**Division of Cannabis Regulation**
**Guidance Document – 08.08.2023**
**Topics: Expiration of 19 CSR 30-95 Variances**

The Division of Cannabis Regulation (DCR) is notifying licensees that the following variances and variance options provided for 19 CSR 30-95 have expired.

1. Variance for Residual Solvent Testing of Flower
    a. **Expired on July 30, 2023**. Variance is no longer applicable or necessary with 19 CSR 100-1 rules, effective July 30, 2023.
2. Variance for Transfer of Untested Product
    a. **Expired on July 30, 2023**. Variance is no longer applicable or necessary with 19 CSR 100-1 rules, effective July 30, 2023.
3. Variance Option (Testing Only) for Reduced Sample Increments
    a. **Expired on July 30, 2023**. Variance option is no longer applicable or necessary with 19 CSR 100-1 rules, effective July 30, 2023.

Copies of the expired variances are below.

**Expired on July 30, 2023. Variance is no longer applicable or necessary with 19 CSR 100-1 rules, effective July 30, 2023.**

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 866-219-0165
Email: mmfacilities@health.mo.gov
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

**Randall W. Williams, MD, FACOG**
Director

**Michael L. Parson**
Governor

October 9, 2020

Missouri's Certified Medical Marijuana Testing Facilities

RE: Variance from Residual Solvent Testing of Raw Flower

Dear Missouri Certified Medical Marijuana Testing Facility:

The Section for Medical Marijuana Regulation is granting a variance from 19 CSR 30-95.070(4)(F)4 for residual solvent testing on dry, unprocessed marijuana. The Department will grant a variance as follows:

- Certified medical marijuana testing facilities are not required to perform residual solvent testing on dry, unprocessed marijuana sampled from licensed cultivation facilities.

The Department has determined good cause for granting this variance is that medical marijuana, from a licensed cultivation facility, should not come into contact with solvents and therefore does not need to undergo this particular test.

Thank you,

Andrea Balkenbush, Director
Facility License & Compliance
Section for Medical Marijuana Regulation
MO Department of Health & Senior Services
Website: https://medicalmarijuana.mo.gov
Email: mmlicenses@health.mo.gov

**Expired on July 30, 2023. Variance is no longer applicable or necessary with 19 CSR 100-1 rules, effective July 30, 2023.**

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 866-219-0165
Email: mmfacilities@health.mo.gov
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

**Randall W. Williams, MD, FACOG**
Director

**Michael L. Parson**
Governor

March 19, 2021

Missouri's Certified Medical Marijuana Cultivation Facilities

RE: Variance for Cultivation facilities to transfer untested medical marijuana to Manufacturing facilities

Dear Missouri Certified Medical Marijuana Cultivation Facility:

Pursuant to 19 CSR 30-95.025(2)(A), the Section for Medical Marijuana Regulation is granting a variance from 19 CSR 30-95.050(2)(E) for cultivation facilities to transfer medical marijuana to an infused product manufacturing facility without it first being tested by a certified lab testing facility. The Department will grant a variance as follows:

- Certified cultivation facilities are not required to have medical marijuana tested by a certified lab testing facility before transporting the medical marijuana to an infused product manufacturing facility.

The Department has determined the good cause for granting this variance is that the Department may only require that medical marijuana be tested once, and mandatory testing must be conducted on the final medical marijuana product that will be dispensed to the patient. Therefore, Cultivation facilities should not be required to test product that will later undergo mandatory testing after incorporation into a manufactured product.

Thank you,

Andrea Balkenbush, Director
Facility License & Compliance
Section for Medical Marijuana Regulation
Website: https://medicalmarijuana.mo.gov
Email: mmlicenses@health.mo.gov

**Expired on July 30, 2023. Variance is no longer applicable or necessary with 19 CSR 100-1 rules, effective July 30, 2023.**

Missouri Department of Health and Senior Services
P.O. Box 570, Jefferson City, MO 65102-0570 Phone: 573-751-6400 FAX: 573-751-6010
RELAY MISSOURI for Hearing and Speech Impaired and Voice dial: 711

**Richard W. Moore**
Acting Director

**Michael L. Parson**
Governor

February 22, 2022

Missouri's Licensed Medical Marijuana Testing Facilities

RE: Variance Option from 19 CSR 30-95.070(3)(B)3 Sample Increments

Dear Licensed Medical Marijuana Testing Facility,

The Section for Medical Marijuana Regulation is providing testing facilities with a variance option for 19 CSR 30-95.070(3)(B)3:

- 19 CSR 30-95.070(3)(B)3: "*In the case of all other infused products, the amount of material required for sampling is—"*

| ***Figure B - 19 CSR 30-95.070(3)(B)3 - Infused Product Sampling Requirements*** | |
|---|---|
| *Units for Sale* | *Sample Increments (Units)* |
| *2 to 15* | *2* |
| *16 to 50* | *3* |
| *51 to 150* | *5* |
| *151 to 500* | *8* |
| *501 to 3,200* | *13* |
| *3,201 to 35,000+* | *20* |

**The variance will be available for request <u>after</u> March 11, 2022.**

If requested, the Department will grant a variance to replace the above chart in 19 CSR 30-95.070(3)(B)3 with the below chart and additional requirements:

- *"In the case of all other infused products, the amount of material required for sampling is—"*

| ***Figure B - 19 CSR 30-95.070(3)(B)3 - Infused Product Sampling Requirements*** | |
|---|---|
| *Units for Sale* | *Sample Increments (Units)* |
| *2 to 15* | *2* |
| *16 to 50* | *3* |
| *51 to 150* | *5* |
| *151 to 500* | *8* |
| *501 to 3,200* | ***10*** |
| *3,201 to 35,000+* | ***12*** |

- A **laboratory validation is required** to show that the method is fit for the purpose of analysis of the intended matrix and that any modifications to the original method do not negatively affect performance. The Department **must approve all validations *prior to implementing*** new sample collection increments. Validations **must have** an acceptable and graded external proficiency test by a third party, per 19 CSR 30-95.070(2)(E), ***where all analytes are shown to have passed***.
    - Validation protocols should include marijuana matrices (e.g. flower, infused products and concentrates). If the initial validation study was not performed on marijuana matrices, an interface study should be performed for each and should include each matrix type analyzed.
    - Validation of analytical chemistry methods must, at a minimum, verify accuracy, precision, analytical sensitivity, analytical selectivity, limit of detection, limit of quantitation, and reportable range.
    - Validation of microbiological methods must, at a minimum, address accuracy precision, repeatability, reproducibility, robustness, inclusivity/exclusivity, limit of detection, and reportable range.
- All test methods should be based on compendia or published methods. In absence of reference to compendia or published methods, Association of Official Analytical Collaboration (AOAC) International Official Methods, AOAC Performance Tested Methods, AOAC Cannabis Standard Method Performance Requirements (SMPR), AOAC Appendix K, AOAC Appendix J *or* other reputable sources may be referenced **with approval** of the Department.
- All test methods must produce data in a format that meets scientific and regulatory requirements.

The Department has determined the good cause for granting this variance is that the current sampling provisions in rule have, in some cases, required a testing facility to sample more product than is necessary to create assurance that all product is adequately assessed for contaminants and cannabinoid profile consistency, per 19 CSR 30-95.070(3)(B). Furthermore, per 19 CSR 30-95.070(2)(D), *"Testing facilities shall become fully accredited to the standard set forth by ISO 17025 by an International Laboratory Accreditation Cooperation recognized accreditation body. Testing facilities shall achieve such accreditation within one (1) year of the date the facility receives department approval to operate and shall maintain its accreditation as long the facility holds a certification."* Finally, ISO/IEC 17025:2017 - 7.2.2.1 states, "*The laboratory shall validate non-standard methods, laboratory-developed methods and standard methods used outside their intended scope or otherwise modified. The validation shall be as extensive as is necessary to meet the needs of the given application or field of application."*

If a licensed facility falls into noncompliance with Article XIV or 19 CSR 30-95 the Department may rescind this variance approval with reasonable notice. If variance approval is rescinded, facilities may submit a new request for variance after all noncompliant issues have been resolved.

Thank you,

Andrea Balkenbush, Director
Facility License & Compliance
Section for Medical Marijuana Regulation
MO Department of Health & Senior Services
Website: https://medicalmarijuana.mo.gov
Email: mmlicenses@health.mo.gov