

1 **Rule 64-4.016 Marijuana Testing Laboratories.**

- 2 (1) For the purposes of the department’s marijuana testing laboratory rules and marijuana testing standards rules,
3 the following words and phrases shall have the meanings indicated.
- 4 (a) Analyst - An employee of a marijuana testing laboratory whose duties include conducting analyses,
5 analyzing and recording results, maintaining testing-related workspaces and equipment, and maintaining
6 marijuana samples in accordance with the requirements of this rule.
- 7 (b) Applicant - An individual or entity that meets the requirements of section 381.988(1), F.S., and applies for
8 certification as a marijuana testing laboratory pursuant to section 381.988(2), F.S., and this rule.
- 9 (c) Certification - Written notification from the department to an applicant that its application for certification
10 as a marijuana testing laboratory has been found to be in compliance with the provisions of sections
11 381.986 and 381.988, F.S., and department rules, and that the department has inspected and authorized the
12 testing facility to begin testing marijuana.
- 13 (d) Employee - Any person whose duties involve activities or responsibilities that support the function of
14 testing useable whole flower marijuana, derivative product, or edibles and are compensated for the
15 performance of such duties.
- 16 (e) Interests - Any form of ownership in or control of an applicant, a marijuana testing laboratory, or medical
17 marijuana treatment center including, but not limited to, ownership of stock, membership interests,
18 partnership interests, a sole proprietorship or otherwise which convey to the holder thereof an ownership
19 right or an interest in or right to the profits, capital, or voting with respect to such applicant, marijuana
20 testing laboratory, or medical marijuana treatment center.
- 21 (f) Investor - Any person who, directly or indirectly, owns a legal or equitable interest (actually or
22 beneficially) or controls, less than a 5% share of interests of the applicant or marijuana testing laboratory.
- 23 (g) Laboratory Director – An individual that oversees all analysts, employees, and functions of testing useable
24 whole flower marijuana, derivative product, and edibles and are compensated for the performance of such
25 duties. A laboratory director may oversee only one physically independent facility operated by the
26 marijuana testing laboratory.
- 27 (h) Manager - Any person with the authority, directly or indirectly, to exercise or contribute to the operational
28 control, direction or management of an applicant or a marijuana testing laboratory or who has direct or
29 indirect authority to supervise any employee of an applicant or a marijuana testing laboratory. The term
30 shall be interpreted broadly and shall include, but not be limited to, all officers, managers, and members of
31 board of directors as well as any other person engaged to undertake management or control of the applicant
32 or a marijuana testing laboratory or any person or persons in control of an entity engaged to undertake
33 management or control of the applicant or marijuana testing laboratory.
- 34 (i) Marijuana Testing Laboratory – A public or private laboratory certified by the department pursuant to
35 s. 381.988, and approved by the department to perform analyses of testing fields within matrix groups that
36 are covered by its ISO/IEC 17025:2017 (revised March 2018) or ISO/IEC 17025:2005 (May 2005)
37 accreditation, and that are supported by documentation of satisfactory results from the two most recent
38 proficiency tests administered by an ISO/IEC 17043:2010 accredited body.
- 39 (j) Matrix Group - The components of a testing sample other than the analytes of interest. For the purposes of
40 this rule, the matrix groups are usable whole flower marijuana, derivative products, and edibles.
- 41 (k) Owner - Any person who, directly or indirectly, owns a legal or equitable interest (actually or beneficially)
42 or controls, a 5% or greater share of interests of the applicant or marijuana testing laboratory. In the event
43 that one person owns a beneficial right to interests and another person holds the voting rights with respect
44 to such interests, both persons are the owner of such interests. In determining the owners of the applicant or
45 a marijuana testing laboratory, the attribution of ownership rules set forth in the Treasury Regulations cited
46 as 26 C.F.R. 1.414(c)-4(b) and (c) (4-1-17 edition), incorporated by reference and available at
47 <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>, apply, but with the following exceptions
48 and additions:
- 49 1. The use of the term “option” in 26 C.F.R. 1.414(c)-4(b) shall be interpreted broadly to include, but not
50 be limited to, options, warrants, calls, rights of first refusal and any other right to acquire an interest (as
51 defined herein), whether such right is vested or unvested and regardless of whether such right is then
52 exercisable or becomes exercisable at a future date or upon the occurrence of a future event.
- 53 2. The exception for attribution of a spouse’s interest, as defined in paragraph (l) above and as set forth in
54 26 C.F.R. 1.414(c)-4(b)(5)(ii), does not apply.

- 55 3. The age limitation contained in 26 C.F.R. 1.414(c)-4(b)(6) applies only to children who have not
56 attained the age of 18 years. The term “interest” as used in 26 C.F.R. 1.414(c)-4(b)(6) shall have the
57 meaning as set forth in subparagraph (j) above.
- 58 4. If a person under the age of 18 owns or is deemed an owner of an interest, such person must be
59 disclosed to the department. Persons under the age of 18 must submit to a background screening only
60 in the event that the interest or ownership was not imputed to another family member or guardian as
61 outlined in paragraph (l)3. above.
- 62 5. To the extent that the above alterations to the provisions of 26 C.F.R. 1.414(c)-4 alter the outcome of
63 any of the examples set forth therein, the example does not apply.
- 64 6. As used in 26 C.F.R. 1.414(c)-4(b)(3), the term “actuarial interest” shall be interpreted broadly and
65 shall include, but not be limited to, the right of a beneficiary of a trust or an estate to receive either
66 income or principal distributions with respect to an interest held by such trust or estate.
- 67 7. With regard to publicly traded companies with ownership interests in the applicant, any person who
68 holds 10% or more interest in the publicly traded company is an owner.
- 69 (l) Potency testing - The analysis of the relative strength of cannabinoids, and the total amount, in milligrams,
70 of d9-THC and CBD in the final retail product.
- 71 (m) Proficiency testing - Testing of unknown samples by an applicant or marijuana testing laboratory, to
72 determine the accuracy of the analysis for specific analytes and matrices. Unknown samples used for
73 proficiency testing must be provided by an ISO/IEC 17043 accredited body.
- 74 (n) Quality assurance - A system developed either by the applicant or marijuana testing laboratory to ensure
75 that products and services delivered are as accurate and precise as possible.
- 76 (o) Quality assurance manual - A written collection of all quality assurance systems or protocols utilized by a
77 marijuana testing laboratory, to include quality control procedures, that is available for review by any
78 marijuana testing laboratory employee during working hours.
- 79 (p) Quality control - System developed in accordance with ISO 17025 standards, to verify that the required
80 level of quality in analyses are met and maintained. Such verification shall include determining that
81 appropriate equipment and instruments are used, continued inspection and overview of all facets of the
82 testing process, and undertaking corrective action as necessary. Quality control samples should contain,
83 where applicable, method blank, duplicate lab fortified blank, duplicate matrix spikes, and duplicate testing
84 samples.
- 85 (q) Sampler - A marijuana testing laboratory employee who collects samples of marijuana from a medical
86 marijuana treatment center for testing and has undergone specific training to fulfill this function.
- 87 (r) Secure storage - The segregation of useable whole flower marijuana, derivative product, or edibles in a
88 manner that prevents access from unauthorized persons, compromise of the product’s integrity, or
89 premature spoilage.
- 90 (s) Testing facility – The location of a real property or the area within a real property to be utilized as a
91 marijuana testing laboratory.
- 92 (t) Testing Field - The suite of analytes tested within a particular matrix category. For the purposes of this
93 rule, the testing categories are microbiology, mycotoxins, residual solvents, heavy metals, agricultural
94 agents, moisture and water activity, and cannabinoid profile.
- 95 (u) Useable Whole Flower Marijuana – means the dried flowers of the female marijuana plant, including low-
96 THC cannabis, that is suitable to be dispensed from a medical marijuana treatment center for medical use
97 by a qualified patient. Useable whole flower marijuana does not include seeds, resin extracted from any
98 part of the plant, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its
99 seeds or resin.
- 100 (2) The certification or renewal of a marijuana testing laboratory by the department shall mean:
- 101 (a) A marijuana testing laboratory or an applicant for certification who has received written notification from
102 the department that its application for certification or application for renewal as a marijuana testing
103 laboratory has been found to be in compliance with the provisions of sections 381.986 and 381.988, F.S.,
104 and department rules. Notification may only be provided by the department after the following
105 requirements have been met:
- 106 1. A marijuana testing laboratory submitted a completed application accompanied by an application fee;
107 2. A marijuana testing laboratory is not owned or controlled by a medical marijuana treatment center;
108 3. A marijuana testing laboratory submitted proof of an accreditation or a certification;
109 4. All owners and managers of a marijuana testing laboratory have submitted and passed a level 2
110 background screening pursuant to section 381.988(1)(d), Florida Statutes; and

- 111 5. A marijuana testing laboratory demonstrated to the department the capability of meeting the standards
112 for certification.
- 113 (b) A marijuana testing laboratory must adhere to the requirements of sections 381.986(8)(d), 381.986(8)(e)10,
114 d., 381.986(8)(g), and 381.988, F.S., this rule, and representations made within the application. A
115 marijuana testing laboratory certified pursuant to this rule may request a variance or waiver from the
116 representations made in its application pursuant to section 120.542, F.S.
- 117 1. Marijuana testing laboratories may request a variance from its initial application by submitting to the
118 department a modified version of its approved application for marijuana testing laboratory
119 certification, with the all modifications clearly labeled. Consideration of such a request shall be based
120 upon the individual facts and circumstances surrounding the request. A variance may not be granted
121 unless the requesting marijuana testing laboratory can demonstrate to the department that it has a
122 proposed alternative to the specific representation made in its application which fulfills the same or a
123 similar purpose as the specific representation in a way that the department can reasonably determine
124 will not be a lower standard than the specific representation in the application.
- 125 (c) The department has authorized a marijuana testing laboratory to contract with a medical marijuana
126 treatment center to conduct tests and perform analyses on marijuana in accordance with its application for
127 certification.
- 128 1. Marijuana testing laboratories may only conduct tests and perform analyses of testing fields within
129 matrix groups at testing facilities under the following conditions:
- 130 a. Tests and analyses of testing fields within matrix groups are documented within the applicant's
131 initial application, as amended, or supplied as a request to amend the applicant's initial application
132 and subsequently approved by the department;
- 133 b. The testing facility is documented within the applicant's initial application, as amended, and has
134 been inspected by the department pursuant to section (8) of this rule;
- 135 c. Tests and analyses of testing fields within matrix groups are covered by the marijuana testing
136 laboratory's ISO/IEC 17025:2017 (revised March 2018) or ISO/IEC 17025:2005 (May 2005)
137 accreditation that is compliant with section; and
- 138 (I) Applicants and certified marijuana testing laboratories must maintain accreditation as
139 required by this rule. A marijuana testing laboratory that loses or has suspended any
140 required accreditation must report the loss or suspension within 24 hours of its occurrence
141 to the Office of Medical Marijuana Use, at OMMULicenseOperation@flhealth.gov;
- 142 (II) Certified marijuana testing laboratories must provide documentation identifying the cause
143 of the suspension or loss of accreditation within five (5) business days of the loss or
144 suspension of its accreditation to the Office of Medical Marijuana Use, at
145 OMMULicenseOperation@flhealth.gov.
- 146 (III) Certified marijuana testing laboratories must provide documentation evidencing that
147 notification has been provided to each medical marijuana treatment center for which it
148 conducts testing or with which it is associated, within five (5) business days of the loss or
149 suspension of its accreditation to the Office of Medical Marijuana Use, at
150 OMMULicenseOperation@flhealth.gov.
- 151 (IV) Any marijuana testing laboratory that loses or has suspended any accreditation required by
152 this rule must not test or provide any results of tests conducted during the time accreditation
153 was lost or suspended.
- 154 (V) A marijuana testing laboratory may correct deficiencies and reestablish accreditation within
155 180 days of the effective date of the loss or suspension. Certification as a medical marijuana
156 testing laboratory is revoked as of the effective date of the loss or suspension of
157 accreditation upon the failure to reestablish lost accreditation within 180 days of the loss or
158 suspension.
- 159 d. Tests and analyses of testing fields within matrix groups are supported by documentation of two
160 satisfactory analyses of the three most recent proficiency testing administered by an ISO/IEC
161 17043:2010 accredited body.
- 162 (I) Proficiency test sample results that are within the acceptance limits established by the
163 contracted ISO/IEC 17043 accredited body are satisfactory.
- 164 (II) A certified marijuana testing laboratory must participate in at least two proficiency testing
165 rounds from an ISO/IEC 17043 accredited body per calendar year beginning on the date of
166 issuance or renewal of the certification. Consecutive rounds of proficiency testing may not

- 167 occur at less than seven-month intervals, as determined by the closing dates of each
168 proficiency testing attempt.
- 169 (III) If a marijuana testing laboratory reports more than one result for a field of proficiency
170 testing on a proficiency testing round, any unsatisfactory result constitutes a failed testing
171 attempt for the corresponding certified or pending field of accreditation.
- 172 (IV) A marijuana testing laboratory that unsatisfactorily completes proficiency testing shall not,
173 for 30 days (“probationary period”), test or provide results for any analyte, matrix, or other
174 measurement for which its analysis was unsatisfactory. During the probationary period, the
175 laboratory must undertake an internal investigation to determine the reason for the
176 unsatisfactory test result and may complete additional proficiency testing including any
177 analyte or matrix that failed. Findings of the internal investigation must be provided to the
178 department.
- 179 (V) If a laboratory that completes proficiency testing during the probationary period receives
180 unsatisfactory results for the analyte or specific matrix, the laboratory shall not test or
181 provide results for that analyte or matrix for 180 days from the date of the notice failure.
182 During the 180 days, the laboratory may cure any deficiencies and complete proficiency
183 testing for any failed analyte, matrix, or other measurement.
- 184 (VI) The failure to complete proficiency testing and report to the department satisfactory results
185 for failed analytes, matrices, or other measurements within 180 days of the notice of failure
186 is revocation of the marijuana testing laboratory’s certification.
- 187 2. The department shall maintain a listing of each testing field within each matrix group that a certified
188 marijuana testing laboratory is approved to analyze.
- 189 3. A marijuana testing laboratory must provide the department with a copy of all contractual relationships
190 with any medical marijuana treatment center to conduct tests and perform analyses on marijuana. Any
191 contract between a medical marijuana treatment center and a marijuana testing laboratory, after the
192 date of certification, must be provided to the Office of Medical Marijuana Use, at
193 OMMULicenseOperation@flhealth.gov, within five (5) business days of execution.
- 194 4. The department shall maintain a listing of each contractual relationships between a marijuana testing
195 laboratory and a medical marijuana treatment center, and the specific products, matrix groups, and
196 testing fields covered by each contract.
- 197 (d) The department has authorized a marijuana testing laboratory to conduct tests and perform analyses at its
198 testing facility.
- 199 1. A marijuana testing laboratory may only conduct tests and perform analyses from the single location
200 identified and documented in its initial application, as amended.
- 201 a. Certified marijuana testing laboratories may only conduct tests and perform analyses at the single
202 testing facility identified and documented in its initial application.
- 203 b. Should the owners or managers of a marijuana testing laboratory seek to conduct tests and perform
204 analyses at any locations other than the testing facility approved by the department, such locations
205 must be applied for under separate cover and are subject to the same standards as an initial
206 applicant for certification.
- 207 (3) Persons or entities applying for certification as a marijuana testing laboratory must:
- 208 (a) Submit a completed Form DH####-OMMU-##/#####, “Application for Marijuana Testing Laboratory
209 Certification,” incorporated by reference herein and available at
210 <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>.
- 211 (b) Submit a non-refundable, non-prorated application fee of \$#####;
- 212 1. The non-refundable, non-prorated renewal fee of \$#####; must be submitted to the department on the
213 same business day as the entity’s submission of Form DH####-OMMU-##/#####. Failure to submit
214 timely may result in suspension or revocation of certification. Failure to submit a non-refundable, non-
215 prorated application fee of \$##### timely is ground for denial of the associated application for
216 certification.
- 217 (c) Request, and undergo, an inspection of its testing facility by the department pursuant to subsection (8) to
218 determine that it is in compliance with sections 381.986 and 381.988, F.S., this rule, and the representations
219 made in its application for certification.
- 220 (d) Deliver applications, fees, exhibits, and supporting documents together to the Department of Health,
221 ATTN: Office of Medical Marijuana Use, at 4052 Bald Cypress Way, Bin M-01, Tallahassee, Florida.
- 222 (4) Marijuana testing laboratories applying for biennial renewal must:

- 223 (a) Previously have been certified as a marijuana testing laboratory that meets the requirements of sections
224 381.986(8)(d), 381.986(8)(e)10.d., 381.986(8)(g), and 381.988, F.S., and this rule;
- 225 (b) Submit an updated and complete Form DH####-OMMU-##/#####, "Application for Marijuana Testing
226 Laboratory Certification," incorporated by reference herein and available at
227 https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX.
- 228 1. Form DH####-OMMU-##/##### must be submitted to the department no less than 30 calendar days
229 prior to every biennial anniversary of certification as a marijuana testing laboratory. The biennial
230 period is defined as the two calendar years directly proceeding the date the department transmits its
231 approval of either a marijuana testing laboratory's initial certification or renewal certification. Failure
232 to submit timely may result in suspension or revocation of certification.
- 233 (c) Submit a non-refundable, non-prorated renewal fee of \$#####;
- 234 1. The non-refundable, non-prorated renewal fee of \$#####; must be submitted to the department on the
235 same business day as the entity's submission of Form DH####-OMMU-##/#####. Failure to submit
236 timely may result in suspension or revocation of certification.
- 237 (d) Request, and undergo, a renewal inspection by the department pursuant to subsection (8) to determine that
238 it is in compliance with sections 381.986 and 381.988, F.S., this rule, and the representations made in its
239 application for certification.
- 240 (e) Deliver applications, fees, exhibits, and supporting documents together to the Department of Health,
241 ATTN: Office of Medical Marijuana Use, at 4052 Bald Cypress Way, Bin M-01, Tallahassee, Florida.
- 242 (5) Form DH####-OMMU-##/#####, "Application for Marijuana Testing Laboratory Certification," shall include
243 the following information and documentation provided by the applicant:
- 244 (a) Documentation of accreditation for ISO/IEC 17025:2017 (revised March 2018) or ISO/IEC 17025:2005
245 (May 2005) by an accreditation body recognized by the International Laboratory Accreditation Cooperation
246 (ILAC) for testing. ISO/IEC 17025:2017 (revised March 2018), incorporated by reference and available at
247 https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX. ISO/IEC 17025:2005 (May 2005),
248 incorporated by reference and available at https://www.flrules.org/Gateway/reference.asp?No=Ref-
249 XXXXX. The department has determined that posting the incorporated materials on the internet would
250 constitute a violation of the federal copyright law. Accreditation must demonstrate that the applicant is
251 qualified to analyze one or more of the following testing fields:
- 252 1. microbiology;
253 2. mycotoxins;
254 3. residual solvents;
255 4. metals;
256 5. pesticides;
257 6. water activity;
258 7. moisture;
259 8. filth and foreign material; and
260 9. cannabinoid potency.
- 261 (b) Documentation clearly showing that the applicant has contracted with an ISO/IEC 17043:2010 accredited
262 body that is a signatory for proficiency testing to an arrangement recognized by ILAC to conduct
263 proficiency testing. The marijuana testing laboratory shall bear the cost of any required proficiency testing.
- 264 (c) Documentation of satisfactory results from the two most recent proficiency tests administered by an
265 ISO/IEC 17043:2010 accredited body covering one or more of the testing fields within one or more of the
266 following matrix groups:
- 267 1. Useable whole flower marijuana
- 268 a. microbiology;
269 b. mycotoxins;
270 c. metals;
271 d. pesticides;
272 e. water activity;
273 f. moisture;
274 g. filth and foreign material; and
275 h. cannabinoid potency.
- 276 2. Derivative products
- 277 a. microbiology;
278 b. mycotoxins;

- 279 c. residual solvents;
280 d. metals;
281 e. pesticides;
282 f. water activity;
283 g. moisture;
284 h. filth and foreign material; and
285 i. cannabinoid potency.
286 3. Edibles
287 a. microbiology;
288 b. mycotoxins;
289 c. residual solvents;
290 d. metals;
291 e. pesticides;
292 f. water activity;
293 g. moisture;
294 h. filth and foreign material; and
295 i. cannabinoid potency.
296 (d) Documentation of the following minimum standards for personnel:
297 1. Documentation of the following minimum standards for laboratory employees:
298 a. All marijuana testing laboratory employees are 21 years of age or older. No marijuana testing
299 laboratory shall employ either directly or indirectly any person who is below 21 years of age.
300 b. All marijuana testing laboratory employees have passed the level 2 background screening pursuant
301 to section 435.04, F.S., and have not been found guilty of, or entered a plea of guilty or nolo
302 contendere to, regardless of adjudication, any offense listed in chapters 837, 895, or 896, F.S., or
303 similar law of another jurisdiction.
304 c. All marijuana testing laboratory employees must have, at a minimum, a high school diploma from
305 a state-approved and accredited public or private school, or an associate degree from an institution
306 accredited by a federally- or nationally-recognized accrediting or state agency; or hold a current
307 certification as a Florida Board of Clinical Laboratory Personnel.
308 2. Documentation of the following minimum standards for samplers:
309 a. All marijuana testing laboratory samplers must meet the requirements for an employee of a
310 marijuana testing laboratory.
311 b. All marijuana testing laboratory samplers must be provided specific training on the minimum
312 requirements for sampling and the applicant's standard operating procedures for sampling and
313 security.
314 3. Documentation of the following minimum standards for analysts:
315 a. All marijuana testing laboratory analysts must meet the requirements for an employee of a
316 marijuana testing laboratory.
317 b. All marijuana testing laboratory analysts must be provided specific training on the minimum
318 requirements for sampling and the applicant's standard operating procedures for sampling and
319 security.
320 c. All marijuana testing laboratory analysts must have, at a minimum, a bachelor's degree in a
321 natural science, to include, but not be limited to, biology, chemistry, physics, engineering, or
322 environmental sciences; or hold a current certification as a Florida Board of Clinical Laboratory
323 Personnel.
324 4. Documentation of the following minimum standards for laboratory directors:
325 a. All marijuana testing laboratory directors must meet the requirements for an employee and for an
326 analyst of a marijuana testing laboratory.
327 b. A marijuana testing laboratory must employ a laboratory director for each physically independent
328 facility operated by the marijuana testing laboratory.
329 c. All marijuana testing laboratory directors have a minimum of five (5) years of experience in a
330 regulated laboratory environment sufficient for any accreditation required by this rule.
331 (e) Documentation which demonstrates the applicant's ability to maintain adequate controls against the
332 diversion, theft, or other loss of marijuana, the tampering or compromise of samples, and the tampering or
333 compromise of testing equipment and materials. Floor plans drawn to scale and clearly identifying all
334 documented security controls must be provided to the department together with written standard operating

335 procedures and must be in accordance with any accreditation required by this rule, and must demonstrate
336 compliance with the following security requirements to ensure the safety and security of all proposed
337 testing facilities and secure storage areas:

- 338 1. A fully operational security alarm system that secures all entry points and perimeter windows and is
339 equipped with motion detector and duress, panic, and hold-up alarms.
 - 340 2. A fully operational video surveillance system that records continuously 24 hours a day, and meets the
341 following criteria:
 - 342 a. Cameras are fixed in a place that allows for the clear identification of persons and activities in
343 controlled areas of any testing facility and secure storage area;
 - 344 b. Cameras are fixed at entrances and exits to the premises, record from both indoor and outdoor, or
345 ingress and egress, vantage points;
 - 346 c. Recorded images legibly and accurately display the time and date; and
 - 347 d. Retain video surveillance recordings for at least 45 days or longer.
 - 348 3. Fully operational dusk-to-dawn safety lighting on the exterior of the facility that provides reasonable
349 illumination to the areas directly around the premises, including all points of ingress and egress.
 - 350 4. All marijuana and marijuana samples are stored in a secured, locked room or a vault in a manner that
351 does not accelerate spoilage or promote other degradation.
 - 352 5. Make available at least two laboratory employees to accept useable whole flower marijuana, derivative
353 product, or edibles for testing at the testing facility.
 - 354 6. At least two employees, or two employees of a contracted security agency, are on the testing facility
355 premises when marijuana is received, when marijuana is tested, and during all normal business hours.
 - 356 7. Each employee wears a legible photo identification badge at all times while on the premises.
 - 357 8. Any non-employee natural persons with access to the premises of the marijuana testing laboratory
358 must brandish an identification badge clearly indicating their visitor status, and be accompanied by an
359 employee;
 - 360 9. Implement an alcohol and drug-free workplace policy.
 - 361 10. Standard operating procedures and training for all employees on the requirement to report to local law
362 enforcement within 24 hours notification or knowledge of the apparent theft, diversion, or loss of
363 marijuana.
- 364 (f) Documentation of implemented quality assurance and quality controls. Quality assurance and quality
365 controls must be contained within written standard operating procedures and be in accordance with any
366 accreditation required by this rule.
- 367 1. Each marijuana testing laboratory shall develop and maintain a written quality-assurance program
368 manual which addresses every aspect of its quality assurance program, to include, but not limited to:
 - 369 (I) quality control procedures;
 - 370 (II) laboratory organization;
 - 371 (III) laboratory employee training;
 - 372 (IV) laboratory employee responsibilities;
 - 373 (V) objectives for measurement data;
 - 374 (VI) data and result traceability;
 - 375 (VII) preventative maintenance of equipment;
 - 376 (VIII) performance audits, to include internal and external laboratory auditing;
 - 377 (IX) corrective action;
 - 378 (X) recordation and maintenance of quality assurance records; and
 - 379 (XI) secure marijuana storage.
 - 380 2. Once a year or whenever a change of method, equipment, or laboratory director occurs, the laboratory
381 director or authorized employee shall review, amend as necessary, and approve of the marijuana
382 testing facility's laboratory quality assurance program.
 - 383 3. Internal quality assurance and quality control audits must occur at least once every year. Internal audit
384 results shall be provided to the Office of Medical Marijuana Use, at
385 OMMULicenseOperation@flhealth.gov within five (5) business days of the completion of the audit.
 - 386 4. Marijuana testing laboratories shall use testing equipment that satisfies the requirements of any
387 accreditation required by this rule chapter. Equipment that is not suitable for a specific method shall
388 not be used for that purpose.
 - 389 (I) Testing equipment shall be used and maintained according to the manufacturer's instructions and
390 shall be calibrated pursuant to the requirements of any accreditation under which it is operated.

391 Marijuana testing laboratories shall retain records of all equipment repairs, maintenance, and
392 calibrations.

393 (II) Internal audits of all laboratory equipment, facilities, personnel, and security occur at least once
394 every year. Audit results shall be provided to the Office of Medical Marijuana Use, at
395 OMMULicenseOperation@flhealth.gov, by the internal auditor that conducted the audit within
396 five (5) business days of the completion of the audit.

397 5. Documentation of the establishment of a tracking system to document the complete chain of custody of
398 marijuana samples from receipt through disposal. Chain-of-custody entries must show the date, time,
399 name of employee or employees handling the sample, the condition of the sample, the condition of any
400 container or packaging the sample was transported or stored in, the location of the sample, the
401 sample's unique identifier, and the seed-to-sale information from the medical marijuana treatment
402 center. The applicant's tracking system must be capable of integration with the department's seed-to-
403 sale tracking system, once implemented.

404 6. Documentation of a procedure to dispose of laboratory waste. Any marijuana in possession by a
405 marijuana testing laboratory but undergoing no preparatory or analytical procedures ("non-laboratory
406 marijuana waste") must be disposed of in accordance with department rule. Dry flower non-laboratory
407 marijuana waste must be ground and mixed with general waste to a 50:50 ratio. Liquid non-laboratory
408 marijuana waste may be mixed with methylene chloride to a 50:50 ratio and disposed of as hazardous
409 waste.

410 (g) Applicants must provide sufficient documentation to the department to provide reasonable assurance that
411 any person or entity seeking certification as a marijuana testing laboratory is not owned and/or controlled
412 by a medical marijuana treatment center.

413 1. Provide a fully diluted capitalization table;

414 a. Fully diluted capitalization table shall mean a listing of all share types and the aggregate sum of
415 shares associated to any natural persons, whether considered owners or investors.

416 b. A fully diluted capitalization table must sum to one hundred percent (100%) of all shares issued
417 and outstanding;

418 c. A fully diluted capitalization table must list all share types and the aggregate sum of shares
419 associated to any natural person as of a date no less than 7 calendar days prior to the date of the
420 applicant's submission of its application for certification or renewal;

421 d. A fully diluted capitalization table must list only natural persons as owners and investors;

422 2. The department must be notified by the applicant all contractual relationships to change the control of
423 the entity holding the certification, or to change its management, owners or investors, whether
424 executed or not executed.

425 (I) Executed contractual relationships must be provided to the department prior to the approval.

426 3. Public companies are not exempt from any requirements in subsection (g) and must include additional
427 documentation identifying all owners and investors that are considered Non-Objecting Beneficial
428 Owners ("NOBOs").

429 4. A list of all owners, officers, board members, and managers that includes the date, within the calendar
430 year prior to submission of the application, of the level 2 background screening required by this rule
431 for each individual. Each owner, officer, board member, and manager shall go to the Florida
432 Department of Law Enforcement (FDLE) or one of its approved vendors for fingerprinting and, at such
433 time, shall give to FDLE or the FDLE-approved vendor the entity ORI number FL924890Z (DOH –
434 OFFICE OF MEDICAL MARIJUANA USE).

435 (6) If the applicant intends to claim any exemption from public records disclosure under section 119.07, F.S., or
436 any other exemption from public records disclosure provided by law for any part of its application, it shall
437 indicate on the application the specific sections for which it claims an exemption and the statutory basis for the
438 exemption. The applicant shall submit a redacted copy of the application redacting those items identified as
439 exempt concurrent with the submission of the application for approval under paragraph (g) below. Failure to
440 provide a redacted copy of the application at the time of submission or failure to identify and redact information
441 claimed as trade secret will result in the release of all application information in response to a public records
442 request, unless the information falls under another public records exemption. All identified trade secrets are
443 subject to the department review in accordance with section 381.83, F.S.

444 (7) The department shall not grant certification to any applicant that fails to correct any deficiency observed by the
445 department during the initial inspection within 30 days of the department's notice to the applicant of the
446 observed deficiency.

- 447 (8) Marijuana testing laboratory inspections, either initial, renewal, or upon the department's discretion, shall be
448 undertaken pursuant to this subsection.
- 449 (a) A certified marijuana testing laboratory must receive written authorization from the department prior to
450 operating its testing facility.
- 451 (b) Within thirty (30) calendar days of receiving an Application for Marijuana Testing Laboratory Certification
452 or Application for Marijuana Testing Laboratory Certification Renewal, the department shall contact the
453 marijuana testing laboratory's primary point of contact to schedule a certification inspection. Upon
454 determination of a certification inspection date and time, the department shall send email confirmation to
455 the marijuana testing laboratory's primary point of contact.
- 456 (c) The department may conduct an on-site inspection of any marijuana testing laboratory facility during
457 normal working hours.
- 458 (d) During any inspection, the marijuana testing laboratory shall ensure that its quality manual, analytical
459 methods, quality control data, proficiency test data, laboratory standard operating procedures, and all
460 records needed to verify compliance with sections 381.986(8)(d), 381.986(8)(e)10.d., 381.986(8)(g), and
461 381.988, F.S., this rule, and the specific representations in its application for certification, to include any
462 subsequent variances approved by the department, are available for review during the inspection. The
463 marijuana testing laboratory shall allow department personnel to examine records; observe the marijuana
464 testing laboratory's facilities, procedures, and equipment; and interview employees during the on-site
465 inspection.
- 466 (e) During any inspection, a marijuana testing laboratory must demonstrate that its facility, equipment,
467 operations, standard operating procedures, and personnel are in compliance with sections 381.986(8)(d),
468 381.986(8)(e)10.d., 381.986(8)(g), and 381.988, F.S., this rule, and the specific representations in its
469 application for certification, to include any subsequent variances approved by the department.
- 470 (f) If the department identifies any violation of sections 381.986(8)(d), 381.986(8)(e)10.d., 381.986(8)(g), and
471 381.988, F.S., or this rule during an inspection of a marijuana testing laboratory facility, the department
472 shall notify the marijuana testing laboratory within thirty (30) calendar days of the completion of the
473 inspection. Within twenty-one (21) calendar days of receipt of a written notice of a violation, the marijuana
474 testing laboratory shall notify the department of the corrective action taken to resolve the violation and the
475 date of the correction in writing. Within thirty (30) days of receipt of any additional information submitted
476 by the renewal applicant, the department shall determine whether the omissions, deficiencies, or violations
477 have been addressed, and whether any additional action must be taken by the marijuana testing laboratory,
478 or if disciplinary action is appropriate. The department shall conduct additional inspections to confirm that
479 the violation has been resolved and corrective action has been taken, unless resolution of the violation can
480 be confirmed absent a physical visit to the facility.
- 481 (g) The failure to resolve any omission, deficiency, or violation identified during an inspection shall be
482 grounds for the denial of certification or renewal as a marijuana testing laboratory, or the revocation of a
483 marijuana testing laboratory certification.