SAFETY COMPLIANCE FACILITY INFORMATION

August 15, 2018

This information is intended for Licensed Safety Compliance Facilities (SCF) regulated by the Bureau of Medical Marihuana Regulation, a division of Michigan's Department of Licensing and Regulatory Affairs

INTRODUCTION

All sampling and analysis described in this guidance shall be conducted by a licensed safety compliance facility in good standing with a third-party accrediting body accredited to International Organization for Standardization (ISO) 17025.

Analytical testing of medical marihuana for safety and potency is increasingly recognized as a critical and necessary component of the industry for several reasons (Freeman et al. 2016):

- Laboratory testing minimizes the risk of pesticides, microbes, heavy metals, mycotoxins and residual solvents from being consumed by an immunocompromised population.
- Quantification of cannabinoid profiles and potency becomes available for the consumer and aids in determining appropriate dosing for individual use.
- Laboratory testing provides a sense of public safety and product quality for the tested medical marihuana.

Medical marihuana safety and potency is to be analyzed based on the most current version of the *Cannabis Inflorescence Monograph*, published by the American Herbal Pharmacopeia (AHP), or a scientifically valid methodology that is equal or superior to that of the AHP monograph. Rule 31 of the Emergency Rules published May 30, 2018 provides information for Safety Compliance Facilities (SCFs) as to what tests and procedures are required. Additionally, advisory bulletins have been issued to clarify and/or establish limits for required testing parameters such as chemical residues and residual solvents. The limits were established following a review of available literature in the marihuana industry as well as references.

The categories of contaminants identified in Rule 31 of the Emergency Rules include:

- Potency
- Moisture content and water activity
- Chemical residue
- Heavy metals
- Residual solvents
- Microbial and mycotoxin screening, including foreign matter

In an effective testing program, standardized sampling procedures are an integral component to quality laboratory testing. The data generated from all analytical methods must be consistently reliable and legally defensible. To achieve this, method precision and accuracy measurements should be performed during the sample testing process. The guidance below will provide some best practices for the sample collection by the SCF.

SAMPLING RECOMMENDATIONS

According to Rule 31(7)(c) a safety compliance facility shall maintain internal standard operating procedures. It is the responsibility of the SCF to define a standard operating procedure that minimizes both imprecision and bias and lists chronological steps that ensure a consistent and repeatable method

The objective of a sampling procedure is to ensure the proper collection, clear labeling, proper preservation, careful transportation and storage of samples by trained personnel for laboratory analyses. Collection of the sample is critical as it must be truly representative of the material being analyzed or the results will not be meaningful. SCFs should develop a statistically valid sampling method to collect a representative sample from each batch of product.

The sample should be adequate to perform the required testing. The amount of sample required for testing may vary due to sample matrix, analytical method and laboratory-specific procedures, but a minimum sample volume of 0.5% of the batch of usable marihuana is required to achieve a representative sample for analysis according to Rule 32(2)(b) of the Emergency Rules published May 30, 2018**.** For concentrates, extracts, and marihuana infused products, the sample volume will be determined by each SCF. In all cases, the amount of sample collected by the laboratory should be large enough and sufficiently homogenized to provide a representative sample of the batch, but not in excess to raise issues with possible diversion or waste disposal.

An example collection procedure is included as a baseline reference. For detailed information regarding sample collection, please refer to “Good Samples: Guidance on Obtaining Defensible Samples” (Thiex 2015), or “Sampling Cannabis for Analytical Purposes” (Sexton 2013).

(See Appendix A for information regarding required testing for each sample matrix).

EXAMPLE COLLECTION PROCEDURE

Representative Sampling

When sampling a harvest batch, the sampler should check for any signs of non-uniformity such as different types or sizes of containers, variations in marks and labels, or mixed batch numbers. During sampling, the sampler should look for differences in the usable marihuana being sampled such as color, shape, size, and treatment. The batch must be uniform for all factors that appear on the label; hence, variations in the product may indicate nonuniformity in the batch and that any sample drawn may not be representative for testing. The sampler should document anomalies on the SCF’s sampling form.

General guidelines for sampling include:

1. Gaining access to the entire batch
2. Use of appropriate sampling equipment and consistently following procedures
3. Taking equal portions for each sample increment
4. Randomly or systematically taking sample increments throughout the batch
5. Obtaining a minimum number of sample increments, which will be based on batch size
6. Recording all observations and procedures used while collecting the sample increments on an appropriate sampling form

Random Sampling

Prior to beginning the sampling procedure, the sampler should survey the site to identify the conditions under which the marihuana is being kept. All sampling must be performed by personnel employed by the SCF and must be in accordance with the Standard Operating Procedure (SOP). The requirements for sampling and sample size are provided in Rule 32(2)b) of the Emergency Rules published May 30, 2018. If the SCF will perform additional testing in addition to the required testing this must be part of the planning process. To ensure representativeness, the sampling plan must be designed such that each flower bud in the batch has an equal chance of being selected.

Note: The sample size must be sufficient to complete all analyses required but shall in no case be less than 0.5% of the weight of the batch. The maximum batch size shall be 10 pounds.

Sample increments should be randomly selected from different locations within a container or set of containers the SOP should describe this process:

1. Assign location numbers within containers
2. Use a random number generator to determine which location to sample
3. Document where each sample increment was sampled, and the volume collected from each increment

Assign divisions based on the type of container in the site-specific sampling plan. Use a random number generator with the higher number equal to the number of divisions for the container. When there are multiple containers use existing or arbitrary order of containers to assign numbers to the total of “divisions multiplied by total number of containers” (divisions x # containers = total number of random increments) and record in the sampling report. The SCF should have details in its SOP, on how it will achieve random sampling in an unclear decision unit.

Equipment and Supplies

Below is a list of equipment and supplies that may be necessary for collecting marihuana samples:

- Sampling equipment such as spoons, spatulas, transfer pipettes, or other matrix specific tools
- Tongs
- Corers
- Teri-wipes, or equivalent
- Field balance (Capable of 0.01 g measurements)
- Calibrated Verification Weights appropriate to verify accuracy of field balance
- Cleaning supplies – solvent, bleach, 70% ethanol
- Gloves (powder-free, nitrile, sterile)
- Mylar bags (for final sample transport and storage) and/or amber glass jars (for final sample transport and storage)

Records and Documentation

The sampling SOP should be readily accessible to all pertinent personnel, should use these guidelines as minimum requirements, and must include additional detail specific to the SCF's procedures. Deviations from, or additions to, the SOP must be documented in detail and included on the final report.

Sampling Records/Field Data

In addition to collecting the sample, a sampling report form should be created for the batch sampled and should include any observations made while taking the sample. Examples on information that should be included:

- Name and address of producer including licensee number
- Product type
- Total mass of batch
- Unique SCF batch ID#, METRC batch ID #, as designated
- Total container number
- Number of sample increments
- Number of containers sampled
- Number of sample containers collected
- Total mass sampled
- Sampling Procedure ID and revision date
- Description of equipment used
- Place where sampled
- Date sampled
- SCF license number
- Sampler's identification and/or signature
- Name of responsible party for the batch and transport information
- Receiving SCF and types of tests required or requested

If any of the above information requested on the sampling report form is unavailable, indicate “N/A” in the appropriate space. All sampling report forms should be signed by the sampler.

Sampling a Batch of Marihuana

1. Locate the batch to be sampled.
2. Review the container label information for harvest lot number, producer, and other pertinent information. Each harvest lot should be separated into batches of 10 lbs. or less and must be assigned a unique batch number by the grower. Do not sample if a unique batch number is not available.
3. Determine the number of containers in the batch and the batch size. Visually verify the batch size for each container. Do not sample if the batch size is unavailable or exceeds 10 lbs. for a container.
4. Determine the number of containers from which sample increments must be collected (Appendix 1).
5. Select the appropriate sampling tool to ensure that it reaches all portions of the container.
6. Collection instruments should be clean prior to use to prevent cross-contamination of sample increments. Sampling tools which appear to be dirty or otherwise compromised shall not be used. To prevent contamination, sampling tools may be cleaned and sealed at the SCF prior to use or may be cleaned in the field between batches using an appropriate solvent and decontaminant to prevent cross contamination of batches during sampling. Results from cleaning procedure tests must be below the reporting limit of the target analyte(s) for the associated analyses. Decontamination should be collected and disposed of according to the SCF’s waste disposal procedure.

   Note: Samplers must take extreme care if sampling from multiple sites in one day to ensure contaminants, pathogens, or organisms are not transferred between facilities. The sampler may clean sampling equipment in the field between samplings at a single facility. However, the sampler is required to bring enough sets of sampling equipment to use a new set at each facility visited. All field equipment shall be returned to the SCF following sampling and cleaned according to the SCF’s procedures. Where aseptic technique is required, please refer to the FDA Aseptic Sample guidelines (Investigations Operations Manual Subchapter 4.3.6) for information.

7. Visually inspect each test sample increment to assess uniformity;
8. If non-uniformity is identified, record observation in the sampling report. It is expected with marihuana to have variable sizes of flowers. When drawing sample increments, approximately equal amounts of product are to be taken with each probing and from each container. Care must be taken by the sampler to not damage the portion of the product which is not being collected.
9. Combine all sample increments to form the composite sample.

10. Ensure sufficient sample increments are taken to meet sample size requirements for all analytical method(s) being performed.
11. Seal and label the composite sample with the following minimum requirements:

    - SCF license number
    - Unique identifier for sampling event
    - Sampling date and name of sampler
    - Producer's license or registration number
    - Harvest batch numbers
    - Label "PRODUCT NOT TESTED" in bold capital letters in minimum 12-point font.

12. Apply a custody seal to the sample container in a manner which prevents the product from being tampered with or transferred prior to testing. This seal may contain the SCF sample identification number.
13. Complete the sampling report while at the sampling location as well as an appropriate chain of custody form.
14. Forward the sample and sampling report to the SCF or other designated location using packaging appropriate for secure and timely transport.
15. Record the sampling event in the SCF's records the registrant number for tracking medicinal Marihuana.

Preparation of the Composite Sample

1. The SCF must have detailed procedures on maintaining custody and sample integrity during transport. These procedures should take into consideration controlling temperature and other environmental factors.
2. Submit the composite sample to the SCF in its entirety.
3. Composite samples must always be identified by labeling or marking the sample container to associate them with the batch from which they originated and with the sampling report. Containers for sample transport must be designed to prevent damage, contamination, spillage, or commingling of the sample during transport. Examples of sampling containers include: glass, amber jar with a PTFE-lined lid or a Mylar bag. A tamper-proof seal is should be marked with the sampler's name, date, and sample number.

Forwarding Samples to the Primary and/or Re-testing SCF

1. Forward the composite sample to the SCF or other designated location using packaging appropriate for secure transport.
2. Protect the sample from moisture and temperature extremes.
3. Include all documentation with the sample.
4. Forward the sample by the most expedient, secure, and legal means to ensure that the sample continues to be representative of the harvest lot sampled and the chain of custody is accounted for to protect its integrity.

Quality Assurance/Quality Control

Representative sampling should meet a 95% confidence level and limit sampling error. Increasing the number of sample increments to compensate for normal batch heterogeneity is the simplest means to achieve a representative sample. Typically, a minimum of ten (10) sample increments is considered a representative decision unit for marihuana. The sampler must be prepared to collect adequate sample mass for all analyses requested by the producer. This must include adequate sample mass for re-testing in the event a sample fails a criterion as well as adequate sample mass for any quality control samples required by the SCF, such as duplicates or matrix spikes.

Field Quality Control

Field sampling equipment shall be certified clean prior to use by the SCF. Cleaning techniques will vary depending upon the desired analysis. In general, sampling equipment must be sterile for microbiology samples and clean for chemistry samples. The SCF shall perform cleanliness checks on each batch of sampling equipment prior to taking that equipment into the field. Results from cleaning procedure tests must be below the reporting limit of the target analyte(s) for the associated analyses. If cleanliness checks fail, the sampling equipment must be re-cleaned, sterilized and tested.

Field Duplicates

Field duplicates are recommended for any marihuana sampling event, but not required. The field duplicate must be collected using the same procedure and contain the same number of sample increments as the primary sample. The lab must have documentation of the client request for a field duplicate with any client specified quality objectives and precision limits must meet the client’s need.

Equipment Blanks

Equipment rinse blank samples provide a Quality Control check on the potential for cross contamination by measuring the effectiveness of the decontamination procedures on the sampling equipment. An equipment blank is required to validate equipment cleaning procedures for all required analyses. It is recommended but not required that an equipment blank is collected upon each sampling event to demonstrate the equipment was not introduced to contamination after cleaning. The equipment rinse blank samples consist of analyte-free matrix, as applicable, rinsed across sample collection and processing equipment. If the analytes of interest are detected in the equipment rinse blank samples, the detected concentrations will be compared to the associated sample results to evaluate the potential for contamination.

The equipment blank must pass the required analysis at <LOQ for cleaning validation.

If the equipment blank is collected at the sampling event, the lab should have detail in the procedures as to how to evaluate it and what actions to take if the evaluation demonstrates unacceptable results.

Demonstration of Capability

Prior to testing patient samples, a satisfactory initial demonstration of capability (IDOC) or competency assessment should be used. The SCF should have a documented procedure for performing the IDOC.

The IDOC should be repeated:

1. Every time there is a change in personnel or method and
2. When the method has not been performed by the SCF or sampler within a 12-month period.

This procedure should employ one of the following approaches to demonstrating capability:

1. Comparison of replicate samples within a defined Relative Standard Deviation (%RSD)[1].
2. Comparison of a sample collected to that of one collected by personnel with an existing IDOC within a defined Relative Percent Difference (RPD).

Thereafter, ongoing continuing demonstration of capability (CDOC) as per the quality control requirements referenced in the SOP should be done at least annually. The SCF should have a documented procedure for performing the CDOC. The SCF should retain documentation verifying CDOC for each sampler and make this documentation available upon request.

Sampler Qualifications

Example qualifications for samplers of marihuana are:

- Physically able to perform the duties of a sampler
- No conflict of interest
- Must be employed by the SCF
- Pass initial and ongoing demonstrations of capability

Education and Training for Samplers

Initial documented training – including principles, procedures, and policies of sampling – should be performed by an instructor that has demonstrated competency in performing and instructing on the sampling methods referenced or equivalent. After personnel goes through initial training, they are qualified to train others in their organization.

Field Audits

The SCF should adopt an ongoing system for performing audits of field activities. Field audits must be conducted periodically and in accordance with a predetermined schedule and procedure. The goal of the field audit is to verify that the sampling operation continues to comply with the requirements of the regulations and is being performed according to the SCF's sampling SOP. Audits are to be carried out by trained and qualified personnel who are, wherever resources permit, independent of the activity to be audited. The field audit shall address all elements of the sampling activities and shall be documented.

When field audit findings cast doubt on the effectiveness of the operations or on the correctness or validity of the field sampling activities, the associated SCF shall take timely corrective action and shall notify customers in writing if investigations show that test results may have been affected.

Auditing Checks

1. Using audit checklists:
   - Review sampling and performance records from the preceding year for deficiencies in the application of sampling protocol
   - Observe the sampler conducting sampling procedures
   - Have the auditor and sampler collect samples from the same harvest lot for evaluation and comparison of results
2. Record any deficiencies and initiate corrective action.

Sample size

As stated in Rule 32(2)(b), the sample size must be sufficient to complete all analyses required but shall in no case be less than 0.5% of the weight of the batch. The maximum batch size is 10 pounds. The required sample size for a given batch size varies depending upon the size of the batch.

Example Sample size requirements based on size of batch

Batch size	Required sample size		
	Pounds (lbs.)	Ounces (oz)	Grams (g)
≤1 lbs.	0.005	0.08	2.3
1.01 ≤2 lbs.	0.010	0.16	4.5
2.01 ≤3 lbs.	0.015	0.24	6.8
3.01 ≤4 lbs.	0.020	0.32	9.1
4.01 ≤5 lbs.	0.025	0.40	11.3
5.01 ≤6 lbs.	0.030	0.48	13.6

6.01 ≤7 lbs.	0.035	0.56	15.9
7.01 ≤8 lbs.	0.040	0.64	18.1
8.01 ≤9 lbs.	0.045	0.72	20.4
9.01 ≤10 lbs.	0.050	0.80	22.7

Sampling a batch

1. When collecting a primary sample from a batch, a minimum of ten (10) sample increments should be collected. Collect the sample increments by following different paths through the batch container or by taking the sample increments systematically at well-separated points along a heptagonal pattern.
2. As the batch increases in size, it is necessary to collect additional sample increments to make primary sample (Table 2).

Table 2 – Minimum number of sample increments for the primary sample based on batch size.

Size of batch (lbs.)	≤ 2	≤ 4	≤ 6	≤ 8	≤ 10
No. of increments	7	7	8	8	9

Concentrate & Extract Sample Increment Suggestions

Process Lot Weight (grams)	Sample Increments (3-gram increments)
0-230	4
231-680	8
621-1360	12
1361-2720	16
2721-4540	20
4580+	32

Marihuana Infused Product Sampling Size Suggestion

Process Lot (units)	Sample Size (units)
2-15	2
16-50	3
51-150	5
151-500	8
501-3200	13
3201-35000	20

Required Safety Tests and Limits

Potency

Cannabinoid potency data quantifies levels of plant cannabinoids present in cannabis products. Producers are required by Rule 31 of the Emergency Rules published May 30, 2018 to obtain potency levels for THC and CBD, the two most common cannabinoids.

It is important for patients to know THC and CBD levels as these will have a strong influence on the effects of the product. For example, some patients may want a strain with a high CBD:THC ratio. The required cannabinoid tests include Tetrahydrocannabinol level (THC), Tetrahydrocannabinol acid level (THC-A), Cannabidiol (CBD) and Cannabidiol acid levels (CBD-A).

Total THC and CBD values should be calculated and reported as follows:

Total THC=(THCa * 0.877) + d9-THC

Total CBD=(CBDa * 0.877)+ CBD

Chemical Residue

BMMR published a list of allowed chemicals for use on medical marihuana. To assure the safety of the public the department published a list of banned chemical ingredients that cannot be used on medical marihuana products. Chemical residue testing for the current banned chemical ingredients and target limits are provided in the table below. Please note these compounds will be continually evaluated and updated based on available scientific and industry information. Target limits will be developed based on limits of quantitation (LOQ) achievable by the SCFs. Marihuana samples with pesticide active ingredients detected above the detection limit listed below fail and the product must be destroyed.

Table 1: List of Banned ingredients Parts Per Million (PPM)

Analyte	Chemical Abstract Services (CAS) Registry number	Detection Limit (ppm)
Abamectin	71751-41-2	0.5
Acephate	30560-19-1	0.4
Acequinocyl	57960-19-7	2
Acetamiprid	135410-20-7	0.2
Aldicarb	116-06-3	0.4
Azoxystrobin	131860-33-8	0.2

Bifenazate	149877-41-8	0.2
Bifenthrin	82657-04-3	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.2
Carbofuran	1563-66-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorfenapyr	122453-73-0	1
Chlorpyrifos	2921-88-2	0.2
Clofentezine	74115-24-5	0.2
Cyfluthrin	68359-37-5	1
Cypermethrin	52315-07-8	1
Daminozide	1596-84-5	1
DDVP (Dichlorvos)	62-73-7	0.1
Diazinon	333-41-5	0.2
Dimethoate	60-51-5	0.2
Ethoprophos	13194-48-4	0.2
Etofenprox	80844-07-1	0.4
Etoxazole	153233-91-1	0.2
Fenoxycarb	72490-01-8	0.2
Fenpyroximate	134098-61-6	0.4
Fipronil	120068-37-3	0.4
Flonicamid	158062-67-0	1
Fludioxonil	131341-86-1	0.4
Hexythiazox	78587-05-0	1
Imazalil	35554-44-0	0.2
Imidacloprid	138261-41-3	0.4
Kresoxim-methyl	143390-89-0	0.4
Malathion	121-75-5	0.2
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752-77-5	0.4
Methyl parathion	298-00-0	0.2
MGK-264	113-48-4	0.2
Myclobutanil	88671-89-0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738-62-0	0.4
Permethrins*	52645-53-1	0.2
Prallethrin	23031-36-9	0.2
Phosmet	732-11-6	0.2
Piperonyl_butoxide	51-03-6	2
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyridaben	96489-71-3	0.2
Pyrethrins+	8003-34-7	1

Spinosad	168316-95-8	0.2
Spiromesifen	283594-90-1	0.2
Spirotetramat	203313-25-1	0.2
Spiroxamine	118134-30-8	0.4
Tebuconazole	80443-41-0	0.4
Thiacloprid	111988-49-9	0.2
Thiamethoxam	153719-23-4	0.2
Trifloxystrobin	141517-21-7	0.2

* Permethrins should be measured as cumulative residue of cis- and trans-permethrin isomers (cas numbers 54774-45-7 and 51877-74-8).
+ 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).

Residual Solvents

Some producers of marihuana products use solvents to extract and/or concentrate the active ingredients. BMMR has adopted a list of target residual solvents based on a literature review of common extraction and concentration techniques in the industry. Concentration limits are based on the “International Conference for Harmonisation (ICH) Guideline Q3C (R5) on Impurities: Guidelines for residual solvents” and information provided by states with current medical marihuana programs.

Table 2: Concentration Limits for Residual Solvents in Parts Per Million (PPM)

	CAS No.	Detection Limit for Medical Marihuana Products Meant for Inhalation (ppm)	Detection Limit for All Other Medical Marihuana–Infused Goods (ppm)
1,2-Dichloroethane	107-06-2	2	5
Acetone	67-64-1	750	5000
Acetonitrile	75-05-8	60	410
Benzene	71-43-2	1	2

Butane and all isomers	106-97-8	800	5000
Chloroform	67-66-3	2	60
Ethanol	64-17-5	1000	5000
Ethyl acetate	141-78-6	400	5000
Ethyl ether	60-29-7	500	5000
Ethylene oxide	75-21-8	5	50
Heptane and all isomers	142-82-5	500	5000
Hexane and all isomers	110-54-3	50	290
Isopropyl alcohol	67-63-0	500	5000
Methanol	67-56-1	250	3000
Methylene chloride	75-09-2	125	600
Pentane and all isomers	109-66-0	750	5000
Petroleum Ether	8032-32-4	400	400
Propane	74-98-6	2100	5000
Trichloroethylene	79-01-6	25	80
Toluene	108-88-3	150	890
Total xylenes (ortho-, meta-, para-)	1330-20-7	150	2170

Microbiological Impurities

The presence of microbes is common in natural products. It is important to distinguish between organisms ubiquitous in nature and those that are known pathogens. "Indicator tests" don't directly test for pathogens but serve as quality tests or indications that follow-up pathogen testing should be performed (Holmes et al. 2015). Additionally, microbial and fungal limits are not typically reported as "pass/fail", BMMR has established detection limits based on the literature available. The criteria for acceptability in Table 3 (below) lists the microbiological impurities and the detection limits associated with each organism to be tested.

Water activity (Aw) is a measure of the available water that can be utilized for microbiological growth. Aw ranges from 0 to 1 with microbial growth unlikely below Aw 0.6. Most marihuana is dried and cured to a final water activity level of Aw 0.3-0.6, most pathogens cannot grow below Aw 0.9 (Holmes et al. 2015). Water activity, or the moisture of the marihuana flower in units, measured below Aw 0.65 will safeguard marihuana products against microbial growth during storage and before sale.

Table 3: Mycotoxin, Microbial Screening, Foreign Matter, Water Activity and Moisture Content Limits

Mycotoxin Testing		
The total of aflatoxin B1, aflatoxin B2, aflatoxin G1 and aflatoxin G2	<20 uG/KG (ppb) of Substance	
Aflatoxin B1	<5 uG/KG (ppb) of Substance	
Microbial Screening		
		Table 9 of the *Marihuana Inflorescence: Standards of Identity, Analysis, and Quality Control monograph* (BMC 2010)
Total viable aerobic bacteria CFU/g	Unprocessed materials 10^5	
	Processed material 10^5	
	CO_2 and solvent-based extracts 10^4	
Total Yeast and mold CFU/g	Unprocessed materials 10^4	
	Processed material 104	

	CO2 and solvent-based extracts 103	
Total Coliforms CFU/g	Unprocessed materials 10^3	
	Processed material 10^3	
	CO_2 and solvent-based extracts 10^2	
Bile Tolerant gram-negative bacteria CFU/g	Unprocessed materials not detected in 1g	
	Processed material not detected in 1g	
	CO2 and solvent-based extracts not detected in 1g	
E. coli (pathogenic strains) and *Salmonella spp*.	Unprocessed materials 10^5	
	Processed material 10^5	
	CO2 and solvent-based extracts 10^4	
Foreign matter inspection (crude marihuana material)		
Not more than 5.0% of stems 3mm or more in diameter; not more than 2.0% of other foreign matter.		*Marihuana Inflorescence: Standards of Identity, Analysis, and Quality Control monograph* **(BMC 2010)**
Water activity content		
Water activity levels for usable marihuana must be less than or equal to Aw 0.65		
Water activity levels for marihuana-infused products must be greater than or equal to Aw 0.85		
Moisture Content of dry material (crude marihuana after packaging):		
Not more than 15%		*Marihuana Inflorescence: Standards of Identity, Analysis, and Quality Control monograph* **(BMC 2010)**

Heavy Metals

Elemental impurities do not provide any therapeutic benefit to the medical marihuana patient. Because of their high degree of toxicity, arsenic, cadmium, lead and mercury rank among the priority metals that are of public health significance (Tchounwou P et al. 2012). The BMMR requires an SCF to test for heavy metal presence in medical marihuana. Table 4 lists the four heavy metals required in contaminant testing and their

associated concentration limits based on a 10 gram/day consumption of medical marihuana.

Table 4: Heavy Metals Concentration Limits in Parts Per Million (PPM)

Heavy metal	PPM
Lead	2.0
Arsenic	0.98
Mercury	2.0
Cadmium	0.63

Proficiency Testing

The Medical Marihuana Facilities Licensing Act (MMFLA) and the May 30, 2018 Emergency Rules, Rule 31(8) require the Dept of Licensing and Regulatory Affairs to establish a proficiency testing program and designate safety compliance facility participation. A safety compliance facility shall analyze proficiency test (PT) samples using the same procedures with the same number of replicate analyses, standards, testing analysts and equipment as used for marihuana product testing.

The following proficiency testing must be performed by Safety Compliance Facilities (SCFs) annually:

- SCFs will need to complete one set of PT samples for all tests on their scope of accreditation.
- Proficiency test results must be conveyed as numerical accuracy percentages, not simply as PASS/FAIL results. Actual PASS/FAIL results must be calculated based on accuracy thresholds generated by reproducibility studies specific to each assay.
- Safety Compliance Facilities may use any ISO 17043 accredited laboratory for their testing needs. There are several ISO 17043 accredited laboratories where samples can be purchased, including The Emerald Test, NSI Lab Solutions, Sigma-Aldrich and Absolute Standards Inc.
- For parameters where there are currently no commercially available PT samples, SCFs should send samples (as blind samples) to another licensed SCF who performs testing by the same or similar methodology. The results should then be compared. A passing grade for the PT requires a score of at least 80%.
- Copies of all proficiency testing (both acceptable and unacceptable) results need to be sent to the department for review via email: LARA-BMMR-Enforcement@michigan.gov. Please indicate in the subject line “Proficiency Testing Results for Review-SCF Name.”

ADDITIONAL TESTING

BMMR is committed to evidence-based decision-making when implementing technical guidance for licensed SCFs. As research into marihuana use and safety advances, this report will be revised and updated to reflect the state of science as it pertains to the medical marihuana industry. Please be aware that once the permanent rules are promulgated, additional testing may be required.

Medical Marihuana Testing Requirements

	Usable Marihuana	Usable Marihuana (Trim/Shake/Plant Material) being sent to Processor	Marihuana Concentrate (non-solvent & non-Co2))	Marihuana Concentrate (solvent based)	Marihuana Concentrate (C02)	Marihuana-Infused Product
Moisture Content	√					
Potency Analysis	√		√	√	√	√
Foreign Matter Inspection	√		√			√
Microbial Screen	√		√			√
Mycotoxin Screen	√		√	√	√	√ (If Extract not previously tested for)
Water Activity	√					√
Heavy Metal Screen	√		√	√	√	√ (If Extract not previously tested for)
Residual Solvent Test				√		√ (If hydrocarbon-based solvent used & not previously tested)
Chemical Residue Analysis	√	√	√	√	√	√ (If Extract not previously tested for)

APPENDIX A-DEFINITIONS

Batch- Means not more than 10 pounds(lbs.) of plants of the same variety of medical marihuana that have been:

(i) Grown, harvested, and processed together; and
(ii) Exposed to substantially similar conditions throughout cultivation and processing.

Chain of Custody- The chronological documentation showing the collection, custody, control, transfer, analysis, and disposition of a sample.

CFU/g- Colony forming units per gram. Refers to a measure of the amount of living bacteria per given amount (1 gram) of a sample.

Safety Compliance Facility- A facility that is licensed to perform tests of medical marihuana and products containing medical marihuana that is:

(a) Accredited as operating to ISO standard 17025 by an accreditation body that is:

(i) Operating in accordance with the International Organization for Standardization (ISO) standard ISO/IEC 17011; and

(ii) A signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA);

(b) Independent from all other persons involved in the Michigan Medical Marihuana industry; and

(c) Licensed with the Bureau of Medical Marihuana.

Limit of Quantification (LOQ)- The lowest concentration at which the analyte can not only be reliably detected but at which some predefined goals for bias and imprecision are met.

METRC- Franwell Marijuana Enforcement Tracking Regulation and Compliance statewide monitoring system.

Medical Marihuana- Any product containing usable marihuana or medical marihuana finished product.

Medical Marihuana Concentrate- A product derived from medical marihuana that is kief, hashish, bubble hash, oil, wax, or other product, derived from marihuana or that includes cannabinoids extracted from the plant by any means.

Medical marihuana-Infused Product-

(a) Any oil, wax, ointment, salve, tincture, capsule, suppository, dermal patch, cartridge or other product containing medical marihuana concentrate or usable marihuana.
(b) Does not include a food.

Representative Sample- A sample obtained according to a sampling procedure designed to ensure that the different parts of a batch or lot or the different properties of a batch or lot are proportionally represented.

Sample- An amount of medical marihuana collected by laboratory personnel from a licensee and provided to a safety compliance facility for testing.

Solvent- A substance that can dissolve another substance, or in which another substance is dissolved, forming a solution.

Target Analyte- A chemical the lab must test for to see if it is present in medical marihuana.

Usable Marihuana-

(a) The dried leaves and flowers of the marihuana plant.
(b) Does not include seedlings, seeds, stems, stalks or roots of the plant.

Water Activity- The partial vapor pressure of water in a substance divided by the standard state partial vapor pressure of water.

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