <ul style="list-style-type: none"> <li>• not approved by local building, health or fire officials</li> <li>• w/in 500 of a place of worship or school</li> <li>• if local gov't has adopted an ordinance prohibiting it</li> </ul>	
ARM 37.107.118(1): licensee must clearly identify all limited access areas at RP	Signage?
ARM 37.107.118(3): Licensee must maintain a daily log of all visitor activity at RP	Names/dates?
ARM 37.107.118(5): Licensee must conspicuously post signs inside RP: <ul style="list-style-type: none"> <li>• minors not permitted unless accompanied by an adult</li> <li>• no on-site consumption of marijuana except by registered cardholders</li> </ul>	
ARM 37.107.118(8): Licensee must have a written security plan maintained on the RP	and emergency procedures, ARM 37.107.118(15)

Rule	Criteria
ARM 37.107.118(9): Commercial grade door locks must be installed on every external door & gate of RP	
ARM 37.107.118(10): Licensee must ensure sanitary requirements are met: <ul style="list-style-type: none"> <li>• handwashing facilities</li> <li>• proper\timely waste removal</li> <li>• toilet facilities maintained</li> </ul>	

## Section 6: Processing/Manufacturing Questions

Rule	Criteria
ARM 37.107.204(6): All licensees using solvent-based or solvent-free extraction processes authorized by rule must obtain a chemical manufacturing endorsement  MCA 50-46-309 (1)(b): Use equipment that used <b><u>EXCLUSIVELY</u></b> for the manuf./prep. of marijuana-infused products	
ARM 37.107.204(1): To produce MIPs, licensee must: <ul style="list-style-type: none"> <li>• ensure RP &amp; Equipment are maintained in a clean &amp; sanitary condition</li> <li>• use equipment, counters, surfaces that are food grade &amp; can be easily cleaned</li> <li>• maintain detailed instructions for making each infused product concentration or extract</li> <li>• conduct safety checks prior to processing</li> <li>• create SOPs for: cleaning, proper handling/storage of solvents gas or other chemical used, proper disposal of any waste product during processing, training EEs, &amp; any other written procedure required by the Dept.</li> </ul>	<p>Recipes?</p> <p>On-site?</p>
ARM 37.107.204(2): A licensee with chemical manufacturing endorsement must: <ul style="list-style-type: none"> <li>• only use hydrocarbon-based solvents that are at least 99% pure</li> <li>• use only non-hydrocarbon-based solvents that are food grade</li> </ul>	Describe process used:

<ul style="list-style-type: none"> <li>• work in an environment with proper ventilation</li> <li>• use only potable water/ice</li> <li>• process in a fully enclosed room</li> <li>• use a professional grade closed-loop extraction system designed to recover solvents</li> <li>• have equipment/facilities approved for processing use by local fire code official</li> <li>• have an emergency eyewash station in any room where manufacturing occurs</li> <li>• have all applicable MSDS sheets available</li> <li>• establish written procedures to be followed in case of fire, chemical spill or other emergencies at all RPs</li> </ul>	
<p>ARM 37.107.204(3): A licensee with a chemical manufacturing endorsement may use:</p> <ul style="list-style-type: none"> <li>• a mechanical extraction process</li> <li>• a chemical extraction process using the solvent CO<sup>2</sup> provided that the process doesn't use heat over 180F &amp; uses a professional grade closed-loop CO<sup>2</sup> gas extraction system where every vessel is rated to 600#/sq."</li> </ul>	<p>Mechanical process used?</p>
<p>ARM 37.107.204(4): A licensee with chemical manufacturing endorsement may not use:</p> <ul style="list-style-type: none"> <li>• Class I solvents, pressurized canned flammable fuel, denatured alcohol</li> </ul>	
<p>ARM 37.107.204(5): A licensee may not treat or alter a marijuana item with any non-cannabinoid additive that increases potency, toxicity or addictive potential</p>	<p>Additives are used?</p>
<p>ARM 37.107.118(13): Licensee must use standardized scale when marijuana items are:</p> <ul style="list-style-type: none"> <li>• packaged for sale by weight</li> <li>• bought &amp; sold by weight</li> <li>• weighed for entry into METRC</li> </ul>	

ARM 37.107.206(5): each marijuana: plant, item, test batch, harvest lot & process lot that's been issued a unique ID# must have a physical tag with the unique ID#.	
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**Section 7: Facility Inventory**

Categories	Expected	Verified
Marijuana Flower		
Pre-rolls		
Concentrates		
Extracts		
Tinctures		
FECO/RSO		
Vape Sticks		
Edibles		
Other		

**Section 8: Waste Management**

Rule	Criteria
ARM 37.107.413(1): Licensee must store all solid & liquid waste in accordance with all state & local laws\regs	
ARM 37.107.413(2): Licensee must store marijuana waste in a secured waste receptacle	
ARM 37.107.413(3): Marijuana plant waste is ground and mixed w/other waste material 50%/50% by volume. <ul style="list-style-type: none"> <li>• Compostable waste – disposed of as feedstock, in anaerobic digester</li> <li>• Non-compostable waste – landfill, incinerator</li> </ul>	
ARM 37.107.413(4): Waste that must be rendered unusable prior to disposal includes: marijuana plant waste, waste solvents, spent solvents, lab waste, excess marijuana from QA testing, marijuana that fails testing	
ARM 37.107.413(5): Licensee must maintain accurate, comprehensive records that accounts for, reconciles, & evidences all marijuana waste activity	
ARM 37.107.413(6): Licensee must Provide 72 hrs notice in METRC prior to rendering marijuana waste unusable and disposing of it	

## Section 9: QA Testing

Rule	Criteria
<p>MCA 50-46-326: A Provider\MIPP may not sell marijuana or MIP until the marijuana or products have been tested by a Lab</p>	
<p>ARM 37.107.407(1): Licensee must submit for testing every test batch from a harvest lot, process lot of marijuana infused products &amp; concentrates prior to sale or transfer to a cardholder</p>	
<p>ARM 37.107.405(1)-(6): Licensee must separate each harvest lot of marijuana into no larger than 5# test batches, each process lot of MIP into no larger than 5K unit-of-sale batches</p> <ul style="list-style-type: none"> <li>• A process lot is considered a test batch for marijuana concentrates and extracts</li> <li>• Usable marijuana consisting of dried leaves and flowers may only be sampled after it is cured</li> <li>• Sufficient sample increments must be taken for analysis of all required tests &amp; the quality control performed by the testing laboratory for these tests</li> <li>• A licensee must provide a Lab the following documentation at the time of testing: Unique ID #, licensee bsns or trade name &amp; reg #, date sample was collected, wt. of sample, &amp; reason for requested test(s) (compliance, QC or R&amp;D, failed test re-sample, re-test after remediation/sterilization)</li> </ul>	
<p>ARM 37.107.405(7): Test batches must be labeled with:</p> <ul style="list-style-type: none"> <li>• Name &amp; accreditation number of the laboratory responsible for the testing</li> <li>• The samples unique ID numbers supplied by the Lab</li> <li>• Date sample was taken in bold capital letters in no smaller than</li> </ul>	

Rule	Criteria
12-point font: "PRODUCT NOT TESTED "Product not tested"	
ARM 37.107.410(1)-(3): If a sample fails any initial test, provider must request re-test w/in 7 days & Lab must reanalyze sample w/in 30 days	
<p>ARM 37.107.407(2):</p> <ol style="list-style-type: none"> <li>1. Cannabinoid profile</li> <li>2. Moisture analysis</li> <li>3. Foreign matter screening</li> <li>4. Microbiological screening</li> <li>5. Pesticides screening</li> </ol> <ul style="list-style-type: none"> <li>• <b>Marijuana concentrate and extract lots must be tested for the following:</b> <ol style="list-style-type: none"> <li>1. Cannabinoid profile</li> <li>2. Microbiological screening</li> <li>3. Residual solvents screening</li> <li>4. Pesticide screening</li> </ol> </li> <li>• <b>Marijuana-infused products must be tested for the following:</b> <ol style="list-style-type: none"> <li>1. Cannabinoid profile</li> <li>2. Microbiological</li> </ol> </li> <li>• <b>The cannabinoid profile for each sample must include:</b> <ol style="list-style-type: none"> <li>3. THCA</li> <li>4. THC</li> <li>5. Total THC</li> <li>6. CBDA</li> <li>7. CBD</li> <li>8. Total CBD</li> </ol> </li> </ul>	

## Section 10: Packaging/Labeling

Rule	Criteria
<p>ARM 37.107.401(2):</p> <ul style="list-style-type: none"> <li>• <b>Labels for all marijuana items must include:</b> <ol style="list-style-type: none"> <li>1. Licensee business or trade name</li> <li>2. Licensee registration number</li> <li>3. Date of harvest of marijuana, or date marijuana item was manufactured</li> <li>4. (Common) Name of strain or marijuana item</li> </ol> </li> </ul>	

Rule	Criteria
<ol style="list-style-type: none"> <li>5. Net weight or volume in both U.S. customary and metric units</li> <li>6. Concentration by weight or volume of: THC, THCA, CBD, CBDA</li> <li>7. A unique identification numbers</li> <li>8. A consumer warning that states:</li> <li>9. “For use by MMP registered cardholders only – keep out of children’s reach”</li> <li>10. “It is illegal to drive a motor vehicle while under the influence of marijuana</li> <li>11. “This product is not approved by the U.S. Food and Drug Administration (FDA) to treat, cure, or prevent any disease.”</li> <li>12. If the marijuana item has passed required testing: “This Product Has Been Tested and Meets the Quality Assurance Requirements of the State of Montana.”</li> <li>13. If the marijuana item has not been tested (because the licensee has ten or fewer registered cardholders who are not required to submit marijuana items for testing): “This Product Has Not Been Tested for compliance with Quality Assurance Requirements for the State of Montana.”</li> </ol> <ul style="list-style-type: none"> <li>• <b>Additional labeling requirements for Marijuana Topicals, Ointments, Suppositories and other marijuana products not intended to be administered orally:</b> <ol style="list-style-type: none"> <li>1. <b>“DO NOT EAT”</b> (Bold/Capitalized)</li> <li>2. List of ingredients used to process the product (in descending order or</li> </ol> </li> </ul>	

Rule	Criteria
<p style="text-align: center;">predominance by weight/volume)</p> <ul style="list-style-type: none"> <li>• <b>Additional labeling requirements for edible marijuana products and tinctures:</b> <ol style="list-style-type: none"> <li>1. <b>“BE CAUTIOUS”</b> (Bold/Capitalized) followed by “This product can take up to two hours or more to take effect”</li> <li>2. If perishable: “Product must be kept refrigerated/frozen</li> <li>3. A “contains” statement w/a list of major food allergens either:               <ol style="list-style-type: none"> <li>a. At the end or immediately adjacent to the ingredients list</li> <li>b. <b>OR:</b> in parenthesis with/in the ingredients list after the common name of the ingredient derived from that major food allergen</li> </ol> </li> </ol> </li> <li>• <b>Additional labeling requirements for marijuana concentrates and extracts:</b> <ol style="list-style-type: none"> <li>1. <b>“DO NOT EAT”</b> (Bold/Capitalized)</li> <li>2. Extraction method &amp; solvent</li> </ol> </li> <li>• <b>All Labels MUST:</b> <ol style="list-style-type: none"> <li>1. Be placed on the container &amp; any packaging that is used to display marijuana items for sale or transfer to a registered cardholder</li> <li>2. Be no smaller than eight-point Times New Roman, Helvetica, or Arial font</li> <li>3. Be in English</li> <li>4. Be unobstructed and conspicuous</li> <li>5. IF a marijuana item is place in a package that is being reused, the old label(s) must be removed and replaced with new labels</li> </ol> </li> <li>• <b>All Labels MAY:</b></li> </ul>	

Rule	Criteria
<ol style="list-style-type: none"> <li>1. Have one or more labels affixed to the container or packaging</li> <li>2. Use a peel-back OR accordion label with the required information IF the label can be identified by a registered cardholder as to containing important information</li> </ol> <ul style="list-style-type: none"> <li>• <b>All Labels MAY NOT:</b> <ol style="list-style-type: none"> <li>1. Contain any untruthful or misleading statements</li> <li>2. Be attractive to minors: In regard to packaging, labeling, &amp; marketing that features: cartoons, designs, brands, or names that resemble a not-cannabis consumer product of the type that is typically marketed to minors, symbols or celebrities that are commonly used to market products to minors, images of minors, words that refer to products that are commonly associated with minors or marketed by minors</li> <li>3. <b>All Exit Packages MUST:</b> contain a label that reads “Keep out of reach of children”</li> </ol> </li> </ul>	
ARM 37.107.402(1)-(2): Packages for useable marijuana must protect the consumer from contamination, and be child resistant	

## Section 11: Transportation

Rule	Criteria
ARM 37.107.124(1): Marijuana items may only be transported between a RP, licensed Lab or cardholder’s home by a licensee\licensee employee	How are items transferred to Lab, dispensary?
ARM 37.107.124(2)-(5): A printed manifest or sales/manifest must accompany every transport & must contain the following info:	

Rule	Criteria
<ul style="list-style-type: none"> <li>• RP address &amp; license # of departure &amp; receiving locations</li> <li>• Product name, quantities &amp; ID numbers</li> <li>• date\time of departure &amp; arrival</li> <li>• delivery vehicle info</li> <li>• name\signature of licensee\EEs accompanying transport</li> <li>• receiving location must review manifest, verify description of inventory, &amp; note and document any discrepancies</li> </ul>	
ARM 37.107.124(3): A transport manifest or sales/manifest may not be voided or changed after departing from the originating RP	
ARM 37.107.124(8): Transport vehicle must shield marijuana from view, must secure (be locked) marijuana during transport	
ARM 37.107.206(15): A receiving location must document in METRC any marijuana items received & any differences between quantity specified in manifest & quantity received.	

## Section 12: Record keeping

Rule	Criteria
ARM 37.107.130(1)(k): Dept. after written notice may revoke license if licensee fails to file a change request reporting they are no longer listed as a cardholder provider	Verify number current of patients and/or any changes.
ARM 37.107.206(1): Licensee must use METRC as primary inventory tracking & record keeping system	
ARM 37.107.206(2): Each 12" marijuana plant must be issued a METRC ID tag that gets attached to & follows the plant through production	Present? Legible?
ARM 37.107.206(8): All on-premises, in-transit inventories must be reconciled in METRC at the close of each business day	
ARM 37.107.206(9): Each marijuana sale\transfer to a cardholder must be recorded in METRC at the close of each business day	

Rule	Criteria
<p>ARM 37.107.206(10): Licensee must record in METRC:</p> <ul style="list-style-type: none"> <li>• Wet weight of all harvested marijuana plants immediately after harvest</li> <li>• Information for marijuana items by unit count</li> <li>• Weight per unit of a product</li> <li>• Weight and disposal of post-harvest waste materials</li> <li>• Theft or loss of marijuana items</li> <li>• Other information as may be required by the department</li> </ul>	
<p>ARM 37.107.206(12)-(14): All samples taken for QA testing &amp; results must be recorded in METRC</p>	
<p>ARM 37.107.118(14): Licensee must maintain the following records in paper or electronic form for at least 3 years:</p> <ul style="list-style-type: none"> <li>• financial records</li> <li>• employee training &amp; payroll</li> </ul>	
<p>MCA 50-46-329(3)(a): Provider\MIPP shall keep a complete set of records to show all transactions w\cardholders</p>	

**Section 13: General Interviewee Questions**

1. Are any of your extractions done by a third party (if so, who & get copies of receipts/contract)?
2. \_\_\_\_\_
3. How many dispensaries are associated with this facility?
4. \_\_\_\_\_
5. Do you have any major concerns?
- \_\_\_\_\_

**Photo Log**

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_
6. \_\_\_\_\_
7. \_\_\_\_\_
8. \_\_\_\_\_
9. \_\_\_\_\_
10. \_\_\_\_\_

11. \_\_\_\_\_
12. \_\_\_\_\_
13. \_\_\_\_\_
14. \_\_\_\_\_

### **Other Attachments**

Describe (scanner data, property receipt for samples taken, copies of documents received from licensee)

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_
6. \_\_\_\_\_
7. \_\_\_\_\_
8. \_\_\_\_\_
9. \_\_\_\_\_
10. \_\_\_\_\_

### **Notes**