

1 **Rule 64-4.300 Certified Marijuana Testing Laboratories**

2  
3 (1) Definitions. The following capitalized words and phrases have the meanings provided and  
4 apply to rules 64-4.301 thru 64-4.313.

5 (a) Acceptable Limit – The maximum concentration allowed for a particular Analyte. Any  
6 Analyte measured above its concentration limit constitutes a failure for that analysis.

7  
8 (b) Agricultural Agents - Any pesticide, herbicide, fungicide, fertilizer, synergist, or root  
9 stimulant applied to the plant or substrate, at any stage of cultivation or processing, for the  
10 purpose of increased growth, vigor, or pest resistance.

11  
12 (c) Analyst - An Employee of an Applicant or Certified Marijuana Testing Laboratory  
13 whose duties include conducting analyses, analyzing and recording results, maintaining  
14 testing-related workspaces and equipment, and maintaining marijuana samples in  
15 accordance with the requirements of Rule 64-4.301.

16  
17 (d) Analytical Batch – A group of Testing Samples, which behave similarly with respect  
18 to the sampling or the testing procedures being employed, that are prepared together. For  
19 Mycotoxin, Residual Solvent, Agricultural Agents, and Heavy Metals analysis, if the  
20 number of Testing Samples in an Analytical Batch is greater than 20, the Analytical Batch  
21 must be split between multiple Laboratory Batches so that each Laboratory Batch has less  
22 than 20 Testing Samples.

23  
24 (e) Analyte - A chemical, compound, element, bacteria, yeast, fungus, or toxin to be  
25 identified and measured.

26  
27 (f) Applicant - An individual or entity that seeks licensure as a Certified Marijuana Testing  
28 Laboratory pursuant to section 381.988(2), F.S., and Rule 64-4.301.

29  
30 (g) Calibration – Set of analyses that establish, under conditions specified in the analysis  
31 Standard Operating Procedure, the relationship between values of quantities indicated by  
32 the measuring instrument or measuring system, or values represented by a material measure  
33 of a Certified Reference Material, and the corresponding values realized by standards.

34  
35 (h) Calibration Curve – The mathematical relationship between the known values, such as  
36 the concentrations of a series of Calibration Standards, and their instrument response.  
37 Calibration Standards are prepared by successively diluting a standard solution to produce  
38 working standards, which cover the working range of the instrument. The correlation  
39 coefficient of the Calibration Standard concentrations plotted against their respective  
40 response factors must be greater than or equal to 0.995. A Calibration Curve must consist  
41 of a minimum of five (5) consecutive points if utilizing a linear correlation, and a minimum  
42 of six (6) consecutive points of utilizing a non-linear correlation. The Calibration Curve  
43 must, at a minimum, span from the Limit of Detection to the Acceptable Limit for each  
44 individual Analyte.

45  
46 (i) Calibration Standard – A Certified Reference Material used to calibrate an instrument.

47  
48  
49  
50  
51  
52  
53  
54  
55  
56  
57  
58  
59  
60  
61  
62  
63  
64  
65  
66  
67  
68  
69  
70  
71  
72  
73  
74  
75  
76  
77  
78  
79  
80  
81  
82  
83  
84  
85  
86  
87  
88  
89  
90  
91  
92

(j) Cannabinoid Profile - A Potency Test conducted to determine the level of concentration of d9-THC, d8-THC, THCA, THCV, CBD, CBDA, CBDV, CBG, CBGA, CBN, and CBC in all Final Product meant for sale to qualified patients.

(k) Certificate of Analysis – A document created by a Certified Marijuana Testing Laboratory which certifies the quality and purity of the tested product.

(l) Certified Marijuana Testing Laboratory – A laboratory that meets the requirements of section 381.988, Florida Statutes and Rules 64-4.301 through 64-4.313, and is licensed by the Department.

(m) Certified Reference Material – A material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability. All Certified Reference Material must be purchased from a vendor accredited to current ISO/IEC 17043 standards.

(n) Contaminants Unsafe for Human Consumption – Any microbe, Mycotoxin, fungus, yeast, mildew, Agricultural Agent, Residual Solvent, or Heavy Metal found in an amount that exceeds any of the Department’s accepted limitations.

(o) Continuing Calibration Verification – A standard solution from a source that is certified and traceable. These standards are used to check the accuracy of a Calibration Curve on daily basis (before the run and every 12 hours thereafter).

(p) Data Packages – Analytical testing data that is prepared by a marijuana testing laboratory and which contains information about the testing performed, Quality Assurance and Quality Control data, and the results of any tests performed.

(q) Derivative Product – Product created from an extracted of marijuana, to include, but not limited to, concentrates, tinctures, vape oil, shatter, budder, RSO, live resin, and keif, and any products containing concentrates, tinctures, vape oil, shatter, budder, RSO, live resin, and keif as an ingredient.

(r) Edible – Commercially produced food items made with marijuana oil, but no other form of marijuana, that are produced and dispensed by the Medical Marijuana Treatment Center

(s) Employee - Any person whose duties involve activities or responsibilities that support the function of testing Useable Whole Flower Marijuana, Derivative Product, or Edibles and are compensated for the performance of such duties, but it does not include non-technical support staff such as maintenance and janitorial Employees.

(t) Environmental Testing – Physical and biological laboratory analyses, to include chemistry and biochemistry in compliance with sections 64E-1.005 F.S.

93 (u) Filth and Foreign Materials – Mold, Mildew, Hair, insects, feces, packaging  
94 contaminants, manufacturing waste, and other similar marijuana cultivation and processing  
95 by-products.

96  
97 (v) Final Product – Any packaged and sealed product intended for use by a qualified  
98 patient.

99  
100 (w) Heavy Metals - A metallic chemical element that has a relatively high density and is  
101 toxic or poisonous at low concentrations.

102  
103 (x) Increment – A subsample taken from an Edible product for the purposes of  
104 homogeneity testing.

105  
106 (y) Initial Calibration Verification – A standard solution from a source, other than normal  
107 Calibration Standards, that is certified and traceable. These standards are used to check the  
108 accuracy of a Calibration Curve.

109  
110 (z) Initial Display of Competency (IDOC) – An examination, administered by a Certified  
111 Marijuana Testing Laboratory, undertaken by an Analyst to determine whether he or she  
112 can correctly, accurately, and repeatedly perform a specific analysis or analyze a specific  
113 measurement.

114  
115 (aa) Interests - Any form of ownership in or control of an Applicant, a Certified Marijuana  
116 Testing Laboratory, or Medical Marijuana Treatment Center including, but not limited to,  
117 ownership of stock, membership Interests, partnership Interests, a sole proprietorship or  
118 otherwise which convey to the holder thereof an ownership right or an Interest in or right  
119 to the profits, capital, or voting with respect to such Applicant, Certified Marijuana Testing  
120 Laboratory, or Medical Marijuana Treatment Center.

121  
122 (bb) Internal Standard – A pure Analyte of known amounts added to the final extract prior  
123 to analysis used to measure the relative response of other Analytes and Surrogates to  
124 correct for variations. The Internal Standard must be a compound that is not expected to be  
125 found in the sample.

126  
127 (cc) Investor - Any person who, directly or indirectly, owns a legal or equitable Interest  
128 (actually or beneficially) or controls less than a 5% share of Interests of an Applicant or  
129 Certified Marijuana Testing Laboratory.

130  
131 (dd) Laboratory Batch – A set that includes the Analytical Batch as well as all applicable  
132 Quality Control samples, to include one Method Blank, duplicate Laboratory Fortified  
133 Blanks, and duplicate Matrix Spike Samples for Mycotoxin, Residual Solvents,  
134 Agricultural Agents, and Heavy Metals. For Microbiological Testing by qPCR, the well  
135 plate shall include the following; at a minimum one positive control, one negative control,  
136 and replicate sample per Analytical Batch.

137

138 (ee) Laboratory Director – An individual that oversees all Analysts, Employees, and  
139 functions of testing Useable Whole Flower Marijuana, Derivative Product, and Edibles and  
140 are compensated for the performance of such duties. A Laboratory Director may oversee  
141 only one physically independent Testing Facility operated by the Certified Marijuana  
142 Testing Laboratory.

143  
144 (ff) Laboratory Fortified Blank – A Quality Control sample, created using a Matrix similar  
145 to the sample Matrix, and initially without Analytes of Interest, prepared along with Testing  
146 Samples, that have been amended with a known concentration of a target Analyte or  
147 Analytes for competency assessment purposes. Laboratory Fortified Blanks shall be  
148 analyzed in duplicate in order to calculate Residual Percent Deviation.

149  
150 (gg) Limit of Detection (LOD) – The lowest quantity of an Analyte that can be  
151 distinguished from the absence of that Analyte within a stated confidence limit. The LOD  
152 must be 10% of the Acceptable Limit or less for the Analyte tested. LOD applicable for  
153 Heavy Metals, Residual Solvents, Agricultural Agents, Mycotoxins, and Cannabinoid  
154 Profile.

155  
156 (hh) Limit of Quantitation (LOQ) – The minimum concentration of an Analyte in a specific  
157 Matrix that can be reliably quantified while also meeting predefined goals for bias and  
158 imprecision. The LOQ must equal to the Acceptable Limit or less for the Analyte tested.  
159 LOQ applicable for Heavy Metals, Residual Solvents, Agricultural Agents, Mycotoxins,  
160 and Cannabinoid Profile.

161  
162 (ii) Manager - Any person with direct or indirect authority to exercise or contribute to the  
163 operational control, direction, or management of an Applicant or a Certified Marijuana  
164 Testing Laboratory or who has direct or indirect authority to supervise any Employee of  
165 an Applicant or a Certified Marijuana Testing Laboratory. The term includes all officers,  
166 Managers, and members of board of directors, as well as any other person engaged to  
167 undertake management or control of the Applicant or a Certified Marijuana Testing  
168 Laboratory or any person in control of an entity engaged to undertake management or  
169 control of the Applicant or Certified Marijuana Testing Laboratory.

170  
171 (jj) Matrix - The component or substrate containing an Analyte of Interest. The three matrix  
172 types contemplated are: Useable Whole Flower Marijuana (plant material), Derivative  
173 Product (concentrates), and Edibles.

174  
175 (kk) Matrix Group - The components of a Testing Sample other than the Analytes of  
176 Interest. The Matrix Groups are Useable Whole Flower Marijuana, Derivative Products,  
177 and Edibles.

178  
179 (ll) Matrix Spike Sample – A aliquot from a Testing Sample, which has been amended with  
180 a known concentration of an Analyte or Analytes of Interest to test for potential Matrix  
181 interference. Matrix Spike Samples shall be analyzed in duplicate in order to calculate  
182 Residual Percent Deviation.

183

184 (mm) Method Blank - An Analyte free Matrix, (Reagent water or appropriate solvent),  
185 which is carried through the complete preparation and analytical procedure, used to  
186 evaluate contamination resulting from the complete analytical procedure. For a Method  
187 Blank to be acceptable for use with the accompanying Testing Samples, the concentration  
188 in the Method Blank of any Analyte of concern shall not be higher than the Limit of  
189 Detection.

191 (nn) Microbiological Testing - The analysis of microbiological organisms, to include  
192 bacteria, yeast, mold, mildew, and Mycotoxins.

194 (oo) Medical Marijuana Treatment Center (MMTC) - An entity licensed by the Department  
195 pursuant to 381.986, Florida Statutes.

197 (pp) Moisture - The total amount of water present in a sample, calculated as percent  
198 Moisture

200 (qq) Mycotoxins - Any toxin substance produced by a fungus.

202 (rr) Non-Oral Transmucosal Product – A Derivative Product with administration routes  
203 other than oral and heated inhalation, to include, but not limited to, nasal sprays, inhalers,  
204 suppositories, and similar transmucosal administration.

206 (ss) Owner - Any person who, directly or indirectly, owns a legal or equitable Interest  
207 (actually or beneficially) or controls a 5% or greater share of Interests of the Applicant or  
208 Certified Marijuana Testing Laboratory. In the event that one person owns a beneficial  
209 right to Interests and another person holds the voting rights with respect to such Interests,  
210 both persons are the Owner of such Interests. In determining who are Owners of the  
211 Applicant or a Certified Marijuana Testing Laboratory, the attribution of ownership rules  
212 set forth in the Treasury Regulations cited as 26 C.F.R. 1.414(c)-4(b) and (c) (4-1-17  
213 edition), incorporated by reference and available at  
214 <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>, apply, but with the  
215 following exceptions and additions:

217 1. The use of the term “Option” in 26 C.F.R. 1.414(c)-4(b) shall be interpreted broadly  
218 to include, but not be limited to, options, warrants, calls, rights of first refusal and any  
219 other right to acquire an Interest (as defined herein), whether such right is vested or  
220 unvested and regardless of whether such right is then exercisable or becomes  
221 exercisable at a future date or upon the occurrence of a future event.

223 2. The exception for attribution of a spouse’s Interest, as defined in paragraph (l) above  
224 and as set forth in 26 C.F.R. 1.414(c)-4(b)(5)(ii), does not apply.

226 3. The age limitation contained in 26 C.F.R. 1.414(c)-4(b)(6) applies only to children  
227 who have not attained the age of 18 years. The term “Interest” as used in 26 C.F.R.  
228 1.414(c)-4(b)(6) shall have the meaning as set forth in subparagraph (j) above.

229

230 4. If a person under the age of 18 owns or is deemed an Owner of an Interest, such  
231 person must be disclosed to the Department. Persons under the age of 18 must submit  
232 to a background screening only in the event that the Interest or ownership was not  
233 imputed to another family member or guardian as outlined in paragraph (l)3. above.

234  
235 5. To the extent that the above alterations to the provisions of 26 C.F.R. 1.414(c)-4  
236 change the outcome of any of the examples set forth therein, the example does not  
237 apply.

238  
239 6. As used in 26 C.F.R. 1.414(c)-4(b)(3), the term “Actuarial Interest” shall be  
240 interpreted broadly and shall include, but not be limited to, the right of a beneficiary of  
241 a trust or an estate to receive either income or principal distributions with respect to an  
242 Interest held by such trust or estate.

243  
244 7. With regard to publicly-traded companies with ownership Interests in the Applicant,  
245 any person who holds 10% or more Interest in the publicly-traded company is an  
246 Owner.

247  
248 (tt) Potency Testing - The analysis of the relative strength of cannabinoids, and the total  
249 amount, in milligrams, of THC as the sum of (d9-THC + (0.877 x THCA)) and CBD as the  
250 sum of (CBD + (0.877 x CBDA)) in the Final Product.

251  
252 (uu) Processed Batch – A homogenous portion of Useable Whole Flower Marijuana,  
253 Derivative Product, or Edible, not to exceed 50 kilograms dry weight or 50 liters volume  
254 diluted. Processed Batches exceeding these sizes must be split into even portions below  
255 the maximum size with unique identifiers.

256  
257 (vv) Proficiency Testing - Testing of unknown samples by an Applicant or Certified  
258 Marijuana Testing Laboratory, to determine the accuracy of the analysis for specific  
259 Analytes and Matrices. Samples used for Proficiency Testing must be supplied to the labs  
260 by an ISO/IEC 17043 accredited body.

261  
262 (ww) Quality Assurance - A system developed by an Applicant or Certified Marijuana  
263 Testing Laboratory to ensure that products and services delivered are as accurate and  
264 precise as possible.

265  
266 (xx) Quality Assurance Manual - A written collection of all Quality Assurance systems or  
267 protocols to include the management policies, objectives, principles, organizational  
268 structure and authority, responsibilities, and implementation of a laboratory to ensure the  
269 quality and utility of the service rendered. The Quality Assurance Manual must be  
270 available for review by any Certified Marijuana Testing Laboratory Employee during  
271 working hours.

272  
273 (yy) Quality Control - System developed in accordance with current ISO 17025 standards,  
274 to verify that the required level of quality in analyses are met and maintained. Such  
275 verification shall include determining that appropriate equipment and instruments are used,

276 continued inspection and overview of all facets of the testing process, and undertaking  
277 corrective action as necessary. Quality Control samples should contain, where applicable,  
278 Method Blank, duplicate Laboratory Fortified Blank, duplicate Matrix Spike Samples, and  
279 duplicate Testing Samples.

280  
281 (zz) Reagent – A compound or mixture added to a system to cause a chemical reaction or  
282 test if a reaction occurs. A Reagent may be used to tell whether a specific chemical  
283 substance is present by causing a reaction to occur with the chemical substance.

284  
285 (aaa) Residual Percent Deviation (RPD) – A calculation of the precision of the measured  
286 recovered concentration of duplicate Laboratory Fortified Blanks, duplicate Matrix Spike  
287 Samples, or duplicate Testing Samples, calculated as follows:  $RPD = |A-B|/(A+B) \times 200$ .  
288 The RPD should be equal to or less than 20% to constitute a pass.

289  
290 (bbb) Residual Solvents - Volatile chemicals that are used during the manufacture of a  
291 Final Product, which have not been completely removed by practical manufacturing  
292 techniques.

293  
294 (ccc) Retail Batch – The portion of one Processed Batch used to create a Final Product that  
295 consists of one product type, at one concentration, at one weight or volume.

296  
297 (ddd) Sampler - Employee who collects samples of medical marijuana from a Medical  
298 Marijuana Treatment Center for testing and has undergone specific training to fulfill this  
299 function.

300  
301 (eee) Secure Storage - The segregation of Useable Whole Flower Marijuana, Derivative  
302 Product, or Edibles in a manner that prevents access from unauthorized persons,  
303 compromise of the product's integrity, or premature spoilage.

304  
305 (fff) Spike Solution – A solution of method Analytes of known concentrations that is used  
306 to fortify an aliquot of clean sample Matrix. For methods with multiple Analytes, a  
307 representative number of Analytes may be chosen for the Spike Solution. For methods that  
308 include one (1) to five (5) Analytes, the Spike Solution must contain all Analytes. For  
309 methods that include five (5) to 20 Analytes, the Spike Solution must contain 50% of the  
310 method Analytes, with a minimum of five (5) Analytes. For methods that include more  
311 than 20 Analytes, the Spike Solution must contain a minimum of 16 Analytes. The  
312 laboratory must ensure all method Analytes are included in the Spike Solution at least once  
313 in a two-year period.

314  
315 (ggg) Standard Operating Procedure (SOP) – A written document which details the method  
316 of an operation, analysis or action whose techniques and procedures are thoroughly  
317 described and which is appropriate as a method of performing certain routine or repetitive  
318 tasks. An SOP must contain information highlighting the scope and application of the  
319 method, apparatus and equipment to be used, Reagents used in the method, Testing Sample  
320 collection, preservation, and handling, Testing Sample preparation procedures, Testing

321 Sample preparation logs, Testing Sample analysis procedures, Quality Control procedures,  
322 safety and hazardous waste warnings, references, and the dates of significant changes.

323  
324 (hhh) Surrogate – A pure Analyte that is added to all testing and Quality Control samples  
325 before Testing Sample preparation to measure method accuracy. Surrogates should be  
326 similar in behavior to method Analytes, but not expected to appear in the sample.

327  
328 (iii) Testing Facility – The location of a real property or the area within a real property to  
329 be utilized as a Certified Marijuana Testing Laboratory.

330  
331 (jjj) Testing Field - The suite of Analytes tested within a particular Matrix category. The  
332 testing categories are Microbiology, Mycotoxins, Residual Solvents, Heavy Metals,  
333 Agricultural Agents, Moisture, Water Activity, and Cannabinoid Profile.

334  
335 (kkk) Testing Sample – A homogenized sample for analysis created from a representative  
336 selection of products from a Retail Batch. Within each Analytical Batch, a minimum of  
337 one Testing Sample must be analyzed in duplicate in order to calculate Residual Percent  
338 Deviation.

339  
340 (lll) Total Contaminant Load (TCL) – The sum of all Heavy Metals and Agricultural  
341 Agents present above the LOD, but below the Acceptable Limit.

342  
343 (mmm) Useable Whole Flower Marijuana – The flowers of the female cannabis plant,  
344 including low-THC cannabis, that is suitable to be dispensed from a Medical Marijuana  
345 Treatment Center for medical use by a qualified patient. Useable Whole Flower Marijuana  
346 does not include seeds, resin extracted from any part of the plant, or any compound,  
347 manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin.

348  
349 (nnn) Water Activity – The measure of the quantity of water in a product that is available  
350 and therefore capable of supporting bacteria, yeasts, mold, and fungi.

351



352 **Rule 64-4.301 Application for Initial Licensure**

353  
354 (1) To receive licensure as a Certified Marijuana Testing Laboratory, an Applicant must adhere to  
355 the requirements of sections 381.986(8)(d), 381.986(8)(e)11.d., 381.986(8)(g), and 381.988, F.S.,  
356 Rules 64-4.300 through 64-4.313, and all representations made within its application for licensure.  
357 This rule establishes the initial application requirements for Certified Marijuana Testing  
358 Laboratories under section 381.986, Florida Statutes. Any testing laboratory seeking licensure as  
359 a Certified Marijuana Testing Laboratory must apply as provided in this rule.

360  
361  
362 (2) Licensure will be on a per-Testing Facility basis. Separate applications must be submitted for  
363 each Testing Facility.

364  
365 (3) To begin the application process, an Applicant must submit a completed Form DH####-  
366 OMMU-##/####, “Application and Instructions for Certified Marijuana Testing Laboratory  
367 Certification,” incorporated by reference herein and available at  
368 <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX>.

369  
370 (4) Form DH####-OMMU-##/#### contains the instructions and guidelines for submission of a  
371 complete application.

372  
373 (5) An Applicant must submit an application fee of \$#####; together with the entity’s submission  
374 of Form DH####-OMMU-##/####. Failure to submit an application fee of \$##### will be grounds  
375 for denial of the associated application.

376  
377 (6) Minimum Standards

378  
379 (a) An Applicant must possess accreditation for ISO/IEC 17025:2017 (revised March  
380 2018) by an accreditation body recognized by the International Laboratory Accreditation  
381 Cooperation (ILAC) for testing. ISO/IEC 17025:2017 (revised March 2018), incorporated  
382 by reference and available at [https://www.flrules.org/Gateway/reference.asp?No=Ref-](https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXX)  
383 XXXXX. The Department has determined that posting the incorporated materials on the  
384 internet would constitute a violation of the federal copyright law. The material is available  
385 for inspection at -----. The accreditation must establish that the Applicant is qualified  
386 to analyze one or more of the following Testing Fields:

- 387 1. Microbiology;
- 388 2. Mycotoxins;
- 389 3. Residual Solvents;
- 390 4. Heavy Metals;
- 391 5. Agricultural Agents;
- 392 6. Water Activity;
- 393 7. Moisture;
- 394 8. Filth and Foreign Material; and
- 395 9. Cannabinoid Profile.

396 (b) An Applicant must have an existing contract with an ISO/IEC 17043:2010 accredited  
397 body that is a signatory for Proficiency Testing to an arrangement recognized by ILAC to

398 conduct Proficiency Testing. The Applicant will bear all costs of any required Proficiency  
399 Testing.

401 (c) An Applicant must have received satisfactory results from the two most recent  
402 Proficiency Tests administered by an ISO/IEC 17043:2010 accredited body covering one  
403 or more of the Testing Fields within one or more of the following Matrix Groups:

404 1. Useable Whole Flower Marijuana

- 405 a. Microbiology;
- 406 b. Mycotoxins;
- 407 c. Heavy Metals;
- 408 d. Agricultural Agents;
- 409 e. Water Activity;
- 410 f. Moisture; and
- 411 g. Cannabinoid Profile.

412 2. Derivative Products

- 413 a. Microbiology;
- 414 b. Mycotoxins;
- 415 c. Residual Solvents;
- 416 d. Heavy Metals;
- 417 e. Agricultural Agents;
- 418 f. Water Activity;
- 419 g. Moisture; and
- 420 h. Cannabinoid Profile.

421 3. Edibles

- 422 a. Microbiology;
- 423 b. Mycotoxins;
- 424 c. Residual Solvents;
- 425 d. Heavy Metals;
- 426 e. Agricultural Agent;
- 427 f. Water Activity;
- 428 g. Moisture; and
- 429 h. Cannabinoid Profile.

430  
431 (d) Personnel:

432  
433 1. Laboratory Employees:

- 434 a. All Certified Marijuana Testing Laboratory Employees engaged in any aspect of  
435 medical marijuana handling or analysis must be 21 years of age or older.
- 436 b. All Certified Marijuana Testing Laboratory Employees have passed the level 2  
437 background screening pursuant to section 435.04, F.S., and have not been found  
438 guilty of, or entered a plea of guilty or nolo contendere to, regardless of  
439 adjudication, any offense listed in chapters 837, 895, or 896, F.S., or similar law of  
440 another jurisdiction.
- 441 c. All Certified Marijuana Testing Laboratory Employees must have, at a minimum,  
442 a high school diploma from a state-approved and accredited public or private  
443 school, or an associate degree from an institution accredited by a federally- or

444 nationally-recognized accrediting or state agency; or hold a current certification as  
445 a Florida Board of Clinical Laboratory Personnel.

446 2. Samplers:

447 a. All Certified Marijuana Testing Laboratory Samplers must meet the  
448 requirements for an Employee of a Certified Marijuana Testing Laboratory.

449 b. All Certified Marijuana Testing Laboratory Samplers must be provided specific  
450 training on the minimum requirements for sampling and the Applicant's Standard  
451 Operating Procedures for sampling and security.

452 3. Analysts:

453 a. All Certified Marijuana Testing Laboratory Analysts must meet the requirements  
454 for an Employee of a Certified Marijuana Testing Laboratory.

455 b. All Certified Marijuana Testing Laboratory Analysts must be provided specific  
456 training on the minimum requirements for sampling and the Applicant's Standard  
457 Operating Procedures for sampling and security.

458 c. All Certified Marijuana Testing Laboratory Analysts must have, at a minimum,  
459 a bachelor's degree in a natural science, to include, but not be limited to, biology,  
460 chemistry, physics, engineering, or environmental sciences; or hold a current  
461 certification as a Florida Board of Clinical Laboratory Personnel.

462 4. Laboratory Directors:

463 a. All Certified Marijuana Testing Laboratory Directors must meet the  
464 requirements for an Employee and for an Analyst of a Certified Marijuana Testing  
465 Laboratory.

466 b. A Certified Marijuana Testing Laboratory must employ a Laboratory Director  
467 for each physically independent Testing Facility operated by the Certified  
468 Marijuana Testing Laboratory.

469 c. All Certified Marijuana Testing Laboratory Directors have a minimum of three  
470 (3) years of experience in a regulated laboratory environment sufficient for any  
471 accreditation required by this rule.

472  
473 (e) An Applicant must have the ability to maintain adequate controls against the diversion,  
474 theft, or other loss of marijuana, the tampering or compromise of samples, and the  
475 tampering or compromise of testing equipment and materials. An Applicant must have  
476 documented security controls together with written Standard Operating Procedures and  
477 must be in accordance with any accreditation required by this rule, and must comply with  
478 the following security requirements to ensure the safety and security of all proposed  
479 Testing Facilities and Secure Storage areas:

480 1. A fully operational security alarm system that secures all entry points and perimeter  
481 windows and is equipped with motion detector and duress, panic, and hold-up alarms.

482 2. A fully operational video surveillance system that records continuously 24 hours a  
483 day, and meets the following criteria:

484 a. Cameras are fixed in a place that allows for the clear identification of persons  
485 and activities in controlled areas of any Testing Facility and Secure Storage area;

486 b. Cameras are fixed at entrances and exits to the premises, record from both indoor  
487 and outdoor, or ingress and egress, vantage points;

488 c. Recorded images legibly and accurately display the time and date; and

489 d. Retain video surveillance recordings for at least 30 days or longer.

- 490 3. Fully operational dusk-to-dawn safety lighting on the exterior of the Testing Facility  
491 that provides illumination to the areas directly around the premises, including all points  
492 of ingress and egress.
- 493 4. All marijuana and marijuana samples are stored in a secured, locked room or a vault  
494 in a manner that does not accelerate spoilage or promote other degradation.
- 495 5. Make available at least two Certified Marijuana Testing Laboratory Employees to  
496 accept Useable Whole Flower Marijuana, Derivative Product, or Edibles for testing at  
497 the Testing Facility.
- 498 6. At least two Employees, or two Employees of a contracted security agency, are on  
499 the Testing Facility premises when marijuana is received, when marijuana is tested,  
500 and during all normal business hours.
- 501 7. Transportation of all marijuana products must adhere to the requirements in  
502 381.896(8)(g), Florida Statutes.
- 503 8. Each Employee wears a legible photo identification badge at all times while on the  
504 premises.
- 505 9. Any non-Employee natural persons with access to the premises of the Certified  
506 Marijuana Testing Laboratory must brandish an identification badge clearly indicating  
507 their visitor status, and be accompanied by an Employee;
- 508 10. Each Employee has training in, and access to, the Applicant's alcohol and drug-  
509 free workplace policy.
- 510 11. Each Employee has training and access to the Applicant's theft and diversion  
511 policies and procedures and have been made aware of the requirement to report to local  
512 law enforcement within 24 hours notification or knowledge of the apparent theft,  
513 diversion, or loss of marijuana.

514

515 (f) An Applicant must have written Quality Assurance and Quality Control procedures.  
516 Quality Assurance and Quality Controls must be contained within written Standard  
517 Operating Procedures and be in accordance with any accreditation required by this rule.

- 518
- 519 1. An Applicant's written Quality Assurance Program Manual must address every  
520 aspect of its Quality Assurance program, including without limitation:
- 521 a. Quality Control procedures;
  - 522 b. laboratory organization;
  - 523 c. laboratory Employee training;
  - 524 d. laboratory Employee responsibilities;
  - 525 e. objectives for measurement data;
  - 526 f. data and result traceability;
  - 527 g. preventative maintenance of equipment;
  - 528 h. performance audits, to include internal and external laboratory auditing;
  - 529 i. corrective action;
  - 530 j. recordation and maintenance of Quality Assurance records; and
  - 531 k. receiving, handling, and Secure Storage of samples.
- 532
- 533 2. Once a year or whenever a change of method, equipment, or Laboratory Director  
534 occurs, the Laboratory Director or authorized Employee shall review, amend as  
535 necessary, and approve of the Certified Marijuana Testing Facility's Laboratory

536 Quality Assurance program. All Quality Assurance and Quality Controls are subject  
537 to Department approval.

538  
539 3. Internal Quality Assurance and Quality Control audits must occur at least once every  
540 year. Internal audit results, including any and all remediation actions, must be provided  
541 to the Office of Medical Marijuana Use, at [OMMULicenseOperation@flhealth.gov](mailto:OMMULicenseOperation@flhealth.gov)  
542 within five (5) business days of the completion of the audit.

543  
544 4. An Applicant must use testing equipment that satisfies the requirements of any  
545 accreditation required by this rule. Equipment that is not suitable for a specific method  
546 shall not be used for that purpose.

547 a. Testing equipment shall be used and maintained according to the manufacturer's  
548 instructions and shall be calibrated pursuant to the requirements of any  
549 accreditation under which it is operated. Certified Marijuana Testing Laboratories  
550 shall retain records of all equipment repairs, maintenance, and Calibrations.

551 b. Internal audits of all Certified Marijuana Testing Laboratory equipment,  
552 facilities, personnel, and security occur at least once every calendar year. Audit  
553 results shall be provided to the Office of Medical Marijuana Use, at  
554 [OMMULicenseOperation@flhealth.gov](mailto:OMMULicenseOperation@flhealth.gov), by the internal auditor that conducted the  
555 audit within five (5) business days of the completion of the audit.

556  
557 5. An Applicant must have a tracking system to document the complete chain of  
558 custody of marijuana samples, and all testing data attributed to those sample, from  
559 receipt through disposal. Chain-of-custody entries must show the date, time, name of  
560 Employees handling the sample, the condition of the sample, the condition of any  
561 container or packaging the sample was transported or stored in, the location of the  
562 sample, the sample's unique identifier, and the seed-to-sale information from the  
563 Medical Marijuana Treatment Center. The Applicant's tracking system will be required  
564 integrate with the Department's seed-to-sale tracking system, once implemented.

565  
566 6. An Applicant must have a written procedure to dispose of waste generated at the  
567 Testing Facility. Any marijuana in possession by a Certified Marijuana Testing  
568 Laboratory but undergoing no preparatory or analytical procedures ("non-laboratory  
569 marijuana waste") must be disposed of in accordance with Department rule. Dry flower  
570 non-laboratory marijuana waste must be ground and mixed with general waste to a  
571 maximum 50% marijuana by volume to render the waste unusable. Liquid non-  
572 laboratory marijuana waste may be mixed with methylene chloride or acetone to a  
573 maximum of 50% marijuana by volume to render the waste unusable, and disposed of  
574 as hazardous waste. Marijuana waste which has undergone preparatory or analytical  
575 procedures must be disposed of as hazardous waste.

576  
577 (g) An Applicant's Owners and Managers must successfully pass a level-2 background  
578 screening pursuant to section 381.988(1)(d), Florida Statutes. An Applicant must maintain  
579 a list of all Owners, officers, board members, and Managers that includes the date, within  
580 the calendar year prior to submission of the application, of the level 2 background screening  
581 required by this rule for each individual. Each Owner, officer, board member, and Manager

582 may go to an FDLE-approved vendor for fingerprinting and, at such time, shall give to the  
583 FDLE-approved vendor the entity ORI number FL924890Z (DOH – OFFICE OF  
584 MEDICAL MARIJUANA USE).

585  
586 (h) An Applicant shall not be owned and/or controlled by a Medical Marijuana Treatment  
587 Center, and must have the following:

588 1. A fully diluted capitalization table;

589 a. Fully diluted capitalization table listing of all share types and the aggregate sum  
590 of shares associated to any natural persons, whether considered Owners or  
591 Investors.

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

594 c. A fully diluted capitalization table must list all share types and the aggregate sum  
595 of shares associated to any natural person as of a date no less than 7 calendar days  
596 prior to the date of the Applicant’s submission of its application for Certification or  
597 renewal;

598 d. A fully diluted capitalization table must list only natural persons as Owners and  
599 Investors;

600 2. An Applicant must notify the Department of all contractual relationships to change  
601 the control of the entity holding the certification, or to change its Management, Owners  
602 or Investors, whether executed or not executed.

603 a. Such executed contractual relationships must be provided to the Department for  
604 approval.

605 3. Publicly-traded companies are not exempt from any requirements of this rule and  
606 must maintain documentation identifying all Owners and Investors that are considered  
607 Non-Objecting Beneficial Owners (“NOBOs”).

608  
609  
610 (7) Business arrangements with Medical Marijuana Treatment Centers. The Applicants must  
611 provide the Department with a copy of all existing written agreements with any Medical Marijuana  
612 Treatment Center to conduct tests and perform analyses on marijuana. Agreements must be in  
613 writing and contain, at a minimum, a Standard Operating Procedure for the random sampling of  
614 Final Product, Standard Operating Procedures for the transport of product for testing to the  
615 Certified Marijuana Testing Laboratory, and the Testing Fields and Matrix Groups to be tested.

616  
617 (a) All written agreements between a Medical Marijuana Treatment Center and a Certified  
618 Marijuana Testing Laboratory entered after the date of initial licensure must be submitted  
619 to the Department as a variance pursuant to Rule 64-4.305.

620  
621  
622

623 **Rule 64-4.302 Testing**

624

625 (1) A Certified Marijuana Testing Laboratory may only conduct tests and perform analyses of  
626 Testing Fields within Matrix Groups under the following conditions:

627

628 (a) Tests and analyses of Testing Fields within Matrix Groups must have been documented  
629 within the Certified Marijuana Testing Laboratory's application for licensure.

630

631 (b) Tests and analyses of Testing Fields within Matrix Groups must be covered by the  
632 Certified Marijuana Testing Laboratory's ISO/IEC 17025:2017 (revised March 2018)  
633 accreditation that is compliant with Rule 64-4.301.

634

635 (c) Tests and analyses of Testing Fields within Matrix Groups must be supported by  
636 documentation of two satisfactory analyses of the three most recent Proficiency Testing  
637 administered by an ISO/IEC 17043:2010 accredited body. Proficiency Test results that are  
638 within the acceptance limits established by the contracted ISO/IEC 17043 accredited body  
639 are satisfactory.

640

641 (d) A Certified Marijuana Testing Laboratory must participate in at least two Proficiency  
642 Testing rounds from an ISO/IEC 17043 accredited body per calendar year beginning on  
643 the date of issuance or renewal of licensure. Rounds of Proficiency Testing may not occur  
644 at greater than six-month intervals, as determined by the closing dates of each Proficiency  
645 Testing attempt. If a Certified Marijuana Testing Laboratory reports more than one result  
646 for a Testing Field of Proficiency Testing in a Proficiency Testing round, any  
647 unsatisfactory result constitutes a failed testing attempt for the corresponding approved or  
648 pending scope of accreditation. The results of all Proficiency Testing must be sent from  
649 the ISO/IEC 17043 accredited body directly to the Department. The Certified Marijuana  
650 Testing Laboratory must direct the ISO/IEC 17045 accredited body to deliver the results  
651 directly to the Department.

652

653 (e) A Certified Marijuana Testing Laboratory may only conduct tests and perform analyses  
654 at its Testing Facility identified and documented in its application.

655

656 **Rule 64-4.303 On-Site Inspection**

657  
658 (1) The Department will undertake inspections of all Certified Marijuana Testing Laboratory.

659  
660 (a) The Department may conduct random, on-site inspections of any Certified Marijuana  
661 Testing Laboratory's Testing Facility during normal working hours.

662  
663 (b) A Certified Marijuana Testing Laboratory must maintain at its Testing Facility all  
664 records needed to verify compliance with sections 381.986(8)(d), 381.986(8)(e)11.d.,  
665 381.986(8)(g), 381.988, F.S., Rule 64-4.301, and the specific representations in its  
666 application for licensure, including without limitation, a Quality Assurance Manual,  
667 analytical method Standard Operating Procedures, Quality Control data, Proficiency Test  
668 data, laboratory Standard Operating Procedures, transport manifests, and any documents  
669 pertinent to receiving and maintaining ISO/IEC 17025 accreditation, for the previous two  
670 years of operation. The Certified Marijuana Testing Laboratory must make such records  
671 available to the Department for review during any inspection.

672  
673 (c) A Certified Marijuana Testing Laboratory shall allow Department personnel to examine  
674 records; observe the Certified Marijuana Testing Laboratory's facilities, procedures, and  
675 equipment; and interview Employees during any on-site inspection.

676  
677 (d) During any inspection, a Certified Marijuana Testing Laboratory must demonstrate that  
678 its Testing Facility, equipment, operations, Standard Operating Procedures, and personnel  
679 are in compliance with sections 381.986(8)(d), 381.986(8)(e)11.d., 381.986(8)(g), and  
680 381.988, F.S., Rule 64-4.301, and the specific representations in its application.

681  
682 (e) If during any inspection the Department identifies any omissions, deficiencies, or  
683 violation of sections 381.986(8)(d), 381.986(8)(e)11.d., 381.986(8)(g), and 381.988, F.S.,  
684 Rule 64-4.301, or the specific representations of the application, the Department will send  
685 written notification after the completion the inspection to the Certified Marijuana Testing  
686 Laboratory identifying the omissions, deficiencies, or violations. Within fourteen (14)  
687 calendar days of receipt of a written notice of a violation, the Certified Marijuana Testing  
688 Laboratory must notify the Department in writing of the corrective action taken to resolve  
689 the omission, deficiencies, or violation and the date of the correction. The Department will  
690 determine whether the omissions, deficiencies, or violations have been addressed, and  
691 whether any additional action must be taken by the Certified Marijuana Testing Laboratory,  
692 or if disciplinary action is appropriate. The Department will conduct additional inspections  
693 to confirm that the omission, deficiency, or violation has been resolved and corrective  
694 action has been taken, unless resolution can be confirmed absent a physical visit to the  
695 Testing Facility.

696  
697 (f) The failure to resolve any omission, deficiency, or violation identified during an  
698 inspection shall be grounds to suspension or license revocation under Rule 64-4.304.  
699



700 **Rule 64-4.304 Suspension and Revocation of Licensure**

701  
702 (1) The Department may initiate an administrative action for violations of section 381.986, F.S.,  
703 section 381.988, F.S., or this rule chapter. Once a Certified Marijuana Testing Laboratory receives  
704 licensure, it must at all times maintain compliance with all the requirements set forth in statute,  
705 Rule 64-4.301, and the representations made in its initial application (as may be amended through  
706 Rule 64-4.305). Failure to do so will result in suspension or revocation of the Certified Marijuana  
707 Testing Laboratory's license.

708  
709 (a) The following will result in revocation of the marijuana testing laboratory's license:

- 710 1. Knowingly falsifying results, to include inappropriate manual peak integrations,
- 711 including peak shaving (removing area from a peak), peak enhancement (adding area
- 712 to a peak), and inconsistent Calibration Curve peak integration.
- 713 2. Altering Testing Samples prior to analysis in any way that could generate inaccurate
- 714 results.
- 715 3. Knowingly Testing Samples that were failed, pursuant to this Rule 64-4.310, by
- 716 another Certified Marijuana Testing Laboratory.
- 717 4. Dispensing any marijuana.
- 718 5. Performing any analysis on marijuana while licensure is suspended.
- 719 6. Falsifying any required accreditation pursuant to Rule 64-4.301.

720  
721 (b) The first instance of the following will result in a 180-day license suspension. The  
722 Certified Marijuana Testing Laboratory's certification shall be revoked upon the second  
723 instance of a violation within one calendar year of the initial occurrence of the first instance.

- 724 1. Allowing an Analyst without a current, valid Initial Display of Competency to
- 725 perform any analysis.
- 726 2. Allowing a non-Analyst to perform any analysis.
- 727 3. Using expired standards, Surrogates, Internal Standards, or Spike Solutions.
- 728 4. Failure to follow and maintain proper security measures.
- 729 5. Using preparation or analytical methods that have not been approved pursuant to
- 730 Rule 64-4.308.
- 731 6. Failure to transport marijuana in accordance section 381.986(8)(g)1.-6., F.S., and
- 732 Rule 64-4.309.
- 733 7. Falsifying travel manifests, field reports, instrument maintenance logs, or chain of
- 734 custody reports.

735  
736 (c) The first instance of the following will result in a 60-day license suspension: use of any  
737 outdated Standard Operating Procedure or manual, or knowingly employing a person who  
738 does not meet the criteria of employment in Rule 64-4.301. The license will be suspended  
739 for 180 days upon the second instance of a violation of this paragraph (c) within one  
740 calendar year of the first instance of a violation. The license will be revoked upon the third  
741 instance of a violation within two calendar years of the first instance of a violation.

742  
743 (d) For violations of subsection (b) and (c), the Department will provide notice and  
744 opportunity to cure in order to reduce the length of suspension. The Certified Marijuana  
745 Testing Laboratory must provide a proposed cured to the Department within 5 business

746 days of notice. If the cure is acceptable to the Department, then the suspension may be  
747 reduced to a period of time to be determined by the Department as reasonable in light of  
748 the severity of the non-compliance or violations. The Department will consider the risk to  
749 the safety of the registered patients, the potential for diversion of product, and the impact  
750 to the Medical Marijuana Treatment Centers that have been using the Certified Marijuana  
751 Testing Laboratory.

752  
753  
754 (e) A Certified Marijuana Testing Laboratory that loses or has its required accreditation  
755 suspended must report the loss or suspension within 24 hours of its occurrence to the Office  
756 of Medical Marijuana Use, at [OMMULicenseOperation@flhealth.gov](mailto:OMMULicenseOperation@flhealth.gov).

757  
758 1. A Certified Marijuana Testing Laboratory must provide documentation identifying  
759 the cause of the suspension or loss of accreditation within five (5) business days of  
760 receiving notice of the loss or suspension of its accreditation to the Office of Medical  
761 Marijuana Use, at [OMMULicenseOperation@flhealth.gov](mailto:OMMULicenseOperation@flhealth.gov).

762  
763 2. A Certified Marijuana Testing Laboratory must provide documentation evidencing  
764 that notification has been provided to each Medical Marijuana Treatment Center for  
765 which it conducts testing or with which it is associated, within five (5) business days  
766 of receiving notice of the loss or suspension of its accreditation to the Office of Medical  
767 Marijuana Use, at [OMMULicenseOperation@flhealth.gov](mailto:OMMULicenseOperation@flhealth.gov).

768  
769 3. Any Certified Marijuana Testing Laboratory that loses or has suspended any  
770 accreditation required by Rule 64-4.301 must not test any product or provide any results  
771 to Medical Marijuana Treatment Centers of tests conducted during the time  
772 accreditation was lost or suspended.

773  
774 4. A Certified Marijuana Testing Laboratory may correct deficiencies and reestablish  
775 accreditation within 180 days of the effective date of the loss or suspension of  
776 accreditation. The Department will revoke the license of a Certified Medical Marijuana  
777 Testing Laboratory as of the effective date of the loss or suspension of accreditation  
778 upon the failure to reestablish lost accreditation within 180 days of the loss or  
779 suspension.

780  
781 (f) A Certified Marijuana Testing Laboratory must satisfactorily complete two of the most  
782 recent three Proficiency Testing rounds. A Certified Marijuana Testing Laboratory that  
783 fails to satisfactorily completes two of the most recent three Proficiency Testing rounds  
784 shall not test or provide results to Medical Marijuana Treatment Centers for any Analyte,  
785 Matrix, or other measurement for which its analysis was unsatisfactory. The Certified  
786 Marijuana Testing Laboratory must undertake an internal investigation to determine the  
787 reason for the unsatisfactory Proficiency Test result and must satisfactorily complete  
788 additional Proficiency Testing for any Analyte or Matrix that failed. The Certified  
789 Marijuana Testing Laboratory must provide the findings of the internal investigation to the  
790 Department within 10 calendar days of completion. A Certified Marijuana Testing  
791 Laboratory must provide evidence, in the form of satisfactory Proficiency Testing Results,

792  
793  
794  
795  
796

to the Department before being authorized to test or provide results to Medical Marijuana Treatment Centers for any Analyte, Matrix, or other measurement for which its analysis was unsatisfactory.

DRAFT

797 **Rule 64-4.305 Updates and Changes to Applications After Licensure**

798  
799 (1) A Certified Marijuana Testing Laboratory licensed pursuant to Rule 64-4.301 may request to  
800 update or change the representations made in its initial application for licensure, subject to  
801 approval from the Department.

802  
803 (2) To obtain approval for updates and changes, a Certified Marijuana Testing Laboratory must  
804 submit the request to the Department in writing detailing the requested update or change.  
805 Consideration of such a request will be based upon the individual facts and circumstances  
806 surrounding the request. Approval may not be granted unless the requesting Certified Marijuana  
807 Testing Laboratory can demonstrate to the Department that it has a proposed an update or change  
808 to the specific representation made in its application which fulfills the same or a similar purpose  
809 as the specific representation in a way that the Department can reasonably determine will not be a  
810 lower standard than the specific representation in the application.

811  
812 (3) A Certified Marijuana Testing Laboratory shall not proceed on the basis of a proposed update  
813 or change until receipt of written approval from the Department.

814  
815 (4) A Certified Marijuana Testing Laboratory may add or remove an officer, board member,  
816 Manager, or Employee by notifying the Department in writing at  
817 OMMULicenseOperation@flhealth.gov of the name and position of the individual to be added or  
818 removed, with an updated copy of the Certified Marijuana Testing Laboratory's organizational  
819 chart if the change in personnel amends the existing organizational chart. However, no officer,  
820 board member, Manager, or Employee may be added by a Medical Marijuana Treatment Center  
821 prior to that individual passing a background screening pursuant to section 381.986(9), F.S.

822  
823 (5) If the Certified Marijuana Testing Laboratory intends to claim any exemption from public  
824 records disclosure under section 119.07, F.S., or any other exemption from public records  
825 disclosure provided by law for any part of its request for update or change to the initial application,  
826 it shall indicate on the request the specific sections for which it claims an exemption and the  
827 statutory basis for the exemption. The Certified Marijuana Testing Laboratory must submit a  
828 redacted copy of the variance request redacting those items identified as exempt concurrent with  
829 the submission of the variance request for approval under subsection (2) above. Failure to provide  
830 a redacted copy at the time of submission, or failure to identify and redact information claimed as  
831 trade secret, will result in the release of all information in response to a public records request  
832 unless the information falls under another public records exemption. All trade secret designations  
833 are subject to the Department review in accordance with section 381.83, F.S.

834

835 **Rule 64-4.306 Licensure Renewal**

836

837 (1) All Certified Marijuana Testing Laboratory licenses expire on September 30 of the biennial  
838 calendar year after initial licensure. It is the responsibility of the Certified Marijuana Testing  
839 Laboratory to seek timely renewal.

840

841 (2) Certified Marijuana Testing Laboratories seeking licensure renewal must apply for renewal by  
842 submitting a “Renewal Confirmation of Compliance” form to establish that the Certified  
843 Marijuana Testing Laboratory is and has maintained compliance with statute, Rule 64-4.301, and  
844 the representations of the its application on file. The “Renewal Confirmation of Compliance,” DH  
845 #####-OMMU-#####, is incorporated by reference and available at  
846 <https://www.flrules.org/Gateway/reference.asp?No=Ref-XXXXXXX>. Form DH####-OMMU-  
847 ##/#### must be submitted to the Department no later than July 31 of the calendar year.

848

849 (3) The renewal request must be accompanied by a non-refundable, non-prorated renewal fee of  
850 \$#####. The non-refundable, non-prorated renewal fee must be submitted to the Department on  
851 the same business day as the entity’s submission of Form DH#####-OMMU-##/####.

852

853 (4) Certified Marijuana Testing Laboratory that fails to pay the required renewal fee and to return  
854 the completed DH XXXXXX to the Department prior to July 31 shall automatically expire without  
855 notice or further proceeding. A Certified Marijuana Testing Laboratory whose certification has  
856 expired may reapply for certification in accordance with Rule 64-4.301, F.A.C.

857

858 (5) After the Department receives the request for renewal, the Department will schedule a renewal  
859 inspection to determine that compliance with sections 381.986 and 381.988, F.S., Rule 64-4.301,  
860 and the representations made in the application on file and the renewal form. A renewal  
861 application will not be deemed complete until the inspection is completed.

862

863 (6) Deliver all renewal applications, fees, exhibits, and supporting documents together to the  
864 Department of Health, ATTN: Office of Medical Marijuana Use, at 4052 Bald Cypress Way, Bin  
865 M-01, Tallahassee, Florida.