SAFETY COMPLIANCE FACILITY SAMPLING AND TESTING INFORMATION

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This information is intended for Licensed Safety Compliance Facilities (SCF) regulated by the Marijuana Regulatory Agency (MRA)

Version 4.0

This information does not constitute legal advice and is subject to change. Licensees are encouraged to seek legal counsel to ensure their operations comply with the Medical Marihuana Facilities Licensing Act and associated Administrative Rules.

INTRODUCTION

MRA is committed to evidence-based decision-making when implementing technical guidance for licensed SCFs. As research into marijuana use and safety advances, this guide will be revised and updated to reflect the state of science as it pertains to the medical marijuana industry.

The sampling and analysis described in this guidance shall be conducted by a licensed SCF accredited by the International Organization for Standardization (ISO) 17025 (Rule 47(9)(b) R 333.247).

Analytical testing of medical marijuana 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, molds 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 marijuana.

Rule 47 (R 333.247) of the Administrative Rules establishes testing and procedural requirements for Safety Compliance Facilities (SCFs).

The tests identified in Rule 47 (R 333.247) of the Administrative Rules include:

- Potency
- Chemical residue
- Heavy metals
- Residual solvents
- Microbial screening including foreign matter
- Mycotoxin (if requested by the agency)
- Moisture content
- Water activity

Medical marijuana safety and potency is to be analyzed using testing methodology validated by an independent third party and approved by the agency. The quality control and quality assurance program must conform to ISO/IEC 17025 standards.

If there are published standard methods and/or performance requirements, they have been adopted for the required safety tests in Rule 47. In instances where there are not

published methods or standard requirements, the agency has chosen best practices which are listed below.

Note: All compliance testing must conform to ISO/IEC 17025 standards for quality control and quality assurance including the validation of matrices not listed here.

Potency

All testing must meet the standard method performance requirements listed below, for matrices not listed the method performance requirements should be as close to the published SMPR's as possible using standard analytical methods.

Concentrates: AOAC SMPR 2017.001
http://www.aoac.org/AOAC_Prod_Imis/AOAC_Docs/SMPRs/SMPR%202017_001.pdf

Dried Plant Materials: AOAC SMPR 2017.002
http://www.aoac.org/AOAC_Prod_Imis/AOAC_Docs/SMPRs/SMPR%202017_002.pdf

Edible Chocolates: AOAC SMPR 2017.019
http://www.aoac.org/AOAC_Prod_Imis/AOAC_Docs/SPSFAM/SMPR2017_019.pdf

Note: All compliance potency must conform to ISO/IEC 17025 standards for quality control and quality assurance including the validation of matrices not listed here.

Please note: Rule 47(16) prohibits a safety compliance facility from desiccating samples prior to performing potency analysis.

Residual Solvent Testing

All testing must meet the standard method performance requirements for the adopted reference method.

United States Pharmacopeia (USP), 2008. "<467> Residual Solvents."
https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/generalChapter467Current.pdf

Note: All compliance testing must conform to ISO/IEC 17025 standards for quality control and quality assurance including the validation of matrices not listed here.

Chemical Residue Testing

All testing must meet the standard method performance requirements listed below.

Pesticides: AOAC SMPR 2018.011
http://www.aoac.org/AOAC_Prod_Imis/AOAC_Docs/SMPRs/SMPR2018_011.pdf

Note: All compliance testing must conform to ISO/IEC 17025 standards for quality control and quality assurance including the validation of matrices not listed here.

Heavy Metals

All testing must meet the standard method performance requirements for the adopted reference method.

United States Pharmacopeia (USP), 233, https://www.usp.org/sites/default/files/usp/document/our-work/chemical-medicines/key-issues/233_ElementalImpuritiesProcedures.pdf

Using EPA 3052 (microwave digestion) for the sample prep.

https://www.epa.gov/sites/production/files/2015-12/documents/3052.pdf

Note: All compliance testing must conform to ISO/IEC 17025 standards for quality control and quality assurance including the validation of matrices not listed here.

Validation Guidelines

In the absence of a standard method, a single laboratory validation or equivalent is required to show that the method is fit for purpose for the intended matrix and, if applicable, that any modifications to the original method do not negatively impact performance. Method validation should, at a minimum, verify accuracy, precision, analytical sensitivity, analytical specificity, limit of detection, limit of quantification, reportable range and the identification of interfering substances.

For microbiological methods adopted from a matrix specific standard method, inclusivity/exclusivity does not require complete reassessment, provided that the referenced media, primers, probes, antibodies, critical chemistries, etc., were not modified. Below are example validation methods that can be used.

- Association of Analytical Communities (AOAC) 2012. “Methods Committee Guidelines for Validation of Microbiological Methods for Food and Environmental Surfaces.” AOAC: http://www.aoac.org/imis15_prod/AOAC_Docs/StandardsDevelopment/AOAC_Validation_Guidelines_for_Food_Microbiology-Prepub_version.pdf
- Association of Analytical Communities (AOAC) 2002. “Guidelines for Single Laboratory Validation of Chemical Methods for Dietary Supplements and Botanicals” AOAC: http://www.aoac.org/imis15_prod/AOAC_Docs/StandardsDevelopment/SLV_Guidelines_Dietary_Supplements.pdf

QUALITY CONTROL

When methods do not include quality control parameters the agency has adopted the following requirements for the analysis of potency, residual solvents, chemical residue and heavy metals. Each method must demonstrate the following standard method parameters.

Initial Demonstration of Capability (IDC): Before beginning the analysis of samples, an initial demonstration of capability (IDC) must be performed. The IDC includes a demonstration of the ability to achieve a low background, the precision and accuracy required by the method, and determination of the limit of detection (LOD) (see below). An IDC should be performed for each instrument. It is also recommended that an IDC be performed by each analyst. In addition, it is recommended that the IDC also address the variability introduced if more than one sample preparation technician is used. Precision, accuracy and LOD should be similar for each technician. The analyst should recalculate IDCs when a change in the method, analyst or instrument is made which could affect the precision, accuracy, or sensitivity. Minor changes should prompt a check to ascertain that the precision, accuracy and sensitivity have been maintained.

Limit of Quantitation (LOQ): Initial LOQ calculations for all regulated contaminants are required. If there is no procedure to determine the detection limits in the method, an LOQ of 1/2 of the published action limit must be achieved. Sample preparation and analyses for the LOQ calculation should be made over a period of at least three days to include day-to-day variation as an additional source of error. The analyst should determine LOQs initially, when any change is made which could affect the LOQs, or more frequently if required by the method. In addition, the analyst must demonstrate low-level capability on an ongoing basis through an LOQ determination or repeated low-level analyses. Presently, no standard procedure exists, so it is recommended that the LOQ be defined as the lowest concentration for which pattern recognition is possible.

Limit of Detection (LOD): The laboratory's limit of detection (LOD) should be reported to the client along with the data. The reporting limit must be below the published action limit. Laboratories should not report contaminants at levels less than the level at which they routinely analyze their lowest standard.

Calibration Check (CC): Where the determinative time is extensive and the instrument is very stable, the calibration curve should be initially developed as specified in following the calibration requirements listed below. Thereafter, each day analyses are performed, this curve should be verified by analysis of at least one standard for each of the target analytes at the expected concentration range. This verification should be done at both

the beginning and end of the analyses. All checks must be within 10% of the known value or the instrument is to be recalibrated as specified in the calibration requirements.

For some methods an initial conditioning injection is to be made to deactivate active sites that may have developed overnight. Depending on the method, the blank may be appropriate for this. It is recommended that a calibration standard of one component of a multicomponent analyte also be analyzed each day or work shift.

Calibration requirements: At the beginning of each day that samples are to be analyzed, a calibration curve covering the sample concentration range and all target analytes should be generated according to the approved SOP. Depending on concentration ranges, the curve should be composed of four or more points. Calibration is to occur not less than monthly.

Blanks: A laboratory reagent blank should be carried through the full analytical procedure with every sample batch. In general, results from laboratory reagent blanks should not exceed the laboratory's Limit of Quantitation (LOQ), the lowest concentration of standard used for quantitation.

Laboratory Fortified Sample Matrix: Laboratory fortified sample matrix requirements in the methods must be met. If there are no laboratory fortified sample matrix requirements in the method, the following are guidelines to be used. The laboratory should add a known quantity of analytes to a percentage (to be described in the approved SOP) of the routine samples to determine sample matrix interference. The fortified concentration should not be less than the concentration of the sample selected for fortification unless specified by the method. If the sample concentration is unknown or less than detectable, the analyst should choose an appropriate concentration (e.g., a percentage of the published action Limit or mid-point in the calibration range). Over time, samples from all routine sample sources should be fortified. The procedure should be described in the SOP. If any of these checks are not within the criteria specified in the method or control limits specified in this document, and the laboratory performance is in control, the result for that sample should be flagged to inform the data user that the results are suspect due to matrix effects.

Quantitation of Multicomponent Organic Analytes (pesticides, fungicides, miticides): The quantitation of multicomponent analytes requires professional judgment on the part of the analyst. This is required due to the complex nature of the chromatography involved, sample weathering, degradation and interferences that may be present in the samples. The pattern of peaks found in the sample should be examined carefully and compared to a standard. The peaks in the sample that match the peak ratios in the standard can be used in quantitation. Peaks that have obvious interferences or peaks exhibiting poor peak shape or that appear to have been degraded or weathered should not be used for quantitation. A representative number (5-9) of peaks is suggested. Peak area should be used for quantitation and the analyst should ensure that the samples and standards have been integrated in the same manner. Quantitation can be done by using the total peak area or height (comparing the area of the 5-9 peaks used for

quantitation of the sample to the area of the standard) or by calculating each peak separately (using area) and taking the average concentration of the 5-9 peaks. Because of factors such as peak shape and baseline rise, the most accurate quantitation is obtained when the concentration of the sample closely matches that of the standard (e.g., within 20% of the standard).

Water Activity

ASTM D8196-18

Note: All compliance testing must conform to ISO/IEC 17025 standards for quality control and quality assurance including the validation of matrices not listed here.

Moisture Content

Loss on drying: Not more than 10.0% of its weight, determined on 1.000g of the marijuana by drying in an oven at 105^0C for 2 hours.

Microbial Qualitative Presence/Absence

Concerning the testing of marijuana product for microbiological contaminants, there is a large pool of standard methods on which to draw. All microbiological methods employed should include applicable controls. Qualitative pathogen methods must confirm presumptive results as either positive or negative by the inclusion of a confirmation step. Confirmation of pathogens should not be addressed by simply rerunning positive sample enrichments or retesting remaining sample.

Methods applicable to *Salmonella spp*., *E. coli* testing and *Aspergillus spp*.:

- Association of Analytical Communities (AOAC) 2019. “Salmonella in Foods, 967.25”
- Association of Analytical Communities (AOAC) 2019. “Total Coliform and E. Coli, 991.14, 998.08”, with an appropriate confirmation step.
- Qualitative PCR assays
- USP 61, 62,1223

Microbial Quantitation

Methods applicable to total aerobic, total coliforms, total yeast and mold and bile-tolerant gram-negative bacteria.

- Association of Analytical Communities (AOAC) 2019. “Yeast and Mold Counts in Foods, 997.02.”
- Association of Analytical Communities (AOAC) 2019. “Total Aerobic Count Plates, 2015.13, 990.12.”
- Association of Analytical Communities (AOAC) 2019. “Total Coliform and E. Coli, 991.14, 998.08”
- Association of Analytical Communities (AOAC) 2019. “Total Bile Tolerant Gram-Negative Bacteria, 2003.01.”

- Quantitative PCR assays
- USP 61, 62,1223

Note: All compliance testing must conform to ISO/IEC 17025 standards for quality control and quality assurance including the validation of matrices not listed here.

Foreign Matter/Filth Analysis

AOAC METHODS: methods are available for light filth in leafy products and excreta in condimental seeds. 969.41

For further information regarding the use of a microscope, please refer to the ORA Laboratory Manual, FDA Office of Regulatory Affairs. Section 4, Microanalytical & Filth Analysis. In this section, please see 4.2.2. Microscopic Examination and Microscope Accessories. Within that section, please refer to Section B (Discussion, Part 1 C re: stereomicroscopes) as well as Section B (Discussion, Part 2 Fundamental Microscopic Techniques and Procedures, part a).

SAMPLING

In an effective testing program, standardized sampling procedures are an integral component to quality laboratory testing. The data generated from all analytical methods should 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.

According to Rule 47(9)(c) (R 333.247) of the Administrative Rules an SCF shall maintain internal standard operating procedures (SOPs). 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 the sample matrix, analytical method and laboratory specific procedures, but a **minimum sample volume of 0.5% of the batch is required to achieve a representative sample for analysis** in accordance with Rule 48(2)(b) (R 333.248) of the Administrative Rules.

An example collection procedure is included in this document, but each SCF is required by rule R 333.247 9(c) to maintain internal standard operating procedures, which

includes having their own collection procedure. 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).

Representative Sampling

When sampling a batch, the sampler should check for 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 marijuana product being sampled such as color, shape and size. The batch should 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 chain of custody and in the statewide monitoring system.

General guidelines for sampling include:

1. Gaining access to the entire batch and in addition, ensuring that the package has the correct Statewide Monitoring System RFID tag.
2. Confirming the source package information (mass, product name, tag number) in Statewide Monitoring System with the physical batch.
3. Use of appropriate sampling equipment and consistently following procedures.
4. Taking equal portions for each sample increment.
5. Randomly or systematically taking sample increments throughout the batch.
6. Obtaining a minimum number of sample increments, which will be based on batch size.
7. Recording all observations and procedures used while collecting the sample increments on an appropriate chain of custody.
8. Samplers should ask the facility to show the source package for derivative packages to ensure that all required tests are selected by the facility at the time of the sampling event.
9. Questions about required testing should be referred to the agency.
10. Chain of custody documents should be written legibly.
11. If errors are made, the incorrect information should have one line through so the previous information is visible. The initials of the person making the correction should be placed above the incorrect data and the correct information written next to it.
12. Sampling weights should be to the hundredths place.

Random Sampling

Prior to beginning the sampling procedure, the sampler should survey the site to identify the conditions under which the marijuana is being kept. All sampling must be performed by personnel employed by the SCF and must be in accordance with the SCF’s internal SOP. The requirements for sampling and sample size are provided in Rule 48(2)(b) (R

333.248) of the Administrative Rules. 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 increment within the batch has an equal chance of being selected.

Sample increments should be randomly selected from different locations within a container or set of containers. The SOP should include how to do the following:

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 marijuana samples:

- Sampling equipment such as spoons, spatulas, transfer pipettes, or other matrix specific tools
- Tongs
- 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.

Please ensure that all information is legible, any errors should have one line through with the initials of the person correcting, date and time. Do not scribble or write over errors.

Information that should be included:

- Name and address of producer including licensee number
- Product type
- Indicate whether the samples are for repeat analysis due to an initial test failure
- Total mass of the source package
- Unique Statewide Monitoring System package tag for the source package
- Total container number
- Number of sample increments
- Number of containers sampled
- Number of sample containers collected
- Unique Statewide Monitoring System package tag for the sample package
- Total mass sampled
- Sampling Procedure ID and revision date
- Description of equipment used
- Marijuana facility where samples were collected
- License number for the marijuana facility
- Date sampled
- SCF license number
- Sampler's signature
- Name of responsible party for the batch and transport information; the transfer manifest can be used for this information
- Receiving SCF and types of tests required or requested

Sampling a Batch of Marijuana

1. Physically locate the batch to be sampled as well as the source package and tag information from the statewide monitoring system. **Please note: it is the responsibility of the SCF to take 0.5% of the batch, each batch mass should be compared to the statewide monitoring system to ensure that the SCF has access to the entire batch of product.**
2. Review the container label information for batch number, producer, and other pertinent information. Each harvest batch should be separated into batches of 15 lbs. or less and must be assigned a source package tag in the statewide monitoring system. **Do not sample if the product is not in the statewide monitoring system or if the batch weight or details do not match.**

3. Determine the number of containers in the batch and the batch size. Verify the batch size for each container. **Do not sample if the batch size is unavailable or the harvest batch exceeds 15 lbs. or if the batch weight does not match the information entered into the statewide monitoring system.**
4. Determine the number of containers from which sample increments must be collected using a random number generator.
5. Select the appropriate sampling tool to ensure that it reaches all portions of the container. **Please note: All samples must be collected in compliance with Rule 33 (4) A marihuana facility shall ensure that the handling of marihuana product is done in compliance with current good manufacturing practice in manufacturing, packing, or holding human food, 21 CFR part 110.**
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 should not be used.
7. To prevent contamination, sampling tools should 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.
8. Results from cleaning procedure tests should be below the reporting limit of the target analyte(s) for the associated analyses.
   Note: Samplers should 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 should bring enough sets of sampling equipment to use a new set at each facility. All field equipment should 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.
9. Visually inspect each test sample increment to assess uniformity;
10. If non-uniformity is identified, record observation in the sampling report. It is expected with marijuana 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.
11. Combine all sample increments to form the composite sample.
12. Ensure enough sample increments are taken to meet sample size requirements for all analytical method(s) being performed.
13. Seal and label the composite sample with the following minimum requirements:

    - Sample package tag assigned in the statewide monitoring system
    - Sampling date and name of sampler
    - Producer's license
    - Harvest batch numbers

14. 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.
15. Complete the sampling report while at the sampling location as well as an appropriate chain of custody form and data entry into the statewide monitoring system.
16. The sample, sampling report and manifest from the statewide monitoring system should be transported to the SCF using packaging appropriate for secure and timely transport.

Preparation of the 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 with the sample package tag assigned in the statewide monitoring system.
4. 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.

Preparing a sample for Retesting

1. As prescribed in Rule 46 (R 333.246), a safety compliance facility may test or retest a sample to validate the results of a failed safety test except as indicated under subrule (2) of this rule.
2. A failed test sample must pass 2 separate retests consecutively to be eligible to proceed to sale or transfer. If both retests pass, the batch is out of quarantine and eligible for sale or transfer. If 1 or both retests fail, the marihuana product must be destroyed as provided in these rules. A failed safety test must include documentation detailing the initial failure and the corrective action in the statewide monitoring system.
3. Rule 48(2)(f) (R 333.248) A safety compliance facility may request additional sample material from the same licensee from which the sample was collected for the purposes of completing the required safety tests as long as the requirements of this rule are met. Each retest will be a new sample and the sample must be enough in mass to perform the testing for the required parameter and must be chosen at random from the harvest batch.
4. A marihuana product is prohibited from being retested in all the following circumstances:

a) The marihuana product is in a final package.

b) A final test for chemical residue failed pursuant to these rules. If the amount of chemical residue or chemical residue active ingredient found is not permissible

by the agency, the marijuana product is ineligible for retesting and the product must be destroyed.

c) A final failed test for microbials on marihuana-infused product is ineligible for retesting and the product must be destroyed.

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 marijuana. The sampler should be prepared to collect adequate sample mass for all analyses requested by the producer.

Field Quality Control

Field sampling equipment should be certified clean prior to use by the SCF. Cleaning techniques will vary depending upon the desired analysis. In general, sampling equipment should be sterile for microbiology samples and clean for chemistry samples. The SCF should 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 retested.

Field Duplicates

Field duplicates are recommended for any marijuana sampling event. Field duplicates should be sampled in such a way as to replicate the primary sampling event and all requirements should be clearly outlined in the SCF's field sampling SOP.
The field duplicate is sampled by the SCF to ensure that the laboratory has enough sample on hand to satisfy any potential need to perform additional analyses on the product.

The SCF may opt to determine the total minimum and maximum required weight for each product type and each analysis in order to determine the necessary amount for the creation of a field duplicate. A field duplicate can be a replicate sample of the primary sample that consists of the minimum sampling weight requirement with the same number of sample increments as the primary sample. If the SCF opts to take an amount greater than 0.5% for the purposes of collecting a field duplicate, Rule 48 them to do so. Please see the applicable section below.

Rule 48 (2)(b) The safety compliance facility shall collect a sample size **sufficient to complete all analyses required**, but the sample **shall not be less than 0.5% of the weight of the batch**.

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 should pass the required analysis at <LOQ for cleaning validation. If the equipment blank is collected at the sampling event, the lab should have acceptability guidelines listed in their SOP and what actions to take if the evaluation demonstrates unacceptable results.

Demonstration of Capability

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

The IDC 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

Model qualifications for samplers of marijuana are:

- Physically able to perform the duties of a sampler
- No conflict of interest
- 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.

Field Audits

The SCF should adopt an ongoing system for performing audits of field activities. Field audits should 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 should take timely corrective action and 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

Rule 1 of the Administrative Rules defines the following terms:

(b) Batch refers to all marihuana product of the same variety that has been processed

together and exposed to substantially similar conditions throughout processing.

(i) Harvest batch refers to a designated quantity of harvested marihuana, all of which is identical in strain and has been grown and harvested together and exposed to substantially similar conditions throughout cultivation.

Rule 48(2)(b) (R 333.248), states 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 15 pounds. The department may publish recommendations for this subdivision based on the type of marihuana product being tested.

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.

REQUIRED SAFETY TESTS AND ACTION LIMITS

Potency

Cannabinoid potency data quantifies levels of plant cannabinoids present in cannabis products. Producers are required by Rule 47 (R 333.247) of the Administrative Rules 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

Please note: Rule 47(16) prohibits a safety compliance facility from desiccating samples prior to performing potency analysis.

Terpene Testing

In accordance with Rule 47 (18) A safety compliance facility may perform terpene analysis on a marihuana product using an ISO accredited method. There are no established safety standards for this analysis. The laboratory shall analyze a sample of marijuana or marijuana infused product to determine whether the terpenoid profile of the sample conforms to the labeled content of terpenoids in accordance with Rule 76 (2). The laboratory shall report the result of the terpenoid testing on the COA both as a percentage and in milligrams per gram (mg/g).

Chemical Residue

MRA published a list of approved chemicals for use on medical marijuana. To assure the safety of the public the agency published a list of banned chemical ingredients that cannot be used on medical marijuana products in accordance with Rule 47(12). The rule states, "the list for acceptable action limits must meet those set forth in legal regulations for tolerances and exemptions for chemical residues in food, 40 CFR part 180, subpart C, or the federal insecticide fungicide, and rodenticide act, 7 USC 136 to 136y, whichever is more stringent." Since there are no federally recognized and published limits for marijuana in 40 CFR part 180, subpart C, or the federal insecticide fungicide, and rodenticide act, 7 USC 136 to 136y; the agency published the below list.

Chemical residue testing will be performed for the published list of banned chemical ingredients, the action limits are provided in the table below. If a sample exceeds the published action limit, the sample will be documented as a fail in the statewide monitoring system. The laboratory shall report the result of the heavy metals test in parts per million (ppm) on the COA and indicate "pass" or "fail" on the COA. Action limits will be updated based on the limits of quantitation (LOQ) achievable by the SCFs. The list will be continually evaluated and updated based on available scientific and industry information, or if the federal government adds marijuana to 40 CFR part 180, subpart C, or the federal insecticide fungicide, and rodenticide act, 7 USC 136 to 136y.

Table 1. List of Banned ingredients Parts Per Million (ppm)

Analyte	Chemical Abstract Services (CAS) Registry number	Action 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	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
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 marijuana products use solvents and other chemicals to extract and/or concentrate active ingredients. MRA has adopted a list of action limits for solvent based products based on a literature review of common extraction and concentration techniques in the industry. Action 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 marijuana programs. The laboratory shall report the result of the residual solvent testing in parts per million (ppm) and indicate "pass" or "fail".

Table 2. Action Limits for Residual Solvents in Parts Per Million (ppm)

Solvent	CAS Number	Action Limit for Inhalation (ppm)	Action Limit for all other products (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
Butanes 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	142-82-5	500	5000
Hexanes 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
Pentanes all isomers	109-66-0	750	5000
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

Foreign Matter Analysis

Pests and other foreign matter including insects, metal fragments and both organic and non-organic debris are found in food as well as tobacco products, and will likely also be detected in marijuana, particularly as manufactured products enter the marketplace. The FDA considers debris of this kind in food to pose a negligible health hazard but recognizes that quality and user experience is compromised. Because of this, the FDA has methods for monitoring (FDA 2013b), which can be consulted to compare standards for different food commodities.

The action limit for crude marijuana is not more than 5.0% of stems, not more than 2.0% of other foreign matter. Failures should be documented photographically. It is recommended that the SCF clearly outline calculation guidelines and ranges for total surface area contamination. Foreign matter analysis should be performed prior to all other testing aside from microbials. The material remaining after Foreign Matter Analysis is acceptable for all chemical testing but should not be used for any microbial testing. The amount of marijuana or marijuana product used for testing should be no less than 30% of the total gram weight or total sample lot obtained for compliance testing.

In the case of marijuana flower, the allotted 30% should come from separate, intact buds.

1. The buds should be separated into no less than 10 increments, the results from which can be averaged together as total foreign matter contamination.

2. Dissection of nodes should be done whenever physically possible.

3. If dissection of distinct nodes is deemed unnecessary, due to the small and compact nature of the bud (“popcorn” buds), the buds then should be examined in their entirety and additionally cut in half to observe the inside portion.

4. In the case of marijuana trim, kief, concentrate or infused product, the calculation to determine 30% of the sampling batch should be included in the SOP.

5. Filth analysis should be performed at a low-power magnification.

6. Quantitation of filth should be done as a total surface area calculation. The laboratory derived calculation should be included in the SOP.

7. If a sample fails for foreign matter, the laboratory should include a note in the statewide monitoring system listing all contaminants identified.

Analysis for organic matter:

The 2% action limit is defined by approximate surface area (SA) and a detailed example of how this value is estimated can be found below:

- 1 node of an average sized marijuana bud has a total surface area of approximately 1.0 inch. It is reasonable to assume that there are, approximately, 5 nodes / 1-gram bud and an average surface area of 5.25 inches / 1-gram bud resulting in a total SA of 52.5 inches for 10, 1-gram buds of flower material.

It is recommended that the SCF determine average surface area for common pests and create an easy-to-use scale for identifying passing and failing samples. Total surface area for contamination by mold could be done by estimating total surface coverage by mycelia or as otherwise determined by the SOP.

Analysis for inorganic matter:

For these purposes, inorganic matter includes, but is not limited to, any material that would not normally be found on a living organism (plant) and includes materials such as glass, metal shavings, or synthetic fibers. In this case, the presence of any inorganic matter on any marijuana plant, concentrate, or infused product would result in an automatic failure for foreign matter. The observed matter should be documented photographically, and a note of the results should be included in the notes entered into the statewide monitoring system.

Moisture Content of dry material (crude marijuana after packaging)

Not more than 15%

Water activity (Aw)

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 marijuana 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).

- A marijuana sample shall be deemed to have passed water activity testing if the water activity does not exceed 0.65 Aw
- A marijuana infused product shall be deemed to have passed water activity testing if the water activity does not exceed 0.85 Aw

Microbial Limits

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” do not directly test for pathogens but serve as quality tests or indications that follow-up pathogen testing should be performed (Holmes et al. 2015). The criteria for acceptability are in Table 5 (below). The table lists the microbiological impurities and the detection limits associated with each organism to be tested. Any detection that exceeds the published limit is considered a fail.

In addition, Aspergillus has been added to the organisms which will require identification. Aspergillus is a mold that produces extremely hardy spores and is

capable of replication at much lower water activity levels compared to other organisms. Under normal conditions, the human immune system removes these from the lungs. In the immunocompromised, however, certain Aspergillus species can cause invasive lung disease. MRA has established detection limits based on the literature available. The laboratory shall report the result of the microbial impurities testing by indicating “pass” or “fail” on the COA.

Table 3. Microbial Screening Limits (CFU/g)

	Total Viable Aerobic Bacteria	**Total Yeast and Mold**	**Total Coliforms**	**Bile-tolerant gram-negative bacteria**	***E. coli* (Shiga toxin-producing E. coli (STEC) and**	***Salmonella spp.***	***Aspergillus spp. (flavus, fumigatus, niger & terreus)***
Unprocessed materials	N/A	10,000	1000	1000	Not detected in 1 gram	Not detected in 1 gram	If *Aspergillus spp*. are detected, the sample fails
Processed material	100,000	10,000	1000	1000			
CO2 and solvent-based extracts	10,000	1000	100	100			

Heavy Metals

Elemental impurities do not provide any therapeutic benefit to the medical marijuana patient. Because of their high degree of toxicity, arsenic, cadmium, lead, chromium and mercury rank among the priority metals that are of public health significance (Tchounwou, P., et al. 2012). The MRA requires an SCF to test for the presence of heavy metals in medical marijuana.

Table 6 lists the heavy metals required and their associated concentration limits based on a 10 gram/day consumption of medical marijuana. A sample shall be deemed to have passed the heavy metals testing if the presence of heavy metals does not exceed the action levels listed in the following table.

Table 4. Heavy Metals Concentration Limits

Heavy metal	Action Limit for all Inhaled Marijuana (ppm)	Action Limit for other Marijuana products (ppm)
Lead	< 0.5	< 0.5
Inorganic Arsenic	< 0.2	< 1.5
Mercury	< 0.1	< 3.0
Cadmium	< 0.2	< 0.5
Total Chromium	< 0.6	2.0

The laboratory shall report the result of the heavy metals test in parts per million (ppm) on the COA and indicate “pass” or “fail” on the COA.

Homogeneity

Please refer to this bulletin for guidance**.**

Proficiency Testing

The Medical Marihuana Facilities Licensing Act (MMFLA) and the Administrative Rules, Rule 47(8) (R 333.247) require the Marijuana Regulatory Agency 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 marijuana product testing.

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

- SCFs will need to complete one set of acceptable PT samples for all tests performed. The samples must be from an approved third-party vendor.
- Any ISO 17043 accredited PT vendor may be used. There are several ISO 17043 accredited vendors 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%.
- At least annually the agency will require unscheduled random testing of matrix matched samples to evaluate the overall performance of the SCF’s.

Copies of all proficiency testing (both acceptable and unacceptable) results must be sent directly to the agency for review from the PT vendor via email to MRA-compliance@michigan.gov.

Table 5. Medical Marijuana Testing Requirements

	Bud, shake/trim from Harvest Batch	Marijuana Extract non-solvent & non-CO_2*	Marijuana Concentrate Solvent-based**	Marijuana Concentrate (Supercritical $C0_2$) no additional solvent used***	Marijuana-Infused Product
Moisture Content	√				
Homogeneity					√
Potency Analysis	√	√	√	√	√
Foreign Matter Inspection	√	√			√
Microbial Screen	√	√			√ **Failed tests cannot be repeated**
Water Activity	√				√
Heavy Metal Screen	√	√	√	√	√ (If Extract or concentrate not previously tested)
Residual Solvents			√		√ (If Extract or concentrate not previously tested
Chemical Residue Analysis	√ **Failed tests cannot be repeated**	√ **Failed tests cannot be repeated**	√ **Failed tests cannot be repeated**	√ **Failed tests cannot be repeated**	√ (If Extract or concentrate not previously tested) **Failed tests cannot be repeated**

*Extraction using ice water, rosin press or dry ice.

**Solvents are used in the extraction process including Butane, Ethanol/Isopropyl alcohol, etc.

***Extraction process without winterization where a solvent is used. This abbreviated testing ONLY applies to products created without the use of a solvent. Products that are winterized MUST follow the solvent-based testing requirements.

APPENDIX A-DEFINITIONS

Batch- means all marijuana product of the same variety that has been processed together and exposed to substantially similar conditions throughout 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 bacteria per given amount (1 gram) of a sample.

Harvest batch- means a designated quantity of harvested marijuana, all of which is identical in strain and has been grown and harvested together and exposed to substantially similar conditions throughout cultivation.

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

Marijuana Infused Product-means any marijuana-infused product containing marijuana that is intended for human consumption in a manner other than smoke inhalation.

Marijuana Product- means marijuana or a marijuana-infused product, or both, as those terms are defined in the act unless otherwise provided for in these rules.

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

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 marijuana 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. Examples of solvents include water, acetone, turpentine and ethanol.

Statewide Monitoring System- Compliance statewide monitoring system.

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

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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