Topic: Petition for Adoption, Amendment, or Repeal of a State

Administrative Rule – (WAC 314-55-102(9) – Extending the Cannabis Certificate of Analysis Expiration Date)

Date: December 20, 2023

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Background

On October 30, 2023, Jeremy Moberg submitted a petition for adoption, amendment, or repeal of a state administrative rule to the Washington State Liquor and Cannabis Board (Board) along with supporting information from the Washington Sun and Craft Growers Association and the Cannabis Alliance. The petitioner requests that the agency consider initiating rulemaking to amend WAC 314-55-102(9) to extend the expiration date for Certificates of Analysis (COA) for required quality control testing from 12 months to 18 months.

The petition requests a change to an existing rule:

■ 2. AMEND RULE - I am requesting the agency to change an existing rule.		
List rule number (WAC), if known: WAC 314	-55-102 (9)	
I am requesting the following change:	hat the expiration date be extended from 12 months to 18 months.	
This change is needed because: <u>Se</u>	ee attached.	
The effect of this rule change will be: S	See attached.	
The rule is not clearly or simply stated:		

In support of the petition, the Washington Sun and Craft Growers Association and The Cannabis Alliance provided additional information that includes the rationale for the petition request with examples describing the impact.

This is additional information to support a petition to amend rule WAC 314-55-102 (9). The current rule requires that QA testing expires after a 12-month period. This petition seeks to extend that 12-month period to 18 months. This change is needed because the current 12-month period creates an unnecessary burden on farmers that grow outdoors and whose crops are planted and harvested seasonally. The problem that the 12 months period creates is that given the seasonal variability of harvest dates a farmer will likely not have harvested the next crop prior to the last harvest QA test expiring. This creates a situation where a farmer may not have sellable crops or strains between the time that the new crop is harvested and the QA test for the prior year's crop is expired. Given the variability of growing crops this may be a significant amount of time. This creates a clear disadvantage for outdoor farmers. Changing the expiration date of the QA test to 18 months would reduce the negative impacts to farmers without any effect on consumer safety.

A recent example of the burden this rule poses to outdoor farmers follows. A farmer harvested in the fall of 22' after the rulemaking was adopted in the spring of 22'. The farmer harvested in mid-September and had the crop dried and ready for testing 3 weeks later. This QA test was received on October 5, 2022, and expires on October 5, 2023. However, the following years crop came later in the year and was not harvested until mid-October and was tested by mid-November. This creates a significant period of time that this farmer would not have product to sell. Retesting the prior year's product is not allowed by rule and this farmer would not be able to continue to generate revenue to keep operations funded.

Another example is a farmer that uses light deprivation techniques and harvests different strains at different times during the harvest period between July and November. A unique strain that this farmer relies on for a significant portion of its revenue has an expiration date in July but is not expected to harvest this strain until late September, leaving the farmer without the ability to sell this unique strain for a period of time that is critical to their revenue and operations. Of course, we all know that farming is intrinsically variable and by allowing 18 months for a test to expire would allow for seasonal variability between harvests and prevent these scenarios from occurring.

We encourage the LCB to accept this petition and adopt the suggested changes in a timely manner. Extending this expiration period to 18 months would provide relief to growers without significantly altering the intent of the rule.

<u>Issue</u>

Whether the Board should accept this petition and file a CR 101 Preproposal Statement of Inquiry to consider initiating the rulemaking process to amend WAC <u>314-55-102(9)</u> to extend the expiration date of Certificates of Analysis (COAs) issued by certified labs for products that have not been transferred to a retail outlet from 12 months to 18 months.

COA expiration dates

The current rules (<u>WAC 314-55-102</u>) requires all cannabis products sold at retail in Washington must have passed a panel of quality control tests conducted by an accredited testing laboratory. These required tests include tests for pesticides, biological contaminants, moisture, potency, and other tests depending on the cannabis product type. Certified labs are required to provide licensees a COA to report quality control testing results for cannabis products.¹

COA expiry for products is a good manufacturing practices (GMP), and standard in many other regulated industries, such as pharmaceuticals and cosmetics. However, instead of prescribing an expiration date in rule, the COA expiration date or retest date is based on results from stability testing studies, which are typically conducted when a new product comes to market. The purpose of stability testing is to provide evidence on how the quality of a product varies with time under the influence of a variety of environmental factors such as temperature, humidity, and light, and to establish a re-test period for the drug substance or a shelf life for the drug. Other states with legal cannabis, like Colorado, require stability testing if an expiration or best-used by date is on a product label, and have methodologies for licensees to conduct shelf-stability studies for different types of cannabis products.

The 12-month COA expiration date requirement became effective in rule on April 2, 2022, filed as <u>WSR 22-06-097</u>, and was included as a part of a larger rulemaking related to <u>quality control testing</u>. Prior to the 2022 rulemaking, the rules did not have COA expiration date requirements. The requirement was included in rule to address the issues with licensees circumventing the testing rules, including re-using a COA for multiple lots or batches to reduce the number of tests, and subsequently, lower costs associated with testing. During public engagement for the 2022 quality testing rule development, the 12-month COA expiration date requirement was proposed, and stakeholders expressed little to no concern with regards to the new requirement.

The COA expiration date in current rule applies to all product types and all analytes for which the products are tested. Therefore, it may be prudent to review and update the current COA expiry requirements, as necessary, considering whether the rule should be applicable for all cannabis product types and analytes required to be tested; what the frequency should be for testing specific analytes for the various product types available on the market; whether the current requirements impose an undue burden; and if there are alternative solutions to rule to consider that may reduce the compliance burden,

provide licensees additional operational flexibility, and has the potential to improve public health and safety.

Analysis

When deciding the Board recommendation, the Director's Office Staff considers the following factors to the extent practicable:

- LCB's statutory authority and obligations;
- Alignment with the Agency's policy goals and priorities;
- The immediacy of the safety, environmental, or security concern raised;
- Potential impact to public health outcomes;
- The potential impact on criminal activity;
- Level of public interest;
- Whether the problems or issues are already under consideration by the LCB in other rulemaking issues;
- Merits of the petition; and
- Equity impacts.

Accepting the rule petition does not mean the Agency would begin developing rules to extend the expiration date of a COA to 18 months, but rather provides an opportunity for the Agency to solicit and gather feedback from the public to assess whether and how a regulation should be revised to ensure the most favorable outcomes. If the Board accepts a petition, the collaborative rulemaking process will be initiated, consistent with the <u>Administrative Procedures Act (APA)</u>.²

Furthermore, although the petitioner requested rulemaking be conducted in a "timely manner," based on the APA requirements and procedures, it takes at least four months, at a minimum, to complete a permanent rule. However, there are a number of factors that affect to the rulemaking timeline, including, but not limited to, the Code Reviser calendar for filing dates and Board meeting dates, public comments and public engagement.

Statutory Authority and Obligations

The proposed rule change is within in LCB's statutory authority and aligned with LCB's statutory obligations. The petitioner is requesting an amendment to <u>WAC 314-55-102(9)</u>, which provides the quality control testing requirements for licensees. <u>RCW 69.50.342</u> and <u>RCW 69.50.345</u> grants the Board statutory authority to adopt rules that ensure the quality and safety of cannabis products.³ Consistent with statute, <u>WAC 314-55-102(9)</u> states the COA for cannabis products that have not already been transferred to a retail location expires 12-months after the issuance of the certificate by a certified lab.⁴

According to the petitioners, the current rule disproportionately adversely affects outdoor producers, and does not allow the flexibility for businesses to use various growing techniques, ultimately hindering innovation. RCW 69.50.345(6)(c) requires the

Board to adopt rules that consider economies of scale, and the impact on licensees' ability to comply with the regulatory requirements and undercut the illegal market.⁵

Safety, Environmental and Security Concerns

The petitioner did not raise any immediate safety, environmental, or security concerns related to extending the COA expiration date. In the letter accompanying the petition, Cannabis Sun Growers and Cannabis Alliance asserted that the proposed amendment would not impact consumer safety.

Public Health Outcomes

To determine the recommendation provided to the Board, studies related to cannabis product quality, including degradation, stability, and microbial contamination, were reviewed to understand how time affects different types of cannabis products. Based on the literature, a variety of factors can affect the quality cannabis products, including, but not limited to the following: storage conditions, temperature, pH conditions, and light. Some of the research highlights are provided below.

Research Highlights

- Capsules containing full spectrum cannabis extract should be stored only at 4 degrees Celsius in darkness to maintain their cannabinoid profile.⁶
- High storage temperatures lead to a more rapid and complete decomposition of THCA to delta-9 THC in cannabis, while at low temperatures there was slight or no change.
- Within the first 100 days of storage, there is a 12 percent degradation in THC.
 The average monthly THCA+THC degradation rate to be 20 degrees Celsius.⁸
- Factors contributing to increased levels of yeast and mold growth over time in cannabis inflorescences included harvest during May-October, method of harvesting and drying, and improper storage.⁹

<u>WAC 314-55-015(8)</u> requires licensees to use "sanitary practices in the production, processing, storage, and sale of all cannabis products." Otherwise, the only other storage requirements for cannabis products are intended to prevent diversion and other criminal activity. The COA expiration date is only applicable to products that have not been transferred to a retailer already. Products that have been transferred to a retail outlet do not have expiration date requirements. In the 2022 quality testing rulemaking, licensees were given a "sell-down" period for products not yet tested for pesticides and LCB received complaints from consumers that old products were being sold at retail.

Since licensees are not required to perform stability testing, the rules do not prescribe storage conditions that are necessary to maintain the stability and quality of the product over time, and do not impose an expiration date for products at retail, LCB is concerned that extending the COA expiration date or making other changes to the quality testing rules without more research may have negative public health consequences. It may be

necessary to review the current COA expiry requirements to evaluate whether the rule needs to be updated to incorporate the most recent and up-to-date scientific evidence; and whether alternatives to rulemaking exist that could improve public health outcomes without creating an undue compliance burden for businesses.

Criminal Activity

It is unclear whether including COA expiration date in rule remedied the issue related to licensees circumventing the rules and reusing COAs for multiple lots or batches to reduce compliance costs. However, LCB's enforcement and education staff have identified other ways licensees may be circumventing the testing rules and not reporting all tests conducting in CCRS. If the Board accepts this petition and rulemaking is initiated, it may be necessary to review and update other sections in WAC 314-55-102 to ensure that LCB has the necessary information needed to conduct effective investigations and verify whether a licensee is complying with COA expiration date requirements.

Level of Public Interest

As of December 19, 2023, seventeen public comments have been received. Sixteen of the comments received were in support of extending the COA expiration date from 12 to 18 months citing the same concerns as the petitioners. One commenter did not support extending the COA expiration date from 12 to 18 months and expressed concerns about consumer health and health equity that was aligned with LCB's analysis. The public comments received are attached.

Equity

Social Equity Licensees

To provide social equity licensees with the greatest opportunity to succeed in the marketplace, it would be prudent to review the current rules and evaluate whether the rule requirements impose an undue compliance burden for licensees, and whether there are ways to reduce costs of testing without sacrificing public health and safety. Furthermore, given that the price of cannabis products has declined in recent years, in part due to overproduction, extending the COA expiration date to 18 months likely means that more products would be on the market. Consequently, the price of cannabis products may further decline, which may be more economically detrimental for all licensees in the long run.

Socioeconomic and Health Equity

Price associated with high levels of THC and CBD are associated with higher per gram prices. ¹⁰ Without retest or labels that provide the harvest date, "best-by" date, or manufactured dates, consumers are using a quality indicator (cannabinoid concentration levels) that may not be accurate to make purchasing decisions.

Consumers that have a low socioeconomic status and younger consumers may not be aware that the quality and stability of cannabis will degrade over time unless certain storage and environmental conditions are met (temperature, humidity, UV exposure, etc.). Retailers purchasing wholesale cannabis products will likely pay less money for products that were harvested or manufactured a year ago, as opposed to three months ago. The selling price at retail will reflect this, which could result in uninformed consumers making purchases based on the cannabinoid content that may no longer be accurate.

WAC 314-55-105(8) provides that the following information is optional on labels:

- Harvest date,
- "Best by" date, and
- Manufactured dates.

Without this information on the label, consumers who are not aware that a retailer must provide the test results from a retailer upon request¹¹, will not be able to make informed decisions about the potential health effects associated with consumption.

Medical patients who rely on cannabis for a variety of reasons that could include lack of access to healthcare (so self-medicating), and since there are not a lot of medically compliant products, patients are consuming recreational products that could harm them.

LCB Policy Goals and Priorities

The petitioners' request is aligned with the Agency's policy goals and priorities to:

- Reduce unnecessary compliance burdens;
- Provide licensees with more operational flexibility and regulate like other-non cannabis industries;
- Develop evidence-based policy and rules with the most up-to-date research;
- Improve public health, safety, and equity; and
- Prevent criminal activity.

Merits of the Petition

In the accompanying letter, the petitioners indicated that the 12-month expiration date negatively impacts outdoor producers because retesting the harvest from the prior year is not allowed. Cannabis products that have an expired COA may be retested to obtain another COA that is valid for 12 months. Retesting is only restricted under WAC 314-55-102(6) when a cannabis product has failed a previous test. The Board must authorize the retest to validate a failed test on a case-by-case basis. Approval by the Board is not required to retest products that have an expired COA. Furthermore, WAC 314-55-102(5) provides that cannabis products that have not been tested, or with an expired COA can be transferred to another licensee. Or, if a licensee has a UBI and multiple locations, cannabis products may be transferred between the licensed locations under the same UBI number. Although retesting or transferring products with an expired COA may be more costly than if the COA expiration date were to be extended to 18-months as the

petitioners requested, the current testing rules provide licensees with options that wouldn't require licensees to waste products with an expired COA, or leave licensees without product to sell between harvests.

Division Impacts and LCB resources

Licensing

The licensing division did not identify any impacts.

Enforcement and Education (E&E)

Enforcement and Education (E&E) expressed that extending the COA expiration date may exacerbate licensees circumnavigating the testing rules. Furthermore, E&E expressed concerns about the testing rules more generally.

Information technology (IT)

The IT division did not identify any impacts.

Public health/prevention

The Public Health/Prevention division did not identify any impact or specific comments, except to reiterate the concern about how time affects the stability and degradation of cannabis products, and subsequently compromises the integrity of the COA results.

Finance

The Finance division did not identify any impacts.

Research

If the Board votes to accept the petition and rulemaking is initiated, to develop evidencebased policy and rules that protects public health and safety, it will be critical that the research team conducts objective research based on the latest science.

Conclusion

Based on the reasons described above, the Director's Office staff recommends that the Board accept the petition and initiate rulemaking to consider amending WAC <u>314-55-102(9)</u> to extend the COA expiration date for cannabis products from 12 months to 18 months.

Board Action

After considering the recommendation of Director's Office staff, the Board accepts/denies the petition for rulemaking received from Jeremy Moberg on October 30, 2023.

	DA C	
X Accept Deny	David Postman, Chair	12.20.2023 Date
X Accept Deny	Ollie Garrett, Board Member	12.20.2023 Date
X Accept Deny	Jim Vollendroff, Board Member	12.20.2023 Date

Attachments

- 1. Email from Jeremy Moberg October 30, 2023, containing rule petition and letter.
- 2. Public comment table
- 3. Degradation and stability research referenced in the petition response.
- 4. E&E doc re: ½ of tests aren't reported

¹ WAC 314-44-102

- (1) Lab certification and accreditation for quality control testing. To become certified, a third-party lab must meet the board's certification and accreditation requirements as described in WAC 314-55-0995 and this chapter before conducting quality control tests required under this section.
 - (a) Certified labs must be certified to conduct the following fields of testing:
 - (i) Water activity;
 - (ii) Potency analysis;
 - (iii) Foreign matter inspection;
 - (iv) Microbiological screening;
 - (v) Mycotoxin screening;
 - (vi) Pesticide screening; and
 - (vii) Residual solvent screening.
- (9) A certificate of analysis issued by a certified lab for any cannabis product subject to the requirements of this chapter that has not already been transferred to a retail location expires 12 calendar months after issuance.
- ² Chapter 34.05 RCW Administrative Procedures Act (APA)
- ³ RCW 69.50.342
- (1) For the purpose of carrying into effect the provisions of chapter 3, Laws of 2013 according to their true intent or of supplying any deficiency therein, the board may adopt rules not inconsistent with the spirit of chapter 3, Laws of 2013 as are deemed necessary or advisable. Without limiting the generality of the preceding sentence, the board is empowered to adopt rules regarding the following:
- (c) Methods of producing, processing, and packaging cannabis, useable cannabis, cannabis concentrates, and cannabis-infused products; conditions of sanitation; safe handling requirements; approved pesticides and pesticide testing requirements; and standards of ingredients, quality, and identity of cannabis, useable cannabis, cannabis concentrates, and cannabis-infused products produced, processed, packaged, or sold by licensees;

RCW 69.50.345

(11) In consultation with the department and the department of agriculture, establishing accreditation requirements for testing laboratories used by licensees to demonstrate compliance with standards adopted by the board, and prescribing methods of producing, processing, and packaging cannabis, cannabis concentrates, useable cannabis, and cannabis-infused products; conditions of sanitation; and standards of ingredients, quality, and identity of cannabis, cannabis concentrates, useable cannabis, and cannabis-infused products produced, processed, packaged, or sold by licensees;

⁴ WAC 314-55-102

(9) A certificate of analysis issued by a certified lab for any cannabis product subject to the requirements of this chapter that has not already been transferred to a retail location expires 12 calendar months after issuance.

⁵ RCW 69.50.345

- (6) In making the determinations required by this section, the board shall take into consideration:
- (c) Economies of scale, and their impact on licensees' ability to both comply with regulatory requirements and undercut illegal market prices;
- ⁶ Villate et al., 2023
- ⁷ Taschwer et al., 2015
- ⁸ Meija et al., 2022
- ⁹ Punja et al., 2023. Total yeast and mold levels in high THC-containing cannabis inflorescence are influenced by genotype, environment, and pre- and post-harvest handling practices. Front. Microbiol. 14:1192035.
- ¹⁰ Smart et al., Addiction. 2017 December; 112(12): 2167–2177. doi:10.1111/add.13886.
- ¹¹ WAC 314-55-105

(10) Upon request materials. A consumer may request the name of the certified lab and quality assurance test results for any cannabis or cannabis product. A retailer must provide the information upon request.

¹² WAC 314-55-102

- (6) Failed test samples.
- (a) Upon approval by the board, failed quantities of cannabis or batches may be used to create extracts. After processing, the extract must pass all quality control tests required in this section before it may be sold, unless failed for tests that require immediate destruction.
- (b) Retesting. A producer or processor must request retesting. The board may authorize the retest to validate a failed test result on a case-by-case basis. The producer or the processor requesting the retest must pay for the cost of all retesting.
- (c) Remediation. Remediation is a process or technique applied to quantities of cannabis flower, lots, or batches. Remediation may occur after the first failure, depending on the failure, or if a retest process results in a second failure. Pesticide failures may not be remediated.
- (i) Producers and processors may remediate failed cannabis flower, lots, or batches so long as the remediation method does not impart any toxic or harmful substance to the useable cannabis, cannabis concentrates, or cannabis-infused product. Remediation solvents or methods used on the cannabis product must be disclosed to:
 - (A) A licensed processor;
 - (B) The producer or producer/processor who transfers the cannabis products;
- (C) A licensed retailer carrying cannabis products derived from the remediated cannabis flower, lot, or batch; or
 - (D) The consumer upon request.
- (ii) The entire quantity of cannabis from which the failed sample(s) were deducted must be remediated.
- (iii) No remediated quantity of cannabis may be sold or transported until quality control testing consistent with the requirements of this section is completed.
- (iv) If a failed quantity of remediated cannabis is not remediated or reprocessed in any way after a first failure, it cannot be retested. Any subsequent certificates of analysis produced without remediation or reprocessing of the failed quantity of cannabis will not supersede the original compliance testing certificate of analysis.

13 WAC 314-55-102

- (5) Useable flower, a batch of cannabis concentrate, or a batch of cannabis-infused product may not be sold until the completion and successful passage of required quality control testing, except:
- (a) Licensees may wholesale and transfer batches or quantities of cannabis flower and other material that will be extracted, and cannabis mix and nonsolvent extracts, for the purposes of further extraction prior to completing required quality control testing.
- (b) Business entities with multiple locations licensed under the same UBI number may transfer cannabis products between the licensed locations under the same UBI number prior to quality control testing.
- (c) Licensees may wholesale and transfer failed batches or quantities of cannabis flower to be extracted pursuant to subsection (6) of this section, unless failed for tests that require immediate destruction.