



June 13, 2017

Ms. Lori Ajax  
Chief, Bureau of Medical Marijuana Regulation  
California Department of Consumer Affairs  
1625 North Market Blvd, Suite S-202  
Sacramento, CA 95834

Transmit Via E-Mail: [BMCR.comments@dca.ca.gov](mailto:BMCR.comments@dca.ca.gov)

**RE: Comments on Proposed Rulemaking for Testing Laboratories**

Dear Ms. Ajax:

On behalf of the Rural County Representatives of California (RCRC), the Urban Counties of California (UCC), and the California State Association of Counties (CSAC), we offer our comments on the proposed regulations for the State's licensing and enforcement criteria for commercial cannabis testing laboratories.

The specific language revisions that counties recommend for the proposed Bureau of Marijuana Control Testing Laboratory Regulations are set forth in an appendix to this letter. These recommendations are largely self-explanatory, but we would also like to provide the following detailed comments:

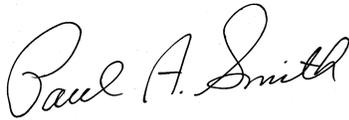
- As indicated in the ISOR (pp. 15-16), the provisional licensure provisions are intended to recognize and mitigate the delays inherent in obtaining ISO certification. While this concern may justify provisionally licensing laboratories *that have actually commenced the application process* and are awaiting action by the accrediting body, it does not justify allowing laboratories who have not yet even submitted an application to fill the critical testing role in California's regulated cannabis system. In that circumstance, the lack of ISO certification is not the result of delays in the ISO process, but the laboratory's unreadiness to proceed - which does not warrant provisional licensure. We have consequently proposed revisions to Sections 5238 and 5244 to require that provisional licensees - at all stages (not just renewal) - demonstrate that they have applied for (but not yet been granted or denied) ISO certification.
- Section 5102(e), in the proposed main BMC regulations package, addresses harvest batches that have failed testing, but can nonetheless be safely processed by a manufacturer - "as determined under Chapter 5 of this division." However, the draft

regulations in Chapter 5 do not address this determination. The draft regulations should clearly specify that it is the laboratory's responsibility to make this determination (not the distributor, who both has a self-interest in the determination and lacks the requisite technical knowledge) – and that this determination must be set forth in the certificate of analysis. Revisions to accomplish this goal have been suggested in Section 5244.

- Section 5110, in the main BMC regulations package, establishes conflict-of-interest provisions for employees of distributors “because if a distributor were to have employees with an interest in other medical cannabis licenses, the employees may have a reason to behave in a less neutral way, which would be contrary to the spirit of the enabling statutes.” (BMC Regs. ISOR, p. 50.) This is no less true – and no less critical – in the context of testing laboratories, upon whose neutrality and independence consumer safety depends. We have consequently proposed to incorporate similar provisions for laboratory employees into Section 5373.

We appreciate the opportunity to provide these comments on the proposed Bureau of Marijuana Control Testing Laboratory Regulations. If you have any questions, please contact Paul A. Smith at [psmith@rcrcnet.org](mailto:psmith@rcrcnet.org), Jolena Voorhis at [jolena@urbancounties.com](mailto:jolena@urbancounties.com) or Cara Martinson at [cmartinson@counties.org](mailto:cmartinson@counties.org).

Sincerely,



PAUL A. SMITH  
Senior Legislative Advocate  
RCRC



CARA MARTINSON  
Legislative Representative  
CSAC



JOLENA L. VOORHIS  
Executive Director  
UCC

cc: Graciela Castillo-Krings, Office of Governor Edmund G. Brown, Jr.  
Kim Craig, Office of Governor Edmund G. Brown, Jr.  
Darci Sears, Office of Assembly Speaker Anthony Rendon  
Gayle Miller, Office of Senate President Pro Tempore Kevin de León

Attachment: Appendix to Counties' Comment Letter

**APPENDIX TO COUNTIES' COMMENT LETTER  
LANGUAGE REVISIONS RECOMMENDED FOR  
BUREAU OF MARIJUANA CONTROL TESTING LABORATORY REGULATIONS**

**Revise Proposed Regulations § 5238 to read:**

§ 5238. Application

In addition to the information required by section 5006 in this division, an applicant for a testing laboratory license shall provide the following information:

- (a) Proof of ISO 17025 accreditation or proof that the applicant ~~is in the process of applying or is preparing to apply~~ has applied for ISO 17025 accreditation;
- (b) Laboratory-employee qualifications; and
- (c) All required standard operating procedures.

**Revise Proposed Regulations § 5244 to read:**

§ 5244. Provisional Testing Laboratory License

- (a) A testing laboratory applicant that meets all qualifications for licensing except that they have applied for but not yet been granted or denied ISO accreditation may apply to the bureau for a provisional testing laboratory license.
- (b) An applicant for a provisional license shall include the information and documentation required for a license as required under section 5006, except that documentation of the laboratory's ISO 17025 accreditation is not required. Instead, documentation required under section 5238(a) is required.
- (c) The bureau may grant the testing laboratory applicant a provisional license. The provisional license, if granted, expires 12 months from the date of issuance.
- (d) The bureau has the discretion to renew a testing laboratory's provisional license. The bureau may renew a testing laboratory's provisional license if the laboratory has applied for ISO 17025 accreditation but has not yet been granted or denied ISO accreditation. ~~A testing laboratory shall provide evidence to the bureau of having submitted an application for ISO 17025 accreditation.~~
- (e) If granted, a provisional license renewal expires after 180 calendar days.
- (f) When a testing laboratory holding a provisional license receives ISO 17025 accreditation, the testing laboratory shall send proof of the accreditation to the bureau within five business days.
- (g) When a laboratory holding a provisional license is denied ISO 17025 accreditation, the laboratory shall notify the bureau of the denial within 24 hours. The bureau shall revoke the provisional license when the laboratory is denied accreditation.

**Revise Proposed Regulations § 5292, subdivision (c) to read:**

- (c) A laboratory shall keep all standard operating procedures on the laboratory premises and in the field, as necessary, and shall ensure that each standard operating procedure is accessible to laboratory personnel during operating hours. A laboratory shall make the standard operating procedures accessible to the bureau and any local jurisdiction in which the laboratory holds a local license, permit, or other authorization upon request.

**Add new Subdivision (d) to Proposed Regulations § 5334 to read:**

- (d) If a failed sample was collected from a harvest batch, the certificate of analysis shall also indicate whether the harvest batch could be processed by a manufacturer without the resulting production batch causing harm to medical cannabis patients, as set forth in Section 5102, subdivision (e) of this division.

**Revise Proposed Regulations § 5355, subdivision (d) to read:**

- (d) The entire data package shall be kept for a minimum of 7 years and shall be made available upon request by the bureau, any local jurisdiction in which the laboratory holds a local license, permit, or other authorization, or the requester of the laboratory testing.

**Revise Proposed Regulations § 5370, subdivision (c) to read:**

- (c) A laboratory shall keep and make available to the bureau and any local jurisdiction in which the laboratory holds a local license, permit, or other authorization the following records:

**Add new Subdivision (h) to Proposed Regulations § 5373 to read:**

- (h)(1) A laboratory shall not hire an employee or volunteer if the person works or volunteers for another person issued a state license to engage in commercial cannabis activity unless the other medical cannabis licensee is a laboratory.
- (2) A licensee shall ensure his or her employees do not have a financial interest as defined in section 5006 subsection (b)(22)(K) of this division in another state license to engage in commercial cannabis activity. A licensee shall have a document for each employee in which the employee signs and attests to not having a financial interest in another state license to engage in commercial cannabis activity unless allowed under subsection (h)(1).

**Revise Proposed Regulations § 5403, subdivision (a) to read:**

- (a) Laboratories shall notify the bureau and any local jurisdiction in which the laboratory holds a local license, permit, or other authorization within 24 hours of discovering any of the following: