

DEPARTMENT OF HEALTH

IN RE:

OFFICE OF MEDICAL MARIJUANA USE

\_\_\_\_\_/

HEARING ON RULE 64-4.300 THROUGH 4.315 PERTAINING TO  
CERTIFIED MARIJUANA TESTING LABORATORIES

DATE TAKEN: June 3, 2025  
TIME: 9:00 AM - 10:37 AM  
LOCATION: Holiday Inn  
2003 Appalachia Parkway  
Tallahassee, Florida 32301

**CERTIFIED COPY**

1 APPEARANCES:

2

3 CHAIRMAN JEREMY ROBERTS, POLICY MANAGER

4 DR. JOHN KABA, ENVIRONMENTAL MANAGER

5 SHENA GRANTHAM, CHIEF COUNSEL

6 OFFICE OF MEDICAL MARIJUANA USE

7 4052 Bald Cypress Way

8 Tallahassee, FL 32399

9

10 PUBLIC SPEAKERS:

11 DR. DAVID VORISEK, USC ANNALYTICS

12 DEVON BAXTER, BAXTER LAW

13 JESS ENGLE, GOLDFLOWER CANNABIS

14 JAMES HORVATH, KAYCHA

15 BRIAN SPANN, TERPLIFE

16 JINI GLAROS, CANNACAS

17 KEITH BROWNING, METHOD TESTING LABS

18 TJ MORTON, LOCKWOOD LAW FIRM

19 ANTOHONY REPAY, METHOD TESTING LABS

20 EVAN BENTZ, COMPASSIONATE ALTERNATIVE CARE

21 DANIEL LOCKE, COMPASSIONATE ALTERNATIVE CARE

22 SHIRLEY XU, ACS LABORATORY

23 AIXIA SUN, ACS LABORATORY

24

25

## 1 P R O C E E D I N G S

2 (Thereupon, the following proceedings were heard at  
3 9:00 AM.)

4 THE COURT: Good morning, everyone. This is a  
5 hearing on Rule 64-4.300 through 4.315 pertaining  
6 to Certified Marijuana Testing Laboratories. This  
7 hearing is being conducted on Tuesday, June 03,  
8 2025, at Holiday Inn 2003 Appalachia Parkway,  
9 Tallahassee, Florida 32301.

10 I am conducting the hearing for the  
11 department. My name is Jeremy Roberts. I am the  
12 policy manager for the Office for Medical Marijuana  
13 Use. Our address is the Florida Department of  
14 Health. 4052 Bald Cypress Way, M01 Tallahassee,  
15 Florida 32399. I am joined by Dr. John Kaba, the  
16 OMMU Environmental Manager and Shena Grantham,  
17 Chief Legal Counsel.

18 This hearing is being conducted in accordance  
19 with section 120.54 Florida Statutes. The notice  
20 for this hearing was published in volume 51, number  
21 95 of the Florida Administrative Register on May  
22 15, 2025. The purpose of this hearing is to allow  
23 the public to participate in the rulemaking  
24 process.

25 Before we begin, I remind all of you to please

1 submit your comments in writing to  
2 OMMUrules@health.gov before the end of the comment  
3 period on the agenda, which I will announce again  
4 at the end of the hearing.

5 Please be advised that this hearing is being  
6 recorded by our court reporter provided by Laws  
7 Reporting.

8 These rules outline standards and requirements  
9 for certified marijuana testing laboratories to  
10 include those for application certification,  
11 inspection, testing and operation. These rules are  
12 being proposed to replace and supersede emergency  
13 rules originally adopted to implement sections  
14 three, eight, 1.986 and 381.988 Florida Statutes.

15 Those of you who wish to comment are asked to  
16 state your name and the organization you represent.  
17 In the interest of time, we ask that you do not  
18 repeat the position of previous speakers. You may,  
19 however, state that you agree with one or more  
20 previous speakers. We also ask that you try to  
21 limit your oral comments to three minutes. I will  
22 remind you when your time is almost up. For a  
23 comment procedure we will go through the rules one  
24 by one. Allow for comments on each. Please raise  
25 your hand if you wish to comment and I'll call you

1 up to the podium. If there are no comments for any  
2 particular rule, we'll just move on to the next one  
3 as they were published in the hearing notice.

4 So, beginning with 64-4.300 CMTLS All  
5 Definitions. Are there any comments?

6 First. Thank you.

7 AIXIA SUN: My name is Aixia Sun. I'm the lab  
8 director of ACS Laboratory.

9 Regarding Rule 64-4.300, definition for number  
10 five, Analytical Batch. So, this rule requires the  
11 batch sample of 30 prepared together by the same  
12 Analyst during the same work shift. So, this rule  
13 is suitable for small laboratory, but for a large  
14 scale, the lab batches are prepared by multiple  
15 Analysts during the different shifts. We recommend  
16 remove this restriction for, "by the same Analyst  
17 during the same work shift."

18 And the second comment, for Flower Batch, a  
19 lot of flowers are grown, not Whole Flowers when  
20 someone received so many recommendation changes.  
21 "Usable Whole Flower" to "Usable Flower" to avoid  
22 confusion.

23 And number three, to (101) Total Active THC  
24 the recommended CVN. So, because the calculation  
25 formula lacks scientific support, CVN should be

1 removed as part of THC calculation.

2 That's all.

3 MR. ROBERTS: Thank you.

4 Next. Please.

5 DEVON BAXTER: Good morning. My name is Devon  
6 Baxter. Baxter Law. And I'm appearing today on  
7 behalf of multiple MMTCs and CMTLS. On behalf of  
8 myself and my clients, I want to thank the  
9 department for collaborating with the industry on  
10 these rules, which we know will have a substantial  
11 impact on lab testing moving forward.

12 My first comment applies to the definition  
13 rule as well as the others. We respectfully  
14 request that the department include a minimum six-  
15 month implementation period following the adoption  
16 of the rules. These proposed rules contain a lot  
17 of significant operational changes for labs and the  
18 MMTCs. They'll likely require new equipment, new  
19 validated methodologies, and some retraining of  
20 staff both for the CMTLS and the MMTCs. So, we're  
21 just asking for a reasonable transition period. I  
22 believe six months was what the department did when  
23 the first lab rules came out. So, I think that  
24 would be helpful again in this circumstance.

25 Moving on to the text of this rule, paragraph

1 34 revises the definition of Final Product to  
2 require that it be in "final labeled form." But  
3 the term "labeled" is not defined. In practice,  
4 products are not labeled with all required  
5 information when they go off for lab testing. So,  
6 for example, the patient information, the physician  
7 information which is required before the product is  
8 dispensed, it's not in their lab testing. And then  
9 the rules make potency labeling optional at lab  
10 testing. So, we just request clarification on what  
11 specific label information is required so that the  
12 CMTLs can be confident that they can accept a  
13 product when they get it.

14 And then moving on to paragraph (105). We're  
15 requesting some clarification there. It appears  
16 that the department intends for mechanically  
17 separated products like kief, bubble hash and  
18 pressed rosin to be tested like Whole Flower. We  
19 just want a little bit of clarification on how this  
20 will affect available routes of dispensation for  
21 those products, if it will at all. And we also  
22 just wanted clarification and confirmation that the  
23 potency reporting requirement in 64-4.308(3), which  
24 triggers that additional reporting and testing  
25 above the 32% THC limit, won't apply to the kief,

1 bubble hash, mechanically separated products.

2 Thanks.

3 CHAIR ROBERTS: Thank you.

4 MR. MORTON: Good morning. TJ Morton with  
5 Lockwood Law Firm here on behalf of licensed MMTCs.  
6 I'd like to thank the panel for the opportunity to  
7 provide the comments.

8 We previously submitted a lower written, lower  
9 cost regulatory alternative proposal to the office.  
10 And these compliments are intended to supplement  
11 what we submitted.

12 Our concerns are with subsection (105) of the  
13 rule is the definition which requires solventless  
14 products to be classified as Usable Whole Flower.  
15 One consequence of this classification is that  
16 sample weight for yeast and mold testing will be  
17 increased from 15g to 25g for solventless products.  
18 Solventless products are much more resistant to  
19 microbial contamination than our Whole Flower  
20 products. And we believe requiring 25 gram samples  
21 for solventless products is unnecessary and will  
22 increase regulatory costs in excess of \$200,000  
23 across the industry over the course of a year.  
24 Based off that, we believe it triggers the  
25 requirement to prepare a statement of estimated

1 regulatory costs.

2 We propose the alternative of maintaining the  
3 15 grams testing standard, which has been standard  
4 across the industry for the past five years under  
5 the emergency rules.

6 Thank you.

7 CHAIR ROBERTS: Thank you.

8 DR. VORISEK: Dr. Daniel Vorisek. I am the  
9 lab director of US Analytics. I'd like to thank  
10 the

11 Department for having us here to talk about  
12 safety and accuracy as well as reliability.

13 I have a follow up comment to -- made earlier  
14 about the proposed same work shift for the Analyst,  
15 on top of this also not working well for a large  
16 laboratory. It does not work well in the sense of  
17 when someone gets sick an Analyst has to leave. It  
18 doesn't accommodate for the workflow of a real lab.  
19 And that causes issues. And it will slow down the  
20 delivery as well as other problems. So, there  
21 should be the allowance for us to have the proper  
22 transfer within our quality system from one Analyst  
23 to another.

24 That's it. Thank you.

25 BRIAN SPANN: Brian Spann, work TerpLife Labs,

1 Lab Director. I agree with the comments made thus  
2 far by my colleagues.

3 I also want to bring up the fact that the  
4 requirement for a four-year college degree for some  
5 of the positions in the laboratory simply does not  
6 meet the requirements. We base our performance  
7 based upon demonstrations and capabilities, and to  
8 have people doing the technical level work where  
9 there are cartoon Samples, to be required to have  
10 the four-year degree is, in our opinion, excessive.

11 Not only that, it does increase the cost that  
12 we have for the employees as well. I believe the  
13 gentleman referenced the \$200,000 a year. Well, if  
14 I have to replace staff with anyone that touches a  
15 sample with a four-year college degree, it's going  
16 to increase our costs.

17 Thank you.

18 CHAIR ROBERTS: Thank you.

19 Any other comments on definition?

20 All right. Next Rule 60-4.301 Requirements  
21 for CMTL Certification and Application.

22 You first.

23 SHIRLEY XU: Good morning. I'm Shirley from  
24 ACS Laboratory, Testing Director.

25 So, my comment for 64-4.301, the first one is

1 (4)(a) Accreditation. So, it basically asks for  
2 ALAC on top of current ISO/IEC 17025:2017.

3 ACS comments: ISO/IEC 17025:2017, it should be  
4 sufficient and we recommend remove the ALAC  
5 guidelines.

6 The second one is (4)(b) Proficiency Testing.  
7 ACS needs clarification of "minimum of 80%" rule.  
8 Does this mean 80% of analytes need to pass for the  
9 PT result to be valid?

10 Last comment is (4)(e)(5), internal audits.  
11 CMTL needs to audit for equipment, facility, and  
12 personnel security. It's just recommended that we  
13 should just use ISO specific guidelines, which is a  
14 two-year plan.

15 And that's it. Thank you.

16 DR. VORISEK: I'm Dr. Vorisek. Again, I have  
17 two quick comments. The first one is on 301(4)  
18 subsection (c)(4) (c). It's about the proposed  
19 rule that the "Laboratory Directors must have a  
20 minimum of three years of experience in an  
21 International Standards Organization, College of  
22 American Pathologists, or the NELAC Institute  
23 accredited laboratory." We find that this language  
24 is overly restrictive and may disqualify other  
25 competent candidates. We recommend that the

1 provision read in an ISO capped, TNI or other  
2 equivalent accredited laboratory environment. This  
3 will help maintain the Department's quality  
4 assurance goals while still allowing flexibility  
5 for laboratory director hiring.

6 The second one is on 301(4)(e) section (6),  
7 where it imposes the additional requirement on the  
8 CMTLs tracking system but does not define tracking  
9 system. US Analytics would like clarification on  
10 what that tracking system requirement is, and what  
11 information would need to be pulled out of the Bio  
12 Track System from the MMTC. I'm not sure everyone  
13 is aware, but the CMTLs have very limited access to  
14 Bio Track and the information that we are provided.  
15 So, we would want to make sure that what we need is  
16 provided through Bio Track.

17 Thank you.

18 And I agree with all the comments made by my  
19 peers. CHAIRMAN ROBERTS: Thank you.

20 MS. BREWER: All right. Cynthia Brewer,  
21 Kaycha Labs. Nice to see you. Thank you for  
22 hosting this.

23 So this is just going to be because this is  
24 our finalized rule, and emergency rule making is no  
25 longer going to be valid. My comment on record is

1 just to possibly be able to relocate a licensed  
2 facility. In the event there is an act of God that  
3 wipes out a location due to a hurricane and you  
4 want to keep providing services to the cannabis  
5 space. We would have to relicense, obviously, and  
6 that process can be very lengthy. The requirements  
7 for us to submit within the 90 days but no earlier  
8 than 120, but not having requirements for the OMMU  
9 to respond back to various RFIs. That process  
10 after submission can be very lengthy. I think we  
11 just went through one for nine months. So just  
12 with banking, always asking for updated licensure  
13 for that to kind of be a little bit more  
14 streamlined, it would make our lives a lot easier.

15 And then possible relocation of an active  
16 license if we are in good standing and paid into  
17 the program.

18 Thank you.

19 CHAIRMAN ROBERTS: Any further comments on  
20 requirements for certification?

21 Come forward.

22 MR. BENZ: Good morning.

23 CHAIRMAN ROBERTS: Good morning.

24 MR. BENZ: My name is Evan Benz. I am a  
25 patient, patient advocate, and medical cannabis

1 expert. I'm here for the second time now to  
2 request that we add terpenes to our testing.  
3 There's debate as to whether that significantly  
4 affects the pharmacodynamics of oral or edible  
5 products, but for it to not be required for all  
6 inhalation products is not very patient forward.  
7 So definitely need that. And there's a pretty big  
8 gap between I mean patients and knowing where their  
9 medicine is coming from and how it's tested. And  
10 we need to be doing better.

11 Thank you.

12 CHAIRMAN ROBERTS: Thank you.

13 All right. Any further comments on this rule?

14 Okay. Next rule 64-4.302 Renewal Application  
15 Requirements.

16 All right. Next rule 64-4.303 Testing.

17 Okay go ahead.

18 MS. SUN: So, I have a few comments regarding  
19 this rule. The first one is (1)(c)(1), (1)(c)(2),  
20 (1)(c)(3) Proficiency Testing. Because the  
21 limitation of supplies of proficiency testing some  
22 Matrix Groups are not available. I think one test  
23 fails with one Matrix with the same method should  
24 satisfy all matches and stated in current emergency  
25 rule.

1           And, I think another recommendation is the  
2           OMMU laboratory should administrate the Inter-  
3           laboratory comparison proficiency test like CAP  
4           surveys to help establish a correct reference range  
5           of quality labs.

6           The second one is regarding rule (1)(c)(4).  
7           Our comment is this increase PT testing from twice  
8           a year to three times a year. Tremendous increase  
9           in cost for the laboratory. Can we stay with  
10          current emergency rule?

11          The next one is regarding (1)(c)(4)(a). ACSs  
12          comments is, if the same method is used for all  
13          Matrix, one proficiency test on any of Matrix  
14          should be efficient and as current rule.

15          The next comment is regarding rule  
16          (1)(c)(4)(b) regarding LOD. I think remove the  
17          requirement of "above CMTLs LOD." And CMTLs should  
18          test PT as "aid" instead of instructing PT  
19          providers on how to make PT. Also LOD should be  
20          removed from all tests for quantitative PT.

21          The next comment Comments regarding  
22          (1)(c)(4)(c) ACS's comments LOD should be changed  
23          to LOQ quantitative PTI report about the limited  
24          quantitation. Levels below LOQ cannot be  
25          quantified accurately and therefore cannot be used

1 to submit for quantitative PT.

2 The next, regarding rule (1)(c)(4)(d) and  
3 (1)(c)(4)(i); we need the clarification for minimum  
4 80% rule.

5 The next one, regarding (1)(c)(4)(k). We also  
6 need clarification, and, as well as scientific  
7 support for this rule.

8 The next one, regarding rule (1)(c)(4)(l)  
9 proficiency test run and due to availability and  
10 lead time of PT samples from PT providers which  
11 should be given five to nine months.

12 The next one is (4), regarding rule (4) CMTLs  
13 Fails to Satisfy. This is, I think, common  
14 regarding this rule because if you failed, if you  
15 are required by this rule only customize the PT can  
16 contain target value, target analyze. Customized  
17 PT can take seven days to four weeks to ship from  
18 the provider. This requirement will put a CMTL out  
19 of the business practice. The CMTL should be able  
20 to continue performing PT from providers without  
21 customization whenever the result is satisfactory.  
22 CMTLs can resume the testing.

23 That's all.

24 CHAIRMAN ROBERTS: Thank you.

25 DR. VORISEK: I have some comments about

1 subsection (1)(c)(4)(g) that requires a certain  
2 result above an LOD and a subsequent proficiency  
3 test. The CMTLs has no ability to inform the  
4 proficiency test providers how to perform or make  
5 them. At this point in time, we order them, and we  
6 receive what we receive. Lack of something present  
7 is also a qualification in a proficiency test.

8 Subsection (1)(c)(4)(k) imposes a mandatory  
9 minimum one day interval before the conduction of  
10 proficiency tests. We request that the department  
11 provide the rationale for this requirement,  
12 particularly in the light that proficiency tests  
13 are supplied as blind. It should not matter that  
14 we do the tests within the same day. The results  
15 are different if they are from different lots. So,  
16 you know.

17 And then last is section five.

18 CHIEF COUNSEL GRANTHAM: Sir, just one moment.  
19 Are you requesting clarification now in real time  
20 or just telling us as a comment?

21 DR. VORISEK: As a comment.

22 CHIEF COUNSEL GRANTHAM: Okay.

23 DR. VORISEK: Section (5) requires the CMTL  
24 notify the Department of results of all proficiency  
25 tests, including those that are exempt from the

1 rule, meaning that we would have to provide  
2 proficiency test results for all internal  
3 proficiency tests regardless of whether they were  
4 for method development, internal quality  
5 improvements, analyst training for competency which  
6 has no relevance towards the quality of testing  
7 towards the patient and anything else there. So,  
8 we would respectfully recommend that this provision  
9 be revised to require reporting only department  
10 mandated proficiency tests as is required by the  
11 licensing structure and the maintenance of our  
12 license.

13 And I agree with all of the comments made by  
14 my peers in this section.

15 Thank you.

16 MR. REPAY: Hello. Anthony Repay, Laboratory  
17 Director of Method Testing Laboratories. Again,  
18 thank you for having us, and an opportunity to  
19 speak on these.

20 Method Testing Labs is seeking clarification  
21 regarding the proposed requirement that all total  
22 yeast and mold, TYM testing, be conducted in  
23 duplicate. While we understand the intention  
24 behind the proposal is to improve quality  
25 assurance, it is important to note that duplicate

1 testing does not improve the accuracy of the  
2 results performed but enhance them -- but it rather  
3 provides precision. If the goal is to better  
4 characterize microbial loads in an inter-laboratory  
5 consistency, we recommend data transformations for  
6 quality control such as log transformation, and z-  
7 score normalization. These approaches are  
8 scientifically appropriate in microbial analysis  
9 and would allow for meaningful trend tracking  
10 without arbitrary inflating results. These are  
11 also similar statistical requirements that the  
12 methods are used to evaluate from a third-party  
13 perspective.

14 We also recommend reevaluating the current 60  
15 hour incubation language indicated in Microbial  
16 Testing requirements. A fixed incubation time does  
17 not reflect the flexibility needed across various  
18 microbial testing platforms and matrices.

19 Included, we replaced the rigid mandate with  
20 language such as incubation time and temperature  
21 must be followed explicitly to the manufacturer's  
22 instruction and be validated for the specific  
23 matrix being tested. This matrix dependent  
24 approach reflects established microbial standards  
25 and supports both accuracy and efficiency. The

1 methods must be validated and approved through an  
2 independent validation program such as AOAC  
3 Performance Test Method, PTM, or AOAC Official  
4 Method of Analysis, OMA.

5           Lastly, we would like to reinforce the need  
6 and explicitly requiring Laboratory Controlled  
7 Samples. LCS in media blinks and all microbial  
8 analysis as defined by AOAC Laboratory  
9 Accreditation Criteria Committee, ALACC. Including  
10 these critical quality control components is  
11 essential for verifying method performance and  
12 ensuring data integrity. Their use is standard in  
13 accredited laboratories across all other testing  
14 fields, and should be required by all CMTLs to  
15 ensure uniform quality assurance.

16           Thank you.

17           MR. SPANN: Brian Spann, TerpLife Labs.

18           Again, I agree with everything my colleagues  
19 have stated specifically over the PT studies. The  
20 laboratories have no control over the PT studies.  
21 This is like the student telling the professor what  
22 the test is going to be.

23           So, with that being said, we ask that you  
24 redefine or do clarification upon what the PT  
25 testing is and how we're doing it. I believe that

1 the PT offer us an opportunity to see the  
2 performance based on each laboratory as we use a  
3 little bit of different methodology for some of our  
4 testing, but we still do the same class of Analytes  
5 and Matrix. PTs allow us to see that performance  
6 across the lab.

7 It also allows us to demonstrate the  
8 performance of our methodology, which will be  
9 addressed in the next section, but also the  
10 performance of our Analysts and our technicians by  
11 them performing the work.

12 Reporting down to the detection limits that  
13 the PT vendors, I support that because it allows us  
14 overall performance, but perhaps there could be  
15 some involvement with the OMMU with the PT  
16 providers on getting something that is more in line  
17 with what you'd like to evaluate.

18 Thank you.

19 CHAIRMAN ROBERTS: Any further comments on  
20 Sample Testing?

21 All right, moving on to the next one.

22 64-4.304 CMTL On-Site Inspection.

23 Devon.

24 MS. BAXTER: Devon Baxter. Baxter Law.

25 So, paragraph two, the revision in the

1 language appears to now require immediate oral  
2 responses from lab personnel during department  
3 inspections. We're concerned that this could force  
4 employees to respond on the spot to complex  
5 questions that may be outside of the scope of their  
6 job or of their area of knowledge.

7 So, we recommend revising this rule to clarify  
8 that the CMTL staff can consult with their lawyer  
9 or their supervisor or manager. And that responses  
10 can come from the appropriate person at the CMTL.  
11 Based on their subject matter expertise.

12 And if oral responses are going to be part of  
13 the investigative process, we believe that  
14 investigators should be required to provide the  
15 speaker with a copy of their statement and give  
16 them an opportunity to review it or revise it,  
17 confirm whether or not it's correct, if necessary,  
18 to avoid any misunderstandings.

19 Paragraph three requires production of records  
20 requested by the department within 48 hours. I  
21 think measuring response times in hours can be a  
22 little bit confusing when a lot of other legal or  
23 regulatory deadlines are measured in days.

24 So, I recommend that this be revised to allow  
25 the CMTL to have at least two business days to

1 produce the records. A lot of labs are not open  
2 late nights or on weekends, so having those two  
3 business days can be important.

4 We recommend that the rule include clear  
5 limits on the size and the scope of the record  
6 requests to prevent overly broad or burdensome  
7 demands that might not be clearly tied to the  
8 purpose of the inspection.

9 And, in addition, we'd like to see a process  
10 for requesting a reasonable extension to produce  
11 those records when large or complex records are  
12 involved. A lot of times it's a lot of data and  
13 depending, you know, it takes a long time to  
14 organize it, download it, transmit it.

15 This proposed rule also says that a CMTL has  
16 to submit a corrective action plan within seven  
17 days of receiving a notice of violation. This  
18 happens even though the violation hasn't yet been  
19 finalized, and it could still be challenged. So,  
20 this sometimes forces labs to respond as if they've  
21 done something wrong, but they may not have even  
22 had a chance to gather all the facts, determine if  
23 they want to contest the allegations or not. So,  
24 there's a real concern sometimes that anything  
25 submitted in the corrective action plan could later

1 be used against the lab in a hearing.

2 So, we'd recommend changing this rule so that  
3 corrective action plans are only required after the  
4 NOV becomes final agency action.

5 Thank you.

6 CHAIRMAN ROBERTS: Thank you.

7 MS. XU: I'm Shirley Xu, ACS Laboratory. 64-  
8 4.304 On-Site Inspection. The first, one the  
9 Department may conduct announced or unannounced  
10 inspections of any CMTL testing facility. ACS  
11 recommends that the OMMU Department should schedule  
12 regular inspections with the CMTL and look over all  
13 documentations on site. This is to prevent  
14 misinterpreting information while working remotely.  
15 Same day unannounced inspections should not last  
16 more than two hours. This is for business to  
17 continue normal operation so that people can  
18 actually continue to work.

19 Thank you.

20 CHAIRMAN ROBERTS: Thank you.

21 All right. Any further comments on On-Site  
22 Inspection?

23 All right. Moving at speed.

24 All right. Next Rule 64-4.305 CMTL Standard  
25 Operating Procedures.

1 All right.

2 MS. XU: This is Shirley from ACS Laboratory  
3 for 64-4.305 CMTL SOP item (2)(j) cleaning  
4 procedures for equipment, workspaces and Secure  
5 Storage. Please elaborate how much detail and  
6 requirements on cleaning procedures.

7 And number (6) "Upon request by the  
8 department, a CMTL must provide the department with  
9 a current...SOP" in 48 hours. CMTL should give  
10 five days to submit the SOPs, depending on how long  
11 the SOP should be.

12 Thank you.

13 CHAIRMAN ROBERTS: Thank you.

14 Any further comments on Standard Operating  
15 Procedures?

16 All right. Next Rule 64-4.306 CMTL Testing  
17 Methods.

18 MS. XU: This is Aixia ACS Lab. Regarding  
19 rule 64-4.306 CMTL Testing Method, regarding rule  
20 (2) "CMTL may request approval from the department  
21 to use..." the method.

22 So, ACS common recommendations, we need the  
23 clarification for those. Since the new rule  
24 require all different from all other current  
25 methods approved by OMMU still valid or existing

1 operation lab should be able to continue using  
2 current methods that were approved by OMMU?

3 For the second, one regarding (5)(a) and  
4 (5)(b), ACS comment is that (a) conflicts with (b).  
5 An MMTCs samples were never a mixture of Analytes  
6 in a solvent. We need to follow PT provider  
7 instructions.

8 And regarding Rule (5)(c), ACSs comment is  
9 (5)(c) contradicts with 64-4.303 (1)(c)(4)(1) and  
10 five/seven months. Here it says six months.

11 That's all. Thank you.

12 CHAIRMAN ROBERTS: Thank you.

13 MR. SPANN: Brian Spann, TerpLife Labs.

14 Concerning the Approved Analytical Methods,  
15 Part one, Part two, I agree with what colleague  
16 said. But we've been utilizing methodology for  
17 several years. We are showing their performance  
18 based upon the PTs. So, we've already got these  
19 methods validated. Are you telling us we need to  
20 modify our methods now to follow the new protocols,  
21 or can we continue to use the methodology that's  
22 already been reviewed approved and we have  
23 proficiencies showing the demonstration.

24 So, I'd like a little more clarification on  
25 that. Additionally, the competency of the Analyst,

1 typically we do IDOCs and or PT studies. I want to  
2 see if a PT study that's documented to be performed  
3 by that Analyst will consist of IDOC requirements.  
4 And that's what I have for those.

5 Thank you.

6 CHAIRMAN ROBERTS: Thank you.

7 DR. VORISEK: Dr. Vorisek, US Analytics. I  
8 agree with everything said by my peers for up to  
9 this point and I have one more comment about  
10 section (1)(a). It's this statement that, "A CMTL  
11 must follow any cannabis-specific Analytical  
12 Methods published by the following entities" is  
13 vague and ambiguous and also out of our control.  
14 If any of these entities decide to diverge, change,  
15 or make major changes, or even disqualify these  
16 methods, that leaves us with the inability to do  
17 anything. We would suggest revising this to a  
18 "CMTL may follow," and maintaining the language  
19 that states that we can have a validated accredited  
20 method that is approved by the State outside of  
21 these.

22 Thank you.

23 CHAIRMAN ROBERTS: Thank you.

24 Any further comments on CMTL Testing Methods?

25 All right.

1 CHAIRMAN ROBERTS: Next Rule, 64-4.307 CMTL  
2 Submission For Product Testing.

3 MS. XU: This is Shirley, ACS Laboratory.  
4 Regarding Rule 64-4.307 CMTL Submission for Product  
5 Testing. ACSs comments below:

6 First one, (3)(k) "Identification of which, if  
7 any, Usable Whole Flower products which were  
8 treated with a sterilization step before testing."

9 ACSs comment: This requirement should be  
10 removed and added as an MMTC requirement because  
11 CMTL cannot distinguish whether the samples are pre  
12 sterilized or not. The rule aims to penalize labs  
13 for things that they are not responsible for.

14 Next number (4) "The CMTL must ensure that  
15 each Retail Batch is sampled only once unless being  
16 resampled and retested..."

17 ACSs comment: The laboratory may require  
18 additional samples to complete the testing. CMTL  
19 should be allowed to request more samples.

20 Number (5) "The CMTL must homogenize all Final  
21 Products into one (1) Testing Sample..." Please  
22 clarify this rule as definition 64-4.300 (105)  
23 states, "Usable Whole Flower Marijuana does not  
24 include seeds or stems..." But if stems are  
25 actually present, do CMTLs remove the stems before

1 homogenizing or before testing for cannabinoids?

2 Last one, number (8) For Micro, Moisture,  
3 Water Activity and Filth and Foreign Testing.

4 "CMTL must begin preparation of Testing Samples  
5 within 72 hours of collection. ACS comment: 72  
6 hour rule is very difficult for weekends, holidays  
7 and some extreme weather season in Florida, such as  
8 hurricane. If the samples were never opened, can  
9 unopened sample be tested within 96 hours during  
10 those circumstances?

11 That's all.

12 CHAIRMAN ROBERTS: Thank you.

13 DR. VORISEK: Dr. Vorisek, US Analytics.

14 Section (5)(c) requires homogenization to a  
15 "standard particle size of 0.1mm." This is not a  
16 universally recognized cannabis testing standard,  
17 as far as I can tell, and researched. But the  
18 bigger problem here is that this exact  
19 conspecification may be inappropriate or  
20 technically unachievable for certain circumstances  
21 and matrices.

22 Also, the requirements in subsection (5)(d)  
23 requires that mixing of ground samples to this  
24 level requires/ensures that no stratification  
25 exists. Scientifically, this is going to be very

1           infeasible as it's going to stratify due to  
2           particle size differentiation, especially due to  
3           this kind of grinding. We just request that we  
4           have a validated method that passes proficiency  
5           tests that is built within our system already as it  
6           has been as opposed to this rule.

7           And then, section (11) requires that samples  
8           be transported in a locked box, container or cage  
9           that is separate from the body of the vehicle and  
10          affixed to the interior. This creates both  
11          practical and safety concerns, particularly for  
12          small vehicles that may have been currently  
13          approved and in use by CMTLs for transportation of  
14          samples at this time. And, in the event of a  
15          collision a fixed cage could increase injury risk  
16          to the passenger or the driver, and this also would  
17          result in us excluding the use of secure trunks,  
18          cargo holds or other secure compartments that  
19          provide equal or better protection to samples  
20          during transportation.

21          I also agree with the comments made by my  
22          peers already.

23          Thank you.

24          CHAIRMAN ROBERTS: Thank you.

25          All right. Any further comments? Please.

1 MR. ENGLE: Good morning. I am Jess Engle.  
2 I'm the VP of Compliance and Quality Assurance at  
3 Gold Flower Cannabis. And on behalf of our entire  
4 team, we just want to thank you for giving us the  
5 opportunity to provide our inputs today.

6 Our comments on proposed Rule 64-4.307  
7 pertaining to the new requirement that CMTLs may  
8 only pick up and transport samples from one MMTC at  
9 a time. This change would disproportionately  
10 impact MMTCs that operate on a smaller scale or in  
11 geographically dispersed areas.

12 The MMTCs may not have enough sample volume to  
13 justify a dedicated pickup which could lead to  
14 pickup delays, testing delays and therefore  
15 availability of products for the patients. The  
16 testing labs would likely need to add additional  
17 routes, additional staff, which would increase  
18 operational costs. Those operational costs will  
19 likely be passed on to the MMTCs and could be  
20 passed on to the patients.

21 For these reasons, we believe that the impact  
22 of the proposed requirement would negatively impact  
23 both affordability of medication to the patients  
24 and the availability. To the best of our  
25 knowledge, there has never been a mix up in lab

1 simple pickups or any sort of cross-contamination  
2 issues. So imposing these unnecessary burdens seem  
3 to be more impactful to the patients in the long  
4 run.

5 That's it. We respectfully request the  
6 department to reconsider this limitation.

7 CHAIRMAN ROBERTS: Thank you.

8 MR. BENTZ: Evan Bents, Compassionate  
9 Alternative Care. This identification of which  
10 Usable Flower products which were treated with a  
11 sterilization step before testing, that's a  
12 wonderful requirement. But as mentioned, how is  
13 that information going to get to patients if we're  
14 just talking about the labs? So that needs to -  
15 I'm requesting some clarification in that stance,  
16 especially within the rules as a comment.

17 Thank you.

18 MR. SPANN: Brian Spann, TerpLife Labs.

19 Again, agree with the previous comments from  
20 the colleagues.

21 This has to do with 307 (4) "CMTL must ensure  
22 the retail batch is sampled only once..." We do  
23 have clientele that use the Retail Batch for, let's  
24 say, a single pre-rolled and a five pack pre-roll.  
25 So, this will create an issue when going into Bio

1 Track. So just want to be aware of that for  
2 putting that requirement down.

3 Thank you.

4 CHAIRMAN ROBERTS: Thank you.

5 MR. MORGAN: TJ Morgan with the Lockwood Law  
6 Firm. I have comments on subsection (5)(a). This  
7 requires a CMTL to homogenize three cartridges  
8 prior to conducting residual solvent and microbial  
9 testing. We don't think this is necessary as the  
10 extraction process produces a homogenous oil,  
11 meaning that the individual cartridges are already  
12 basically essentially identical from the same  
13 batch. So, we think requiring three cartridges is  
14 unnecessary and imposes unnecessary costs.

15 Subsection (5)(e), this paragraph imposes a  
16 requirement that, "A minimum of three (3) Final  
17 Products must be sampled..." We believe imposing a  
18 blanket rule to sample from three final products  
19 per batch, regardless of batch size could stifle  
20 innovation on the part of the UMTCs. Sometimes  
21 they want pretty small batches to create a new  
22 product for a very small patient population and  
23 requiring a sampling from three final products  
24 could hinder that process.

25 Thank you.

1 CHAIRMAN ROBERTS: All right. Any further  
2 comments on this rule?

3 All right. Next Rule 64-4.308 CMTL Sample  
4 Testing.

5 MS. SUN: This is Aixia from ACS Laboratory.  
6 Regarding Rule 64-4.308 CMTL Sample Testing. The  
7 first one, regarding Rule (1)(a) regarding  
8 moisture, correct, testing. ACSs comment,  
9 recommendation, is test samples as received for all  
10 testing fields instead potency interpreting  
11 differently and the other one has the moisture  
12 correct.

13 The second one, regarding Rule (1)(d) "test  
14 results that meets requirement..." and you cannot  
15 correct. You know, when a CMTL found some errors  
16 after the COA was issued. CMTL should be able to  
17 correct those COA instead, leaving those COA  
18 incorrect and waiting for OMMU to find.

19 Another comment regarding Rule (1)(e) is like  
20 after you receive you cannot go back to retest.

21 This rule, ACSs comment is regarding this rule  
22 is this rule conflicts with ISO 17025:2017 rule.  
23 For ISO rule, if clients submit a complaint for  
24 retesting, CMTL needs to go back retest, I think  
25 the recommendation is remove this rule in

1 compliance with ISO 17025:2017.

2 The next comment regarding Rule (2)(f) is  
3 Departmental require which testing for GC.

4 I will say, and ACS comments regarding this  
5 rule is Analytes required to be tested by GC  
6 Chromatograph or under liquid chromatograph mass  
7 spec should be synchronized with validated approved  
8 method and ISO certification.

9 The next one, regarding Rule (3) Potency  
10 Testing. This is talk about giving a package for  
11 32% potency over 32%.

12 The ACS comments regarding this rule, if the  
13 same strain was cloned, produced repeatedly testing  
14 with similar results, and the OMMU has no reason to  
15 believe the potency value is incorrect, the data  
16 packages should not be needed. Excessive data  
17 packaging occupied large data review in -- review  
18 time from OMMU. OMMU still review data from a year  
19 ago indicated that reduce unnecessary data packages  
20 needed to improve government efficiency.

21 Next comment, (9) CMTL must maintain at least  
22 two and test portion of each testing sample. We,  
23 ACS, we seek more clarification if we interpret it  
24 with this rule. The minimum sample of Flower is  
25 30g. This will conflict with minimum sampling

1 requirement of 25g in Rule 307-5e. An unopened  
2 portion is not homogenized with rest of sample and  
3 therefore not part of testing.

4 That's all. Thank you.

5 MR. BENTZ: Evan Bentz, Compassionate  
6 Alternative Care.

7 So, the COAs being reported to the DOH after  
8 24 hours, are these tests going to be made public?

9 DR. KABA: I have -- that's kind of a big  
10 thing for us to gather that and then have some sort  
11 of online thing where you can just type something  
12 in, something come up, that is something that we  
13 have talked about and it's probably pretty down the  
14 road because that's kind of a heavy lift to get all  
15 of that. But it is something we are actively  
16 thinking about and would like to go to at some  
17 point. But that's a pretty heavy lift and there's  
18 a lot of -- there's a lot of other moving parts  
19 that jump in the way of cool things like that.

20 MR. BENTZ: Absolutely. Absolutely.

21 So, both as a patient and a patient advocate  
22 and being in the industry, I'm -- patients  
23 obtaining the COAs and obtaining all parts of the  
24 COAs is very difficult. And it really does seem to  
25 be that the MMTCs are the ones kind of hiding the

1 COAs. So that being available to everyone would  
2 just be wonderful for the, you know, the  
3 transparency and the real reason why these tests  
4 are being made in the first place.

5 And going forward with ethanol not being  
6 reported for oral, topical, and MDIs, although I do  
7 agree that you know, it's most of the time it's  
8 just being used -- it could be used as a carrier,  
9 but other times it's used as a solvent. So we need  
10 to know, especially in oral products, especially if  
11 it's a child.

12 Yeah. Thank you.

13 CHAIRMAN ROBERTS: Thank you.

14 Yes.

15 MS. ENGLE: Jesse Engle, VP of Compliance at  
16 Gold Flower. My comment is on 64-4.308, subsection  
17 (1), paragraph (3), subparagraph (4), pertaining to  
18 the proposed new requirement to retest a passing  
19 Target Analyte if the result is within 10% of the  
20 acceptable limit.

21 Because all testing is performed using  
22 Department approved validated methodologies, there  
23 is no scientific or statistical reason to treat  
24 these results any differently from any others. If  
25 the concern is a standard deviation on lab results

1 up to 10%, mandating a retest when a result falls  
2 within 10% of that limit doesn't actually solve the  
3 concern it compounds it.

4 Who's to say the second result won't deviate  
5 just as much or even more? Analytical methods have  
6 always involved a degree of measurement  
7 uncertainty. That's why we validate methods,  
8 quality controls and statistical parameters.  
9 Forcing a retest of a passing result doesn't  
10 improve accuracy, it introduces more variability,  
11 more cost, and more confusion.

12 In effect, this rule assumes that a second  
13 test is more trustworthy than the first without any  
14 scientific basis to support that assumption. To my  
15 knowledge, there are no comparable regulatory  
16 bodies that require retesting on passing results in  
17 proximity to a specification limit.

18 It's like moving the finish line after the  
19 race has been run, and we're starting to blur the  
20 purpose of having clear, measurable specifications  
21 in the first place.

22 From MMTC perspective, this additional testing  
23 of passing product creates unnecessary red tape  
24 that will delay product releases and pose  
25 additional lab testing costs and ultimately reduce

1 access for patients.

2 Secondly, I just would like to address the  
3 ambiguity around labeled weight and measured weight  
4 for edible potency calculations. It's unclear  
5 whether measured weight in the rule refers to  
6 weight measured by the certified laboratory when  
7 they receive the sample, or if it's the usable  
8 weight from the MMTC that's tracked in Bio Track.

9 This could lead to inconsistent application  
10 enforcement, so we urge the Department to clearly  
11 define this term to ensure uniform understanding  
12 across MMTCs and CMTLs.

13 Thank you.

14 CHAIRMAN ROBERTS: Just like to clarify that  
15 COAs are available via public records request, at  
16 the moment. But not so easily as online.

17 MR. MORTON: TJ Morton with the Lockwood Law  
18 firm.

19 I just want to state that I completely agree  
20 with the comments made by Ms. Engel regarding  
21 subsection (1)(b)(4).

22 Also add that we believe it imposes  
23 unnecessary costs that exceed \$200,000 annually  
24 across the industry, which would trigger this  
25 requirement to prepare a statement of estimated

1 regulatory costs.

2 As an alternative, we'd recommend eliminating  
3 that language altogether and kind of go back to the  
4 current requirement, which is no mandatory  
5 retesting of a passing product.

6 Have concerns with subsection (3). This  
7 requires that, "All Usable Whole Flower potency  
8 results greater than 32% must be confirmed by  
9 repreparation and reanalyzing..." of the sample.

10 We don't believe there's any legal or  
11 scientific basis for establishing those 32%  
12 threshold. We also believe it imposes unnecessary  
13 regulatory costs that could exceed the \$200,000  
14 threshold.

15 Again, as an alternative. We'd recommend  
16 going back to the current standard, which is not  
17 requiring retesting based solely on potency.

18 Thank you.

19 DR. VORSISEK: Dr. Vorisek, US Analytics.

20 I have a quick addition to make to my  
21 colleagues comment about section (a)(1) with the  
22 proposed rule for the dry weight basis correction.  
23 You're asking us to increase the measurement of  
24 uncertainty on things that are at parts per  
25 billion, with the measurement of uncertainty on a

1 oven. Just want to point that one out.

2 We have validated methods for doing this. And  
3 we are now increasing our measurements of  
4 uncertainty as well as having an effect on other  
5 quantification aspects of that testing, which is  
6 not scientifically accurate.

7 Section (2)(c), which exempts the products for  
8 oral administration from ethanol Acceptable Limits  
9 but does not extend the same exemption to edibles.

10 So, if -- I understand that edibles exist  
11 under their own carveout and under a different  
12 classification, but they are orally administered  
13 the same as orals and therefore should be caught  
14 within this change.

15 We recommend revising the rule to reflect that  
16 edibles should be exempt from the ethanol content.

17 Subsection (2)(d) adds nickel and tin to the  
18 list of required heavy metals for testing, without  
19 providing any justification or reference to a  
20 health-based standard. We would like, would  
21 respectfully request that the Department explain  
22 this or remove it. We can do that now or in  
23 further comment, if you would like.

24 And then the last one is in section (6)(b).  
25 The sample size requirements for edibles under this

1 gets to an unreasonably large level. Within a  
2 pharmaceutical environment or a food environment,  
3 you would test a larger subset from the batch as a  
4 better representation. Dissolution does not  
5 require 50 tablets from a batch that is much larger  
6 than what an MMTC can put out for edibles.

7 We respectfully request that the Department  
8 lower these to help with cost effective standards,  
9 as well as to be better representative of other  
10 industries that do homogeneity and dissolution  
11 testing.

12 The last one is section (8), the requirement  
13 that analytes tested at multiple dilutions must be  
14 reported at the lowest dilution factor within the  
15 calibration curve is inappropriate. The selection  
16 of where we report, based off of our curve, and the  
17 dilution factors that we use to get there as part  
18 of our validated and accredited methods within our  
19 SOPs. And we would respectfully request that the  
20 Department of Health allow us to continue to do our  
21 business as we have in the past.

22 Thank you.

23 CHAIRMAN ROBERTS: Thank you.

24 Any further comments on the CMTL Sample  
25 Testing?

1 All right. Next Rule 64-4.309 CMTL Quality  
2 Control Samples.

3 MS. XU: Shirley XU, ACS Laboratory.

4 Regarding comments for 64-4.309 CMTL Quality  
5 Control Samples (1)(b)(2)(b), (1)(b)(2)(c),  
6 (1)(b)(2)(d), (1)(c)(2)(b), and (1)(c)(2)(c), they  
7 require the laboratory to conduct recovery studies  
8 of all fortified and spike samples every six  
9 months.

10 So it is recommended that we can do it yearly,  
11 as every single time it takes days for Analysts to  
12 analyze and calculate all the recovery.

13 For (1)(b)(3) and (1)(c)(3), requiring that,  
14 "All analytes in the Lab Fortified Blanks..." and  
15 matrix spikes "...above the LOD must be integrated  
16 and quantified."

17 So ACS comments: LOD should be changed to LOQ  
18 as LOD is limit of detection, LOQ is limit of  
19 quantitation, so that labs should be allowed to  
20 quantify above the limit of quantitation.

21 (1)(g)(1) requiring CCV results may only be  
22 reported from one CCV injection.

23 ACS comment: CCV results may be reported from  
24 one CCV injection for the same analytes. Due to  
25 stability issues, not all analytes are in one

1 injection.

2 And, also, here LOD should be changed to LOQ.

3 Section (1)(i) requiring, "All analytes  
4 present in the Spike Solution must be fully  
5 analyzed and conform to all Quality Control  
6 requirements."

7 ACS comments: Standards were pre-grouped into  
8 five to six groups based on stability and  
9 compatibility of the analytes by the manufacturer.  
10 CMTLs should be able to select analytes and use  
11 those as target analytes.

12 ACS recommends remove "All analytes present in  
13 a Spike Solution must be fully analyzed."

14 Section (1)(j) Heavy Metal analysis requiring  
15 three replicates of each injection.

16 ACS seeks clarification as heavy metal assay,  
17 if it's set up for three injections for each value  
18 obtained, an average value was actually reported;  
19 is that the same?

20 Section (2)(a)(1) regarding Microbiology  
21 Testing for PCR by PCR requiring, "One positive  
22 Quality Control Sample able to detect Microbe  
23 presence in a minimum one gram."

24 ACS needs clarification on a positive sample  
25 as PCR test kits all come with a positive DNA.

1 Also, how to maintain a positive sample of one CFU.

2 Section (3) For Total Combined Yeast and Mold  
3 Analysis. Analysis in duplicate with calculated  
4 RPD.

5 ACS comment: Please clarify 10 gram sample  
6 rule and duplicate testing sample weight  
7 requirement.

8 Section (3)(a) "Analysis for Total Combined  
9 Yeast and Mold must use a culture based method."

10 ACS comment: CMTLs should be able to use PCR  
11 method that is AOAC approved for total combined  
12 yeast and mode testing for screening. Once  
13 detected, culture method can be utilized to verify.

14 Section (3)(d) "Confirmation of failed results  
15 must use the same method as the original analysis."

16 ACS comment: All validated and approved  
17 methods should be equally used to confirm.

18 Section (3)(g) requiring "Total Combined Yeast  
19 and Mold culture-based protocols must incubate for  
20 a minimum of 60 hours."

21 ACS recommendation, incubation for 60 hours is  
22 against some plating methods that are approved by  
23 AOAC. Please remove this 60 hour requirements and  
24 follow AOAC method for the time of incubation.

25 Section (6) data must be reported once all

1 quality control samples pass the requirements, and  
2 retesting of a testing sample may only be performed  
3 to confirm a failing result or if quality control  
4 does not meet criteria.

5 ACS question: If CMTL tests R&D for the MMTC.  
6 Can MMTC submit a complaint for deviation in  
7 compliance testing as per ISO 17025:2017  
8 requirement.

9 Additionally, quality control samples do not  
10 check for pre-analytic deviations. Example if a  
11 person weights a sample wrong.

12 Thank you.

13 MR. HORVATH: Thanks again.

14 And I also agree with everybody here.

15 James Horvath, CEO for Kaycha Labs. I have a  
16 few comments. Again, not for now, but I've  
17 submitted the comments formally.

18 So, on section -- in 4.309 (1)(m) can you  
19 clarify whether or not surrogates are acceptable  
20 alternatives to internal standards or just another  
21 option?

22 And then, (1)(m)(1) through (3) we're looking  
23 for clarification on the specified internal  
24 standard recovery ranges because the purpose of an  
25 internal standards to account for matrix effects by

1 tracking the analytes behavior, if the internal  
2 standard is suppressed or enhanced because of the  
3 matrix, the analytes should be similarly affected.  
4 That preserves the reliability of the response  
5 ratio.

6 Imposing a strict recovery limit on that  
7 reflects an unintended purpose of leading to an  
8 unnecessary rejection of validated data.

9 Again, I think John understands what I'm  
10 trying to go there. The reality is, if we put  
11 limits on the item that's creating the limits, we  
12 may no longer be able to test with that particular  
13 method.

14 On Quality Control Samples (2)(b) The  
15 mandatory enrichment. Again, we're following  
16 manufacturer AOAC. I think it's been said about 10  
17 times. So, we'd just like to be able to follow  
18 whatever method you guys have approved previously  
19 in there rather than forcing a particular time  
20 limit on that aspect.

21 For 309 (3) we're requesting the revising the  
22 requirement for duplicate preparation and analysis  
23 for total yeast and mold to exclude matrices such  
24 as concentrates and edibles. These product types  
25 rarely exhibit any microbial growth, and making

1 duplicate testing is unnecessary resources, meaning  
2 many of them are anti-microbial at that point.

3 For Quality Control Samples 309 (3)(e) we  
4 recommend revising the language regarding dilution  
5 requirements for total yeast and mold. Mandating  
6 enumeration from 100 dilution is overly  
7 prescriptive and may compromise the data accuracy.

8 The method should allow reporting from the  
9 lowest countable dilution within the manufacturer  
10 specified CFU range, which may be a 10X plate. So  
11 again, we're trying to follow the original rules  
12 that you guys are telling us. Follow AOAC, follow  
13 whatever validated method. These rules sometimes  
14 are contradicting that.

15 So, I've got (3)(g) as well. We request the  
16 Department reconsider the requirement for the  
17 additional 48-hour incubation for irradiated  
18 Flower. We have -- I mean, I'm sure you're going  
19 to try to figure out a way for us to know about  
20 that. But this is not a responsibility on our end.  
21 We have no idea if it was irradiated unless  
22 somebody tells us.

23 So now we're holding ourselves responsible for  
24 -- and this has been brought up before as well.

25 Additional comment. On (4)(b) we'd like to

1 respectfully request clarification on the rationale  
2 behind restricting moisture analysis temperatures  
3 to no more than 90 degrees C. We don't have any  
4 data showing that anything higher than that is  
5 restrictive, and many of the commonly used moisture  
6 analytes operate efficiently and accurately at  
7 higher temperatures than that. Again, I'm  
8 following manufacturer rules.

9 DR. KABA: I can speak on that right now.

10 MR. HORVATH: Sure.

11 DR. KABA: When you go too high with moisture,  
12 especially on Flower, you'll also burn off a lot  
13 of terpenes --

14 MR. HORVATH: Sure.

15 DR. KABA: -- decarboxylating stuff. So that  
16 will increase the weight that you have. So, now  
17 you're calculating the moisture and the terpene  
18 loss and some decarboxylation. And you're calling  
19 all of that a moisture level.

20 MR. HORVATH: Right. But it's a small portion  
21 of the total sample. We're not utilizing that in  
22 testing.

23 DR. KABA: It can be a fairly significant  
24 sample. There's been some research on this now  
25 that when you get over 90, 95, 100C a bunch of

1 other stuff starts coming out too that end up  
2 upping that moisture content.

3 And I've mentioned this to a lot of the MMTCs  
4 when I've been on site there. And they're like,  
5 oh, that makes a lot of sense because sometimes  
6 they dry a little bit too much because they're  
7 losing all this extra stuff.

8 MR. HORVATH: Sure. I mean --

9 MS. GRANTHAM: I think Dr. Kaba has provided  
10 his rationale, but if you would like to provide  
11 some --

12 MR. HORVATH: No. I understand.

13 MS. GRANTHAM: -- language for us to consider.

14 MR. HORVATH: But I mean, back to previous  
15 comments. You know, we're doing dry weight in some  
16 areas and as received in others. Obviously we  
17 would prefer to pick one, right? If it was up to  
18 the MMTCs, obviously, we'd be reporting everything  
19 dry weight. But that's neither here nor there.  
20 But you know, reporting a portion in dry weight and  
21 a portion as received does create ambiguity and  
22 situations like this. If we were doing nothing but  
23 as received, then this wouldn't be an issue.

24 MS. GRANTHAM: Well, we understand your  
25 concerned, but it's very helpful for us if you

1 provide alternative language in your comments  
2 because that's what this is for, for us to hear  
3 from you.

4 MR. HORVATH: Yeah. Appreciate it.

5 And last comment on 309. Clarification  
6 expansion on the allowable conditions under which a  
7 testing sample may be retested. As currently  
8 written, the rule permits retesting only to confirm  
9 a failing result or when quality control sample  
10 fails.

11 However, there's legitimate and scientifically  
12 valid scenarios such as suspected sample  
13 preparation errors. Humans make mistakes. And  
14 when we see that an infused pre-roll is coming back  
15 at 9%, we can pretty much guarantee somebody made a  
16 mistake somewhere. And this happens. And the rule  
17 prevents us from using common sense.

18 So I'd just like to have the ability for us  
19 to, if there's an obvious situation where we have a  
20 12% derivative, it needs to be retested. There was  
21 a problem with extraction. A human made a mistake.

22 Okay. Thanks.

23 CHAIRMAN ROBERTS: Thank you.

24 Any further comments?

25 MR. MORTON: TJ Morgan with the Lockwood Law

1 firm. First comment is on subsection (3). And  
2 this is the requirement to have duplicate  
3 preparation analysis of Yeast and Mold Testing  
4 Samples.

5 We agree with the comments that were  
6 previously made. Just point out that, obviously,  
7 requiring duplicate samples is going to double the  
8 cost of the test. And we think that will exceed  
9 \$200,000 threshold, which you guys have heard me  
10 talk about quite a bit so far.

11 Proposed the alternative of just returning to  
12 single sample testing.

13 Concerns with subsection (3)(g), this is the  
14 minimum 60 hour incubation period.

15 Again, we agree with the comments that were  
16 previously made on this. We do think that this  
17 additional incubation period will increase costs.  
18 We think it will result in testing bottlenecks that  
19 could delay putting product on shelf and ultimately  
20 result in cost in human TCs, which could exceed the  
21 \$200,000 threshold.

22 Propose the alternative of allowing peer  
23 reviewed, validated 48 hour testing methods.

24 Thank you.

25 CHAIRMAN ROBERTS: Thank you.

1 Any further comments on this rule?  
2 Next Rule 64-4.310 CMTL Calibration Standards.  
3 MS. XU: This is Aixia from ACS Lab regarding  
4 rule 64-4.310 CMTL Calibration Standards. For the  
5 first one regarding Rule (1) starting with,  
6 "Calibration Standard must be prepared by diluting  
7 Certified Reference Material..." The rule says  
8 that you have to make the Category Standard Matrix  
9 match.  
10 So, ACS comments recommendations: If I say  
11 Material did the Matrices recovery study and there  
12 are acceptable for ISO certification for all  
13 matrices, the CMTL should be able to use  
14 calibration prepared follow the approved SOPs.  
15 The second comment regarding the rule number  
16 (2) the LOD must be calculated for Mycotoxins,  
17 Heavy Metal and other things are determined that  
18 the Department wants us to use US Environmental  
19 Protection method.  
20 The ACS comment on regarding this rule, for  
21 existing approved CMTLs should be able to continue  
22 to use previous determined LOD.  
23 Number (4), regarding (4)(sic)(f) and "Have a  
24 correlation of determination ( $r^2$ )..." for "standard  
25 curve points equal or greater than 0.99."

1           So, ACSs comments recommendation, we should  
2           stay at a current emergency rule (r) equal or  
3           greater than 0.98. Or we can build a screen  
4           method. If nothing is detected less than LOD, (r)  
5           can be equal or greater than 0.98. If there is  
6           anything detected ( $r^2$ ) or greater than 0.99 should  
7           be meet.

8           That's all. Thank you.

9           CHAIRMAN ROBERTS: Thank you.

10          Any other comments? CMTL Calibration  
11          Standards.

12          All right.

13          Next Rule 64-4.311 CMTL Certificate of  
14          Analysis.

15          Go ahead.

16          MS. XU: This is Shirley Xu, ACS Laboratory  
17          regarding 64-4.311 CMTL Certificate of Analysis,  
18          section (1)(b)(5), which requires, "The numerical  
19          concentration for each Target Analyte measured in  
20          the Testing Sample above the LOD and the LOQ."

21          ACS comment: Values should not be reported if  
22          they are detected under limit of quantitation LOQ.

23          Section (1)(b)(11) Regarding the package label  
24          deviation on the Certificate of Analysis.

25          ACS comment: There is a conflict per 64-

1 4.308(5). Samples are not required to be labeled  
2 for potency at the time of testing. Therefore,  
3 CMTL cannot generate COA that has label variation  
4 calculated.

5 Section (5) Supporting documentation upon  
6 request by the Department. A CMTL must provide the  
7 Department copies of the following within 48 hours  
8 of the Department's request.

9 ACS comments: To allow time for a business to  
10 operate the, CMTL should not be asked for multiple  
11 48 hour overlapping or staggering requests in one  
12 working week. These document requests should be  
13 extended to 72 hours and one request per week.  
14 Additionally, given CMTL have time and time limits  
15 to test samples, OMMU should respond to the CMTL in  
16 the same time frame for CMTLs questions.

17 Thank you.

18 MR. HORVATH: Real quick. Last comment.

19 So, the three significant figures. The  
20 situation -- can we find a way to have it either  
21 minimum or associated to the specific testing?  
22 Because it's sort of a -- it's confusing to us and  
23 to the client because if we're even for potency,  
24 you have situations where it's going to come to 99%  
25 and then we have smaller cannabinoids that come

1 down into the fractions of a percent. And then  
2 we're testing things at parts per billion and parts  
3 per million. And now we have three significant  
4 figures.

5 It's taxing on the technology, it's taxing on  
6 the Analysts, and it's taxing on the whole  
7 situation. I understand you want to make sure that  
8 it's uniform, but maybe we can create an  
9 environment where it's -- you set a minimum because  
10 it's not an accurate representation of what we're  
11 testing at, because if we have if we're testing  
12 down to parts per trillion and reporting in  
13 million, this creates an environment, three  
14 significant figures becomes a problem. There's a  
15 lot of problems with it.

16 But I understand you guys want uniformity.  
17 Maybe my recommendation would be to create a  
18 minimum for each one of the tests for significant  
19 figures and then let us go ahead and put the  
20 accuracy that's based on what's really happening  
21 with that test, please.

22 Thank you.

23 CHARIMAN ROBERTS: Thank you.

24 MS. ENGLE: I did not have the same comment as  
25 James. I just realized that.

1           So, the only thing I have a -- just would  
2 prefer a little bit of continuity between how you  
3 are requesting the data and how we submit it to  
4 you. So, obviously, we get the request just fine,  
5 but sometimes it's not clear how submission is  
6 going to be conducted. It may be omitted on the  
7 RFI or the NOV all together. Might be through the  
8 portal. Might be on a USB flash drive sent  
9 redacted and not. Might be emailed. We just --  
10 just maybe if there's a way for us to just kind of  
11 link all that into one format because we get a  
12 little confused about that part.

13           And I wasn't sure if it was covered as far as  
14 the WSBs redacted and not during the renewal, for  
15 each RFI during the renewal process. I don't think  
16 it was covered. I didn't see it there, but it was  
17 something that we went through this year but not  
18 before.

19           So that's all. Thank you. We're having a  
20 great time.

21           DR. VORISEK: Yes. Just one small one. On  
22 section (1)(a)(17) the provision requires CMTLs to  
23 include an expiration date on the COA of one year  
24 or less. This raises several concerns.

25           The first one is, is that CMTLs don't conduct

1 product stability testing or are in no position at  
2 all to determine shelf life for something. That  
3 responsibility lies, once again, with the MMTC.

4 Second, some products may legitimately have  
5 shelf life longer than one year if the MMTC  
6 themselves has conducted shelf stability testing in  
7 the past. So, this is a bit of an arbitrary  
8 requirement that's being put on us to put in there.  
9 It really needs to be MMTC provided data that is  
10 given to us through an appropriate channel that is  
11 verified.

12 CHAIRMAN ROBERTS: Thank you.

13 All right. Any further comments on  
14 Certificate of Analysis.

15 All right. Next Rule 64-4.312 CMTL Manual  
16 Integration. Go ahead.

17 MS. SUN: This is the Aixia from ACS Lab  
18 regarding Rule 64-4.312 CMTL Manual Integration.

19 Regarding Rule (2)(b) "If upon calculation,  
20 the resolution is less than 1.0."

21 ACS recommendation: Remove this requirement  
22 or add this only apply to GC or LCM we based tests.  
23 We know LCM mass or GCM mass, they have another  
24 like a mass ratio, MRM, to determine that it's not  
25 just resolution the chromatograph.

1           Second one is regarding (8)(b) "A report must  
2           be generated after the review is completed..." And  
3           the Department required five days for all the  
4           documents they request.

5           ACS comments: It's like I say, why does it  
6           need five days restriction for one year old data?  
7           ACS recommend this quality assurance report and can  
8           be saved and signed by the lab director and inspect  
9           during OMMU inspection. OMMU inspection occurs  
10          every six months and can be done that during that.

11          Thank you.

12          CHAIRMAN ROBERTS: Thank you.

13          Any other comments? Manual Integration.

14          All right. Moving quickly. Next Rule 64-  
15          4.313 Waste Management and Disposal.

16          Go ahead.

17          MS. XU: This is Shirley Xu, ACS Laboratory.

18          Regarding Rule 64-4.313 CMTL Waste Management  
19          and Disposal. Section (4)(c). "At least two  
20          employees of the CMTL, one of whom must be a  
21          Manager, shall be present when rendering the  
22          Marijuana Waste unusable, unrecognizable or  
23          irretrievable."

24          ACS comment and recommendation: Can this  
25          present be broader such as a manager can watch live

1 surveillance cameras while employee is disposing  
2 waste?

3 Section (10) and (11), which require the  
4 packaging of the Usable Whole Flower, Marijuana or  
5 Derivative Products to be rendered unusable on  
6 unrecognizable or irretrievable. And then, after  
7 rendered unusable and unrecognizable the CMTL must  
8 securely lock the non-hazardous waste in an  
9 enclosed container.

10 ACSs comment: If the packagings are which  
11 does not contain marijuana, are like claimed and  
12 empty and defaced and unusable, why do we need them  
13 to be locked? And it is unnecessary to securely  
14 lock the non-hazardous waste that has no marijuana.

15 And that's it. Thanks.

16 CHAIRMAN ROBERTS: Thank you.

17 Any further comments? Waste Management and  
18 Disposal.

19 All right. Next Rule 64-4.314 CMTL Background  
20 Screening.

21 All right. No comments.

22 Next rule. Last Rule 64-4.315 CMTL Fines,  
23 Suspension, and Revocation. And relinquishment.  
24 Baxter's person?

25 MS. BAXTER: Devon Baxter. Baxter Law.

1           We actually have some pretty serious concerns  
2 with this rule, particularly paragraph (2), which  
3 appears to allow the department to notify a labs  
4 accrediting body of a notice of a violation at the  
5 time it's being issued. So that would be before  
6 the matter's been adjudicated. NOV, the notice of  
7 violation, it's not final agency action when it's  
8 issued. And in many cases the lab is going to  
9 dispute the facts. They may dispute the  
10 department's interpretation of the law. So  
11 prematurely involving the accrediting body implies  
12 wrongdoing. And that could jeopardize, potentially  
13 jeopardize, a lab's accreditation based on what, at  
14 that point, are unproven allegations.

15           So, we recommend that this provision be  
16 removed, or at a minimum, just revised to limit  
17 notification until after that notice of violation  
18 has become final, if it becomes final.

19           Moving down that rule, paragraph (6), it  
20 allows for a quote/unquote an immediate three week  
21 suspension after three written notices of violation  
22 are issued within twelve months for the same  
23 violation.

24           I think this -- we have a problem between this  
25 and Florida's APA. So section 120.60, which limits

1 that immediate license suspension to very specific  
2 circumstances that involve a serious threat to  
3 public health or safety.

4 So, I think in -- outside of that very limited  
5 circumstance, I think that statute makes clear that  
6 a licensee needs to be given the opportunity to  
7 request and receive a hearing on the issue before  
8 any suspension or revocation would go into effect.

9 So, we'd request that this rule be revised,  
10 just to make clear that the Department will not  
11 seek to implement that suspension before -- again,  
12 before that notice has become final agency action.

13 Thanks.

14 CHAIRMAN ROBERTS: Thank you.

15 MS. XU: This is Aixia from ACS Lab regarding  
16 64-4.315. Regarding number (2) "The department  
17 will provide the CMTL write a notice of violation."

18 The ACS comment: Recommendation back in  
19 February 2023 ACS wrote comments on some clerical  
20 error should be solved by brief communication than  
21 instead of fine. OMMU should give any CMTL a  
22 chance to explain before a fine imposed. Today,  
23 again, we are asking that OMMU contact CMTL  
24 verbally regarding NOV before issuing a written  
25 one. This is to avoid misinterpretation or partial

1 interpretation that cause unfairness and mistrust  
2 in the government agency. CMTL should be able to  
3 continue to use ISO approved copper templates  
4 instead of changing templates to STM to keep  
5 consistency.

6 The next comment regarding number (6) "The  
7 department may immediately suspend, for a period up  
8 to three (3) weeks..."

9 ACS comment: The OMMU needs to grant due  
10 process for CMTL for previous NOV such as  
11 investigation, discussion, and conclusion before  
12 issuing new NOV on the same matter, same subject.  
13 The department should allow CMTL to correct and NOV  
14 before another identical NOV is issued. Once the  
15 correct action is accepted, the department should  
16 not go back retroactively. You issue more NOV on  
17 data happened before the correct action date.

18 The comments regarding number (13) "For the  
19 purpose of following schedule of fines, the  
20 descriptions of the violation..."

21 The ACS comment recommendation: Increasing  
22 fines does not help CMTLs or the Florida Patient.  
23 CMTL needs guidance from the OMMU and the MMU needs  
24 to have professionals to have scientific  
25 discussions with CMTLs.

1 Thank you. That's all.

2 MS. ENGLE: Okay. My question is about the  
3 relinquishing of the license. So, upon, obviously,  
4 if you're going to relinquish a license, I've done  
5 this before and gone through that process  
6 personally. And my question is for us specifically  
7 with moving locations, it says we have to destroy  
8 all the samples from the original license.

9 Are we not able to transfer between licensure  
10 while active before relinquishing, so that we don't  
11 have to destroy stuff that may still be in  
12 retention for the time being, because our clients  
13 aren't going to change? So just because you move  
14 facilities doesn't mean that you get a whole new  
15 set of clients. They don't sign up with a new  
16 group. I just want to make sure that we aren't  
17 destroying stuff in one location, that we can  
18 actually transfer it to the secondary location.

19 DR. KABA: Right. I think that we can look at  
20 the language and specify a little more, but that's  
21 the sort of thing where you would transfer stuff  
22 before you relinquish the license so that you kind  
23 of have two at the same time, and then you move  
24 stuff over and then once it's relinquished then  
25 anything left over you have to make sure it's

1 destroyed properly.

2 MS. ENGLE: Okay. Yeah, because it says you  
3 want us to destroy and then before you come to  
4 relinquish, I assume, because you're -- the exit  
5 interview is going to go and take photos and make  
6 sure there's no cannabis on site.

7 DR. KABA: Right. And we can we can, you  
8 know, doctor up that language.

9 MS. ENGLE: I appreciate that.

10 DR. KABA: More better.

11 MS. ENGLE: More better sounds delightful.

12 And then as far as the fines go, this isn't --  
13 so these fines and violations are crossing from  
14 381986/381988 because they have language about both  
15 punishments for CMTLs and MMTCs. Is there a -- is  
16 this echoed in their regulations as well?

17 MS. GRANTHAM: So, the only regulations that  
18 are at issue in this hearing are these. So, if you  
19 have comments about these or questions about these,  
20 that's appropriate. But to ask what's in the MMTC  
21 regulations, which are not at issue in this  
22 proceeding --

23 MS. ENGLE: Okay.

24 MS. GRANTHAM: -- so it's kind of beyond the  
25 scope.

1 MS. ENGLE: Okay. That sounds good.

2 MS. GRANTHAM: But please submit a comment if  
3 you have recommendations or --

4 MS. ENGLE: Yeah we submitted all the  
5 technical stuff. We're good. Just wanted to  
6 housekeep, so.

7 Thank you.

8 MS. GRANTHAM: You're welcome.

9 MR. BROWNING: Keith Browning. I'm with  
10 Method Testing Labs. We'd love to thank you guys  
11 for all the hard work you've been putting into this  
12 over the last two and a half years.

13 We support the comments that have been placed  
14 today. From all of the comments today.

15 I'd also like to ask, I know we had talked  
16 earlier about a six month implementation of the  
17 rules. There's a lot to these rules. There's a  
18 lot of employees we're going to have to hire.  
19 There's due process we're going to have to put in  
20 place. I think six months is still not enough.  
21 I'd like to say between six and 12 months to be  
22 able to implement this.

23 We're going to have to hire some people.  
24 We're going to have to be able to put some new  
25 process in place. The PTs have to be put in place.

1 There's a lot of heavy lifting, as Dr. John says.  
2 A heavy lifting we have to do in this whole  
3 process. So we'd like to extend it between six and  
4 12 months for -- depending on the complexity of the  
5 of the process.

6 That's it. Thank you.

7 CHAIRMAN ROBERTS: All right. Are there any  
8 further comments on this final rule?

9 Okay.

10 MR. LOCKE: Good morning. My name is Daniel  
11 Locke, Compassionate Alternative Care. I want to  
12 apologize in advance. What I have to say is  
13 completely off topic of what we're talking about  
14 today. I have sent emails to the state trying to  
15 get a response. I can't ever get a response.

16 My question is about -- and you guys don't  
17 have to answer this question. I just want it on  
18 record. Okay. Since I can't get a response via  
19 the OMMU. The question is, does the OMMU  
20 understand what, according to science, a lethal  
21 dose of a medical patient? According to science,  
22 anything more than 30mg per day is beyond medical  
23 use. Currently we have 350mg on the high THC. You  
24 extrapolate it, 2.5oz comes out to another 428.  
25 Combined is 26 times more than science says is

1 beyond medicinal.

2 The question comes in with the doctor's  
3 override. Okay. We're allowing doctors to do  
4 overrides to submit something that's completely  
5 unethical because there's nothing evidence based  
6 that says a patient needs a quarter a pound of  
7 wheat in a month. Number one. Okay.

8 Number two, cannabis hyperemesis syndrome.  
9 You guys may or may not be aware. A lot of science  
10 has evolved since you guys came in to fruition. So  
11 I don't I'm not pointing fingers at anybody. But I  
12 do think these things need to be addressed as more  
13 and more patients are developing cannabis  
14 hyperemesis patients.

15 And as I answer my phone every day, hey, I'm  
16 at the dispensary. They told me to tell my doctor  
17 to give me an override for four ounces. I'm not  
18 sure that's exactly where that conversation should  
19 happen. And I just want it on public record.  
20 That's what's going on every single day.

21 The grey market is now taking over the black  
22 market, which I'm not opposed to that. I'm just  
23 supposed to my doctor having to put his license  
24 online just to stay in business. It's completely  
25 unethical. It doesn't comply with evidence-based

1 medicine.

2 Thank you for your time today.

3 MS. GRANTHAM: Thank you for that feedback.  
4 And obviously it is beyond the scope of this  
5 proceeding. But we always consider any feedback  
6 about our program and that was very helpful.

7 Thank you.

8 CHAIRMAN ROBERTS: Any further comments on  
9 this rule?

10 All right. If there are no further comments I  
11 would like to thank you all for your participation  
12 in this highly efficient rule hearing. We will  
13 accept written comments and material until 5:00 PM  
14 June 10, 2025. That's one week from now. Please,  
15 again, submit your comments to  
16 OMMUrules@FLHealth.gov.

17 There being no further comments, I'd like to  
18 inform you that this hearing is closed.

19 Thank you.

20

21 (Thereupon, the proceedings were concluded at 10:37  
22 AM.)

23

24

25

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

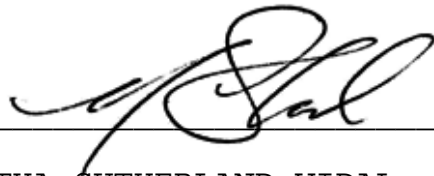
REPORTER'S CERTIFICATE

THE STATE OF FLORIDA  
COUNTY OF MIAMI-DADE:

I, MARTHA SUTHERLAND-VIDAL, Court Reporter and  
Notary Public, certify that this transcript is a true and  
complete record of my notes.

I further certify that I am not a relative,  
employee, attorney, or counsel of any of the parties, nor  
am I a relative or employee of any of the parties'  
attorney or counsel with the action, nor am I financially  
interested in the action.

DATED on this 3rd day of June 2025.



---

MARTHA SUTHERLAND-VIDAL, Court Reporter