ATTACHMENT C

Quality assurance sampling protocols.

(1) To ensure quality assurance samples submitted to certified third-party laboratories (certified labs) are representative from the lot or batch from which they were sampled as required in MCA 37.107.405, licensed providers, certified labs, and their employees must adhere to the minimum sampling protocols as provided in this section.

(2) Sampling protocols for all marijuana product lots and batches:

(a)Personnel carrying out the sampling must be trained and cerified in the appropriate procedures.

(b) Samples must be deducted in a way that is most representative of the lot or batch and maintains the structure of the marijuana sample. Sufficient sample increments should be taken to meet sample size requirements for all analytical method(s) being performed. Licensees, certified labs, and their employees may not adulterate or change in any way the representative sample from a lot or batch before submitting the sample to certified labs. This includes adulterating or changing the sample in any way as to inflate the level of potency, or to hide any microbiological contaminants from the required microbiological screening such as, but not limited to:

(i) Adulterating the sample with kief, concentrates, or other extracts;

(ii) Treating a sample with solvents to hide the microbial count of the lot or batch from which it was deducted. This subsection does not prohibit the treatment of failed lots or batches with methods approved by DPHHS; or

(iii) Pregrinding a flower lot sample.

(c) All samples must be taken in a sanitary environment using sanitary practices and ensure facilities are constructed, kept, and maintained in a clean and sanitary condition in accordance with rules.

(d) Persons collecting samples must wash their hands prior to collecting a sample from a lot or batch, wear appropriate gloves while preparing or deducting the lot or batch for sample collection, and must use sanitary utensils and storage devices when collecting samples.

(e) Samples must be placed in a sanitary plastic or glass container, and stored in a location that prevents the propagation of pathogens and other contaminants, such as a secure, low-light, cool and dry location.

(f) The licensee must maintain the lot or batch from which the sample was deducted in a secure, low-light, cool, and dry location to prevent the marijuana from becoming contaminated or losing its efficacy.

(g) Each quality assurance sample must be clearly marked "quality assurance sample" and be labeled with the following information:

(i) The sixteen digit identification number generated by the traceability system;

(ii) The license number and name of the certified lab receiving the sample;

(iii) The license number and name of the licensee sending the sample;

(iv) The date the sample was collected; and

(v) The weight of the sample.

(3) **Additional sampling protocols for flower lots:**

(a) Licensees or certified labs must collect a minimum of four separate samples from each marijuana flower lot up to five pounds. Licensees or certified labs may collect more samples than this minimum, but must not collect less.

(i)

Test Batch Size	Minimum Required Sample Size
Up to 1 lbs	2.8 grams
1.01 to 2 lbs	4.5 grams
2.01 to 3 lbs	6.8 grams
3.01 to 4 lbs	9.1 grams
4.01 to 5 lbs	11.3 grams

(4) Additional sampling protocols for Extracts (oils or shatters):

(a) Licensees or certified labs must collect a minimum of one sample from each extract batch lot. Licensees or certified labs may collect more samples than this minimum, but must not collect less.

(b) Extract lots not to exceed 5000 units (5 lb)

(c) Sample size is to be no less than 1.5g per lot

(5) Additional sampling protocols for Tinctures:

(a) Licensees or certified labs must collect a minimum of one sample from each tincture batch lot. Licensees or certified labs may collect more samples than this minimum, but must not collect less.

(b) Tincture lots not to exceed 5000 units

(c) Sample size is to be no less than 5g per lot

(6) Additional sampling protocols for "Vape Pen" cartridge:

(a) Licensees or certified labs must collect a minimum of one sample from each product batch lot. Licensees or certified labs may collect more samples than this minimum, but must not collect less.

(b) Vape pen lots not to exceed 5000 units

(7) Additional sampling protocols for Kief or Hash:

(a) Licensees or certified labs must collect a minimum of one sample from each product batch lot. Licensees or certified labs may collect more samples than this minimum, but must not collect less.

(b) Kief or hash lots not to exceed 2.5 lb.

(c) Sample size is to be no less than 1.5g per lot

(8) Additional sampling protocols for MIPs , Edibles, and Capsules:

(a) Licensees or certified labs must collect a minimum of one packaged unit from each product batch lot or 2g, whichever is greater. Licensees or certified labs may collect more samples than this minimum, but must not collect less.

(b) There is no maximum size of MIP or edible product batch lot, but each batch must be sampled separately.

(c) The maximum capsule batch lot is 5000 units (capsules)
The samples must be of roughly equal weight.

(d) The four separate samples must be taken from different quadrants of the flower lot. A quadrant is the division of a lot into four equal parts. Dividing a lot into quadrants prior to collecting samples must be done in a manner that ensures the samples are collected from four evenly distributed areas of the flower lot and may be done visually or physically.

(e) The four samples may be placed together in one container conforming to the packaging and labeling requirements in subsection (2) of this section for storage and transfer to a certified lab.

(9) Certified labs may retrieve samples from a marijuana licensee's licensed premises and transport the samples directly to the lab. Certified labs may also return any unused portion of the samples.

(10) Certified labs may reject or fail a sample if the lab has reason to believe the sample was not collected in the manner required by this section, adulterated in any way, contaminated with known or unknown solvents, or manipulated in a manner that violates the sampling protocols, limit tests, or action levels.

(11) DPHHS will take disciplinary action against any licensee or certified lab that fails to comply with the provisions of this section or falsifies records related to this section including, without limitation, revoking the license the licensed producer or processor, or certification of the certified lab.

MONTANA DPHHS	**MEDICAL MARIJUANA QUALITY ASSURANCE TESTING**	Last Updated 03/22/2018

Quality Assurance Testing

A third-party testing lab must be licensed by the State of Montana, Department of Health and Human Services (DPHHS) as meeting the state requirements MCA 37.107.301 and 37.107.306 prior to conducting quality assurance tests required under this section.

(1) **Quality assurance fields of testing.** Certified labs must be certified to the following fields of testing by ISO approved auditor and must adhere to the guidelines for each quality assurance field of testing listed below. A lab must become certified or be actively seeking certification in all fields of testing regardless of whether the test is required under this section. Labs are required to submit proof they are seeking ISO certification and demonstrate proficiency in each area of testing within 180 days of being issued a license.

(a) **Potency analysis.**

(i) Certified labs must test and report the following cannabinoids when testing for potency:

(A) THCA;

(B) THC;

(C) Total THC;

(D) CBDA;

(E) CBD; and

(F) Total CBD.

(ii) Calculating total THC and total CBD.

(A) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA: M total delta-9 THC = M delta-9 THC + (0.877 x M delta-9 THCA).

(B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: M total CBD = M CBD + (0.877 x M CBDA).

(iii) Regardless of analytical equipment or methodology, certified labs must accurately measure and report the acidic (THCA and CBDA) and neutral (THC and CBD) forms of the cannabinoids.

(b) **Potency analysis for flower lots.**

(i) Certified labs must test and report the results for the required flower lot samples for the following required cannabinoids:

(A) THCA;

(B) THC;

(C) Total THC;

(D) CBDA;

(E) CBD; and

(F) Total CBD.

(ii) Calculating total THC and total CBD.

(A) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA: M total delta-9 THC = M delta-9 THC + (0.877 x M delta-9 THCA).

(B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: M total CBD = M CBD + (0.877 x M CBDA).