4770.3002 TESTING SAMPLES; COLLECTION; HANDLING; DISPOSAL.

A. A batch sample of cured cannabis flower from each batch of dried raw cannabis must be sent to a testing laboratory for testing. The batch sample must pass all required tests before the dried raw cannabis may be packaged for distribution to patients.

B. The manufacturer must schedule with a testing laboratory with which it has a contract to test medical cannabis to collect the batch sample at least 48 hours before the batch sample is collected. An employee of the manufacturer must be present to observe the sample collection. The testing laboratory employee must minimize potential contamination when collecting a batch sample, such as using sterile gloves and equipment.

C. A batch sample must be composed of 15 grams of intact cannabis flowers from a single batch of dried raw cannabis, taken from different bulk containers, if applicable, and from different areas within the bulk container.

D. The testing laboratory employee or contractor collecting the batch sample must certify the batch number from which the sample is collected and the date and time of collection and document the bulk container or containers and the general locations within the containers from which the sample is collected. The manufacturer employee who observed the collection must certify that the batch sample collected is representative of the batch and that the collection followed procedures to minimize contamination of the batch sample.

E. Before the batch sample is transported to a testing laboratory, the batch sample must be placed in a transport container with a tamper-evident seal affixed by the testing laboratory employee or contractor who collected the sample.

F. The manufacturer must transport the batch sample to a testing laboratory for testing within 48 hours of the sample collection. The testing laboratory must certify upon receipt that the tamper-evident seal is intact and that the sample was collected less than 48 hours earlier. If the tamper-evident seal is broken or if the collection occurred more than 48 hours earlier, the testing laboratory must not accept the batch sample for testing.

G. The testing laboratory must grind the batch sample to create a representative composite batch sample for testing. The testing laboratory may also use a paddle blender on all or part of the batch sample to produce a homogenous composite batch sample. All required testing must be performed on the composite batch sample.

H. Within 30 calendar days after testing of a batch sample is complete, the manufacturer must retrieve from the testing laboratory the analyzed batch sample and the waste containing medical cannabis. The manufacturer must transport the waste material either to the manufacturer's production facility where it must be quarantined before disposal or directly to a waste-to-energy disposal site.

Statutory Authority: MS s 14.389 History: 46 SR 1011 Published Electronically: June 15, 2022