



DRAFT INDUSTRY-WIDE BULLETIN: 19-02
RE: Audited Product and Testing Related Requirements

Dear Marijuana Industry Stakeholders:

Please note the following reminders and updates regarding testing requirements pursuant to the Medical Marijuana Rules, 1 CCR 212-1, and Retail Marijuana Rules, 1 CCR 212-2 (MED Rules):

Audited Products

Effective July, 1 2019, Medical and Retail Marijuana Product Manufacturing Facilities manufacturing Audited Products must fully comply with MED Rules M & R 607. These rules establish public health and safety requirements regarding the manufacturing of Audited Products, including but not limited to, the submission of an independent third-party audit, restrictions on the use of inactive ingredients, and requirements for product development testing, personnel training, and specific record keeping.

With regard to microbial contaminant testing, Rules M & R 607(F) and M & R 712(E)(1), require Audited Products to be subject to additional microbial contaminant testing for the following substances:

- Total aerobic microbial count
- Staphylococcus Aureus
- Pseudomonas aeruginosa
- Bile tolerant gram negative bacteria
- Candida albicans

At this time, no Medical or Retail Marijuana Testing Facilities are certified to conduct these additional tests. To ensure licensees can reasonably comply with these additional testing provisions, requirements to test Audited Products for the substances listed above will not take effect until one or more Testing Facilities are certified to conduct such tests, and only following notification to licensees. At that time, the Division will issue an Industry-Wide Bulletin to provide a reasonable timeline for compliance with these additional testing requirements. The Division will also update the MED Licensed Testing Facility lists published on the Division's MED Licensee Website at this [link](#).

Please note, Audited Products remain subject to all other testing requirements provided in the MED Rules, including microbial contaminant testing for total yeast and mold. Further, Testing Facilities are not required to recertify to perform total yeast & mold, salmonella or STEC testing on Audited Products; therefore Medical Marijuana Infused-Product Manufacturers and Retail Marijuana Product Manufacturing Facilities should continue to submit test samples of Audited Products in accordance with MED Rule M & R 1501.

Heavy Metals Testing

MED Rules M & R 712(E)(4) establish acceptable limits for heavy metals in Medical and Retail Marijuana, and MED Rules M & R 1501(C)(7) establish required testing of heavy metals for Harvest and Production Batches. **The implementation of heavy metals testing will begin January 1, 2020.**



A licensee is permitted to begin required heavy metals testing prior to January 1, 2020 if they wish to begin working towards achieving process validation. For Test Batches to count toward process validation they must:

- Be submitted to a Medical or Retail Marijuana Testing Facility that is certified in heavy metals testing. To view which Testing Facilities have been certified in heavy metals testing, please visit this webpage: [MED Licensed Facilities](#).
- Be collected in accordance with MED Rule M & R 1504 and the sampling procedures found in the Colorado Department of Public Health and Environment Reference Library (<https://www.colorado.gov/pacific/cdphe/marijuana-sampling-procedures>).
- Be properly designated as counting toward process validation in the Inventory Tracking System.

In addition, licensees are subject to testing requirements in MED Rules M & R 1501 (A-B).

For Testing Facilities, please note that heavy metals testing must be on their ISO 17025 scope of accreditation in order to obtain certification.

Pesticide and Mycotoxin Certification

Pursuant to MED Rules M & R 703, beginning July 1, 2019 Medical and Retail Marijuana Testing Facilities must be certified in mycotoxin testing to **obtain** certification in Pesticide testing. Testing Facilities certified in Pesticide testing will maintain their Pesticide certification until the date it expires. After July 1, 2019 a Testing Facility will not be re-certified without mycotoxin certification. Also, please note that mycotoxin testing must be on the ISO 17025 scope of accreditation in order to obtain certification.

Sincerely,

James Burack
Director
Marijuana Enforcement Division