May 31, 2017

Date:

То:	Jane Rushford, Board Chair Ollie Garrett, Board Member Russ Hauge, Board Member			
From:	Karen McCall, Agency Rules	s Coordinator		
Сору:	Rick Garza, Agency Director Peter Antolin, Deputy Director Justin Nordhorn, Chief of Enforcement Becky Smith, Licensing Director			
Subject:	Subject: Approval of final rules (CR 103) for Chapter 314-02, 314-07, 314-11, and 314-12 WAC.			
and Cannabis	9	ne rules coordinator requests tha emaking (CR 103) for Chapter 31	•	
The Board was briefed on the rule making background and public comment for this rule making. An issue paper and text of the rules is attached.				
If approved, the Rules Coordinator will send an explanation of the rule making to all persons who submitted comments.				
After sending this explanation, the Rules Coordinator will file the rules with the Office of the Code Reviser. The effective date of the rules will be 31 days after filing.				
Appro	ve Disapprove	Jane Rushford, Chair	Date	
Appro	ve Disapprove	Ollie Garrett, Board Member	 Date	
Approv	veDisapprove	Russ Hauge, Board Member	Date	

Washington State Liquor and Cannabis Board

Issue Paper

Rulemaking on Chapters 314-02, 314-07, 314-11, and 314-12 WACs

Date: May 31, 2017

Presented by: Karen McCall, Agency Rules Coordinator

Description of the Issue

The purpose of this Issue Paper is to recommend that the Washington State Liquor and Cannabis Board proceed with final rulemaking and adopt rules for Chapter 314-02, 314-07, 314-11, and 314-12 WAC

Why is rule making necessary?

As part of the Liquor and Cannabis Board's on-going rules review process, rules in the following WAC Chapters were reviewed for relevance, clarity, and accuracy:

- Chapter 314-02 Requirements for retail liquor licenses.
- Chapter 314-07 How to apply for a liquor license.
- Chapter 314-11 General requirements for licensees.
- Chapter 314-12 General Applicable to all licensees.

Public Comment

No comments were received at the public hearing held May 17, 2017.

CR 102 filed November 2, 2016 WSR 16-22-094. The following written comments were received:

Holly Chisa – Northwest Grocers Association

Comment: WAC 314-02-103 poses a "per day" limit on sales between on-premises and off-premises retailer. The court struck this language so it needs to be removed.

LCB response: The language was removed in the supplemental CR 102, filed March 22, 2017.

Julia Gorton – Washington Hospitality Association

Comment: WAC 314-02-103 poses a "per day" limit on sales between on-premises and off-premises retailer. The court struck this language so it needs to be removed.

LCB response: The language was removed in the supplemental CR 102, filed March 22, 2017.

Comment: WAC 314-02-015(3) definition of a restaurant. The proposed rule changes the definition of "restaurant". The proposed rule lacks clarity and is subjective.

LCB response: The proposed rule language was taken from RCW 66.24.410. The current rule referred to the RCW. The proposed rule adds statute language.

Comment: The WHA feels the barrier requirement needs to be revised.

LCB response: The barrier requirement is not addressed in this rulemaking. The board may, at a later date, look into this issue.

Comment: WAC 314-02-035 food service requirements. The proposed rule further restricts what items can and cannot be used to determine a complete meal.

LCB response: The only change to this rule was to clarify that garnishes do not qualify as a side dish. The complete meal language did not change.

Dan Sharp – Washington State Fair

Comment: Self-service of alcohol should be allowed if self-serving dispensing machines are used as in Interim Board Policy BIP 07-2011.

LCB response: Interim Board Policy BIP 07-2011 was adopted to allow self-service beer taps in a restaurant or tavern setting, not a sports/entertainment facility where the crowds are much larger than patrons at a restaurant or tavern. The board will not be changing the rules to allow self-service alcohol at a sports/entertainment facility.

Brett Enright - Juicys

Comment: Allow self-service of alcohol at sports/entertainment facilities. **LCB response:** The board will not be changing the sports/entertainment facility rules to allow self-service of alcohol.

Dave Malone - Miller, Malone & Tellefson

Comment: WAC 314-02-058 – the proposed rule change requires submission of all operating plan changes to the WSLCB's Licensing division for approval. The language doesn't designate what changes would require approval. Only changes that materially alter the size of the facility, its attendance capacity or seek to increase the facility's alcohol beverage service capacity should be required to obtain an approval.

LCB response: Any changes to an operating plan need to be reported and a revised operating plan approved. The board has found many issues where sports/entertainment facilities have made substantial changes to how they operate without notification to the board. The operating plan needs to be correct and represent the operation of the facility.

Comment: WAC 314-02-058 site plans and beer gardens. Licensees don't necessarily use beer gardens for all of their events. The board should approve a maximum number of beer gardens at a facility so the licensee doesn't have to obtain an approval each time they want to add additional beer gardens.

LCB response: The site plan for the facility should include the location of all beer gardens. It is then up to the licensee to decide which, if not all, of the beer

gardens they will use for a given event. The board will already have approved all the beer garden locations whether they are used or not.

Comment: WAC 314-02-058 approval for walk around consumption at trade shows and special events. Requests for this activity should go to enforcement as they do now.

LCB response: These requests will go to enforcement as they do now. The language was added to clarify what information the licensee needs to provide. **Comment:** WAC 314-02-058 darkened house rules. Darkened house has been a board policy since 2006. Intervening statutory and rule changes call into

question whether the proposed rules are necessary.

LCB response: There have been no law or rule changes regarding sports/entertainment facility licenses. The rules are needed to clarify the process to get alcohol consumption in a darkened sports/entertainment facility. Local jurisdictions are required to approve of this activity and take full responsibility for control of the darkened area of the establishment.

Supplemental CR 102 was filed March 22, 2017, WSR 17-07-134. The following comments were received:

Josh McDonald – Washington Wine Institute

Comment: WAC 314-03-100 requires prior written notice to the board if a licensee is having a one-time event outside service extending beyond their licensed premises. This requirement would impose an unnecessary burden on wineries.

LCB response: The language of this rule was not changed in any way. The rule was moved from WAC 314-02-125 to Chapter 314-03. The language has been in rule since 2010. The rule has not appeared to create a burden to wineries.

Comment: WAC 314-07-055 temporary retail licenses. The privilege of having a temporary license is currently not available for wineries or breweries. We would ask the board to allow temporary licenses for wineries and breweries.

LCB response: RCW 66.24.010 does not authorize a temporary license for breweries or wineries.

Comment: WAC 314-03-200 would negatively impact our wineries that hold outdoor events.

LCB response: The language of this rule was not changed in any way. The rule was moved from WAC 314-02-130 to Chapter 314-03. The rule has not appeared to negatively impact wineries.

Dan Sharp – Washington State Fair

Comment: Operating plan changes should be submitted to enforcement, not licensing.

LCB response: All license information and approvals are kept in the licensing division. Licensing staff will send copies of any approvals to the appropriate enforcement office.

Comment: Self-service of alcohol should be allowed if self-serving dispensing machines are used as in Interim Board Policy BIP 07-2011.

LCB response: Interim Board Policy BIP 07-2011 was adopted to allow self-service beer taps in a restaurant or tavern setting, not a sports/entertainment facility where the crowds are much larger than patrons at a restaurant or tavern. The board will not be changing the rules to allow self-service alcohol at a sports/entertainment facility.

Adam Smith, Distilled Spirits Council

Comment: We urge the board to include spirits consumption in all seating areas of a sports/entertainment facility. We also urge the board to allow roving servers to sell spirits and wine (not only beer) in seating areas at professional sporting events.

LCB response: The board will not be revising the sports/entertainment rules to allow spirits consumption or roving servers at this time.

Comment: Eliminate the revised definition of "building" that does not include a licensed premises if it is not a "stationary structure" or is a "food truck"

LCB response: The board revised the definition to clarify to applicants and licensees what type of structure is required to obtain a liquor license.

Comment: The ration of staff to attendees appears to be excessive (1:50). **LCB response:** This is not new language. Staff includes alcohol servers and security. The number is not excessive when you combine the staff. Sports/entertainment facility licensees have not had issues with this current requirement.

Comment: A limit of two beverage alcohol drinks per patron to be sold and served per transaction creates unnecessary burdens for both the patron and the venue.

LCB response: This is not new language. Sports/entertainment facility licensees have not had issues with this current rule.

Comment: Requiring sports/entertainment facility licensees to have different containers for alcoholic and non-alcoholic beverages needs to be removed.

LCB response: This is not new language. Sports/entertainment facility licensees have not had issues with this current rule. This is also a public safety issue.

Comment: The board should not require a sports/entertainment facility to obtain prior approval for a special event.

LCB response: This is not new language. The sports/entertainment facility licensees have not had issues with this current rule. Enforcement needs to be aware of special events in order to coordinate enforcement resources for the event.

What changes are being made?

Amended Section. WAC 314-02-005 What is the purpose of chapter 314-02 WAC? Updated the license types covered in this chapter.

Amended Section. WAC 314-02-010 Definitions. Clarified the definition of "dedicated dining area".

Amended Section. WAC 314-02-015 What is a spirits, beer, and wine restaurant license? Defined "bona fide restaurant".

Amended Section. WAC 314-02-020 What are the fee categories for a spirits, beer, and wine restaurant license? Clarified designated dining area must be inside of a restaurant.

Amended Section. WAC 314-02-025 What are the floor space requirements to obtain and maintain a spirits, beer, and wine restaurant or a beer and wine restaurant? Corrected the name of the board. Clarified structures where customers can sit or stand and consume food or liquor is not acceptable as a barrier. Added qualifications for floor space in at a convention center.

Amended Section. WAC 314-02-035 What are the food service requirements for a spirits, beer, and wine restaurant license? Clarified garnishes do not qualify as a side dish.

Amended Section. WAC 314-02-037 What are the floor space requirements for a spirits, beer, and wine nightclub license? Corrected the name of the board.

Amended Section. WAC 314-02-043 What is a VIP airport lounge license? Corrected the RCW reference.

Amended Section. WAC 314-02-044 Application process and guidelines for a VIP airport lounge liquor license. Removed reference that alcohol must be purchased from the board.

Amended Section. WAC 314-02-056 Sport/entertainment facility license – Purpose. Corrected the name of the board. Added information on amateur sports organizations and racetracks.

Amended Section. WAC 314-02-057 Definitions. Added to the definition of "hawking".

Amended Section. WAC 314-02-058 Sports/entertainment facility licenses – Operating plans. Clarified changes to an operating plan must be submitted to licensing division for approval. Added site plan requirements. Corrected the name of the board. Clarified that self-service alcohol is prohibited. Added darkened house events to the matrix. Added requirements to request alcohol consumption at darkened house events.

Amended Section. WAC 314-02-060 What is a caterer's endorsement? Clarified where catered events may be held.

Amended Section. WAC 314-02-070 What is a tavern license? Clarified requirements for the sale of growlers of beer.

Amended Section. WAC 314-02-097 What is a spirits, beer, and wine theater license? Clarified the required number of seats is per theater room. Clarified garnished do not qualify as a side dish.

Amended Section. WAC 314-02-105 What is a beer and/or specialty shop? Clarified that a sketch must be submitted showing the area that sampling will be conducted.

Amended Section. WAC 314-02-106 What is a spirits retailer license? Removed language that limited sales to on-premises licensees to one per day.

Amended Section. WAC 314-02-109 What are the quarterly reporting and payment requirements for a spirits retailer license? Added language that failure of a spirits retailer licensee to submit its quarterly reports and payment for two consecutive quarters will be sufficient grounds for the board to revoke the liquor license.

Amended Section. WAC 314-02-112 What is a caterer's license? Added language allowing the caterer's licensees to share a commissary kitchen under certain conditions. Corrected the name of the board.

Amended Section. WAC 314-02-120 How do licensees get keg registration forms? Corrected the name of the board.

Repealed Section. WAC 314-02-125 What types of activities on a licensed premises require notice to the board? Moved this section to WAC 314-03.

Repealed Section. WAC 314-02-130 What types of changes to a licensed premises require board approval. Moved this section to WAC 314-03.

New Section. WAC 314-03-100 What types of activities on a licensed premises require notice to the board. Moved from WAC 314-02-125.

New Section. WAC 314-03-200 Outside or extended alcohol service. Moved from WAC 314-02-130.

New Section. WAC 314-03-300 Alterations to a licensed premises. Moved from WAC 314-02-130.

Amended Title. Chapter 314-07 WAC How to apply for and maintain a liquor license.

Amended Section. WAC 314-07-005 What is the purpose of this chapter. Added the purpose was to outline the qualifications and steps necessary to receive and maintain a liquor license or permit.

Amended Section. WAC 314-07-010 Definitions. Clarified the definition of "building". Clarified the definition of "financier".

Amended Section. WAC 314-07-015 General information about liquor licenses. Clarified language that required qualifications to receive a license must be continued. Added conditions for issuance of a liquor license at a personal residence.

Amended Section. WAC 314-07-035 What persons or entities have to qualify for a liquor license. Clarified the board reserves the right to investigate any person or entity in a liquor license application or current liquor license where hidden ownership or misrepresentation of fact is suspected. Added clarifying language on who is considered a true party of interest.

Amended Section. WAC 314-07-040 What criminal history might prevent a liquor license applicant or licensee from receiving or keeping a liquor license? Added the word "licensee" in the title of the WAC. Changed the name in the rule from "an applicant" to "a true party of interest". Added language that current liquor licensees are required to notify the board within 30 days of any arrests or criminal convictions. Failure to do so may result in revocation of the liquor license.

Amended Section. WAC 314-07-055 Temporary retail license. Clarified the qualifications and process to receive a temporary retail license.

Amended Section. WAC 314-07-060 Reasons for denial or revocation of a temporary license. Changed the word "cancellation" to "revocation" in the WAC title.

Amended Section. WAC 314-07-065 Reasons the board may deny a liquor license application. Changed the words "applicant or financier" to "person or entity associated with the application".

Amended Section. WAC 314-11-065 What type of liquor is allowed on a licensed premises? Corrected the RCW reference. Added language "under the authority of a special occasion license".

Amended Section. WAC 314-12-020 Continuing conditions to hold a liquor license. Changed the title of the WAC. Repealed most of the WAC and added minimum required qualifications to receive a license must be continued in order to maintain the liquor license.

Amended Section. WAC 314-12-030 Display of license. Revised title of WAC. Repealed most of section with the exception of requiring licenses be prominently displayed.

Repealed Section. Limited partnerships. This rule was no longer needed.

Amended Section. WAC 314-12-050 Loss or destruction of licenses, permits, etc. – Fee. Clarified how to replace a license or permit issued by the board.

Amended Section. WAC 314-12-070 Applications for currently licensed locations. Removed RCW reference. Repealed most of the section

Repealed Section. WAC 314-12-200 Converting a public house license to a domestic brewery, microbrewery or domestic winery license. This section was no longer needed.

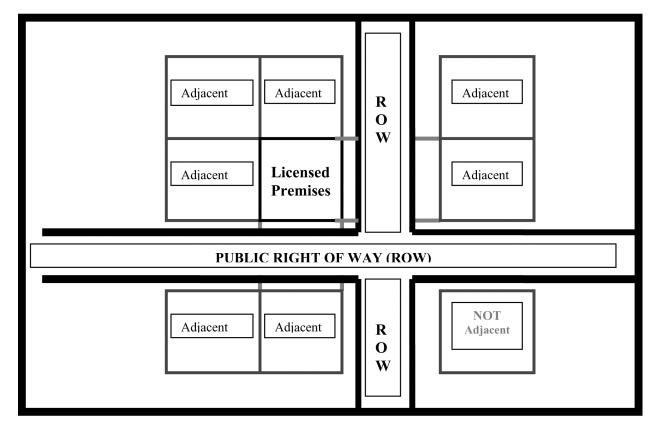
AMENDATORY SECTION (Amending WSR 11-01-133, filed 12/21/10, effective 1/21/11)

WAC 314-02-005 What is the purpose of chapter 314-02 WAC? Chapter 314-02 WAC outlines the qualifications for the following liquor licenses:

- (1) Spirits, beer, and wine restaurants;
- (2) Nightclubs;
- (3) Spirits, beer, and wine restaurant restricted;
- (4) Hotels;
- (5) Spirits, beer, and wine theater;
- (6) Beer and wine theater;
- (7) VIP airport lounge;
- (8) Beer and/or wine restaurants;
- $((\frac{6}{1}))$ (9) Sports/entertainment facilities;
- $((\frac{7}{10}))$ (10) Snack bars;
- $((\frac{8}{11}))$ Taverns;
- $((\frac{9}{12}))$ <u>(12)</u> Motels;
- (((10))) (13) Nonprofit arts organizations;
- $((\frac{(11)}{(12)}))$ $\overline{(14)}$ Grocery stores; $((\frac{(12)}{(12)}))$ $\overline{(15)}$ Beer/wine specialty shops; $((\frac{11}{(12)}))$
- (13))) (16) Beer/wine gift delivery businesses;
- (17) Spirits retailer;
- (18) Caterers; and
- (19) Senior center.

AMENDATORY SECTION (Amending WSR 11-01-133, filed 12/21/10, effective 1/21/11)

- WAC 314-02-010 Definitions. The following definitions are to clarify the purpose and intent of the rules and laws governing liquor licenses and permits. Additional definitions can be found in RCW 66.04.010.
- (1) "Adjacent" means having a common endpoint or border where the extension of the property lines of the licensed premises contacts that common border.



- (2) "Appetizer" means a small portion of food served before the main course of a meal to stimulate the appetite. An appetizer does not qualify as minimum food service.
- (3) "Banquet room" means any room used primarily for the sale and service of food and liquor to private groups.
- (4) "Customer service area" means areas where food and/or liquor are normally sold and served to the public, i.e., lounges and dining areas. A banquet room is not considered a customer service area.
- (5) "Dedicated dining area." In order for an area to qualify as a dedicated dining area, it must be a distinct portion <u>inside</u> of a restaurant that is used primarily for the sale, service, and consumption of food, and have accommodations for eating, e.g., tables, chairs, booths, etc. See WAC 314-02-025 for more information.
- (6) "Designated area" means a space where alcohol may be sold, served, or consumed.
- (7) "Entertainer" means someone who performs for an audience such as a disc jockey, singer, or comedian, or anyone providing entertainment services for the licensee. An entertainer is considered an employee of the liquor licensee per WAC 314-01-005. Patrons participating in entertainment are not considered employees.
- (8) "Entertainment" means dancing, karaoke, singing, comedy shows, concerts, TV broadcasts, contests with patron participation and/or performing for an audience.
- (9) "Food counter" means a table or counter set up for the primary purpose of food service to customers who sit or stand at the counter. Any alcohol served is incidental to food service.
- (10) "Game room" means an area of a business set up for the primary purpose of patrons using games or gaming devices.
- (11) "Limited food service" means items such as appetizers, sand-wiches, salads, soups, pizza, hamburgers, or fry orders.

[2] OTS-8310.3

- (12) "Liquor bar" means a table or counter where alcohol is stored or prepared and served to customers who sit or stand at the bar. Liquor bars can only be in lounges or in premises where minors are not allowed at any time.
- (13) "Lounge" means the portion of a restaurant used primarily for the preparation, sale, and service of beer, wine, or spirits. Minors are not allowed in a lounge (see RCW 66.44.316 for information on employees and professional musicians under twenty-one years of age).
- (14) "Minimum food service" means items such as sandwiches, salad, soup, pizza, hamburgers, and fry orders.
 - (15) "Minor" means a person under twenty-one years of age.
- (16) "On-premises liquor licensed premises" means a building in which a business is located inside that is allowed to sell alcohol for consumption on the licensed premises.
- (17) "Service bar" means a fixed or portable table, counter, cart, or similar work station primarily used to prepare, mix, serve, and sell alcohol that is picked up by employees or customers. Customers may not be seated or allowed to consume food or alcohol at a service bar.
- (18) "Snack food" means items such as peanuts, popcorn, and chips.

AMENDATORY SECTION (Amending WSR 15-01-001, filed 12/3/14, effective 1/3/15)

- WAC 314-02-015 What is a spirits, beer, and wine restaurant license? (1) Per RCW 66.24.400, this license allows a restaurant to:
- (a) Serve spirits by the individual glass for on-premises consumption;
- (b) Serve beer by the bottle or can or by tap for on-premises consumption;
 - (c) Serve wine for on-premises consumption;
- (d) Allow patrons to remove recorked wine from the licensed premises;
- (e) Sell wine by the bottle for off-premises consumption with the appropriate endorsement; and
- (f) Sell kegs of malt liquor with the appropriate endorsement. This endorsement also allows the sale of beer or cider as defined in RCW 66.24.210(6) to a purchaser in a sanitary container brought to the premises by the purchaser or furnished by the licensee and filled at the tap by the retailer at the time of sale.
- (2) To obtain and maintain a spirits, beer, and wine restaurant license, the restaurant must be open to the public at least five hours a day during the hours of 8:00 a.m. and 11:00 p.m., three days a week.
- (3) All applicants for a spirits, beer, and wine license must establish, to the satisfaction of the board, ((that)) the premises will operate as a bona fide restaurant. The term "bona fide restaurant" ((that)) means a business where the board can clearly determine that the primary purpose of the business is the service of complete meals. "Complete meals" is defined in WAC 314-02-035.

[3] OTS-8310.3

AMENDATORY SECTION (Amending WSR 11-23-045, filed 11/9/11, effective 12/10/11)

WAC 314-02-020 What are the fee categories for a spirits, beer, and wine restaurant license? (1) Per RCW 66.24.420, the annual fee for a spirits, beer, and wine restaurant license is graduated, as follows:

Amount of customer service area dedicated to dining	Annual fee
100%	\$1,000
50 - 99%	\$1,600
Less than 50%	\$2,000

- (2) In order for an area to qualify as a dedicated dining area it must be a separate and distinct portion <u>inside</u> of a restaurant that is used primarily for the sale, service, and consumption of food, and have accommodations for eating, e.g., tables, chairs, booths, etc. Areas dedicated to live music or entertainment, such as dance floors or stages are not considered dedicated dining areas. Dedicated dining areas may not contain:
 - (a) Liquor bars (see definition under WAC 314-02-010(2)); or
 - (b) Areas dedicated to games or gaming devices.
- (3) The fee for a spirits, beer, and wine restaurant license outside of an incorporated city or town will be prorated according to the calendar quarters the licensee is open for business. This proration does not apply in the case of a suspension or revocation of the license.
- (4) A duplicate license is required in order to sell liquor from more than one site on your property. These sites must be located on the same property and owned by the same licensee. The following types of businesses may apply for a duplicate license:

Type of Business	Annual fee per duplicate license
Airport terminal	25% of annual license fee
Civic center (such as a convention center)	\$10
Privately owned facility open to the public	\$20

 $\underline{\text{AMENDATORY SECTION}}$ (Amending WSR 11-01-133, filed 12/21/10, effective 1/21/11)

WAC 314-02-025 What are the floor space requirements to obtain and maintain a spirits, beer, and wine restaurant license or a beer and wine restaurant license? (1) The liquor ((control)) and cannabis board has the responsibility to classify what licensed premises or what portions of the licensed premises are off-limits to minors. (RCW 66.44.310(2).) Minors may not purchase, possess, or consume liquor, and may not enter any areas that are classified as off-limits to minors. (RCW 66.44.290 and 66.44.310.) The purpose of this rule is to

clarify the ways in which licensees can prevent minors from consuming alcohol or entering restricted areas.

- (2) Dedicated dining areas If a spirits, beer, and wine restaurant licensee or a beer and wine restaurant licensee that allows minors chooses to have live music, Karaoke, patron dancing, live entertainment, or contests involving physical participation by patrons in the dedicated dining area after 11:00 p.m., the licensee must either:
- (a) Request board approval to reclassify the dining area to a lounge for the period of time that live entertainment is conducted, thus restricting minors during that time; or
- (b) Notify the board's licensing and regulation division in writing at least forty-eight hours in advance that the sale, service, and consumption of liquor will end in the dedicated dining area after 11:00 p.m.

Request or notifications may cover one event or a series of recurring events over a period of time.

- (3) **Barriers** Licensees must place barriers around areas that are classified as off-limits to minors and around game rooms.
- (a) The barriers must clearly separate restricted areas, and must be at least forty-two inches high.
- (b) The barriers must be permanently affixed (folding or retractable doors or other barriers that are permanently affixed are acceptable). A portable or moveable rope and stanchion is not acceptable. Those licensees that have been approved by the board for moveable barriers prior to the effective date of this rule may keep their ((movable)) moveable barriers until the licensee requests alterations to the premises or the premises change ownership.
- (c) ((Liquor bars cannot be used as the required barriers (see definition of liquor bar in WAC 314-02-010(10)).)) Structures where customers can sit or stand and consume food or liquor are not acceptable as a barrier.
- (d) Entrances to restricted areas may not be wider than ten feet. If a licensee has more than one entrance along one wall, the total entrance areas may not exceed ten feet.
- (e) "Minor prohibited" signs, as required by WAC 314-11-060(1), must be posted at each entrance to restricted areas.
- (4) If the business allows minors, the business's primary entrance must open directly into a dedicated dining area or into a neutral area, such as a lobby or foyer, that leads directly to a dedicated dining area. Minors must be able to access restrooms without passing through a lounge or other age-restricted area.
- (5) **Floor plans** When applying for a license, the applicant must provide to the board's licensing and regulation division two copies of a detailed drawing of the entire premises. The drawing must:
 - (a) Be drawn one foot to one-quarter-inch scale;
- (b) Have all rooms labeled according to their use; e.g., dining room, lounge, game room, kitchen, etc.; and
- (c) Have all barriers labeled in a descriptive way; e.g., "full wall," "half wall," etc.
- (6) Convention centers To qualify for a convention center there must be two or more rooms that provide space and accommodations for private events only. Licensees holding a convention center may only sell alcohol for private events at the licensed premises.

[5] OTS-8310.3

WAC 314-02-035 What are the food service requirements for a spirits, beer, and wine restaurant license? (1) A spirits, beer, and wine restaurant licensee must serve at least eight complete meals. The board may make an exception to the eight complete meal requirement on a case-by-case basis. Establishments shall be maintained in a substantial manner as a place for preparing, cooking and serving of complete meals. For purposes of this title:

- (a) "Complete meal" means an entree and at least one side dish.
- (b) "Entree" means the main course of a meal. Some examples of entrees are fish, steak, chicken, pork, pasta, pizza, hamburgers, seafood salad, Cobb salad, chef's salad, sandwiches, and breakfast items (as long as they include a side dish). Entrees do not include snack items, or menu items which consist solely of precooked frozen food that is reheated, or consist solely of carry-out items obtained from another business.
- (c) Examples of side dishes are soups, vegetables, salads, potatoes, french fries, rice, fruit, and bread. <u>Garnishes such as, but not limited to, pickles, salsa, and dips do not qualify as a side dish.</u>
- (2) The restaurant must maintain the kitchen equipment necessary to prepare the complete meals required under this section.
- (3) The complete meals must be prepared on the restaurant premises.
- (4) A chef or cook must be on duty while complete meals are offered.
 - (5) A menu must be available to customers.
- (6) The food items required to maintain the menu must be on the restaurant premises. These items must be edible.
- (7) Restaurants that have one hundred percent dedicated dining area must maintain complete meal service any time liquor is available for sale, service, or consumption.
- (8) Restaurants with less than one hundred percent dedicated dining area must maintain complete meal service for a minimum of five hours a day during the hours of 8:00 a.m. and 11:00 p.m., ((five)) three days a week. ((The board may consider written requests for exceptions to this requirement due to demonstrated hardship, under such terms and conditions as the board determines are in the best interests of the public.))

Limited food service, such as appetizers, sandwiches, salads, soups, pizza, hamburgers, or fry orders, must be available outside of these hours. Snacks such as peanuts, popcorn, and chips do not qualify as limited food service.

(9) The hours of complete meal service must be conspicuously posted on the premises or listed on the menu. A statement that limited food service is available outside of those hours must also be posted or listed on the menu.

- WAC 314-02-037 What are the floor space requirements for a spirits, beer, and wine nightclub license? (1) The liquor ((control)) and cannabis board has the responsibility to classify what licensed premises or what portions of a licensed premises are off limits to minors.
- (a) Any areas in the licensed premises where alcohol is sold, served, or consumed is classified as off-limits to minors (RCW 66.44.310(2)).
- (b) Minors may be allowed on the licensed premises but only in areas where alcohol is not served or consumed.
- (2) **Barriers** Licensees must place barriers separating restricted areas from areas where minors will be allowed.
- (a) The barriers must clearly separate restricted areas and must be at least forty-two inches high.
 - (b) The barriers may be moveable.
- (c) ((Liquor bars cannot be used as barriers (see definition of liquor bar in WAC 314-02-010(10)).
- $\frac{(d)}{(d)}$)) Entrances to restricted areas may not be wider than ten feet. If a licensee has more than one entrance along one wall, the total entrance areas may not exceed ten feet.
- $((\frac{(e)}{(e)}))$ $\underline{(d)}$ "Minor prohibited" signs, as required under WAC 314-11-060(1), must be posted at each entrance to a restricted area.
- (3) If the business allows minors, the primary entrance must open directly into a nonrestricted area. Minors must be able to access restrooms without passing through a restricted area.
- (4) Floor plans When applying for a spirits, beer, and wine nightclub license, the applicant must provide to the board's licensing and regulation division two copies of a detailed drawing of the entire premises. If there will be different floor plans for different types of events that change the location and/or dimensions of the restricted area(s), the applicant must provide two copies of a detailed drawing for each floor plan. All restricted areas must be designated on the floor plan(s) and be approved by the board. The drawing must be labeled with the type of event. The drawing must:
- (a) Have all rooms labeled according to their use; e.g., lounge, dance floor, stage area, foyer, restrooms, etc.; and
- (b) Have all barriers labeled in a descriptive way; e.g., "full wall," "half wall," etc.

<u>AMENDATORY SECTION</u> (Amending WSR 11-23-045, filed 11/9/11, effective 12/10/11)

- WAC 314-02-043 What is a VIP airport lounge license? (1) Per RCW ((66.24.XXX)) 66.24.610, a VIP airport lounge liquor license allows a VIP airport lounge licensee to sell or provide spirits, wine, and beer for on-premises consumption as a retail licensed premises.
- (a) A VIP airport lounge is a retail establishment in an international airport, beyond security checkpoints.
- (b) The VIP airport lounge liquor licensee must be the entity in control of the day-to-day operations of the VIP airport lounge.

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- (c) Spirits, beer, and wine to be sold or provided complimentary by the individual serving for on-premises consumption to persons at least twenty-one years of age or older.
- (d) Customers may not remove spirits, beer, and wine from the premises at any time.
- (e) The VIP airport lounge licensee may only serve liquor from a service bar. A service bar is a work station primarily used to prepare and sell alcoholic beverages that are picked up by the customer. Customers are not permitted to mix their own drinks, sit or consume food or alcohol at the service bar.
 - (f) All alcohol servers must have a valid MAST permit.
 - (2) The annual fee for this license is two thousand dollars.

AMENDATORY SECTION (Amending WSR 11-23-045, filed 11/9/11, effective 12/10/11)

- WAC 314-02-044 Application process and guidelines for a VIP airport lounge liquor license. (1) RCW 66.24.010 states the board will only issue licenses and permits to applicants and locations that meet certain qualifications. Please see chapter 314-07 WAC for liquor license qualifications and application process.
- (2) An applicant for a VIP airport lounge license must include a sketch of the VIP airport lounge area including the service bar area and where the alcohol inventory will be stored.
- (3) All alcohol inventory must be stored on the VIP airport lounge licensed premises.
- (4) ((All spirits must be purchased from the board at the assigned liquor store. Beer and wine must be purchased from a licensed distributor or retail outlet. A VIP lounge licensee may purchase wine directly from a licensed manufacturer if the licensee holds an endorsement to receive direct shipments from a manufacturer.
 - (5))) Access to a VIP airport lounge is generally limited to:
- (a) Ticketed airline passengers of any age who have first class, executive, or business class tickets;
- (b) Qualified members or guests of loyalty incentive programs, members or guests of enhanced amenities programs;
- (c) Passengers or airline employees issued a pass by the airline for access; and
- (d) Airport, airline employees, government officials, and attendees of airport authority or airlines for business promotion with controlled access by the VIP airport lounge licensee.
- ((+6))) (5) Between the hours of 2 a.m. and 6 a.m., licensees or employees may not:
 - (a) Provide, offer, or sell liquor;
- (b) Deliver liquor (except that beer and/or wine distributors may deliver beer and/or wine to retail licensees between the hours of 2 a.m. and 6 a.m.);
 - (c) Allow liquor to be consumed on the premises; or
- (d) Possess liquor, except that persons working on the premises may possess liquor between the hours of 2 a.m. and 6 a.m. while in the performance of their official duties.
- $((\frac{7}{}))$ (6) A local government subdivision may fix later opening hours or earlier closing hours than those specified in this rule, so long as the hours apply to all licensed premises in the local govern-

ment subdivision's jurisdiction. See WAC 314-12-215(3) for exceptions when a premises is in a board recognized alcohol impact area.

AMENDATORY SECTION (Amending WSR 11-01-133, filed 12/21/10, effective 1/21/11)

WAC 314-02-056 Sports/entertainment facility license—Purpose. (1) What is the purpose of the rules governing the use of alcohol in sports/entertainment facilities?

- (a) In RCW 66.24.570, the legislature established a spirits, beer, and wine license for arenas, coliseums, stadiums, or other facilities where sporting, entertainment, and special events are presented.
- (b) These rules provide a framework for the enforcement of liquor laws and regulations, particularly those prohibiting the sale of alcohol to persons under twenty-one years of age or persons who are apparently intoxicated.
- (c) This framework recognizes the unique conditions associated with events attended by large crowds consisting of diverse age groups.
- (2) Will the liquor ((control)) and cannabis board recognize the differences between types of sports/entertainment facilities; professional sports/entertainment facilities, amateur sporting facilities, and racetracks? Yes. A sports/entertainment facility must submit an operating plan, which must be approved by the board prior to the issuance of a license. All plans are required to meet the minimum standards outlined in WAC 314-02-058. The board will take into consideration the unique features of each facility when approving an operating plan, including the seating accommodations, eating facilities, and circulation patterns. The board will allow proration of the sports/entertainment license fees under certain conditions:
 - (a) The licensee is an amateur sports organization; or
 - (b) The licensee is a racetrack that meets specific criteria.
- (3) Amateur sports organizations must meet the following criteria:
- (a) Season length must not be more than three months, with an additional month allowed for playoffs if applicable (requests/approval for any additional months must be made on a case-by-case basis). The venue must remain closed for the remainder of the year.
- (b) Must comply with all elements contained in WAC 314-02-056 through 314-02-059.
 - (c) Must provide proof of amateur status.
- (d) Must provide a statement regarding removal/disposal of alcohol inventory at the end of the season.
 - (e) Seating capacity of the venue may not exceed five thousand.
 - (4) Racetracks must meet the following criteria:
- (a) Must be a seasonal operation of two quarters or less (requests/approval for any additional quarters must be made on a case-by-case basis).
 - (b) Seating capacity of the venue may not exceed five thousand.
 - (c) Maximum number of race days allowed per week is two.
- (d) Per RCW 66.24.010(9) a motor sports facility is required to enforce a program reasonably calculated to prevent alcohol or alcoholic beverages not purchased within the facility from entering the fa-

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cility and such program must be approved by the local law enforcement agency. A copy of this program showing the local law enforcement approval must be submitted to the board's licensing division.

AMENDATORY SECTION (Amending WSR 15-18-040, filed 8/26/15, effective 9/26/15)

- WAC 314-02-057 Definitions. (1) Premises Buildings, parking lots, and any open areas that are adjacent to and owned, leased, or managed by the licensee and under the licensee's control.
- (2) **Event categories** Types of events that the licensee expects to hold on the premises:
- (a) **Professional sporting event** A contest involving paid athletes and sanctioned by a professional sports organization that regulates the specific sport.
- (b) Amateur sporting event A contest or demonstration involving athletes who receive no monetary compensation that is sanctioned by a national or regional amateur athletic regulatory organization.
- (c) **Entertainment event** A concert involving a live musician, a live comedy act, or similar event intended for the entertainment of the audience. Broadcast television or background videos or music does not qualify as live entertainment.
- (d) **Special event** A convention, trade show, or other like public event with prior approval.
- (e) **Private event** An event not open to the public such as a wedding, private party, or business meeting, where the facility or a portion of the facility where the event is held is not accessible to the general public during the time of the private event.
- (3) **Hawking** The practice of selling alcohol in seating areas by roving servers who carry the beverages with them, as outlined in WAC 314-02-058(4). Because of row seating arrangements, servers normally do not have direct access to customers. Therefore, service usually requires that drinks, money, and identification be passed down rows, involving other spectators. Hawking is only allowed at professional sporting events.
- (4) **Club seats** A specifically designated and controlled seating area that is distinct from general seating with food and beverage service provided by servers directly to the customer.

AMENDATORY SECTION (Amending WSR 15-18-040, filed 8/26/15, effective 9/26/15)

- WAC 314-02-058 Sports/entertainment facility licenses—Operating plans. (1) What requirements govern the submission of operating plans?
- (a) To receive a license, a sports/entertainment facility must submit an operating plan for board approval.
- (b) Once approved, the plan remains in effect until the licensee requests a change or the board determines that a change is necessary due to demonstrated problems or conditions not previously considered

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or adequately addressed in the original plan. Changes to an operating plan must be submitted to the board's licensing division for approval.

- (c) The plan must be submitted in a format designated by the board.
 - (d) The plan must contain all of the following elements:
- (i) How the sports/entertainment facility will prevent the sale and service of alcohol to persons under twenty-one years of age and those who appear to be intoxicated.
- (ii) The ratio of alcohol service staff and security staff to the size of the audiences at events where alcohol is being served. The minimum ratio allowed is one staff person to fifty attendees at the event.
- (iii) Training provided to staff who serve, regulate, or supervise the service of alcohol. Mandatory alcohol server training is required for all staff.
- (iv) The facility's policy on the number of alcoholic beverages that will be served to an individual patron during one transaction. Two alcoholic beverages is the maximum number allowed to be sold and served to an individual patron during one transaction.
- (v) An explanation of the alcoholic beverage containers that will be used to ensure they are significantly different from containers utilized from nonalcoholic beverages.
- (vi) A list of event categories (see WAC 314-02-057(2)) to be held in the facility at which alcohol service is planned, along with a request for the level of alcohol service at each event.
 - (vii) The date must be included in the operating plan.
 - (viii) The pages must be numbered in the operating plan.
- (ix) A site plan designating all alcohol service areas. Identify all beer garden areas to include dimensions of the area, capacity, number of alcohol service/security employees staffing the area, and what type/size of barrier will surround the alcohol service area.
- $\underline{(x)}$ The operating plan must be signed by a principal of the licensed entity.
- (e) Prior to the first of each month, the licensee must provide a schedule of events for the upcoming month to the facility's local liquor enforcement office. This schedule must show the date and time of each event during which alcohol service is planned. The licensee must notify the local enforcement office at least seventy-two hours in advance of any events where alcohol service is planned that were not included in the monthly schedule. Notice of private events is not required when the event is being held in conjunction with a professional or amateur sporting event, an entertainment event, or a special event as outlined in WAC 314-02-057(2).
- (2) May the liquor ((control)) and cannabis board impose any other mandatory standards as a part of an operating plan? Yes. To prevent persons who are under twenty-one years of age or who appear intoxicated from gaining access to alcohol, the board may impose the following standards as part of an operating plan:
- (a) The board may require that an operating plan include additional mandatory requirements if it is judged by the board that the plan does not effectively prevent violations of liquor laws and regulations, particularly those that prevent persons under twenty-one years of age or who are apparently intoxicated from obtaining alcohol.
- (b) To permit alcohol servers to establish the age of patrons and to prevent over-service, sports/entertainment facilities must meet minimum lighting requirements established by WAC 314-11-055 in any area where alcohol is served or consumed. For the purpose of estab-

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lishing a permanent technical standard, an operating plan may include a lighting standard measured in foot candles, so long as the candle power of the lighting is, at all times, sufficient to permit alcohol servers to establish the validity of documents printed in eight point type.

- (3) Where will spirits, beer, and wine be allowed in a sports/entertainment facility? The purpose of the following matrix is to outline where and when alcohol service will normally be permitted. Due to the unique nature of each facility, the board will determine the permitted alcohol service based on the facility's approved operating plan.
 - (a) <u>Self-service of alcohol is prohibited</u>.
- (b) If alcohol service is requested outside of the parameters listed below, a special request with justification for the alcohol service area must be submitted with the operating plan for consideration by the board.

Type of event as defined in WAC 314-02-057	Beer, wine, and spirits may be sold and served in approved restaurants, lounges, private suites, and club rooms	Beer, wine, and spirits may be sold and served in temporary lounges, beer gardens, or other approved service areas	Spirits, beer, and wine may be served and consumed in club seats during events	Beer and wine may be consumed throughout seating areas during events	Hawking - beer may be served throughout seating areas, subject to the provisions of WAC 314-02-058(4)
Professional sporting events of baseball, football, basketball, soccer, tennis, volleyball, horse racing, hockey, and track and field events	X	X	X	X	х
All other professional sporting events including WWE, UFC, rodeo, motorcross, national auto racing, and monster truck events (level of alcohol service will be determined on a case-by-case basis per the approved operating plan)	X	X	X	X	
Amateur sporting events (nonpaid athletes)	х	х		<u>X</u>	
Entertainment events	X	X			
Special events (trade shows, conventions)	х	Х			
<u>Darkened house</u> <u>events</u>	<u>X</u>	<u>X</u>	<u>X</u>	<u>X</u>	

- $((\frac{b}{b}))$ <u>(c)</u> For private events, beer, wine, and spirits may be served in the area where the event is held. This area may be a separate meeting or banquet room or the entire facility.
- $((\frac{(c)}{(c)}))$ (d) In order to minimize youth access to alcohol, the board may prohibit or restrict the service of alcohol at events where the attendance is expected to be over thirty percent persons under twenty-one years of age. This restriction will not apply to the professional sporting events outlined in WAC 314-02-057 (2)(a).
- ((4))) (e) To request approval for walk around beer and/or wine consumption at special events, the licensee must provide the board the following information about the event:
 - (i) Type of event;
 - (ii) Demographics of the event;
 - (iii) Lighting at the event; and
 - (iv) If the event is located indoors or outdoors.
- (4) Darkened house. Consumption of alcohol within the darkened seating portions of the venue during entertainment activities are subject to the following conditions:
- (a) Request for darkened house activities will be part of the operating plan.
- (b) The board will only approve darkened house events after notification to the local authority as identified by the licensing division and approval by the designated local authority. The notification will clearly state:
- (i) Primary responsibility for the control of the darkened area of the establishment will rest with the licensee and local law enforcement authorities; and
- (ii) The board will not entertain contradictory recommendations from subdivisions of the local jurisdictions.
- (c) Violation of the darkened house addendum to the operating plan will be viewed as an aggravating factor to a violation rather than a primary enforcement issue.
- (5) Will hawking be allowed at sports/entertainment facilities? Subject to the provisions of this rule, hawking may be permitted in general seating areas for the sale and consumption of beer, at the professional sporting events of baseball, football, basketball, soccer, tennis, volleyball, horse racing, hockey, and track and field events only, as defined by WAC 314-02-057 (2)(a).
- (a) An operating plan must include procedures for hawkers to verify the age of purchasers and to prevent service to apparently intoxicated persons.
- (b) During hawking, any patron may decline to handle alcoholic beverages, either on behalf of themselves and for any person under their supervision. When a patron objects to handling alcohol, hawkers must accommodate the objection. The facility operating plan will address how hawking will be managed, including how hawkers will respond to patron objections to handling alcohol.

AMENDATORY SECTION (Amending WSR 11-23-045, filed 11/9/11, effective 12/10/11)

WAC 314-02-060 What is a caterer's endorsement? (1) A spirits, beer, and wine restaurant and a beer and/or wine restaurant applicant or licensee may apply for a caterer's endorsement, in order to extend

the on-premises license privilege to allow the sale and service of liquor at $((\frac{approved}{approved}))$ locations other than $((\frac{b}{approved}))$ licensed premises. See RCW 66.24.420(6) and 66.24.320(2) for more information about this endorsement.

(2) The annual fee for this endorsement is three hundred fifty dollars.

AMENDATORY SECTION (Amending WSR 15-01-001, filed 12/3/14, effective 1/3/15)

WAC 314-02-070 What is a tavern license? (1) Per RCW 66.24.330 and 66.24.354, this license allows a tavern to:

Privilege	Annual fee
(a) Serve beer by the bottle or can or by tap for on-premises consumption.	\$200
(b) Serve wine for on-premises consumption.	\$200
(c) Sell beer and/or wine in the original, unopened containers for off-premises consumption.	\$120
(d) Sell tap beer for off-premises consumption in a sanitary container holding less than four gallons of beer, ((and brought to the premises by the purchaser)) provided by the purchaser, licensee, or manufacturer and filled by an employee at the time of purchase.	In conjunction with off- premises privilege outlined in (c) of this subsection.
(e) Sell cider as defined in RCW 66.24.210(6) for off-premises consumption to a purchaser in a sanitary container brought to the premises by the purchaser or provided by the licensee and filled at the tap in the tavern at the time of purchase. The licensee must comply with federal regulations.	In conjunction with off- premises privilege outlined in (c) of this subsection.
(f) Sell beer in kegs or other containers holding at least four gallons of beer (see WAC 314-02-110 regarding the requirements for registering kegs).	In conjunction with off-premises privilege outlined in (c) of this subsection.

(2) A tavern licensee may not allow persons under twenty-one years of age on the premises at any time (see RCW 66.44.316 for information regarding employees and professional musicians under twenty-one years of age).

- WAC 314-02-087 What is a spirits, beer, and wine theater license? (1) A spirits, beer, and wine theater is a place of business where motion pictures or other primarily nonparticipatory entertainment or events are shown. The holder of a beer and wine theater license is allowed to sell spirits, beer, strong beer, and wine, at retail, for consumption on the licensed premises.
- (2) The requirements for the spirits, beer, and wine theater license are as follows:
- (a) The theater has no more than one hundred twenty seats per ((screen)) theater room.
- (b) All servers of beer and wine are required to attend a mandatory alcohol server training (MAST) program.
- (c) The serving size for spirits is one and one quarter ounce. The serving size for wine is five ounces. The serving size for beer is twelve ounces.
 - (d) There must be tabletop accommodations for in theater dining.
- (e) If the theater premises will be frequented by minors an alcohol control plan agreement must be signed and submitted to the board during the application process.
- (3) A spirits, beer, and wine theater licensee must serve at least eight complete meals. Establishments shall be maintained in a substantial manner as a place for preparing, cooking, and serving of complete meals.
 - (a) "Complete meal" means an entree and at least one side dish.
- (b) "Entree" means the main course of a meal. Some examples of entrees are fish, steak, chicken, pork, pasta, pizza, hamburgers, seafood salad, Cobb salad, chef's salad, sandwiches, and breakfast items (as long as they include a side dish). Entrees do not include snack items, or menu items which consist solely of precooked frozen food that is reheated, or consist solely of carry-out items obtained from another business.
- (c) Examples of side dishes are soups, vegetables, salads, potatoes, french fries, rice, fruit, and bread. <u>Garnishes such as, but not limited to, pickles, salsa, and dips do not qualify as a side dish.</u>
- (d) The restaurant must maintain the kitchen equipment necessary to prepare the complete meals required under this section.
- (e) The complete meals must be prepared on the restaurant premises.
- (f) A chef or cook must be on duty while complete meals are offered.
 - (g) A menu must be available to customers.
- (h) The food items required to maintain the menu must be on the restaurant premises. These items must be edible.
- (4) The alcohol control plan agreement will be provided on a form by the board and includes the following requirements:
- (a) Ensure that alcoholic beverages are not sold to persons under the age of twenty-one, staff will request identification from any patron who appears to be age thirty or under and who is attempting to purchase an alcoholic beverage.
- (b) Alcoholic beverages must be served in containers that differ significantly from containers utilized for nonalcoholic beverages.
- (c) All alcoholic beverages sold under this license must be sold by the individual drink.

- (d) If staff observes a patron who is in the possession of or who is consuming an alcoholic beverage, who appears to be of questionable age, staff will request identification from that patron. If the patron is unable to produce an acceptable form of identification verifying their age, the alcohol will be confiscated.
- (e) Staff will accept only those forms of identification that are acceptable per WAC 314-11-025 to verify a person's age for the purpose of selling, serving, or allowing a person to possess or consume alcohol.
- (f) All employees involved in the sale, service, and/or supervision of alcoholic beverages will be required to attend MAST to obtain the appropriate permit for their level of service.
- (g) Sufficient lighting must be maintained at the point of sale so that identification can be confirmed and patrons observed for signs of intoxication.
- (h) To ensure alcoholic beverages are served in a safe, responsible, and controlled manner, sales and service of alcoholic beverages will be limited to one serving per person per transaction.
- (i) If a patron is accompanied by another patron who wants to pay for both people's drinks, they may do so, provided that both patrons are of legal age to purchase, and have proper identification, if requested, and are not displaying signs of intoxication.
- (j) Alcohol may only be sold, served, and consumed in areas designated in the alcohol control plan agreement and approved by the board.
- (k) Staff will refuse to sell an alcoholic beverage to any person who appears to be intoxicated. Alcoholic beverages will be removed from any person who appears to be intoxicated.
- (1) This alcohol control plan agreement will be prominently posted on the licensed premises.
- (5) Penalties are doubled for a violation involving minors or the failure to follow the signed alcohol control plan agreement.
- (6) If the theater premises has a restaurant located outside of the actual theater screening areas, spirits, beer, and wine may be served and consumed in the restaurant area.
 - (a) Spirits may be sold by the individual drink.
- (b) Beer may be sold by the pitcher as well as by individual serving for consumption in the restaurant area.
- (c) Wine may be sold by the bottle as well as by the individual serving for consumption in the restaurant area.

<u>AMENDATORY SECTION</u> (Amending WSR 15-01-001, filed 12/3/14, effective 1/3/15)

- WAC 314-02-105 What is a beer and/or wine specialty store license? (1) Per RCW 66.24.371, a beer and/or wine specialty store license allows a licensee to sell beer and/or wine for off-premises consumption.
 - (2) The annual fee for this license is one hundred dollars.
- (3) Qualifications for license To obtain and maintain a beer and/or wine specialty store license, the premises must be stocked with an inventory of beer and/or wine in excess of three thousand dollars wholesale value. This inventory must be:
 - (a) Stocked within the confines of the licensed premises; and

- (b) Maintained on the premises at all times the premises is licensed, with the exception of beginning and closing inventory for seasonal operations or when the inventory is being sold out immediately prior to discontinuing or selling the business.
- (4) Qualifications to sample A beer and/or wine specialty store licensee may allow customers to sample beer and wine for the purpose of sales promotion, if the primary business is the sale of beer and/or wine at retail, and the licensee meets the requirements outlined in either (a) or (b) of this subsection:
- (a) A licensee's gross retail sales of alcohol exceeds fifty percent of all annual gross sales for the entire business; or
- (b) The licensed premises is a beer and/or wine specialty store that conducts bona fide cooking classes for the purpose of pairing beer and/or wine with food, under the following conditions:
- (i) The licensee must establish to the satisfaction of the board that the classes are bona fide cooking courses. The licensee must charge participants a fee for the course(s).
- (ii) The sampling must be limited to a clearly defined area of the premises. The licensee must provide a sketch of the sampling area.
- (iii) The licensee must receive prior approval from the board's licensing and regulation division before conducting sampling with cooking classes.
- (iv) Once approved for sampling, the licensee must provide the board's enforcement and education division a list of all scheduled cooking classes during which beer and/or wine samples will be served. The licensee must notify the board's enforcement and education division at least forty-eight hours in advance if classes are added.
- (5) Licensees who qualify for sampling under subsection (4) of this section may sample under the following conditions:
- (a) Employees conducting sampling must hold a class 12 alcohol server permit;
- (b) No more than a total of ten ounces of alcohol may be provided to a customer during any one visit to the premises;
 - (c) Each sample must be two ounces or less.
- (6) A beer and/or wine specialty store licensee may sell beer in kegs or other containers holding at least four gallons of beer. See WAC 314-02-115 regarding keg registration requirements.
- (7) A beer and/or wine specialty store licensee may receive an endorsement to permit the sale of beer and cider as defined in RCW 66.24.210(6) to a purchaser in a sanitary container brought to the premises by the purchaser, or provided by the licensee or manufacturer, and filled at the tap by the licensee at the time of sale under the following conditions:
- (a) The beer and/or wine specialty store sales of alcohol must exceed fifty percent of their total sales;
- (b) The board may waive the fifty percent beer and/or wine sale criteria if the beer and/or wine specialty store maintains a wholesale alcohol inventory that exceeds fifteen thousand dollars.

AMENDATORY SECTION (Amending WSR 16-01-102, filed 12/16/15, effective 1/16/16)

WAC 314-02-109 What are the quarterly reporting and payment requirements for a spirits retailer license? (1) A spirits retailer must submit quarterly reports and payments to the board.

The required reports must be:

- (a) On a form furnished by the board;
- (b) Filed every quarter, including quarters with no activity or payment due;
- (c) Submitted, with payment due, to the board on or before the twenty-fifth day following the tax quarter (e.g., Quarter 1 (Jan., Feb., Mar.) report is due April 25th). When the twenty-fifth day of the month falls on a Saturday, Sunday, or a legal holiday, the filing must be postmarked by the U.S. Postal Service no later than the next postal business day; and
 - (d) Filed separately for each liquor license held.
- (2) What if a spirits retailer licensee fails to report or pay, or reports or pays late? Failure of a spirits retailer licensee to submit its quarterly reports and payment to the board as required in subsection (1) of this section will be sufficient grounds for the board to suspend or revoke the liquor license.

Failure of a spirits retailer licensee to submit its quarterly reports and payment to the board for two consecutive quarters will be sufficient grounds for the board to revoke the liquor license.

A penalty of one percent per month will be assessed on any payments postmarked after the twenty-fifth day quarterly report is due. When the twenty-fifth day of the month falls on a Saturday, Sunday, or a legal holiday, the filing must be postmarked by the U.S. Postal Service no later than the next postal business day.

Absent a postmark, the date received at the Washington state liquor ((control)) and cannabis board, or designee, will be used to determine if penalties are to be assessed.

<u>AMENDATORY SECTION</u> (Amending WSR 14-24-128, filed 12/3/14, effective 1/3/15)

- WAC 314-02-112 What is a caterer's license? (1) A caterer's license allows the licensee to sell spirits, beer, and wine by the individual serving for consumption on the premises at a catered event location.
- (2) The catered event location must be owned, leased, or operated by:
 - (a) The holder of the caterer's license; or
- (b) The sponsor of the event for which the catering services are being provided.
- (3) The caterer licensee is responsible for all areas of a location where alcohol is sold, served, consumed, or stored.
- (4) If the catered event is open and advertised to the public, the event must be sponsored by a nonprofit society or organization as defined in RCW 66.24.375.

- (a) A registered nonprofit holding a public or civic event may invite a caterer to provide alcohol service at a location within the parameters of the event.
- (b) If attendance at the catered event is limited to members or invited guests of the sponsoring individual, society, or organization, the requirement in subsection (2) of this section does not apply.
- (5) A spirits, beer, and wine caterer licensee must have the ability to serve at least eight complete meals. A commissary kitchen, licensed by the city and/or county health department, shall be maintained in a substantial manner as a place for preparing and cooking complete meals. The caterer licensee must maintain the kitchen equipment necessary to prepare the complete meals required under this section. The complete meals must be prepared at the licensed commissary kitchen premises. For the purposes of this title:
 - (a) "Complete meal" means an entrée and at least one side dish.
- (b) "Entrée" means the main course of a meal. Some examples of entrées are fish, steak, chicken, pork, pasta, pizza, hamburgers, seafood salad, Cobb salad, chef's salad, sandwiches, and breakfast items (as long as they include a side dish). Entrées do not include snack items, or menu items which consist solely of precooked frozen food that is reheated, or consist solely of carry-out items obtained from another business.
- (c) Examples of side dishes are soups, vegetables, salads, potatoes, french fries, rice, fruit, and bread.
- (6) A beer and wine caterer licensee must have the ability to provide minimum food service. A commissary kitchen shall be maintained in a substantial manner as a place for preparing and cooking minimum food service. The caterer licensee must maintain the kitchen equipment necessary to prepare minimum food service required under this section. The minimum food service must be prepared at the licensed commissary kitchen premises. For purposes of this title:

"Minimum food service" means items such as sandwiches, salad, soup, hamburgers, pizza, and fry orders.

<u>Licensees holding a caterer's license may share a commissary kitchen under the following conditions:</u>

- (a) Each licensee has their own secure area for their own liquor stock. Liquor stock cannot be shared.
- (b) If using a shared commissary kitchen, each applicant/licensee must provide a sketch of the commissary kitchen to licensing indicating the separate secured area for each licensee.
- (7) The applicant must provide the liquor ((control)) and cannabis board with a copy of their commissary kitchen license issued by the city or county health department.
- (8) The licensee is required to send a list of scheduled catered events to their regional enforcement office on the first of each month. The licensee must provide the following information:
 - (a) Date of the catered events;
 - (b) Time of the catered events; and
 - (c) Place and location of catered events.
- Any changes to the information provided to the board must be reported to the regional enforcement office seventy-two hours prior to the catered event.
- (9) A caterer's license holder is not allowed to cater events at a liquor licensed premises.
- (10) The holder of the caterer's license may store liquor on other premises operated by the licensee if the licensee owns or has a leasehold interest at the other premises. Documentation must be provi-

ded to the board showing the licensee owns or has a leasehold interest in the property.

- (11) All employees that sell or serve alcohol must hold MAST permits.
 - (12) The annual fee for the caterer's license is as follows:
 - (a) The annual fee for beer is two hundred dollars;
 - (b) The annual fee for wine is two hundred dollars; and
- (c) The annual fee for a combined spirits, beer, and wine is one thousand dollars.

 $\underline{\text{AMENDATORY SECTION}}$ (Amending WSR 11-01-133, filed 12/21/10, effective 1/21/11)

- WAC 314-02-120 How do licensees get keg registration forms? (1) The board will provide keg registration forms free of charge to licensees who hold (a) a beer and/or wine restaurant license in combination with an off-premises beer and/or wine endorsement; (b) a tavern license in combination with an off-premises beer and/or wine endorsement; or (c) a beer and/or wine specialty shop license with a keg endorsement.
- (2) Licensees who hold a grocery store license with a keg endorsement, or a spirits, beer, and wine restaurant license with a keg endorsement, must purchase the keg registration forms. Keg registration books can be ordered online at the liquor ((control)) and cannabis board web site or from the enforcement customer service line for four dollars per book of twenty-five forms.

REPEALER

The following sections of the Washington Administrative Code are repealed:

WAC 314-02-125	What types of activities on a licensed premises require notice to the board?
WAC 314-02-130	What types of changes to a licensed premises require board approval?

Chapter 314-07 WAC HOW TO APPLY FOR AND MAINTAIN A LIQUOR LICENSE

<u>AMENDATORY SECTION</u> (Amending WSR 05-07-012, filed 3/4/05, effective 4/4/05)

WAC 314-07-005 What is the purpose of this chapter? RCW 66.24.010 states the board will only issue licenses and permits to applicants and locations that meet certain qualifications. The purpose of this chapter is to outline the qualifications and steps necessary to receive and maintain a liquor license or permit.

AMENDATORY SECTION (Amending WSR 15-11-106, filed 5/20/15, effective 6/20/15)

- WAC 314-07-010 Definitions. Following are definitions for the purpose of this title. Other definitions are in WAC 314-01-005 and RCW 66.08.010.
- (1) "Applicant" or "liquor license applicant" means any person or business entity who is considered by the board as a true party of interest in a liquor license or permit application, as outlined in WAC 314-07-035.
- (2) "Building" means a <u>stationary</u> structure with floor to ceiling solid walls and a roof. A food truck is not a "building."
- (3) "Business name" or "trade name" means the name of a licensed business as used by the licensee on signs, advertising, etc.
- (4) "Financier" means any person or entity who has made or will make an investment in the licensed business of more than ten thousand dollars. A "financier" can be someone who provides money as a gift, someone who loans money to the business and expects to be paid back the amount of the loan without interest, or someone who invests money into the business expecting a percentage of the profits, but accepts the risk that there may not be a full return on the investment. These persons or entities shall submit appropriate investigation level "financier" financial documents.
- (5) "Licensee" or "liquor licensee" means any person or entity that holds a liquor license or permit, or any person or entity who is a true party of interest in a liquor license or permit, as outlined in WAC 314-07-035.
- (6) "Public institution" means a public college or university. (See WAC 314-07-020 regarding the liquor control board notifying public institutions of liquor license applications.)

[1] OTS-8311.3

AMENDATORY SECTION (Amending WSR 15-11-106, filed 5/20/15, effective 6/20/15)

- WAC 314-07-015 General information about liquor licenses. (1) A person or entity must meet required qualifications to receive a liquor license, ((which are continuing)) and must continue to meet the qualifications in order to maintain the license.
- (2) A liquor license may be approved at a personal residence under the following conditions:
- (a) The proposed licensed premises is either separate from or walled off from personal living quarters.
- (b) The proposed licensed premises has its own entrance separate from the entrance to the personal living quarters.
- (c) Any access from the proposed licensed premises into the personal living quarters is permanently secured.
- (d) Any and all items related to the operation of the proposed licensed business are contained within the licensed premises. This includes, but is not limited to, liquor inventory, business records, computers, equipment and anything else needed for the operation of the licensed business.
- (3) A liquor license applicant may not exercise any of the privileges of a liquor license until the board approves the license application (see WAC 314-07-055 regarding temporary licenses).
- $((\frac{3}{2}))$ $\underline{(4)}$ In approving a liquor license, the board reserves the right to impose special conditions as to the involvement in the operations of the licensed business of any former licensees, their former employees, or any person who does not qualify for a liquor license.

AMENDATORY SECTION (Amending WSR 15-11-106, filed 5/20/15, effective 6/20/15)

WAC 314-07-035 What persons or entities have to qualify for a liquor license? Per RCW 66.24.010(1), a liquor license must be issued in the name(s) of the true party(ies) of interest.

(1) **True parties of interest** - For purposes of this title, "true party of interest" means:

True party of interest	Persons to be qualified	
Sole proprietorship	Sole proprietor and spouse.	
General partnership	All partners and spouses.	
Limited partnership, limited liability partnership, or limited liability limited partnership	 All general partners and spouses; All limited partners that have more than 10% interest in the partnership and their spouses. 	

[2] OTS-8311.3

True party of interest	Persons to be qualified	
Limited liability company	• All members (or persons with equivalent title) with more than 10% interest in the LLC and spouses. (Note: In order for the liquor control board to identify the persons to be qualified, we will need to know all parties that have an interest in the limited liability company or have a pending interest.)	
	All managers (or persons with equivalent title) and their spouses.	
Privately held corporation	All corporate officers (or persons with equivalent title) and their spouses.	
	All stockholders (or persons with equivalent title) and their spouses who hold more than 10% of the issued or outstanding stock. (Note: In order for the liquor control board to identify the persons to be qualified, we will need to know all parties who have been issued or will be issued corporate stock.)	
Publicly held corporation	All corporate officers (or persons with equivalent title).	
Multi-level ownership structures	The liquor control board will review each entity to determine which individuals are to qualify according to the guidelines in this rule.	
Any entity	Any person who is in receipt of, or has the right to receive, more than ten percent of the gross or net sales from the licensed business during any full or partial calendar or fiscal year. For the purposes of this chapter:	
	"Gross sales" includes the entire gross receipts from all sales and services made in, upon, or from the licensed business.	
	"Net sales" means gross sales minus cost of goods sold.	

- (2) For purposes of this section, "true party of interest" does not mean:
- (a) A person or entity receiving reasonable payment for rent (as determined by the board) on a fixed or percentage basis under a bona fide lease or rental obligation, unless the lessor or property manager exercises control over or participates in the management of the business.
- (b) A person who receives a bonus as an employee, if: The employee is on a fixed wage or salary and the bonus is not more than twenty-five percent of the employee's prebonus annual compensation; or the

[3] OTS-8311.3

bonus is based on a written incentive/bonus program that is not out of the ordinary for the services rendered.

- (c) A person or entity contracting with the applicant(s) to sell the property, unless the contract holder exercises control over or participates in the management of the licensed business.
- (d) A person or entity receiving payment of franchise fees on a fixed or percentage basis under a bona fide franchise agreement, unless the person or entity receiving payment of franchise fees exercises control over or participates in the management of the licensed business.
 - (e) A 401K, IRA, or nonfamilial trust.
- (3) **Financiers** The board may conduct a financial investigation of financiers.
- (4) **Persons who exercise control of business** The board may conduct an investigation of any person or entity who exercises any control over the applicant's business operations.

In cases where there is an entity who is in control of the day-to-day business operation (other than the owner) because of an agreement between the owner and the operator, the operating party becomes a true party of interest. The operator must meet all the qualifications of any other true party of interest and if approved, must be the licensee. The owner may be required to be named on the license as a party of interest based on the terms of the agreement, but will not normally be required to meet all the qualifications of a true party of interest.

- (5) The board reserves the right to investigate any person or entity in a liquor license application or current liquor license where hidden ownership or misrepresentation of fact is suspected.
- (6) For purposes of this section, a person or entity who takes more than ten percent of the profits and/or exercises control over the licensed business in a given agreement may be named on the license as a party of interest per this rule. Examples of this are lease, operating plan, concession or management agreement.

WAC 314-07-040 What criminal history might prevent a liquor license applicant or license from receiving or keeping a liquor license? (1) When the board processes a criminal history check on ((an applicant)) a true party of interest, it uses a point system to determine if the person qualifies for a license. The board will not normally issue a liquor license to an applicant who has accumulated eight or more points as indicated below:

Description	Time period during which points will be assigned	Points assigned
Felony conviction	Ten years	12 points
Gross misdemeanor conviction	Three years	5 points

Description	Time period during which points will be assigned	Points assigned
Misdemeanor conviction	Three years	4 points
Currently under federal or state supervision for a felony conviction	n/a	8 points
Nondisclosure of any of the above	n/a	4 points each

- (2) If a case is pending for an alleged offense that would earn eight or more points, the board will hold the application for the disposition of the case. If the disposition is not settled within ninety days, the board may administratively close the application.
- (3) The board will not normally issue a liquor license to any person who has demonstrated a pattern of disregard for laws and rules. A pattern or disregard for laws and rules is inclusive of violation history outside of the liquor and cannabis board, to include other regulatory agencies and other states.
- (4) Current liquor licensees are required to notify the board within thirty days of any arrests or criminal convictions. Failure to do so may result in revocation of the liquor license.

AMENDATORY SECTION (Amending WSR 15-11-106, filed 5/20/15, effective 6/20/15)

- WAC 314-07-060 Reasons for denial or ((eancellation)) revocation of a temporary license. Following is a list of reasons a temporary permit may not be issued or can be revoked. Per RCW 66.24.010, the board has broad discretionary authority to approve or deny a liquor license or permit application. Refusal by the board to issue or extend a temporary license shall not entitle the applicant to request a hearing.
- (1) An applicant who has received a temporary license and their application is later administratively closed, and they reapply for a liquor license at the same location.
 - (2) The local authority objects for any reason.
- (3) The applicant affirmatively refuses to submit documents requested by the board to conduct the application investigation.
- (4) The applicant accrues or is involved in an administrative violation committed while operating under a temporary license.
- (5) The investigator is unable to determine the true party of interest.
- (6) The applicant fails to meet the basic requirements of the license
- (7) An objection is received from a privately or publicly funded elementary or secondary school within five hundred feet of the proposed location.
- (8) Violation history of the applicant is found to be sufficient to raise the application to threshold decision.

[5] OTS-8311.3

(9) Upon denial of the permanent license, the temporary license will be immediately revoked.

AMENDATORY SECTION (Amending WSR 15-11-106, filed 5/20/15, effective 6/20/15)

- WAC 314-07-065 Reasons the board may deny a liquor license application. Following is a list of reasons the board may deny a liquor license application. Per RCW 66.24.010, the board has broad discretionary authority to approve or deny a liquor license or permit application.
- (1) Failure to meet qualifications or requirements for the specific liquor license or privilege, as outlined in this Title 314 WAC and Title 66 RCW.
- (2) Failure by any ((applicant or financier)) person or entity associated with the application to submit information or documentation requested by the board.
- (3) Refusal by any ((applicant or financier)) person or entity associated with the application to submit information or documentation requested by the board.
- (4) Misrepresentation of fact by any ((applicant or financier)) person or entity associated with the application.
- (5) Failure to meet the criminal history standards outlined in WAC 314-07-040.
- (6) Failure to meet the liquor law or rule violation history standards outlined in WAC 314-07-045.
- (7) Source of funds used for the acquisition, startup and operation of the business is questionable or unverified.
- (8) Objection from the local authority or from the public (see WAC 314-09-010 and RCW 66.24.010(8)).
- (9) Objection from the following entities if they are within five hundred feet of the proposed business: A public school, a private school that meets the requirements of chapter 28A.195 RCW, a church, or a public college or university. See WAC 314-09-010 and RCW 66.24.010(9) for more information. Note: Per RCW 66.24.010(9), the board may not issue a new liquor license if the board receives objection from a public school within five hundred feet of the proposed licensed business.
- (10) The board determines that the issuance of the liquor license will not be in the best interest of the welfare, health, or safety of the people of the state.

[6]

AMENDATORY SECTION (Amending WSR 04-15-162, filed 7/21/04, effective 8/21/04)

- WAC 314-11-065 What type of liquor is allowed on a licensed premises? (1) Licensees may only possess and allow persons to consume or possess the type of liquor permitted by the type of liquor license held on the premises; except:
 - (a) Under authority of a banquet permit (see chapter 314-18 WAC);
- (b) Restaurant licensees may allow patrons to bring wine into the premises for consumption with a meal; ((and))
- (c) Beer and/or wine restaurant or tavern licensees may keep spirituous liquor on the premises for use in the manufacture of food products, provided that:
- (i) All food products manufactured contain one percent or less of alcohol by weight (per RCW ((66.12.16.160 [66.12.160]),)) 66.12.160);
- (ii) Customers are made aware that the food products contain liquor($(\frac{1}{2})$); and
- (iii) The beer and/or wine restaurant or tavern licensee notifies the local liquor control board enforcement office in writing before they bring spirituous liquor on the premises.
 - (d) Under the authority of a special occasion license.
- (2) For on-premises liquor licenses, the licensee or employees may not permit the removal of liquor in an open container from the licensed premises, except:
- (a) Liquor brought on a licensed premises under authority of a banquet permit may be resealed in its original container and removed at the end of the banquet permit function;
- (b) Per RCW $66.\overline{24.320}$ and 66.24.400, wine that is sold with a meal may be recorked or resealed and removed from the premises;
- (c) Liquor purchased by registered guests for consumption inside a hotel or motel room may be resealed in its original container and removed from the hotel or motel premises by the guest; and
- (d) Liquor removed from a licensed premises that holds a caterer's endorsement, for the purpose of catering an approved event.

[1] OTS-8312.1

WAC 314-12-020 ((Applicants—Qualifications—Fingerprinting—Criminal history record information checks—))Continuing conditions((—Agreements—Reconsideration of denied applications)) to hold a liquor license. (((1) Where a married person is an applicant for, or holder of a license, the spouse of such applicant, if the parties are maintaining a marital community, shall be required to have the same qualifications as the applicant.

(2) The board may require, as a condition precedent to the original issuance of any annual license, fingerprinting and criminal history record information checks on any person not previously licensed by the board. In addition to the applicant, fingerprinting and criminal history record information checks may be required of the applicant's spouse. In the case of a corporation, fingerprinting and criminal history record information checks may be required of its present and any subsequent officers, manager, and stockholders who hold more than ten percent of the total issued and outstanding stock of the applicant corporation if such persons have not previously had their fingerprints recorded with the board. In the case of a partnership, fingerprinting and criminal history record information checks may be required of all general partners and their spouses. Such fingerprints as are required by the board shall be submitted on forms provided by the board to the Washington state identification section of the Washington state patrol and to the identification division of the Federal Bureau of Investigation in order that these agencies may search their records for prior arrests and convictions of the individuals fingerprinted. The applicant shall give full cooperation to the board and shall assist the board in all aspects of the fingerprinting and criminal history record information check. The applicant may be required to pay a minimal fee to the agency which performs the fingerprinting and criminal history process.

(3) The restrictions on license issuance specified in RCW 66.24.010(2) shall be construed to be continuing conditions for retaining an existing license and any licensed person who ceases to be eligible for issuance of a license under RCW 66.44.010(2) shall also cease to be eligible to hold any license already issued.

(4) The board, in considering an application for a license, may require, in addition to all other information requested concerning the proposed licensed premises (see WAC 314-12-035), that the applicant justify the issuance of the license sought based on an analysis of population trends compared to licenses in the area, any uniqueness of the proposed operation, any unusual circumstances present, plus any other information the applicant(s) may feel will justify the issuance of the license sought.

The board may, at its discretion and for good cause shown, reconsider an application denied for reasons other than objection upon receipt of new information within sixty days of the original denial date. Such reconsiderations are not considered part of the normal license application procedure and must be justified on an individual basis. Should the board determine to reconsider a denied application, notice of such reconsideration shall be given to those persons and/or entities entitled to receive notice of an original license application pursuant to RCW 66.24.010(8). Such notice shall be given at least

[1] OTS-8313.1

twenty days prior to final determination on the reconsideration. Additionally, at the same time the notice is given, a press release will be issued informing the public of the impending reconsideration. The process for applications denied due to objection is outlined in chapter 314-09 WAC.)) A person or entity must meet minimum required qualification to receive a liquor license, and must continue to meet the qualifications in order to maintain the liquor license.

AMENDATORY SECTION (Amending WSR 93-18-094, filed 9/1/93, effective 10/2/93)

- WAC 314-12-030 ((License to reflect true party in interest —))Display of licenses. (1) Pursuant to the requirements of RCW 66.24.010(1), any license issued shall be issued in the name(s) of the true party or parties in interest.
- (2) All licenses (except certificates of approval and agent's licenses) shall be prominently displayed on the licensed premises.
- (((3) For purposes of this section, "true party" shall apply to any person or entity having a substantial interest in the business conducted on the premises to be licensed.
- (4) For purposes of this section, "substantial interest" shall mean any of the following:
- (a) Receipt of, or the right to receive, ten percent or more of the gross sales from the licensed business during any calendar or fiscal year of the licensed business. Gross sales, as used in this section, shall include the entire gross receipts of every kind and nature from the sales and services made in, upon, or from the premises, whether on a credit or cash basis, whether operated by the licensee or manager, except:
 - Any rebates or refunds to customers;
 - The licensee's cost of meals and beverage provided to employees;
 - The amount of sales tax receipts or admission taxes;
- (b) An investment in the licensed business of ten thousand dollars or more; or
- (c) Ownership of stock constituting more than ten percent of the issued or outstanding stock of the licensed business.
- (5) For purposes of this section, "substantial interest" shall not mean:
- (a) A bonus paid to an employee, if the employee is on a fixed wage or salary and the bonus is not more than twenty-five percent of the employee's prebonus annual compensation, or the bonus is based on a written incentive/bonus program and is not out of the ordinary for the services rendered;
- (b) Repayment of a loan or payment on a contract to purchase property unless the loan or contract holder exercises control over or participates in the management of the licensed business;
- (c) Reasonable payment for rent on a fixed or percentage basis under a bona fide lease or rental obligation unless the lessor or property manager exercises control over or participates in the management of the business;
- (d) Payment of franchise fees on a fixed or percentage basis under a bona fide franchise agreement;
 - (e) Payment of dividends to corporate stockholders.))

[2] OTS-8313.1

WAC 314-12-050 Loss or destruction of licenses, permits, etc.— Fee. Upon the loss or destruction of ((any)) <u>a</u> license or permit <u>issued by the board</u> to purchase liquor ((thereunder)), application for a duplicate must be made to the board. Fee: \$5.00.

AMENDATORY SECTION (Amending WSR 96-03-004, filed 1/4/96, effective 2/4/96)

- WAC 314-12-070 Applications for currently licensed locations. (((+1))) No application for any license shall be made except in conformance with RCW 66.24.010, and subject to the following conditions: (((+1))) Except as authorized by WAC 314-12-025,)) The license applicant shall not take possession of the premises, nor exercise any of the privileges of a licensee, nor shall such application be effective until the board shall have approved the same((+))
- (b) In approving any license, the board reserves the right to impose special conditions as to the future connection of the former licensee or any of his employees with the licensed business as in its judgment the circumstances may justify;
- (c) A change of trade name may be made coincident with the issuance of the license without any additional fee.
- (2) The sale of a partnership interest or any change in the partners, either by withdrawal or addition or otherwise, shall be considered a change of ownership and subject to the applicable regulations.
- (3) If the licensee is a corporation, whether as sole licensee or in conjunction with other entities, a change in ownership of any stock shall be deemed a corporate change. The licensed corporation shall report to and obtain written approval from the board, for any proposed change in principal officers and/or the proposed sale of more than ten percent of the corporation's outstanding and/or issued stock before any such changes are made. The board may inquire into all matters in connection with any such sale of stock or proposed change in officers. The board will waive the fee for a corporate change when the proposed change consists solely of dropping an approved officer.
 - (4) For purposes of this regulation:
- (a) "Principal officer" shall mean the president, vice-president, secretary, and treasurer, or the equivalent in title, for a publicly traded corporation, and president, vice-president, secretary, treasurer, or the equivalent in title, and all other officers who hold more than ten percent of the corporate stock, for a privately held corporation.
- (b) The "proposed sale of more than ten percent of the stock" will be calculated as a cumulative total and must be reported to the board when the accumulation of stock transfers or newly issued stock totals more than ten percent of the outstanding and/or issued stock of the licensed corporation)).

[3] OTS-8313.1

REPEALER

The following sections of the Washington Administrative Code are repealed:

Limited partnerships. WAC 314-12-033

WAC 314-12-200

Converting a public house license (RCW 66.24.580) to a domestic brewery, microbrewery or domestic winery

license.

NEW SECTION

- WAC 314-03-100 What types of activities on a licensed premises require notice to the board? Liquor licensees must notify their local enforcement office in writing at least five days prior to conducting the following activities unless the licensee has received an exception from their enforcement officer:
- (1) Male/female dance reviews, subject to the provision of WAC 314-11-050;
 - (2) Live boxing or wrestling;
- (3) Contests or games where patrons are part of the entertainment;
- (4) Hours of operation in between 2:00 a.m. and 6:00 a.m. for licensees that sell liquor for on-premises consumption;
- (5) Closing the business to the general public for a private party; and
- (6) Outside service for one-time events such as a holiday celebration where liquor service and consumption is planned to extend to an area of the premises that does not have board approval for liquor service. The licensee must have leasehold rights to the area where alcohol service and consumption is planned.

NEW SECTION

- WAC 314-03-200 Outside or extended alcohol service. A licensee must request approval from the board's licensing division for ongoing outside or extended alcohol service. The following conditions must be met:
- (1) The area must be enclosed with a permanent or movable barrier a minimum of forty-two inches in height; and
- (2) There must be an interior access to the licensed premises. If the interior access is from a minor restricted area of the premises, minors are prohibited in the outside or extended alcohol service area.
- (3) There must be an attendant, wait staff, or server dedicated to the outside service area when patrons are present.
- (4) Must have leasehold rights to the area and have and be connected to the licensed premises.
- (5) Openings into and out of the outside area cannot exceed ten feet. If there is more than one opening along one side, the total combined opening may not exceed ten feet.
- (6) **Exception.** For sidewalk cafe outside service, the board allows local regulations that, in conjunction with a local sidewalk cafe permit, requires a forty-two inch barrier or permanent demarcation of the designated alcohol service areas for continued enforcement of the boundaries.
- (a) The permanent demarcation must be at all boundaries of the outside service area;
- (b) The permanent demarcation must be at least six inches in diameter;
- (c) The permanent demarcation must be placed at a minimum of ten feet apart;
- (d) There must be an attendant, wait staff, or server dedicated to the outside service area when patrons are present;

[1] OTS-8317.1

- (e) This exception only applies to restaurant liquor licenses with sidewalk cafe service areas contiguous to the liquor licensed premises. "Contiguous" means touching along a boundary or at a point;
- (f) This exception does not apply to beer gardens, standing room only venues, and permitted special events. Board approval is still required with respect to sidewalk cafe barrier requirements.
- (7) Limited exception. The board may grant limited exceptions to the required forty-two inch high barrier for outside alcohol service areas.
- (a) The licensee must have exclusive leasehold rights to the outside service area.
- (b) There must be permanent demarcations at all boundaries of the outside service area for continued enforcement of the boundaries.

NEW SECTION

- WAC 314-03-300 Alterations to a licensed premises. The following changes to a licensed premises require approval from the board's licensing division:
- (1) Any alteration that affects the size of a premises' customer service area.
- (a) The licensee must submit two sets of floor plans showing the changes.
- (b) The board's licensing division will make an initial response on the licensee's request for alterations within five business days.
- (c) The licensee must contact their local liquor enforcement officer when the alteration is completed.
- (d) The licensee may begin liquor service in conjunction with the alteration after the completed alteration is inspected by the liquor enforcement officer.
- (2) Excluding persons under twenty-one years of age from a spirits, beer, and wine restaurant or a spirits, beer, and wine night-club.

The licensee must submit their request to the board's licensing division for an approval.

(3) Excluding persons under twenty-one years of age from the dining area of a beer and/or wine restaurant.

The licensee must submit their request to the board's licensing division for an approval.

(4) Reclassifying a lounge as open to persons under twenty-one years of age for a special event.

The licensee must submit their request to the board's licensing division for an approval.

[2] OTS-8317.1

AMENDATORY SECTION (Amending WSR 15-07-036, filed 3/11/15, effective 4/11/15)

- WAC 314-02-106 What is a spirits retailer license? (1) A spirits retailer licensee may not sell spirits under this license until June 1, 2012. A spirits retailer is a retail license. The holder of a spirits retailer license is allowed to:
- (a) Sell spirits in original containers to consumers for offpremises consumption;
- (b) Sell spirits in original containers to permit holders (see chapter 66.20 RCW);
- (c) Sell spirits in original containers to on-premises liquor retailers, for resale at their licensed premises, although no single sale may exceed twenty-four liters((, and single sales to an on-premises licensee are limited to one per day)); and
 - (d) Export spirits in original containers.
- (2) A spirits retailer licensee that intends to sell to another retailer must possess a basic permit under the Federal Alcohol Administration Act. This permit must provide for purchasing distilled spirits for resale at wholesale. A copy of the federal basic permit must be submitted to the board. A federal basic permit is required for each location from which the spirits retailer licensee plans to sell to another retailer.
- (3) A sale by a spirits retailer licensee is a retail sale only if not for resale to an on-premises spirits retailer. On-premises retail licensees that purchase spirits from a spirits retail licensee must abide by RCW 66.24.630.
- (4) A spirits retail licensee must pay to the board seventeen percent of all spirits sales. The first payment is due to the board October 1, 2012, for sales from June 1, 2012, to June 30, 2012 (see WAC 314-02-109 for quarterly reporting requirements).

Reporting of spirits sales and payment of fees must be submitted on forms provided by the board.

- (5) A spirits retail licensee may apply for a spirits sampling endorsement to conduct spirits sampling if they meet the following criteria:
 - (a) Be a participant in the responsible vendor program;
 - (b) Advertising:
- (i) For spirits retail licensees that also hold a grocery store license, signs advertising spirits samplings may not be placed in the windows or outside of the premises that can be viewed from the public right of way;
- (ii) For spirits retail licensees that also hold a beer/wine specialty store license, advertising of spirits sampling may be advertised but not state that sampling is free of charge.
- (c) Spirits samplings are to be conducted in the following manner:
- (i) Spirits samplings service area and facilities must be located within the licensees' fully enclosed retail area and must be of a size and design that the licensee can observe and control persons in the area.
- (ii) The licensee must provide a sketch of the sampling area. Fixed or moveable barriers are required around the sampling area to ensure that persons under twenty-one years of age and apparently intoxicated persons cannot possess or consume alcohol. The sketch is to be included with the application for the spirits sampling endorsement.

[1] OTS-8616.1

- (iii) Each sample may be no more than one-half ounce of spirits, and no more than a total of one and one-half ounces of spirits samples per person during any one visit to the premises. Spirits samples may be altered with mixers, water, and/or ice.
- (iv) The licensee must have food available for the sampling participants.
- (v) Customers must remain in the service area while consuming samples.
- (vi) All employees serving spirits during sampling events must hold a class 12 server permit.
- (vii) There must be at least two employees on duty when conducting spirits sampling events.
- (viii) Spirits sampling activities are subject to RCW 66.28.305 and 66.28.040.
- (d) Licensees are required to send a list of scheduled spirits samplings to their regional enforcement office at the beginning of each month. The date and time for each sampling must be included.
- (6) The annual fee for a spirits retail license is one hundred sixty-six dollars.

[2]

WAC 314-07-055 Temporary retail license. Applicants may request a temporary retail liquor license in addition to an annual license for the same business. If granted, the temporary license allows the applicant to operate for a period of up to one hundred twenty days while the annual license application is being processed.

Type of Application	Qualification and process to receive a temporary retail license	
(1) New business, existing licensed business, or new license type:	In order to receive a temporary license, the applicant(s) must:	
Applicant is applying for a license at a business location that does not hold a current, valid liquor license.	((• Sign the acknowledgment form.))	
Applicant is applying for the same license privilege at a location that has a valid license that has not expired.	((* Clear a criminal history check, per WAC 314-07-040.))	
Applicant is applying for a license or a business that has an existing license at the location, but the applicant is applying for a different license privilege(s).	 Complete ((a briefing on liquor laws and regulations, per WAC 314-07-020(7))) licensing requirements as determined by the board. The local authority and any churches, schools, or public colleges or universities within 500 feet of the proposed licensed business must have responded to the liquor control board's notice of liquor license application, or the time period must have passed. See WAC 314-07-020, subsections (1), (2), and (3) for more information. 	
	When the annual liquor license is issued, the fee will be pro-rated back to the date of issuance of the temporary license.	

[1] OTS-8617.1

- (2) For the purposes of this section, "retail liquor license" shall include all classes of liquor licenses that allow the holder to sell liquor directly to the public.
- (3) The privilege of having a temporary license issued upon an application for license does not apply to breweries $((\Theta r))_{\perp}$ wineries, or distilleries.
- (4) A temporary license under subsection (1) ((above)) of this section may be issued for a distributor license applicant.

Washington State Liquor and Cannabis Board

Issue Paper

Producer Licenses and Tiers Rules

Date: May 31, 2017

Presented by: Joanna Eide, Policy and Rules Coordinator

Description of the Issue

The purpose of this Issue Paper is to request approval from the Board to file proposed rules (CR 102) for new rules and amendments to rules in Chapter 314-55 WAC Marijuana Licenses, Application Process, Requirements, and Reporting regarding producer licenses and related rules.

Why is rule making necessary?

The WSLCB has heard concerns that small producers are struggling and an interest from the industry for licensees and true parties of interest to hold an interest in more than one producer license. Initially, WSLCB rules stated that a person or business entity may hold interest in up to three (3) producer licenses, which was later limited by a Board Interim Policy (BIP-02-2014) to interest in only one (1) license due to the high volume of producer license applications received and concerns about the level of canopy of marijuana grown in Washington State.

This proposal includes allowing interests in up to three (3) producer license through assumptions of existing licenses only, and adds additional requirements around violation history for license applications. If the increase to interests in producer licenses is approved by the Board, staff will coordinate rescinding the existing Board Interim Policy limiting persons or entities to interest in only one (1) license when the rule changes become effective.

Allowing interests in up to 3 licenses will allow greater flexibility for businesses to be able to "move up the ladder" of tiers by forming partnerships with other licensees if they choose or through assuming an additional, existing license. This will be easier to accomplish if licensees can hold interests in more than one license to accommodate buying and selling of businesses. Further, the market will control whether businesses can expand since many are not currently growing at capacity and readiness to acquire additional license interests can be determined by the licensee who is best suited to determine whether they are ready to expand. Lastly, the proposed changes in this rulemaking maintains the 3 tier structure.

The WSLCB considered adjustments to the tier structure of producer licenses as proposed by industry and through public comment. A full assessment of canopy impacts was done for each of these proposals, each of which involved increases to canopy of varying degrees. Many comments were received with concerns

about canopy impacts. The WSLCB also understands that many producers are not currently growing up to the maximum amount allowed under their license type.

At this time, the WSLCB proposes adjusting tier 1 producer licenses up to 4,000 square feet, which are currently limited to up to 2,000 square feet of canopy. No other adjustments or increases to canopy are included in this proposal. The WSLCB will continue to gather more data on canopy in Washington and may bring forward a proposal for more tier adjustments, if needed, at a later date. Many activities are currently underway to enhance WSLCB's understanding of existing canopy.

Other changes related to producer license rules needed as a result of changing circumstances and upcoming changes to laws are incorporated into this rulemaking. These changes are primarily technical and clarifying in nature, as well as changes required only as a result of 2017 legislation. It should be noted that many of these changes relate to voluntary or optional activities for producer licenses, such as sales of immature marijuana plants or clones and marijuana seeds to marijuana research licensees, qualified patients, or designated providers. Additional rulemaking already planned as a result of 2017 legislation will further provide provisions in rule for these activities, but minor changes were needed in this rulemaking for logistical purposes since a WAC may not be open in two rulemakings at once (codifying issues).

What changes are being proposed?

Amendatory Section. WAC 314-55-045, What is a marijuana producer license and what are the requirements and fees related to a marijuana producer license?

Proposed changes include new regulatory violation history considerations for new license applicants and license renewals. The point system included in the proposed changes is similar to point systems for other licenses the WSLCB regulates, and includes provisions related to considering verbal or written warnings when assessing applicants or current licensees. The title of the WAC is amended slightly to communicate that the requirements apply at initial licensure and at renewal. Provisions regarding unpaid fines for administrative violations are included so the WSLCB can take those into account when for license assumptions and license renewals.

Amendatory Section. WAC 314-55-075, What is a marijuana producer license and what are the requirements and fees related to a marijuana producer license?

 Added language regarding upcoming changes to law (effective July 23, 2017) that will allow producers to sell immature plants or clones and seeds to members of a registered cooperative, qualified patients, and

- designated providers. Provisions on how sales to qualified patients and designated providers must occur will be addressed in a separate rulemaking.
- Removed language regarding the initial application window as it is now closed.
- Specified that the maximum amount of space for marijuana production cannot exceed the amount licensed. Current rule language states that it would be imposed at a later date. Setting the maximum amount at the amount licensed is a natural and logical limit.
- Clarified language regarding sight obscure fencing to provide clarity as some issues have been encountered with fencing and walls that are not sight obscure.
- Increased tier 1 producers from 2,000 sq. ft. maximum canopy to 4,000 sq. ft. maximum.

NOTE: As noted above, additional adjustments to other rules to accommodate the changes in this rulemaking will be made in the Technical/Clarifying Changes to Chapter 314-55 WAC Rulemaking and the upcoming 2017 Marijuana Legislation Rulemaking.

WAC 314-55-045 What marijuana law or rule violation history might prevent an applicant from receiving or renewing a marijuana license? The WSLCB will conduct an investigation of all applicants' marijuana law or rule administrative violation history.

(1) The WSLCB will not normally issue a marijuana license to a person, or to an entity with a true party of interest, who has the following violation history; or to any person who has demonstrated a pattern of disregard for laws or rules.:

Violation Type (see WAC 314-55-515)	Period of Consideration
Three or more public safety violations;	 Violations issued within three years of the date the application is received by the board's licensing and regulation division.
Four or more regulatory violations; or	
One to four, or more license violations.	Violations issued within the last three years the true party(ies) of interest were licensed.

(2) The WSLCB will not normally issue or renew a marijuana license to an applicant or licensee who has accumulated eight or more points as indicated below:

Violation Type (See WAC 314-55-515 through 314- 55-537)	Time period during which points will be assigned	Points assigned
Violations involving:	Five years	10 points

Violation Type (See WAC 314-55-515 through 314-	Time period during which points will be	D. C.
<u>55-537)</u>	<u>assigned</u>	Points assigned
• True Party of Inter- est/Undisclosed Fi- nanciers		
 Refusal to allow an inspection and/or obstructing a law enforcement officer from performing their official duties. RCW 69.50.401 		
WAC 314-55-110		
WAC 314-55-185		
RCW 9A.76.020		
• Violations against Public Safety as prescribed in WAC 314- 55-520	Three years	4 points
TraceabilitySecurityPesticides	Three years	3 points
WAC 314-55-083 WAC 314-55-084		
Other Regulatory vi- olations of RCW 69.50 and/or WAC 314-55	Three years	2 points

(3) The WSLCB will not normally issue or renew a marijuana license to a person or entity who has demonstrated a pattern of disregard for laws or rules including, but not limited to, written or verbal warnings.

(4) The WSLCB will not normally issue or renew a marijuana license if the applicant or licensee has unpaid fines related to violations of rules under this chapter.

[Statutory Authority: RCW 69.50.342 and 69.50.345. WSR 16-11-110, § 314-55-045, filed 5/18/16, effective 6/18/16. Statutory Authority: RCW 69.50.325, 69.50.331, 69.50.342, 69.50.345. WSR 13-21-104, § 314-55-045, filed 10/21/13, effective 11/21/13.]

WAC 314-55-075 What is a marijuana producer license and what are the requirements and fees related to a marijuana producer license? (1)(a) A marijuana producer license allows the licensee to produce, harvest, trim, dry, cure, and package marijuana into lots for sale at wholesale to marijuana processor licensees and to other marijuana producer licensees. A marijuana producer can also produce and sell:

- (i) Marijuana plants, seed, and plant tissue culture to other marijuana producer licensees; and
- (ii) <u>Immature Mmarijuana plants or clones and marijuana seeds</u> to members of a registered cooperative, qualified patients, or designated <u>providers</u> under the conditions provided in WAC 314-55-410.this chapter; and

- (iii) Immature marijuana plants or clones and marijuana seeds to a licensed marijuana researcher under the conditions provided in this chapter.
- (b) Marijuana production must take place within a fully enclosed secure indoor facility or greenhouse with rigid walls, a roof, and doors. Outdoor production may take place in nonrigid greenhouses, other structures, or an expanse of open or cleared ground fully enclosed by a physical barrier. To obscure public view of the premises, outdoor production must be enclosed by a sight obscure commercial-grade security fence or wall or fence at least eight feet high. Outdoor producers must meet security requirements described in WAC 314-55-083. An outdoor grow must be physically separated at least twenty feet from another licensed outdoor grow. Outdoor grows cannot share common walls or fences.
- (2) The application fee for a marijuana producer license is two hundred fifty dollars. The applicant is also responsible for paying the fees required by the approved vendor for fingerprint evaluation.
- (3) The annual fee for issuance and renewal of a marijuana producer license is one thousand three hundred dollars. The WSLCB will conduct random criminal history checks at the time of renewal that will require the licensee to submit fingerprints for evaluation from the approved

vendor. The licensee will be responsible for all fees required for the criminal history checks.

- (4) The WSLCB will initially limit the opportunity to apply for a marijuana producer license to a thirty-day calendar window beginning with the effective date of this section. In order for a marijuana producer application license to be considered it must be received no later than thirty days after the effective date of the rules adopted by the WSLCB. The application window for marijuana producer licenses is closed. The WSLCB may reopen the marijuana producer application window after the initial evaluation of the applications received and at subsequent times when the WSLCB deems necessary.
- (5) Any entity and/or principals within any entity are limited to an interest, as defined in WAC 314-55-035(1), in no more than three marijuana producer licenses.
- (6) The maximum amount of space for marijuana production will be imposed at a later datecannot exceed the amount licensed. Applicants must designate on their operating plan the size category of the production premises and the amount of actual square footage in their premises that will be designated as plant canopy. There are three categories as follows:
 - (a) Tier 1 Less than two Up to four thousand square feet;

- (b) Tier 2 $\frac{1}{1}$ Two Four thousand square feet $\frac{1}{1}$ to ten thousand square feet; and
- (c) Tier 3 Ten thousand square feet <u>up</u> to thirty thousand square feet.
- (7) The WSLCB may reduce a licensee's or applicant's square footage designated to plant canopy for the following reasons:
- (a) If the amount of square feet of production of all licensees exceeds the maximum square feet the WSLCB will may reduce the allowed square footage by the same percentage.
- (b) If fifty percent production space used for plant canopy in the licensee's operating plan is not met by the end of the first year of operation the WSLCB may reduce the tier of licensure.
- (8) If the total amount of square feet of marijuana production exceeds the maximum square feet, the WSLCB reserves the right to reduce all licensee's production by the same percentage or reduce licensee production by one or more tiers by the same percentage.
- (9) The maximum allowed amount of marijuana on a producer's premises at any time is as follows:
- (a) Outdoor or greenhouse grows One and one-quarter of a year's harvest; or
 - (b) Indoor grows Six months of their annual harvest.

[Statutory Authority: RCW 69.50.342, 69.50.345, 2016 c 170, 2016 c 171, and 2016 c 17. WSR 16-19-102, § 314-55-075, filed 9/21/16, effective 10/22/16. Statutory Authority: RCW 69.50.342 and 69.50.345. WSR 16-11-110, § 314-55-075, filed 5/18/16, effective 6/18/16; WSR 15-11-107, § 314-55-075, filed 5/20/15, effective 6/20/15; WSR 14-10-044, § 314-55-075, filed 4/30/14, effective 5/31/14. Statutory Authority: RCW 69.50.325, 69.50.331, 69.50.342, 69.50.345. WSR 13-21-104, § 314-55-075, filed 10/21/13, effective 11/21/13.]

Date: May 31, 2017

To: Jane Rushford, Board Chair

Ollie Garrett, Board Member Russ Hauge, Board Member

From: Joanna Eide, Policy and Rules Coordinator

Copy: Rick Garza, Agency Director

Peter Antolin, Agency Deputy Director Justin Nordhorn, Chief of Enforcement

Becky Smith, Licensing Director

Karen McCall, Agency Rules Coordinator Peter Corier, Marijuana Examiners Unit

Subject: Approval for filing proposed rules (CR 102) regarding producer

licenses and other related rules.

Rule changes are needed to allow producers to hold interests in up to 3 licenses through assumptions of existing licenses only, and to provide additional requirements on eligibility for those license assumptions and for license renewals. The proposed rules also include an increase from 2,000 sq. ft. of possible canopy to 4,000 sq. ft. maximum canopy for tier 1 producers. Additional changes are proposed to accommodate changes in circumstances and upcoming changes to laws that will be effective on July 23, 2017. A separate rulemaking is forthcoming to supplement the changes made in this rulemaking related to upcoming changes to the law.

Process

The Rules Coordinator requests approval to file the proposed rules (CR 102) for the rule making described above. An issue paper on these rule was presented at the Board meeting on May 31, 2017, and is attached to this order.

If approved for filing, the tentative timeline for the rule making process is outlined below:

March 8, 2017	Board approved filing the pre-proposal statement of
	inquiry (CR 101)
May 31, 2017	Board is asked to approve filing the proposed rules (CR
	102 filing)
June 21, 2017	Code Reviser publishes notice
July 12, 2017	Public Hearing
July 12, 2017	End of written comment period
July 24, 2017	Board is asked to adopt rules*

July 24, 2017	Agency sends notice to those who commented both at
	the public hearing and in writing.
July 24, 2017	Agency files adopted rules with the Code Reviser (CR 103)
August 24, 2017	Rules are effective (31 days after filing)

^{*}Tentative and subject to change

Approve	Disapprove	Jane Rushford, Chair	Date
Approve	Disapprove	Ollie Garrett, Board Member	Date
Approve	Disapprove	Russ Hauge, Board Member	 Date

Attachment: Issue Paper

Washington State Liquor and Cannabis Board

Issue Paper

Lab QA Rules – CR 103

Date: May 31, 2017

Presented by: Joanna Eide, Policy and Rules Coordinator

Description of the Issue

The purpose of this issue paper is to recommend that the Washington State Liquor and Cannabis Board (WSLCB) proceed with final rule making and adopt new rules and amendments to rules in Chapter 314-55 WAC Marijuana Licenses, Application Process, Requirements, and Reporting regarding laboratory certification requirements, proficiency testing, pesticide action levels, requirements to promote lab accuracy and consistency, and quality assurance requirements.

Why is rule making necessary?

Rule changes are needed regarding laboratory certification requirements, proficiency testing, pesticide action levels, requirements to promote lab accuracy and consistency, and quality assurance requirements. The Board approved a CR-101 to initiate permanent rulemaking on this subject on April 20, 2016. Several CR-101s are combined into this rulemaking, including CR-101s for lab certification and proficiency testing and pesticide action levels. WSLCB staff also held several meetings with industry members, certified labs, and other state agencies to inform the proposed rule changes in the CR-102. Due to the high level of comments received on the CR-102, as well as changes needed due to other considerations, the WSLCB brought a Supplemental CR-102 with adjusted proposed rule language for the Board's consideration. A public hearing on the Supplemental CR-102 was held on May 3, 2017.

Rule changes are needed to protect consumer safety through ensuring laboratories employ appropriate testing methodologies and achieve accurate testing results for marijuana. Creating proficiency testing requirements to achieve and maintain certification and parameters for laboratories will promote accuracy and accountability in marijuana testing by certified laboratories. Additionally, current permanent rules provide how a laboratory may be certified by the WSLCB, but do not contain provisions on what a laboratory must do to remain certified or how the WSLCB may suspend or revoke the certification of a laboratory. WSLCB needs the authority to suspend or revoke the certification of a laboratory that does not follow rule requirements for testing or for those laboratories that do not consistently achieve accurate testing results.

Rules for pesticide action levels are needed for pesticide action levels for pesticides not allowable for use in the production of marijuana. Currently, permanent rules contain a zero tolerance for disallowed pesticides, which is

unworkable and virtually untestable. The WSLCB needs action levels for pesticides to determine when a sample should fail quality assurance testing and when a recall should be initiated.

Public Comment

There were many comments received as part of this rulemaking. The last public hearing for this rulemaking was held on May 3, 2017, in which several people offered public comment. Comments received in this rulemaking are summarized in the Concise Explanatory Statement, prepared under RCW 34.05.325, accompanying this issue paper.

What changes are being proposed?

New Section. WAC 314-55-0995, Laboratory certification and accreditation requirements.

This section pulls lab certification requirements out of WAC 314-55-102 to create a stand-alone section. Labs will more easily be able to locate these requirements. Some adjustments and clarifications were made to the certification requirements, including clarification on education requirements for laboratory personnel, and language added to clearly state that the certification requirements are continuing requirements for maintaining certification. Additional changes were made to reduce redundancy.

Amendatory Section. WAC 314-55-101, Sampling protocols.

Sample labeling requirements are adjusted to clearly mark samples with all necessary information for identification.

The changes revert lot size back to five (5) pounds as provided in current rule, as well as the number of samples that need to be collected for each lot. Adjustments are intended to reduce self-selection bias with sample deduction. Labs may collect samples if they choose.

Technical changes to accommodate other changes within the rule and to increase rule clarity and organization.

Amendatory Section. WAC 314-55-102, Quality assurance testing. Editing for clarity, consistency, and organization. Removed lab certification requirements for placement in a new separate section to increase rule organizational logic and clarity.

Adjustments to how potency is calculated to increase accurate reporting and labeling of potency levels. Specific direction on calculating potency, both THC and CBD, is included in the rule language. The proposed language in this Supplemental CR-102 filing reverts to a single potency test, rather than three

separate tests as initially proposed in this rulemaking. The WSLCB intends to check for potency inflation and accuracy through secret shopper activities and testing.

Moisture analysis and microbiological testing changes. Changes include testing and reporting for water activity rate, which is a more accurate indicator of the risk of growth of microbes, mold, etc. Moisture content testing changes were made making a sample with more than 15% moisture content fail quality assurance testing. Microbiological screening was changed to test for enterobacteria. Many of these changes to when these tests are required are offset by the addition of testing for aflatoxins and ochratoxin (under mycotoxin screening).

Residual solvent screening was changed heavily and mirrored after the standards used in the United States Pharmacopea. Only the solvents that are classified as having the least risk are allowed to be used in marijuana processing. The solvent levels correlate to the level of risk they pose for consumption. Residual solvent results of more than 5,000 ppm for class three solvents, 50 ppm for class two solvents, and 2 ppm for class one solvents as defined in *United States* Pharmacopea, USP 30 Chemical Tests / <467> - Residual Solvents (USP <467>) not listed in the table in the rule fail quality assurance testing. (Similar construct as pesticide action levels). Labs must test for the residual solvents listed in the rule at a minimum. Labs and licensees may choose to test for additional solvents. The construct is aimed at identifying those solvents that have the highest risk for misuse. Ethanol residual solvents was removed after consulting with WSLBC's certifying vendor and the Oregon Dept. of Health. The Oregon Dept. of Health recently removed ethanol form the residual testing requirements as it was determined that there was little to no health risk associated with ethanol and the previous limit of 5,000 ppm in Oregon's rules was not achieving added benefit.

Adjustments to when testing must be performed are proposed to allow for greater flexibility while still ensuring the proper tests are performed prior to products being sold at retail. There is also a requirement that concentrates be tested after production. Allowances for remediating failed lots or batches are made under certain conditions.

Technical changes to accommodate other changes within the rule and to increase rule clarity and organization.

New Section. WAC 314-55-108, Pesticide action levels.

This new section incorporates the pesticide action levels previously established by the Board through emergency rule. It adds direction for testing and retesting, conditions for remediation techniques (currently unknown, but this will be a placeholder if there are techniques developed in the future), and destruction requirements for harvest, lots, or batches that test above the pesticide action levels established in this section. The action levels in this draft mirror the action levels established by Oregon and to provide action levels for those disallowed pesticides beyond those that appear on the list. These action levels are supported by a report issued by the Oregon Health Authority. The WLSCB made some minor changes to the details for action levels for pyretherins to ensure consistency with the requirements in the Washington Department of Health's rules.

New Section. WAC 314-55-1025, Proficiency testing.

This new section incorporates the proficiency testing requirements for labs previously established by the Board through emergency rule. The rule creates requirements for proficiency testing for laboratories seeking certification, and for certified laboratories to maintain certification. Laboratories may only use proficiency testing programs that are approved by the WSLCB or WSLCB's vendor. Laboratories seeking certification must complete one successful round of proficiency testing and provide proof of the successful completion prior to receiving certification, and certified laboratories must complete a minimum of two successful rounds of proficiency testing for each field of testing per year to maintain certification. The rule also provides requirements for laboratories that fail proficiency testing, as well as the ability of WSLCB to suspend a certification should the laboratory fail to successfully complete proficiency testing. Lastly, the rules detail an avenue for laboratories to remediate if the laboratory fails proficiency testing so that the laboratory's suspended certification may be reinstated.

New Section. WAC 314-55-1035, Laboratory certification — Suspension and revocation.

This rule provides the ways in which the WSLCB may suspend or revoke the certification of laboratories that do not follow rule requirements for laboratories or testing of marijuana. The rule provides two separate levels of suspensions:

- 1. A summary suspension or revocation applying to more egregious and substantial violations, and
- 2. A graduated suspension and revocation approach for less serious violations.

The language also references suspensions for failing proficiency testing requirements under proposed WAC 314-55-1025. Lastly, the rule recognizes the right of a laboratory that receives a suspension or revocation to receive an administrative hearing if they choose under the provisions of the Administrative Procedure Act (Chapter 34.05 RCW).

Amendatory Section. WAC 314-55-103, Good laboratory practice checklist.

Changes and enhancements to this section are made to incorporate portions of ISO 17025 5.4 instead of requiring ISO 17025 accreditation for WSLCB certified labs. WSLCB staff worked with our laboratory certifying and auditing vendor, RJ Lee, to incorporate the changes proposed. Incorporating the new requirements in this section is intended to increase lab accuracy and consistency and are proposed as a cost savings measure as ISO 17025 accreditation is costly to achieve and maintain. The WSLCB will continue to look into ISO 17025 accreditation for certified labs as a requirement for achieving and maintaining WSLCB certification and may revisit this issue at a later date. The WSLCB believes that incorporating these changes will achieve the desired outcomes of ISO accreditation, such as accuracy and consistency, without the high costs of ISO accreditation. Minor changes were made to the checklist to ensure accuracy.

NOTE: Additional adjustments to other rules to accommodate the changes in this rulemaking will be made in the Technical/Clarifying Changes to Chapter 314-55 WAC Rulemaking which will take place in combination with any rule changes needed as a result of 2017 legislation.



PROPOSED RULE MAKING

CR-102 (June 2012)
(Implements RCW 34.05.320)
Do NOT use for expedited rule making

Agency. Washington State Elquor and Cannaois Board			
Preproposal Statement of Inquiry was filed as WSR 16-09-117 and 16-08-			
<u>127</u> ; or	Supplemental Notice to WSR 16-24-094		
Expedited Rule MakingProposed notice was filed as WSR	; or Continuance of WSR		
Proposal is exempt under RCW 34.05.310(4) or 34.05.330(1).			
Title of rule and other identifying information: (Describe Subject) New Section WAC 314-55-0995, Laboratory certification and accred			
WAC 314-55-101, Sampling protocols;	mation requirements,		
WAC 314-55-101, Sampling protocols, WAC 314-55-102, Quality assurance testing;			
New Section WAC 314-55-1025, Proficiency testing;			
WAC 314-55-103, Good laboratory practice checklist;			
New Section WAC 314-55-1035, Laboratory certification – Suspens	ion and revocation; and		
New Section WAC 314-55-108, Pesticide action levels.			
Hearing location(s):	Submit written comments to:		
3 (,	Name: Joanna Eide, Policy and Rules Coordinator		
Washington State Liquor and Cannabis Board	Address: P.O. Box 43080		
Board Room	Olympia, WA 98504		
3000 Pacific Ave SE Olympia, WA 98504	e-mail rules@lcb.wa.gov		
Olympia, WA 98504	fax (360) 664-9689 by (date) May 3, 2017		
Date: May 3, 2017 Time: 10:00 am			
Date. <u>May 3, 2017</u> Time. <u>10.00 am</u>	Assistance for persons with disabilities: Contact		
	Joanna Eide by April 26, 2017		
Date of intended adoption: on or after May 17, 2017 (Next. This is NOT the effective data) TTY () or (360) 664-1622			
(Note: This is NOT the effective date)	, , ,		
Purpose of the proposal and its anticipated effects, including an make necessary rule changes for laboratory certification requiren			
promote lab accuracy and consistency, and quality assurance required			
promote tab accuracy and consistency, and quanty assurance requ	anomones.		
Reasons supporting proposal: Rule changes are needed to protect	t consumer safety through ensuring laboratories employ		
appropriate testing methodologies and achieve accurate testing re			
achieve and maintain certification and parameters for laboratories			
by certified laboratories. Additionally, current permanent rules pr			
not contain provisions on what a laboratory must do to remain certified or how the WSLCB may suspend or revoke the			
	end or revoke the certification of a laboratory that does not follow		
rule requirements for testing or for those laboratories that do not			
action levels are needed for pesticide action levels for pesticides			
permanent rules contain a zero tolerance for disallowed pesticide	· · · · · · · · · · · · · · · · · · ·		
needs action levels for pesticides to determine when a sample sho	ould fail quality assurance testing and when a recall should be		
initiated.			
Statutory authority for adoption: RCW 69.50.342 and 69.50.345	Statute being implemented: RCW 69.50.342 and 69.50.345		
	CODE DEVISED LISE ONLY		
Is rule necessary because of a: Federal Law?	CODE REVISER USE ONLY		
Federal Court Decision?	OFFICE OF THE CODE REVISER		
State Court Decision? Yes 🗵 NO STATE OF WASHINGTON			
If yes, CITATION:	FILED		
	DATE: March 17, 2017		
DATE	·		
March 17, 2017	TIME: 9:31 AM		
NAME (type or print)	WSR 17-07-078		
Jane Rushford	WSK 17-07-076		
SIGNATURE			
I died to			
TITLE Chair			

Agency comments or recommendations, if an matters: None.	ny, as to statutory language, implementation	on, enforcement, and fiscal
Name of proponent: (person or organization) W	ashington State Liquor and Cannabis Board	☐ Private ☐ Public ☑ Governmental
Name of agency personnel responsible for:		
Name	Office Location	Phone
Drafting Joanna Eide, Policy and Rules Coord	3000 Pacific Ave SE, Olympia, WA 98504	(360) 664-1622
ImplementationMarijuana Examiners Unit	3000 Pacific Ave SE, Olympia, WA 98504	(360) 664-1600
Enforcement Justin Nordhorn, Chief Enforcement	3000 Pacific Ave SE, Olympia, WA 98504	(360) 664-1726
Has a small business economic impact state fiscal impact statement been prepared under		CW or has a school district
☑ Yes. Attach copy of small business econd	omic impact statement or school district fiscal	impact statement.
A copy of the statement may be obta Name: Joanna Eide, Policy and Rules Address: 3000 Pacific Ave SE Olympia, WA 98504 phone (360) 664-1622 fax (360)664-9689 e-mail Joanna.Eide@lcb.wa.gov No. Explain why no statement was prepa	Coordinator	
_		
Yes A preliminary cost-benefit analysis Name: Address:	may be obtained by contacting:	
phone () fax () e-mail		
No: Please explain: A cost-benefit analys qualify as a significant legislative rule or other rule re	is was not required under RCW 34.05.328 because equiring a cost benefit analysis under RCW 34.053	

Date: March 8, 2017

To: Jane Rushford, Board Chair

Ollie Garrett, Board Member Russ Hague, Board Member

From: Joanna Eide, Policy and Rules Coordinator

Copy: Rick Garza, Agency Director

Justin Nordhorn, Chief of Enforcement

Becky Smith, Licensing Director

Karen McCall, Agency Rules Coordinator Peter Corier, Marijuana Examiners Unit

Subject: Small Business Economic Impact Statement

Lab QA Rules Supplemental CR-102

Chapter 19.85 RCW, the Regulatory Fairness Act, requires an analysis of the economic impact proposed rules will have on regulated businesses. Preparation of a Small Business Economic Impact Statement is required when proposed rules will impose more than minor costs on businesses.

"Minor cost" means a cost that is less than 1% of annual payroll or the greater of either .3% of annual revenue or \$100.

"Small business" means any business entity that is owned and operated independently from all other businesses and has 50 or fewer employees.

Describe the proposed rule changes, including a brief history of the issue and an explanation of why the proposed rule change is needed.

Rule changes are needed regarding laboratory certification requirements, proficiency testing, pesticide action levels, requirements to promote lab accuracy and consistency, and quality assurance requirements. Rule changes are needed to protect consumer safety through ensuring laboratories employ appropriate testing methodologies and achieve accurate testing results for marijuana. Creating proficiency testing requirements to achieve and maintain certification and parameters for laboratories will promote accuracy and accountability in marijuana testing by certified laboratories. Additionally, current permanent rules provide how a laboratory may be certified by the WSLCB, but do not contain provisions on what a laboratory must do to remain certified or how the WSLCB may suspend or revoke the certification of a laboratory. WSLCB needs the authority to suspend or revoke the certification of a laboratory that does not follow rule requirements for testing or for those laboratories that do not consistently achieve accurate testing results.

Rules for pesticide action levels are needed for pesticide action levels for pesticides not allowable for use in the production of marijuana. Currently, permanent rules contain a zero tolerance for disallowed pesticides, which is unworkable and virtually untestable. The WSLCB needs action levels for pesticides to determine when a sample should fail quality assurance testing and when a recall should be initiated.

The WSLCB convened an informal work group to gather information and receive recommendations for the changes proposed in this rulemaking. The work group was comprised of WSLCB staff, certified labs, marijuana businesses, WSLCB's certifying and auditing vendor, and other state agencies, including the Department of Health, the Department of Agriculture, and the Department of Ecology. Several meetings were held over a period of six months to gather information and suggestions for this rulemaking in addition to the comments and recommendations received as part of the rulemaking process.

Identify which businesses are required to comply with the proposed rule changes. How many businesses of each type are involved? (Use the North American Industry Classification System (NAICS) codes where possible).

There are no NAICS codes for marijuana production, processing, or retail businesses. There is no current data on payroll for marijuana production, processing, retail, or testing businesses. Certified labs and licensed producers and processors will be required to adhere to the proposed rule changes.

The following numbers are based on information pulled on March 3, 2017.

Certified Laboratories: 18

Licensed Producers/Processors: 968

Licensed Producers: 169 Licensed Processors: 152

Producers by Tier (active):

- Tier 1 (up to 2,000 sq. ft.): 210
- Tier 2 (2,000 10,000 sq. ft.): 492
- Tier 3 (10,000 30,000 sq. ft.): 435

Summary of the compliance requirements included in the proposed rule changes.

The proposed rules include the following compliance requirements:

- Increases and adjustments to quality assurance (QA) testing requirements.
- Additions, including recordkeeping and testing methodology adjustments, to the good laboratory practice checklist in WAC 314-55-103, incorporating 5.4 of ISO 17025.



- Proficiency testing (PT) requirements for labs seeking certification and for certified labs to maintain certification.
- Pesticide action levels to detect compliance with restrictions on the use of pesticides.
- Sample labeling requirements are adjusted to clearly mark samples with all necessary information for identification.

Analyze the probable cost of compliance. Identify the probable costs to comply with the proposed rule changes, including: cost of equipment, supplies, labor, professional services and increased administrative costs; and whether compliance with the proposed rule will cause businesses to lose sales or revenue.

Lab equipment cost estimates for testing water activity rate (new): \$1200-\$4000. These equipment costs are one-time costs. Ongoing costs are estimated at ten percent of the initial equipment cost per year, at a rate of \$120-\$400.

Lab equipment costs for mycotoxin testing (new): Mycotoxin testing can be accomplished with a liquid chromatography system with a mass spectrometer (LC/MS) or by purchasing Enzyme-Linked Immunosorbent Assay (ELISA) kits. It is estimated that about half of the certified labs could use existing equipment to perform these new testing requirements.

Increased inspections for auditing of certified labs due to changes with the good laboratory practice checklist in WAC 314-55-103. These changes also include increased recordkeeping requirements and may require increased training of employees of certified labs.

Increased residual solvent testing requirements will also result in some additional administrative and operational costs for certified labs.

Labs may collect samples if they choose, which may result in an increased cost to producers and processors should they agree to this, but would be an optional cost.

Some labs estimate the need for all additional equipment to adjust to the changes in the proposed rules will cost around \$500,000. If this is true, they estimate that if sample volumes increase at a rate of 50% per year and assume that labs intend to aim for a 24 month return on investment for purchasing that equipment, the five labs that do the majority of the QA testing in Washington will need to increase average per sample price for QA testing by \$17.42 to meet that return on investment goal. However, WSLCB's certifying and auditing vendor believes that around half of the currently certified labs already have the equipment to comply with the majority of the proposed changes in this rulemaking.



Professional services.

Labs will need to use professional services of WSLCB approved proficiency testing providers. Proficiency testing (PT) – currently required by emergency rule. This rulemaking will make those requirements permanent. Under these proposed rules, labs must successfully complete PT for each field of testing the lab seeks to be certified for. Certified labs must participate in two rounds of PT per year for each field of testing and maintain a passing score on an ongoing basis, in a minimum of two out of three successive rounds of PT. Currently, there are three PT programs available: potency analysis, microbial analysis, and residual solvents. As more PT programs for other fields of testing become available, certified labs will be required to complete those programs for the fields of testing that the lab is certified for. Costs for compliance should decrease over time as more PT programs become available on the market and competition increases. Examples of PT testing costs range from \$75 for one calibration to \$575 for a Blind PT for THC and Cannabinol. Many PT rounds are priced around \$250 per round, though some are higher.

Marijuana producers and processors will have to continue to use the services of one or more certified labs to provide required quality assurance tests under current rules and the proposed changes to rules in this rulemaking.

Whether the increased costs will result in lost sales or revenue.

Licensed marijuana businesses may see a small loss comparative to overall wholesale value of lots in sales due to increased testing requirements and increased costs for labs to comply with the requirements, which will likely be passed on to the marijuana businesses by the labs. Increased testing costs and administrative costs for certified lab compliance with the changes may be offset by increases to testing charges to licensed marijuana producers and processors. These increased costs may be passed on to consumers at retail.

Analyze whether the proposed rule changes may impose more than minor costs on businesses in the industry.

"Minor cost" means a cost that is less than 1% of annual payroll or the greater of either .3% of annual revenue or \$100. Based upon the available data, costs of compliance and administrative costs, and increases to testing requirements, the WSLCB concludes that the proposed rule changes may result in more than minor costs to businesses in the marijuana industry depending on the business size involved.

Average wholesale price per gram of marijuana was \$2.98 over the past year (2016). The average retail price of marijuana per gram, including excise tax, was \$8.61 in the month of October 2016. On average, the price per gram of marijuana from October 2015 to October 2016 was approximately \$8.67/gram. Since the WSLCB is reverting to the lot/batch sizes in current rule and the sample sizes as provided in current rule in this proposal, no losses should be incurred as far as in the wholesale value of marijuana.



Lot size	Total lot wholesale value	# of samples	Total grams	Costs (wholesale sales)
Up to 5 lbs. (2268 grams)	\$6,758.64	3	6	\$17.88

The impact of costs incurred will depend on the amount of marijuana produced or processed by licensees, which varies by licensee.

According to industry and through researching pricing for QA tests that currently certified labs offer, pricing estimated averages for QA testing under current rules and the proposed changes in this rulemaking are as follows:

Test	Current rules costs	Proposed rules costs
Potency	\$40.00	\$40.00 (no change)
Microbial	\$40.00	\$40.00 (no change)
Mycotoxin	N/A	\$20.00
Residual Solvent	\$40.00	\$60.00

As detailed above, costs for testing for each lot will increase, on average, by \$40.00 where mycotoxin testing is required. Mycotoxin testing is not required in every case, and replaces the microbiological screening requirements in many cases where it is required. These estimates are conservative, so actual costs impacts may be lower.

Costs may be passed along to the ultimate consumer at retail. Some retailers have stated screening marijuana products for toxins is a selling point and converts customers to the regulated marijuana market rather than the illicit market.

Determine whether the proposed rule may have a disproportionate impact on small businesses as compared to the 10 percent of businesses that are the largest businesses required to comply with the proposed rule.

It is likely that the quality assurance testing changes will disproportionately impact smaller producers and processors simply because they produce smaller amounts of product overall, so costs are a larger percentage of their business costs. However, the changes proposed in this supplemental CR-102 which revert back to the lot size and sample sizes in current rules will avoid the costs increases that were associated with the proposed changes in the CR-102.

It is estimated that virtually all of the certified labs qualify as small businesses. For this reason, all changes to rule requirements will impact those small businesses.



If the proposed rule changes have a disproportionate impact on small businesses, identify the steps taken to reduce the costs of the rule on small businesses. If the costs cannot be reduced, provide a clear explanation of why or the justification for not reducing costs.

The WSLCB initially considered adopting a requirement that labs seeking certification to test marijuana and current certified labs achieve ISO 17025 accreditation as a condition of acquiring and maintaining WSLCB certification. The costs associated with achieving ISO accreditation would have been quite substantial and ongoing and labs expressed concerns relative to that. Instead, WSLCB worked with its certifying and auditing vendor to incorporate certain provisions (section 5.4 – Test and Calibration Methods and Method Validation) from ISO accreditation into its good laboratory standards checklist, rather than requiring ISO accreditation. This change was also recommended by certified labs that participated in informal work group discussions. This change will help to achieve the goals of promoting good laboratory practices, sound testing methodologies, consistency, and accuracy while avoiding the higher costs of ISO accreditation in addition to lab certification costs. The new items in the good laboratory standards checklist in WAC 314-55-103 will increase costs and compliance requirements for labs, including increased auditing costs, but at a lesser expense than ISO accreditation.

The WSLCB initially proposed changes to lot sizes and sampling requirements, as well as requiring three separate potency tests as part of the CR-102 for this rulemaking. The changes proposed in this supplemental CR-102 revert back to the lot size and sample sizes/amounts in current rules and single potency test requirement, which will avoid the costs increases that were associated with the proposed changes to those requirements in the CR-102.

Added mycotoxin testing as a required QA test. This change is proposed as a response to removal of certain microbiological tests requirements, and due to the value to consumer safety that screening for mycotoxin affords. This change makes mycotoxin testing requirements consistent with the Washington Department of Health's rules for compliant products in chapter 246-70 WAC. This adjustment does not result in a net increase to testing costs where it replaces microbiological screening, and some industry members estimate that licensed marijuana producers in Washington could collectively save upwards of \$30 million due to the adjustments in the microbiological limits tests. However, due to other changes in QA testing requirements, specifically with the requirement of three potency tests rather than one, industry members estimate a 25% increase to testing costs. This estimate may be higher than actual cost impacts due to mitigating factors, such as the removal of some testing requirements, flexibility of lot sizes, and ability to pass along additional costs to consumers. Some industry members have expressed that the monetary benefit of the proposed rules to the marijuana producers may "far outweigh any costs associated with enhanced quality assurance."

Adjustments to when testing must be performed are proposed to allow for greater flexibility while still ensuring the proper tests are performed prior to products being sold at retail. This change was made to promote flexibility aimed at cost savings. Specifically,



it will avoid having to test certain products (concentrates) twice prior to being sold at retail.

Costs will likely be passed along to consumers at retail, which is a mitigating factor. The additional costs associated with the increased testing, proficiency testing, and good laboratory practice checklist enhancements are necessary to promote accurate testing and information for consumers. Many of the changes proposed in this rulemaking are to include standards that are common for environmental labs which are similar to certified labs that test cannabis in Washington and are necessary to promote consistency, accuracy, and the proper information provided to consumers at retail.

Though these proposed rule changes will mean increased costs for businesses in the marijuana industry, these costs are justifiable. Rule changes are needed to protect consumer safety and convey accurate information to consumers through ensuring laboratories employ appropriate testing methodologies and achieve accurate testing results for marijuana. Creating proficiency testing requirements to achieve and maintain certification and parameters for laboratories will promote accuracy and accountability in marijuana testing by certified laboratories.

Describe how small businesses were involved in the development of the proposed rule.

WSLCB staff held several meetings with industry members, certified labs, WSLCB's certifying and auditing vendor, and other state agencies to inform the proposed rule changes in this CR-102 and to gather information relating to costs and effectiveness of potential rule changes. WSLCB staff collected comments both in writing and verbally from industry members as part of the rulemaking process and informal work group meetings. Many of the changes included in this rulemaking are directly in response to requests from certified labs and the cannabis industry, as well as recommendations from partner science agencies. Additionally, the Cannabis Alliance in conjunction with the Washington Cannabis Laboratory Association conducted a survey of marijuana licensees at each level of the cannabis market which it shared with the WSLCB to assist in the development of this SBEIS. WSLCB received and assessed a large volume of comments as part of the formal comment process with the CR-102. The WSLCB did additional outreach and information gathering with its certifying vendor, other states, and licensees and labs to develop the changes included in this supplemental CR-102.

Identify the estimated number of jobs that will be created or lost as the result of compliance with the proposed rule changes.

It is possible that these proposed rule changes could increase jobs in laboratories as additional tests would be required, which may create a need to hire additional staff. It is unclear whether the proposed changes will cause job losses as increased costs may be offset by passing along to the consumer at retail.

- WAC 314-55-1025 Proficiency testing. (1) For the purposes of this section, the following definitions apply:
- (a) "Field of testing" means the categories of subject matter the laboratory tests, such as pesticide, microbial, potency, residual solvent, heavy metal, mycotoxin, foreign matter, and moisture content detection.
- (b) "Proficiency testing (PT)" means the analysis of samples by a laboratory obtained from providers where the composition of the sample is unknown to the laboratory performing the analysis and the results of the analysis are used in part to evaluate the laboratory's ability to produce precise and accurate results.
- (c) "Proficiency testing (PT) program" means an operation offered by a provider to detect a laboratory's ability to produce valid results for a given field of testing.
- (d) "Provider" means a third-party company, organization, or entity not associated with certified laboratories or a laboratory seeking certification that operates an approved PT program and provides samples for use in PT testing.
- (e) "Vendor" means an organization(s) approved by the WSLCB to certify laboratories for marijuana testing, approve PT programs, and perform on-site assessments of laboratories.
- (2) The WSLCB or its vendor determines the sufficiency of PTs and maintains a list of approved PT programs. Laboratories may request authorization to conduct PT through other PT programs but must obtain approval for the PT program from WSLCB or WSLCB's vendor prior to conducting PT. The WSLCB may add the newly approved PT program to the list of approved PT programs as appropriate.
- (3) As a condition of certification, laboratories must participate in PT and achieve a passing score for each field of testing for which the lab will be or is certified.
- (4) A laboratory must successfully complete a minimum of one round of PT for each field of testing the lab seeks to be certified for and provide proof of the successful PT results prior to initial certification.
- (5)(a) A certified laboratory must participate in a minimum of two rounds of PT per year for each field of testing to maintain its certification.
- (b) To maintain certification, the laboratory must achieve a passing score, on an ongoing basis, in a minimum of two out of three successive rounds of PT. At least one of the scores must be from a round of PT that occurs within six months prior to the laboratory's certification renewal date.
- (6) If the laboratory fails to achieve a passing score on at least eighty percent of the analytes in any proficiency test, the test is considered a failure. If the PT provider provides a pass/fail on a per analyte basis but not on the overall round of PT the lab participates in, the pass/fail evaluation for each analyte will be used to evaluate whether the lab passed eighty percent of the analytes. If the PT provider does not provide individual acceptance criteria for each analyte, the following criteria will be applied to determine whether the lab achieves a passing score for the round of PT:
- (a) +/- 30% recovery from the reference value for residual solvent testing; or

[1] OTS-8027.2

- (b) +/- 3 z or 3 standard deviations from the reference value for all other fields of testing.
- (7) If a laboratory fails a round of PT or reports a false negative on a micro PT, the laboratory must investigate the root cause of the laboratory's performance and establish a corrective action report for each unsatisfactory analytical result. The corrective action report must be kept and maintained by the laboratory for a period of three years, available for review during an on-site assessment or inspection, and provided to the WSLCB or WSLCB's vendor upon request.
- (8) Laboratories are responsible for obtaining PT samples from vendors approved by WSLCB or WSLCB's vendor. Laboratories are responsible for all costs associated with obtaining PT samples and rounds of PT
- (9) The laboratory must manage, analyze and report all PT samples in the same manner as customer samples including, but not limited to, adhering to the same sample tracking, sample preparation, analysis methods, standard operating procedures, calibrations, quality control, and acceptance criteria used in testing customer samples.
- (10) The laboratory must authorize the PT provider to release all results used for certification and/or remediation of failed studies to WSLCB or WSLCB's vendor.
- (11) The WSLCB may require the laboratory to submit raw data and all photographs of plated materials along with the report of analysis of PT samples. The laboratory must keep and maintain all raw data and all photographs of plated materials from PT for a period of three years.
- (12) The WSLCB may waive proficiency tests for certain fields of testing if PT samples or PT programs are not readily available or for other valid reasons as determined by WSLCB.
- (13)(a) The WSLCB will suspend a laboratory's certification if the laboratory fails to maintain a passing score on an ongoing basis in two out of three successive PT studies. The WSLCB may reinstate a laboratory's suspended certification if the laboratory successfully analyzes PT samples from a WSLCB or WSLCB's vendor approved PT provider, so long as the supplemental PT studies are performed at least fifteen days apart from the analysis date of one PT study to the analysis date of another PT study.
- (b) The WSLCB will suspend a laboratory's certification if the laboratory fails two consecutive rounds of PT. WSLCB may reinstate a laboratory's suspended certification once the laboratory conducts an investigation, provides the WSLCB a deficiency report identifying the root cause of the failed PT, and successfully analyzes PT samples from a WSLCB or WSLCB's vendor approved PT provider. The supplemental PT studies must be performed at least fifteen days apart from the analysis date of one PT study to the analysis date of another PT study.
- (14) If a laboratory fails to remediate and have its certification reinstated under subsection (13)(a) or (b) of this section within six months of the suspension, the laboratory must reapply for certification as if the laboratory was never certified previously.
- (15) A laboratory that has its certification suspended or revoked under this section may request an administrative hearing to contest the suspension as provided in chapter 34.05 RCW.

- WAC 314-55-1035 Laboratory certification—Suspension and revocation. (1) The board may summarily suspend or revoke the certification of any lab certified under WAC 314-55-0995 for any of the following reasons:
- (a) The laboratory owner or science director violates any of the requirements of chapter 314-55 WAC relating to the operations of the laboratory.
- (b) The laboratory owner or science director aids, abets, or permits the violation of any provision of chapters 314-55 WAC, 69.50 RCW, 69.51A RCW, or Title 9 or 9A RCW related to the operations of the laboratory, or the laboratory owner or science director permits laboratory staff to do so.
- (c) Evidence the certificate holder or owner made false statements in any material regard:
 - (i) On the application for certification;
- (ii) In submissions to the board relating to receiving or maintaining certification; or
- $(\bar{i}ii)$ Regarding any testing performed or results provided to WSLCB or the marijuana licensee by the certificate holder or owner pursuant to WAC 314-55-102.
- (d) The laboratory owner or science director is convicted of any crime substantially related to the qualifications or duties of that owner and related to the functions of the laboratory, including a conviction for falsifying any report of or that relates to a laboratory analysis. For purposes of this subsection, a "conviction" means a plea or finding of guilt regardless of whether the imposition of sentence is deferred or the penalty is suspended.
- (e) The laboratory submits proficiency test sample results generated by another laboratory as its own.
- (f) The laboratory staff denies entry to any employee of the WSLCB or WSLCB's vendor during normal business hours for an on-site assessment or inspection, as required by WAC 314-55-0995, 314-55-102, 314-55-1025, or 314-55-103.
- (2)(a) The following violations are subject to the penalties as provided in (b) of this subsection:
- (i) The laboratory fails to submit an acceptable corrective action report in response to a deficiency report, and failure to implement corrective action related to any deficiencies found during a laboratory assessment.
- (ii) The laboratory fails to report proficiency testing results pursuant to WAC 314-55-1025.
- (iii) The laboratory fails to remit certification fees within the time limit established by a certifying authority.
- (iv) The laboratory fails to meet recordkeeping requirements as required by chapter 314-55 WAC unless the failure to maintain records is substantial enough to warrant a suspension or revocation under subsection (1) of this section.
- (b) The penalties for the violations in (a) of this subsection are as follows:
- (i) First violation: Ten-day suspension of the lab's certification or until the lab corrects the violation leading to the suspension, whichever is longer.

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- (ii) Second violation within a three-year period: Thirty-day suspension of laboratory certification or until the laboratory corrects the violation leading to the suspension, whichever is longer.
- (iii) Third violation within a three-year period: Revocation of the lab's certification.
- (3) A certified lab may also be subject to a suspension of certification related to proficiency testing requirements under WAC 314-55-1025.
- (4) A laboratory that has its certification suspended or revoked under this section may request an administrative hearing to contest the suspension or revocation as provided in chapter 34.05 RCW.

- WAC 314-55-108 Pesticide action levels. (1) Only pesticides allowed under WAC 314-55-084 may be used in the production of marijuana, and they must be registered by the Washington state department of agriculture (WSDA) under chapter 15.58 RCW.
- (2) Pursuant to WAC 314-55-102, if the WSLCB, WSDA, other designee of the WSLCB, or certified lab identifies a pesticide that is not allowed under subsection (1) of this section and is above the action levels provided in subsection (3) of this section, that lot or batch from which the sample was deducted has failed quality assurance testing and may be subject to a recall as provided in WAC 314-55-225.
- (3) The action levels for pesticides are provided in the table below. The action level for all other pesticides that are not listed in the table below or not allowed under subsection (1) of this section is 0.1 ppm.

Analyte	Chemical Abstract Services (CAS) Registry Number	Action Level
Abamectin	71751-41-2	0.5
Acephate	30560-19-1	0.4
Acequinocyl	57960-19-7	2
Acetamiprid	135410-20-7	0.2
Aldicarb	116-06-3	0.4
Azoxystrobin	131860-33-8	0.2
Bifenazate	149877-41-8	0.2
Bifenthrin	82657-04-3	0.2
Boscalid	188425-85-6	0.4
Carbaryl	63-25-2	0.2
Carbofuran	1563-66-2	0.2
Chlorantraniliprole	500008-45-7	0.2
Chlorfenapyr	122453-73-0	1
Chlorpyrifos	2921-88-2	0.2
Clofentezine	74115-24-5	0.2
Cyfluthrin	68359-37-5	1
Cypermethrin	52315-07-8	1
Daminozide	1596-84-5	1
DDVP (Dichlorvos)	62-73-7	0.1
Diazinon	333-41-5	0.2
Dimethoate	60-51-5	0.2
Ethoprophos	13194-48-4	0.2
Etofenprox	80844-07-1	0.4
Etoxazole	153233-91-1	0.2
Fenoxycarb	72490-01-8	0.2
Fenpyroximate	134098-61-6	0.4
Fipronil	120068-37-3	0.4
Flonicamid	158062-67-0	1
Fludioxonil	131341-86-1	0.4

[1] OTS-8152.3

	Chemical Abstract Services (CAS) Registry	Action Level
Analyte	Number	ppm
Hexythiazox	78587-05-0	1
Imazalil	35554-44-0	0.2
Imidacloprid	138261-41-3	0.4
Kresoxim-methyl	143390-89-0	0.4
Malathion	121-75-5	0.2
Metalaxyl	57837-19-1	0.2
Methiocarb	2032-65-7	0.2
Methomyl	16752-77-5	0.4
Methyl parathion	298-00-0	0.2
MGK-264	113-48-4	0.2
Myclobutanil	88671-89-0	0.2
Naled	300-76-5	0.5
Oxamyl	23135-22-0	1
Paclobutrazol	76738-62-0	0.4
Permethrins ^a	52645-53-1	0.2
Phosmet	732-11-6	0.2
Piperonyl butoxide ^b	51-03-6	2
Prallethrin	23031-36-9	0.2
Propiconazole	60207-90-1	0.4
Propoxur	114-26-1	0.2
Pyrethrins ^{bc}	8003-34-7	1
Pyridaben	96489-71-3	0.2
Spinosad	168316-95-8	0.2
Spiromesifen	283594-90-1	0.2
Spirotetramat	203313-25-1	0.2
Spiroxamine	118134-30-8	0.4
Tebuconazole	80443-41-0	0.4
Thiacloprid	111988-49-9	0.2
Thiamethoxam	153719-23-4	0.2
Trifloxystrobin	141517-21-7	0.2

aPermethrins should be measured as cumulative residue of cis- and transpermethrin isomers (CAS numbers 54774-45-7 and 51877-74-8 respectively).

[2] OTS-8152.3

bAction level applies to marijuana concentrates, marijuana extracts,

[.] Econ level applies to marijuana concentrates, marijuana extracts, intermediate products, and imported cannabanoids. cPyrethrins should be measured as the cumulative residues of pyrethrin 1, cinerin 1, and jasmolin 1 (CAS numbers 121-21-1, 25402-06-6, and 4466-1-2 respectively).

⁽⁴⁾ Except as otherwise provided in this section, licensed marijuana producer or processor that provided a sample that fails quality assurance testing must dispose of the entire lot or batch from which the sample was taken as provided by marijuana waste disposal requirements in WAC 314-55-097 and document the disposal of the sample pursuant to traceability requirements in WAC 314-55-083(4) and recordkeeping requirements in WAC 314-55-087. A licensee's sample that does not test above the pesticide action levels under this section where test results show the presence of a pesticide that is not allowed un-

der subsection (1) of this section may still be subject to an administrative violation if the disallowed pesticide was applied.

- (5) Except as otherwise provided in this section, a licensed marijuana producer or processor which provided a sample that fails quality assurance testing must dispose of the entire lot or batch from which the sample was taken as provided by marijuana waste disposal requirements in WAC 314-55-097 and document the disposal of the sample pursuant to traceability requirements in WAC 314-55-083(4) and record-keeping requirements in WAC 314-55-087.
- (6) Pursuant to WAC 314-55-102, at the request of the producer or processor, the WSLCB may authorize a retest to validate a failed test result on a case-by-case basis. All costs of the retest will be borne by the producer or the processor requesting the retest.
- (7) Producers and processors may remediate failed harvests, lots, or batches so long as the remediation method does not impart any toxic or deleterious substance to the usable marijuana, marijuana concentrates, or marijuana-infused product. Remediation solvents or methods used on the marijuana product must be disclosed to a licensed retailer or consumer upon request. The entire harvest, lot, or batch the failed sample(s) were deducted from must be remediated using the same remediation technique. No remediated harvest, lots or batches may be sold or transported until the completion and successful passage of quality assurance testing as required in this section and WAC 314-55-102.
- (8) Pursuant to WAC 314-55-102, upon request a marijuana licensee must disclose and make available all quality assurance tests and retest results for the lot or batch of usable marijuana, marijuana concentrates, or marijuana-infused products to the marijuana licensee or retail customer who is considering purchasing the usable marijuana, marijuana concentrates, or marijuana-infused products.

[3] OTS-8152.3

- WAC 314-55-0995 Laboratory certification and accreditation requirements. The following requirements apply to third-party labs seeking certification by the WSLCB or its designee to do quality assurance testing on marijuana and marijuana products in Washington state, and for certified third-party laboratories (certified labs) to remain certified by the WSLCB. The requirements provided in this section are continuing requirements, and must be adhered to and maintained for a third-party lab to remain certified. The WSLCB may summarily suspend a lab's certification if a certified lab is found out of compliance with the requirements of this chapter.
- (1) A third-party laboratory must be certified by the WSLCB or their vendor as meeting the WSLCB's accreditation and other requirements prior to conducting quality assurance tests required under this chapter. Certified labs must conspicuously display the certification letter received by the WSLCB upon certification at the lab's premises in a conspicuous location where a customer may observe it unobstructed in plain sight.
- (2) A person with financial interest in a certified lab may not have direct or indirect financial interest in a licensed marijuana producer or processor for whom they are conducting required quality assurance tests. A person with direct or indirect financial interest in a certified lab must disclose to the WSLCB by affidavit any direct or indirect financial interest in a licensed marijuana producer or processor.
- (3) The following provisions are conditions of certification for third-party testing labs. Failure to adhere to the below requirements may result in the suspension or revocation of certification.
- (a) Each lab must employ a scientific director responsible to ensure the achievement and maintenance of quality standards of practice. The scientific director must possess the following minimum qualifications:
- (i) A doctorate in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of two years' post-degree laboratory experience;
- (ii) A master's degree in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of four years' of post-degree laboratory experience; or
- (iii) A bachelor's degree in the chemical or microbiological sciences from a college or university accredited by a national or regional certifying authority with a minimum of six years of post-education laboratory experience.
- (b) Certified labs must follow the analytical requirements most current version of the Cannabis Inflorescence and Leaf Monograph published by the American Herbal Pharmacopoeia or notify the WSLCB or its designee what alternative scientifically valid testing methodology the lab is following for each quality assurance test. Third-party validation by the WSLCB or its designee is required for any monograph or analytical method followed by a certified lab to ensure the methodology produces scientifically accurate results prior to use of alternative testing methods to conduct required quality assurance tests.
- (c) The WSLCB may require third-party validation and ongoing monitoring of a certified lab's basic proficiency to correctly execute

the analytical methodologies employed by the certified lab. The WSLCB may contract with a vendor to conduct the validation and ongoing monitoring described in this subsection. The certified lab must pay all vendor fees for validation and ongoing monitoring directly to the WSLCB's vendor.

- (4) Certified labs must allow the WSLCB or the WSLCB's vendor to conduct physical visits and inspect related laboratory equipment, testing and other related records during normal business hours without advance notice.
- (5) As a condition of certification, labs must adopt and follow minimum good lab practices (GLPs) as provided in WAC 314-55-103, and maintain internal standard operating procedures (SOPs), and a quality control/quality assurance (QC/QA) program as specified by the WSLCB. The WSLCB or authorized third-party organization (WSLCB's designee) may conduct audits of a lab's GLPs, SOPs, QC/QA, and inspect all other related records.
- (6) The WSLCB or its designee will take immediate disciplinary action against any certified lab that fails to comply with the provisions of this chapter or falsifies records related to this section including, without limitation, revoking the certification of the certified lab.

AMENDATORY SECTION (Amending WSR 16-11-110, filed 5/18/16, effective 6/18/16)

WAC 314-55-101 Quality assurance sampling protocols. $(1)((\frac{(a)}{(a)}))$ To ensure $((\frac{bat}{(abs)}))$ quality assurance samples submitted to certified third-party $(\frac{(abs)}{(abs)})$ laboratories (certified labs) are representative from the lot or batch from which they were sampled as required in RCW 69.50.348, licensed producers, licensed processors, certified $(\frac{batch}{(abclowing)})$ labs, and their employees must adhere to the $(\frac{abclowing}{(abclowing)})$ minimum sampling protocols as provided in this section.

$((\frac{b}{b}))$ (2) Sampling protocols for all marijuana product lots and batches:

- (a) Samples must be deducted in a way that is most representative of the lot or batch and maintains the structure of the marijuana sample. Licensees, certified ((third party laboratories)) labs, and their employees may not adulterate or change in any way the representative sample from a lot or batch before submitting the sample to certified ((third party laboratories)) labs. This includes adulterating or changing the sample in any way as to inflate the level of potency, or to hide any microbiological contaminants from the required microbiological screening such as, but not limited to:
- (i) Adulterating the sample with kief, concentrates, or other extracts;
- (ii) Treating a sample with solvents to hide the microbial count of the lot or batch from which it was deducted. This ((is not meant to be construed as prohibiting)) subsection does not prohibit the treatment of failed lots or batches with methods approved by the WSLCB; ((and)) or
 - (iii) Pregrinding a flower lot sample.
- ((\frac{1}{2}) Sampling protocols for all marijuana product lots and batches: The deduction of all quality assurance samples must adhere to the following sampling protocols:

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- $\frac{(a)}{(b)}$ All samples must be taken in a sanitary environment using sanitary practices and ensure facilities are constructed, kept, and maintained in a clean and sanitary condition in accordance with rules and as prescribed by the Washington state department of agriculture under chapters 16-165 and 16-167 WAC.
- $((\frac{b}{b}))$ <u>(c)</u> Persons $(\frac{taking}{b})$ <u>collecting</u> samples must wash their hands prior to $(\frac{deducting\ samples}{b})$ <u>collecting a sample</u> from a lot or batch, wear <u>appropriate</u> gloves while preparing or deducting the lot or batch for $(\frac{sampling}{b})$ <u>sample collection</u>, and must use sanitary utensils and storage devices when collecting samples.
- $((\frac{c}{c}))$ <u>(d)</u> Samples must be placed in a $(\frac{sterile}{c})$ <u>sanitary</u> plastic or glass container, and stored in a location that prevents the propagation of pathogens and other contaminants((. This includes low light levels, mild temperatures, and low humidity environments.
 - (d))), such as a secure, low-light, cool and dry location.
- $\underline{\text{(e)}}$ The licensee ((shall)) <u>must</u> maintain the lot or batch from which the sample was deducted in a secure, <u>low-light</u>, cool, and dry location to prevent the marijuana from becoming contaminated or losing its efficacy.
- (f) Each quality assurance sample must be clearly marked "quality assurance sample" and be labeled with the following information:
- (i) The sixteen digit identification number generated by the traceability system;
- (ii) The license number and name of the certified lab receiving the sample;
- (iii) The license number and trade name of the licensee sending the sample;
 - (iv) The date the sample was collected; and
 - (v) The weight of the sample.
 - (3) Additional sampling protocols for flower lots:
- (a) Licensees or certified ((third party labs are required to deduct four)) labs must collect a minimum of four separate samples from each marijuana flower lot ((in order to ensure representativeness of the lot. The four)) up to five pounds. Licensees or certified labs may collect more samples than this minimum, but must not collect less. The samples must be of roughly equal weight((τ)) not less than one gram each((τ) and the cumulative weight of the four samples may not be more than the maximum allowed in WAC 314-55-102)).
- (b) The four separate samples must be taken from different quadrants of the flower lot. A quadrant is the division of a lot into four equal parts. ((This may be done visually or physically, but)) Dividing a lot into quadrants prior to collecting samples must be done in a manner that ensures the samples ((were deducted)) are collected from four evenly distributed areas of the flower lot and may be done visually or physically.
- (c) The four ((separate)) samples may be placed together in ((a)) one container ((that conforms to)) conforming to the packaging and labeling requirements in subsection (2) of this section for storage and transfer to a certified ((third party)) lab.
- (4) <u>Certified labs may retrieve samples from a marijuana licensee's licensed premises and transport the samples directly to the lab.</u> <u>Certified labs may also return any unused portion of the samples.</u>

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or ((was)) manipulated in a ((way)) manner that violates the sampling protocols, limit tests, or action levels.

 $((\frac{(5)}{)}))$ (6) The WSLCB or its designee will take immediate disciplinary action against any licensee or certified ((third-party labwhich)) lab that fails to comply with the provisions of this section or falsifies records related to this section including, without limitation, revoking the license ((or certificate of)) the licensed producer or processor, or certification of the certified ((third-party)) lab.

AMENDATORY SECTION (Amending WSR 16-11-110, filed 5/18/16, effective 6/18/16)

- WAC 314-55-102 Quality assurance testing. (((1))) A third-party testing lab must be certified by the WSLCB or ((their)) the WSLCB's vendor as meeting the WSLCB's accreditation and other requirements prior to conducting ((their)) quality assurance tests ((their)) and must conspicuously display this letter in the lab in plain sight of the customers. The WSLCB can summarily suspend a lab's certification if a lab is found out of compliance with the requirements of this chapter.
- (2) A person with financial interest in a certified third-party testing lab may not have direct or indirect financial interest in a licensed marijuana producer or processor for whom they are conducting required quality assurance tests. A person with direct or indirect financial interest in a certified third-party testing lab must disclose to the WSLCB by affidavit any direct or indirect financial interest in a licensed marijuana producer or processor.
- (3) As a condition of certification, each lab must employ a scientific director responsible to ensure the achievement and maintenance of quality standards of practice. The scientific director shall meet the following minimum qualifications:
- (a) Has earned, from a college or university accredited by a national or regional certifying authority a doctorate in the chemical or biological sciences and a minimum of two years' post-degree laboratory experience; or
- (b) Has earned a master's degree in the chemical or biological sciences and has a minimum of four years' of post-degree laboratory experience; or
- (c) Has earned a bachelor's degree in the chemical or biological sciences and has a minimum of six years of post-education laboratory experience.
- (4) As a condition of certification, labs must follow the most current version of the Cannabis Inflorescence and Leaf monograph published by the American Herbal Pharmacopoeia or notify the WSLCB what alternative scientifically valid testing methodology the lab is following for each quality assurance test. The WSLCB may require third-party validation of any monograph or analytical method followed by the lab to ensure the methodology produces scientifically accurate results prior to them using those standards when conducting required quality assurance tests.
- (5) As a condition of certification, the WSLCB may require third-party validation and ongoing monitoring of a lab's basic proficiency to correctly execute the analytical methodologies employed by the lab.

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The WSLCB may contract with a vendor to conduct the validation and ongoing monitoring described in this subsection. The lab shall pay all vendor fees for validation and ongoing monitoring directly to the vendor.

- (6) The lab must allow the WSLCB or their vendor to conduct physical visits and inspect related laboratory equipment, testing and other related records during normal business hours without advance notice.
- (7) Labs must adopt and follow minimum good lab practices (GLPs), and maintain internal standard operating procedures (SOPs), and a quality control/quality assurance (QC/QA) program as specified by the WSLCB. The WSLCB or authorized third party organization can conduct audits of a lab's GLPs, SOPs, QC/QA, and inspect all other related records.
- (8) The WSLCB or its designee will take immediate disciplinary action against any certified third-party lab which fails to comply with the provisions of this chapter or falsifies records related to this section including, without limitation, revoking the certificate of the certified third-party lab.
- (9) The general body of required quality assurance tests for marijuana flowers and infused products may include moisture content, potency analysis, foreign matter inspection, microbiological screening, pesticide and other chemical residue and metals screening, and residual solvents levels.
- (10) Table of required quality assurance tests defined in the most current version of the *Cannabis Inflorescence and Leaf* monograph published by the American Herbal Pharmacopoeia.
 - (a))) required under this section.
- (1) Quality assurance fields of testing. Certified labs must be certified to the following fields of testing by the WSLCB or its designee and must adhere to the guidelines for each quality assurance field of testing listed below, with the exception of mycotoxin, heavy metal, or pesticide residue screening. Certification to perform mycotoxin, heavy metals and pesticides may be obtained but is not required to obtain certification as a testing lab. A lab must become certified in all fields of testing prior to conducting any testing or screening in that field of testing, regardless of whether the test is required under this section.
 - (a) Potency analysis.
- (i) Certified labs must test and report the following cannabinoids to the WSLCB when testing for potency:
 - (A) THCA;
 - (B) THC;
 - (C) Total THC;
 - (D) CBDA;
 - (E) CBD; and
 - (F) Total CBD.
 - (ii) Calculating total THC and total CBD.
- (A) Total THC must be calculated as follows, where M is the mass or mass fraction of delta-9 THC or delta-9 THCA: M total delta-9 THC = M delta-9 THC + (0.877 x M delta-9 THCA).
- (B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: M total CBD = M CBD + $(0.877 \times M)$ CBDA).
- (iii) Regardless of analytical equipment or methodology, certified labs must accurately measure and report the acidic (THCA and CBDA) and neutral (THC and CBD) forms of the cannabinoids.

- (b) Potency analysis for flower lots.
- (i) Certified labs must test and report the results for the required flower lot samples as described in WAC 314-55-101(3) for the following required cannabinoids:
 - (A) THCA;
 - (B) THC;
 - (C) Total THC;
 - (D) CBDA;
 - (E) CBD; and
 - (F) Total CBD.
 - (ii) Calculating total THC and total CBD.
- (B) Total CBD must be calculated as follows, where M is the mass or mass fraction of CBD and CBDA: M total CBD = M CBD + $(0.877 \times M)$ CBDA).
- (c) Certified labs may combine in equal parts multiple samples from the same flower lot for the purposes of the following tests after the individual samples described in WAC 314-55-101(3) have been tested for potency analysis.
- (i) Moisture analysis. The sample and related lot or batch fails quality assurance testing for moisture analysis if the results exceed the following limits:
 - (A) Water activity rate of more than 0.65 a_w; and
 - (B) Moisture content more than fifteen percent.
- (ii) Foreign matter screening. The sample and related lot or batch fail quality assurance testing for foreign matter screening if the results exceed the following limits:
 - (A) Five percent of stems 3mm or more in diameter; and
 - (B) Two percent of seeds or other foreign matter.
- (iii) Microbiological screening. The sample and related lot or batch fail quality assurance testing for microbiological screening if the results exceed the following limits:

	Enterobacteria (bile-tolerant gram-negative bacteria)	E. coli (pathogenic strains) and Salmonella spp.
Unprocessed Plant Material	<u>10</u> ⁴	Not detected in 1g
Extracted or processed Botanical Product	<u>10³</u>	Not detected in 1g

- (iv) Mycotoxin screening. The sample and related lot or batch fail quality assurance testing for mycotoxin screening if the results exceed the following limits:
 - (A) Total of Aflatoxin B1, B2, G1, G2: 20 μg/kg of substance; and
 - (Β) Ochratoxin A: 20 μg/kg of substance.
- (d) Residual solvent screening. Except as otherwise provided in this subsection, a sample and related lot or batch fail quality assurance testing for residual solvents if the results exceed the limits provided in the table below. Residual solvent results of more than 5,000 ppm for class three solvents, 50 ppm for class two solvents, and 2 ppm for class one solvents as defined in United States Pharmacopoeia, USP 30 Chemical Tests / <467> Residual Solvents (USP <467>) not listed in the table below fail quality assurance testing. When residual solvent screening is required, certified labs must test for the solvents listed in the table below at a minimum.

Solvent*	<u>ppm</u>
<u>Acetone</u>	<u>5,000</u>
<u>Benzene</u>	2
<u>Butanes</u>	<u>5,000</u>
Cyclohexane	<u>3,880</u>
Chloroform	2
<u>Dichloromethane</u>	<u>600</u>
Ethyl acetate	<u>5,000</u>
<u>Heptanes</u>	<u>5,000</u>
<u>Hexanes</u>	<u>290</u>
Isopropanol (2-propanol)	5,000
Methanol	3,000
Pentanes	<u>5,000</u>
Propane	<u>5,000</u>
<u>Toluene</u>	<u>890</u>
Xylene**	2,170

^{*}And isomers thereof.

(e) Heavy metal screening. A sample and related lot or batch fail quality assurance testing for heavy metals if the results exceed the limits provided in the table below.

<u>Metal</u>	μ/daily dose (5 grams)
Inorganic arsenic	<u>10.0</u>
<u>Cadmium</u>	<u>4.1</u>
Lead	<u>6.0</u>
Mercury	<u>2.0</u>

- (2) Quality assurance testing required. The following quality assurance tests are the minimum required tests for each of the following marijuana products, respectively. Licensees and certified labs may elect to do multiple quality assurance tests on the same lot or testing for mycotoxin, pesticides, or heavy metals pursuant to chapter 246-70 WAC.
- $\underline{\text{(a)}}$ General quality assurance testing requirements for certified labs.
- (i) Certified labs must record an acknowledgment of the receipt of samples from producers or processors in the WSLCB seed to sale traceability system. Certified labs must also verify if any unused portion of the sample was destroyed or returned to the licensee after the completion of required testing.
- (ii) Certified labs must report quality assurance test results directly to the WSLCB traceability system when quality assurance tests for the field of testing are required within twenty-four hours of completion of the test(s).
- (iii) Certified labs must fail a sample if the results for any limit test are above allowable levels regardless of whether the limit test is required in the testing tables in this section.
- (b) Marijuana flower lots and other material lots. Marijuana flower lots or other material lots require the following quality assurance tests:

^{**}Usually 60% *m*-xylene, 14% *p*-xylene, 9% *o*-xylene with 17% ethyl benzene

Product	Test(s) Required	((Maximum Sample Size))
	((Flower Lots and Other Material Lots))	
Lots of marijuana flowers or other material that will not be extracted	 Moisture content Potency analysis Foreign matter inspection Microbiological screening Mycotoxin screening 	((7 grams))

- $((\frac{b}{b}))$ <u>(c) Intermediate products.</u> Intermediate products must meet the following requirements <u>related to quality assurance testing</u>:
- (i) All intermediate products must be homogenized prior to quality assurance testing;
- (ii) ((A batch)) For the purposes of this section, a batch is defined as a single run through the extraction or infusion process;
- (iii) A batch of marijuana mix may not exceed five pounds and must be chopped or ground so no particles are greater than 3 mm; and
- (iv) All batches of intermediate products require the following quality assurance tests:

Product	Test(s) Required Intermediate Products	((Maximum Sample Size))
Marijuana mix	Noisture content* Potency analysis Foreign matter inspection* Microbiological screening Mycotoxin screening	((7 grams))
Concentrate or extract made with hydrocarbons (solvent based made using n-butane, isobutane, propane, heptane, or other solvents or gases approved by the board of at least 99% purity)	1. Potency analysis 2. ((Microbiological screening (only if using flowers and other plant material that has not passed QA testing))) Mycotoxin screening* 3. Residual solvent test	((2 grams))
Concentrate or extract made with a CO ₂ extractor like hash oil	1. Potency analysis 2. ((Microbiological screening (only if using flowers and other plant material that has not passed QA testing))) Mycotoxin screening* 3. Residual solvent test	((2 grams))
Concentrate or extract made with ethanol	1. Potency analysis 2. ((Microbiological screening (only if using flowers and other plant material that has not passed QA testing))) Mycotoxin screening* 3. Residual solvent test	((2 grams))
Concentrate or extract made with approved food grade solvent	1. Potency analysis 2. Microbiological screening (((only if using flowers and other plant material that has not passed QA testing)))* 3. Mycotoxin screening* 4. Residual solvent test	((2 grams))
Concentrate or extract (nonsolvent) such as kief, ((hashish)) hash, rosin, or bubble hash	Potency analysis Microbiological screening Mycotoxin screening	((2 grams))
Infused cooking oil or fat in solid form	1. Potency analysis 2. Microbiological screening (((only if using flowers and other plant material that has not passed QA testing)))* 3. Mycotoxin screening*	((2 grams))

Field of testing is only required if using lots of marijuana flower and other plant material that has not passed QA testing.

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 $((\frac{\langle c \rangle}{}))$ <u>(d) **End products.**</u> All marijuana, marijuana-infused products, marijuana concentrates, marijuana mix packaged, and marijuana mix infused sold from a processor to a retailer require the following quality assurance tests:

Product	Test(s) Required End Products	((Maximum Sample Size))
Infused solid edible	((1.)) Potency analysis	((1 unit))
Infused liquid (like a soda or tonic)	((4.)) Potency analysis	((1 unit))
Infused topical	((4.)) Potency analysis	((1 unit))
Marijuana mix packaged (loose or rolled)	((1.)) Potency analysis	((2 grams))
Marijuana mix infused (loose or rolled)	((4.)) Potency analysis	((2 grams))
Concentrate or marijuana-infused product for inhalation	((1.)) Potency analysis	((1 unit))

- $((\frac{d}{d}))$ <u>(e)</u> End products consisting of only one intermediate product that has not been changed in any way $(\frac{d}{d})$ <u>are</u> not subject to potency analysis.
- ((11) Certified third-party labs may request additional sample material in excess of amounts listed in the table in subsection (10) of this section for the purposes of completing required quality assurance tests. Labs certified as meeting the WSLCB's accreditation requirements may retrieve samples from a marijuana licensee's licensed premises and transport the samples directly to the lab and return any unused portion of the samples.
- (12) Labs certified as meeting the WSLCB's accreditation requirements are not limited in the amount of usable marijuana and marijuana products they may have on their premises at any given time, but they must have records to prove all marijuana and marijuana-infused products only for the testing purposes described in WAC 314-55-102.
- (13) At the discretion of the WSLCB, a producer or processor must provide an employee of the WSLCB or their designee samples in the amount listed in subsection (10) of this section or samples of the growing medium, soil amendments, fertilizers, crop production aids, pesticides, or water for random compliance checks. Samples may be screened for pesticides and chemical residues, unsafe levels of metals, and used for other quality assurance tests deemed necessary by the WSLCB. All costs of this testing will be borne by the producer or processor.
- (14))) (3) No lot of usable flower, batch of marijuana concentrate, or batch of marijuana-infused product may be sold or transported until the completion ((of all required)) and successful passage of quality assurance testing((\div)) as required in this section, except:
- (a) Business entities with multiple locations licensed under the same UBI number may transfer marijuana products between the licensed locations under ((their)) the same UBI number prior to quality assurance testing((\div
- (15) Any usable marijuana or marijuana-infused product that passed the required quality assurance tests may be labeled as "Class A." Only "Class A" usable marijuana or marijuana-infused product will be allowed to be sold.

(16))); and

(b) Licensees may wholesale and transfer batches or lots of flower and other material that will be extracted and marijuana mix and nonsolvent extracts for the purposes of further extraction prior to completing required quality assurance testing. Licensees may wholesale

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and transfer failed lots or batches to be extracted pursuant to subsection (5) of this section.

- (4) Samples, lots, or batches that fail quality assurance testing.
- (a) Upon approval ((of)) by the WSLCB, ((a lot that fails a quality assurance test and the associated trim, leaf and other usable material)) failed lots or batches may be used to create extracts ((using hydrocarbon or CO_2 closed loop system)). After processing, the ((CO_2 or hydrocarbon based)) extract must ((still)) pass all ((required)) quality assurance tests ((in WAC 314-55-102)) required in this section before it may be sold.
- $((\frac{17}{17}))$ (b) **Retesting.** At the request of the producer or processor, the WSLCB may authorize a retest to validate a failed test result on a case-by-case basis. All costs of the retest will be borne by the producer or the processor(($\frac{1}{17}$))
- (18) Labs must report all required quality assurance test results directly into the WSLCB's seed to sale traceability system within twenty-four hours of completion. Labs must also record in the seed to sale traceability system an acknowledgment of the receipt of samples from producers or processors and verify if any unused portion of the sample was destroyed or returned to the licensee.)) requesting the retest. Potency retesting will generally not be authorized.
- (c) Remediation. Producers and processors may remediate failed harvests, lots, or batches so long as the remediation method does not impart any toxic or deleterious substance to the usable marijuana, marijuana concentrates, or marijuana-infused product. Remediation solvents or methods used on the marijuana product must be disclosed to a licensed processor the producer or producer/processor transfers the products to; a licensed retailer carrying marijuana products derived from the remediated harvest, lot, or batch; or consumer upon request. The entire harvest, lot, or batch the failed sample(s) were deducted from must be remediated using the same remediation technique. No remediated harvest, lots or batches may be sold or transported until the completion and successful passage of quality assurance testing as required in this section.
- (5) Referencing. Certified labs may reference samples for mycotoxin, heavy metals, and pesticides testing to other certified labs by subcontracting for those fields of testing. Labs must record all referencing to other labs on a chain-of-custody manifest that includes, but is not limited to, the following information: Lab name, certification number, transfer date, address, contact information, delivery personnel, sample ID numbers, field of testing, receiving personnel.
- (6) Certified labs are not limited in the amount of usable marijuana and marijuana products they may have on their premises at any given time, but a certified lab must have records proving all marijuana and marijuana-infused products in the certified lab's possession are held only for the testing purposes described in this section.
- (7) Upon the request of the WSLCB or its designee, a licensee or a certified lab must provide an employee of the WSLCB or their designee samples of marijuana or marijuana products or samples of the growing medium, soil amendments, fertilizers, crop production aids, pesticides, or water for random compliance checks. Samples may be screened for pesticides and chemical residues, unsafe levels of heavy metals, and used for other quality assurance tests deemed necessary by the WSLCB.

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WAC 314-55-103 Good laboratory practice checklist. A third-party testing lab must be certified by the WSLCB or its vendor as meeting the WSLCB's accreditation and other requirements prior to conducting required quality assurance tests. The following checklist will be used by the WSLCB or its vendor to certify third-party testing labs:

	IZATION eted by: ved by:	Document Reference	Y	N	NA	Comments
1.	The laboratory or the organization of which it is a part of shall be an entity that can be held legally responsible.	-	-	-	-	-
2.	The laboratory conducting third-party testing shall have no financial interest in a licensed producer or processor for which testing is being conducted.	-	-	-	-	-
	If the laboratory is part of an organization performing activities other than testing ((and/or calibration)), the responsibilities of key personnel in the organization that have an involvement or influence on the testing ((and/or calibration)) activities of the laboratory shall be defined in order to identify potential conflicts of interest.	-	-	-	-	-
3.	The laboratory shall have policies and procedures to ensure the protection of its client's confidential information and proprietary rights, including procedures for protecting the electronic storage and transmission of results.	-	-	-	-	-
4.	In every instance where the lab references certification status they shall clearly indicate which tests they are currently certified for.	Ξ	=	=	=	=
<u>5.</u>	The laboratory is responsible for all costs of initial certification and ongoing site assessments.	-	-	-	-	-
((5.)) <u>6.</u>	The laboratory must agree to site assessments every ((two)) year for the first three years to maintain certification. Beginning year four of certification, on-site assessments will occur every two years to maintain certification.	-	-	-	-	-
((6.)) <u>7.</u>	The laboratory must allow WSLCB staff or their representative to conduct physical visits and check I-502 related laboratory activities at any time.	-	-	-	-	-
((7-)) <u>8.</u>	The laboratory must report all test results directly into WSLCB's traceability system within twenty-four hours of completion. Labs must also record in the traceability system an acknowledgment of the receipt of samples from producers or processors and verify if any unused portion of the sample was destroyed or returned to the customer.	-	-	-	-	-

	RESOURCES eted by: ved by:	Document Reference	Y	N	NA	Comments
((8.)) <u>9a.</u>	Job descriptions for owners and all employees((: Key staff)). A written and documented system detailing the qualifications of each member of the staff including any specific training requirements applicable to analytical methods.	-	-	-	-	-
<u>b.</u>	Specialized training such as by vendors, classes granting CEUs, etc., shall be documented in each training file.	=	Ξ	=	Ξ	=
((9.)) <u>10.</u>	Qualifications of owners and staff: CVs for staff on file.	-	-	-	-	-

	N RESOURCES eted by: ved by:	Document Reference	Y	N	NA	Comments
a.	Have technical management which has overall responsibility for the technical operations and the provision of the resources needed to ensure the required quality of laboratory operations.	-	-	-	-	-
b.	Documentation that the scientific director meets the requirements of WSLCB rules.	-	-	-	-	-
c.	Chain of command, personnel organization/flow chart, dated and signed by the laboratory director.	-	-	-	-	-
d.	Written documentation of delegation of responsibilities in the absence of the scientific director and management staff (assigned under chapter 314-55 WAC as related to quality assurance testing) ((to qualified personnel, signed and dated by the laboratory director)).	-	-	-	-	-
e.	Documentation of employee competency (<u>DOC</u>): Prior to independently analyzing samples, <u>and on an annual, ongoing basis</u> , testing personnel must demonstrate acceptable performance on precision, accuracy, specificity, reportable ranges, blanks, and unknown challenge samples (proficiency samples or internally generated quality controls). Dated and signed by the laboratory director.	-	-	-	-	-
f.	The laboratory management shall ensure the competence of all who operate specific equipment, perform tests and/or calibrations, evaluate results, and sign test reports and calibration certificates.	=	Ξ	Ξ	Ξ	=
<u>g.</u>	When using staff who are undergoing training, appropriate supervision shall be provided.	=	=	=	Ξ	Ξ
<u>h.</u>	Personnel performing specific tasks shall be qualified on the basis of appropriate education, training, experience and/or demonstrated skills, as necessary.	Ξ	Ξ	=	Ξ	=
<u>i.</u>	The management shall authorize specific personnel to perform particular types of sampling, test and/or calibration, to issue test reports and calibration certificates, to give opinions and interpretations and to operate particular types of equipment.	=	=	Ξ	Ξ	Ξ
<u>j.</u>	The laboratory shall maintain records of the relevant authorization(s), competence, educational and professional qualifications, training, skills and experience of all technical personnel, including contracted personnel.	Ξ	Ξ	=	=	=
<u>k.</u>	Successful training (in-house courses are acceptable) in specific methodologies used in the laboratory shall be documented.	Ξ	Ξ	=	Ξ	Ξ
<u>1.</u>	Designate a quality manager (however named) who, irrespective of other duties and responsibilities, shall have defined responsibility and authority for ensuring that the quality system is implemented and followed; the quality manager shall have direct access to the highest level of management at which decisions are made on laboratory policy or resources.	-	-	-	-	-
((10.	Written and documented system detailing the qualifications of each member of the staff.	-	-	-	-	-
	The need to require formal qualification or certification of personnel performing certain specialized activities shall be evaluated and implemented where necessary.	<u>-</u>	-	-	-	-
11.	Standard operating procedure manual that details records of internal training provided by facility for staff. Laboratory director must approve, sign and date each procedure.	-	-	-	-	-))
<u>m.</u>	The laboratory shall delegate responsibilities for key managerial personnel to be acted upon in cases of absence or unavailability.	Ξ	=	=	=	=

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_	N RESOURCES eted by: ved by:	Document Reference	Y	N	NA	Comments
<u>n.</u>	The laboratory shall provide adequate supervision of testing staff, including trainees, by persons familiar with methods and procedures, purpose of each test and/or calibration, and with the assessment of the test or calibration results.	=	Ξ	=	=	=
<u>11.</u>	Standard operating procedure for the following:	=	=	Ξ	1.1	=
a.	Instructions on regulatory inspection and preparedness.	-	-	-	-	-
b.	Instruction on law enforcement interactions.	-	-	-	-	-
c.	Information on U.S. federal laws, regulations, and policies relating to individuals employed in these operations, and the implications of these for such employees.	-	-	-	-	-
d.	Written and documented system of employee training on hazards (physical and health) of chemicals in the workplace, including prominent location of MSDS or SDS sheets and the use of appropriate PPE.	-	-	-	-	-
e.	Written and documented system on the competency of personnel on how to handle chemical spills and appropriate action; spill kit on-site and well-labeled, all personnel know the location and procedure.	-	-	-	-	-
f.	Information on how employees can access medical attention for chemical or other exposures, including follow-up examinations without cost or loss of pay.	-	-	-	-	-
g.	Biosafety <u>at a minimum covering sterilization and disinfection procedures</u> and sterile technique training.	-	-	-	-	-

	STANDARD OPERATING PROCEDURES	Document Reference	Y	N	NA	Comments
12.	As appropriate, laboratory operations covered by procedures shall include, but not be limited to, the following:	-	-	-	-	-
a.	Environmental, safety and health activities;	-	-	-	-	-
b.	Sample shipping and receipt;	-	-	-		-
c.	Laboratory sample chain of custody and material control;	ı	-	-	-	-
d.	Notebooks/logbooks;	-	-	-	-	-
e.	Sample storage;	-	-	-		-
f.	Sample preparation;	-	-	-		-
g.	Sample analysis;	-	-	-		-
h.	Standard preparation and handling;	-	-	-	-	-
i.	Postanalysis sample handling;	-	-	-	-	-
j.	Control of standards, reagents and water quality;	-	-	-	-	-
k.	Cleaning of glassware;	-	-	-	-	-
1.	Waste minimization and disposition.	-	-	-	-	-
13.	The following information is required for procedures as appropriate to the scope and complexity of the procedures or work requested:	-	-	-	-	-
a.	Scope (e.g., parameters measured, range, matrix, expected precision, and accuracy);	-	-	-	-	-
b.	Unique terminology used;	-	-	-	-	-
c.	Summary of method;	-	-	-	-	-
d.	Interferences/limitations;	-	_	_	-	-
e.	Approaches to address background corrections;	-	_	-	-	-
f.	Apparatus and instrumentation;	-	-	_	-	-
g.	Reagents and materials;	-	-	_	-	-

	STANDARD OPERATING PROCEDURES	Document Reference	Y	N	NA	Comments
h.	Hazards and precautions;	-	-	-	-	-
i.	Sample preparation;	-	-	-	-	-
j.	Apparatus and instrumentation setup;	-	-	-	-	-
k.	Data acquisition system operation;	-	-	-	-	-
1.	Calibration and standardization;	-	-	-	-	-
m.	Procedural steps;	-	-	-	-	-
n.	QC parameters and criteria;	-	-	-	-	-
0.	Statistical methods used;	-	-	-	-	-
p.	Calculations;	-	-	-	-	-
q.	Assignment of uncertainty;	-	-	-	-	-
r.	Forms used in the context of the procedure.	-	-	-	-	-
<u>s.</u>	Document control with master list identifying the current revision status of documents.	=	Ξ	=	=	=
	FACILITIES AND EQUIPMENT	Document Reference	Y	N	NA	Comments
14.	Allocation of space: Adequate for number of personnel and appropriate separation of work areas.	-	-	-	-	-
15.	Arrangement of space.	-	-	-	-	-
a.	Allows for appropriate work flow, sampling, lab space separate from office and break areas.	-	-	-	-	-
b.	Employee bathroom is separate from any laboratory area.	-	-	-	-	-
16.	Adequate eyewash/safety showers/sink.	-	-	-	-	-
17.	Procurement controls.	-	-	-	-	-
a.	The laboratory shall have procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures covering reagents and laboratory consumables shall exist for the	-	-	-	-	-
	purchase, receipt ((and)), storage ((of reagents and laboratory consumable materials relevant for the tests and ealibrations)), and disposition of expired materials.					

b. Employee bathroom is separate from any laboratory area. 16. Adequate eyewash/safety showers/sink. 17. Procurement controls. a. The laboratory shall have procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of the tests and/or calibrations. Procedures covering reagents and laboratory consumables shall exist for the purchase, receipt ((and)), storage (of reagents and laboratory consumable materials relevant for the tests and ealibrations), and disposition of expired materials. b. The laboratory shall ensure that purchased supplies and reagents and consumable materials that affect the quality of tests and/or calibrations are inspected or otherwise verified as complying with standard specifications or requirements defined in the methods for the tests and/or calibrations concerned. i. Reagents and standards shall be inspected, dated and initialed upon receipt, and upon opening. ii. Calibration standards and analytical reagents shall have an expiration or reevaluation date assigned. iii. Solutions shall be adequately identified to trace back to preparation documentation. c. Prospective suppliers shall be evaluated and selected on the basis of specified criteria. d. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented. ((e: When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information shall be forwarded to appropriate management for action.	a.	Allows for appropriate work flow, sampling, lab space separate from office and break areas.	-	-	-	-	-
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d. Processes to ensure that approved suppliers continue to provide acceptable items and services shall be established and implemented. ((e. When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information shall be forwarded to appropriate management for action.	<u>iii.</u>		=	Ξ	=	Ξ	=
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supplied items or services of substandard quality, this information shall be forwarded to appropriate management for action.	d.	provide acceptable items and services shall be established	-	-	-	-	-
18. Subcontracting.	((e.	supplied items or services of substandard quality, this information shall be forwarded to appropriate management	-	-	-	-	-))
	<u>18.</u>	Subcontracting.	=	Ξ	=	1.1	=

	FACILITIES AND EQUIPMENT	Document Reference	Y	N	NA	Comments
<u>a.</u>	The laboratory shall advise the customer of the subcontract arrangement in writing, including the subcontractors' accreditation credentials under chapters 69.50 RCW and 314-55 WAC.	Ξ	=	=	Ξ	=
<u>b.</u>	The laboratory shall maintain a register of all subcontractors that it uses for tests and/or calibrations and a record of the evidence of compliance with chapter 314-55 WAC for the work in question.	=	=	Ξ	Ξ	Ξ
<u>c.</u>	When there are indications that subcontractors knowingly supplied items or services of substandard quality, this information shall be forwarded to appropriate management for action.	=	Ξ	Ξ	Ξ	=
((18.)) <u>19.</u>	Utilities (items verified upon on-site inspection).	-	-	-	-	-
a.	Electrical:	-	-	-	-	-
i.	Outlets: Adequate, unobstructed, single-use, ((no)) multiplug adaptors with surge control;	-	-	-	-	-
ii.	((No)) Single-use extension cords;	-	-	-	-	-
iii.	Ground fault circuit interrupters near wet areas.	-	-	-	-	-
b.	Plumbing:	-	-	-	-	-
i.	Appropriateness of sink usage: Separate sinks for work/personal use;	-	-	-	-	-
ii.	Adequate drainage from sinks or floor drains;	-	-	-	-	-
iii.	Hot and cold running water.	-	-	-	=.	-
c.	Ventilation:	-	-	-	-	-
i.	Areas around solvent use or storage of solvents or waste solvents;	-	-	-	-	-
ii.	Vented hood for any microbiological analysis - Class II Type A biosafety cabinet as applicable.	-	-	-	-	-
<u>iii.</u>	Fume hood with appropriate ventilation.	=	=	=	Ξ	=
d.	Vacuum: Appropriate utilities/traps for prevention of contamination (as applicable).	-	-	-	-	-
e.	Shut-off controls: Located outside of the laboratory.	-	-	-	-	-
((19.)) <u>20.</u>	Waste disposal: Appropriate for the type of waste and compliant with WAC 314-55-097 Marijuana waste disposal —Liquids and solids.	-	-	-	-	-
((20.)) <u>21.</u>	Equipment ((list)). Equipment and/or systems requiring periodic maintenance shall be identified and records of major equipment shall include:	-	-	-	-	-
	((Equipment and/or systems requiring periodic maintenance shall be identified and records of major equipment shall include:	-	-	1	-	-))
a.	Name;	-	-	-	-	-
b.	Serial number or unique identification from name plate;	-	-	-	-	-
c.	Date received and placed in service;	-	-	-	-	-
d.	Current location;	-	-	-	-	-
e.	Condition at receipt;	-	-	-	-	-
f.	Manufacturer's instructions;	-	-	-	-	-
g.	Date of calibration or date of next calibration;	-	-	-	-	-
h.	Maintenance;	-	-	-	-	-
i.	History of malfunction.	-	-	-	-	-
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	FACILITIES AND EQUIPMENT	Document Reference	Y	N	NA	Comments
((21.)) <u>22.</u>	Maintenance.	-	-	-	-	-
a.	((Regular)) Documented evidence of routine preventive maintenance and calibration of equipment ((demonstration in logbook)) including, but not limited to: Thermometer ((ealibration)), pipette ((ealibrations)), analytical balances, and additional analytical equipment. ((Documentation of a schedule and reviewed by the laboratory director.))	-	-	-	-	-
((b.)) <u>i.</u>	<u>Calibration programs shall be established for key quantities</u> or values of the instruments where these properties have a <u>significant effect on the results.</u>	Ξ	Ξ	-	Ξ	=
<u>ii.</u>	Before being placed into service, equipment, including equipment used for sampling, shall be calibrated or checked to establish that it meets the laboratory's specification requirements and complies with the relevant standard specifications.	=	Ξ	11	Ξ	=
iii.	Equipment that has been subjected to overloading or mishandling, gives suspect results, or has been shown to be defective or outside of specified limits, shall be taken out of service. Such equipment shall be isolated to prevent its use or clearly labeled or marked as being out-of-service until it has been repaired and shown by calibration or test to perform correctly.	Ξ	Ξ	11	-	Ξ
<u>b.</u>	<u>Documentation of a maintenance schedule and reviewed by the laboratory director.</u>	Ξ	=	=	=	=
<u>i.</u>	Calibration procedures shall specify frequency of calibration checks.	Ξ	=	=	Ξ	Ξ
<u>ii.</u>	Instruments that are routinely calibrated shall be verified daily or prior to analyzing samples (as applicable).	Ξ	Ξ	=	Ξ	=
<u>iii.</u>	Acceptance criteria shall be determined, documented and used.	Ξ	=	-	Ξ	=
<u>iv.</u>	When possible, any external calibration service (metrological laboratory) used shall be a calibration laboratory accredited to ISO/IEC 17025:2005 by a recognized accreditation body.	Ξ	=	-	Ξ	=
<u>V.</u>	Laboratories shall demonstrate, when possible, that calibrations of critical equipment and hence the measurement results generated by that equipment, relevant to their scope of accreditation, are traceable to the SI through an unbroken chain of calibrations.	Ξ	Ξ	=	Ξ	=
<u>vi.</u>	External calibration services shall, wherever possible, be obtained from providers accredited to one of the following: ISO/IEC 17025, ISO Guide 34, an ILAC recognized signatory, a CIPM recognized National Metrology Institute (NMI), or a state weights and measures facility that is part of the NIST laboratory metrology program. Calibration certificates shall be endorsed by a recognized accreditation body symbol or otherwise make reference to accredited status by a specific, recognized accreditation body, or contain endorsement by the NMI. Certificates shall indicate traceability to the SI or reference standard and include the measurement result with the associated uncertainty of measurement.	Ξ	=		Ξ	Ξ
<u>vii.</u>	Where traceability to the SI is not technically possible or reasonable, the laboratory shall use certified reference materials provided by a competent supplier.	=	=	=	=	=

	FACILITIES AND EQUIPMENT	Document Reference	Y	N	NA	Comments
viii.	Calibrations performed in-house shall be documented in a manner that demonstrates traceability via an unbroken chain of calibrations regarding the reference standard/material used, allowing for an overall uncertainty to be estimated for the in-house calibration.	Ξ	=	Ξ	Ξ	=
<u>ix.</u>	Calibrations shall be repeated at appropriate intervals, the length of which can be dependent on the uncertainty required, the frequency of use and verification, the manner of use, stability of the equipment, and risk of failure considerations.	Ξ	=	Ξ	Ξ	Ξ
<u>X.</u>	Periodic verifications shall be performed to demonstrate the continued validity of the calibration at specified intervals between calibrations. The frequency of verifications can be dependent on the uncertainty required, the frequency of use, the manner of use, stability of the equipment, and risk of failure considerations.	Ξ	Ξ	Ξ	=	Ξ
<u>c.</u>	Documentation of curative maintenance in logbook, signed and dated by laboratory director.	-	-	-	-	-
((e .	Temperature maintenance logbook for refrigerators.	-		-	-	-))
d.	Evidence of temperature monitoring for equipment requiring specific temperature ranges.	Ξ	=	=	=	=
<u>e.</u>	Test and calibration equipment, including both hardware and software, shall be safeguarded from adjustments which would invalidate the test and/or calibration results.	Ξ	Ξ	Ξ	Ξ	=
<u>f.</u>	Decontamination and cleaning procedures for:	-	-	-	1	-
i.	Instruments;	-	-	-	-	-
ii.	Bench space; and	-	-	-	-	-
iii.	Ventilation hood/microbial hood.	-	-	-	-	-
((e.)) g.	Documentation of adequacy of training of personnel and responsibility for each maintenance task.	-	-	-	-	-
((f.)) <u>h.</u>	The organization shall describe or reference how periodic preventive and corrective maintenance of measurement or test equipment shall be performed to ensure availability and satisfactory performance of the systems.	-	-	-	-	-
((22.)) <u>23.</u>	Computer systems (items verified upon on-site inspection).	-	-	-	-	-
a.	Adequate for sample tracking.	-	-	-	-	-
b.	Adequate for analytical equipment software.	-	-	-	-	-
c.	Software control requirements applicable to both commercial and laboratory developed software shall be developed, documented, and implemented.	-	-	_	-	-
d.	In addition, procedures for software control shall address the security systems for the protection of applicable software.	-	-	-	-	-
e.	For laboratory-developed software, a copy of the original program code shall be:	-	-	-	-	-
i.	Maintained;	-	-	-	-	-
ii.	All changes shall include a description of the change, authorization for the change;	_	-	-	-	-
iii.	Test data that validates the change.	-	-	-	-	-
f.	Software shall be acceptance tested when installed, after changes, and periodically during use, as appropriate.	-	-	-	-	-
g.	<u>Software testing</u> ((may consist of)) shall include performing manual calculations or checking against another software product that has been previously tested, or by analysis of standards.	-	-	-	-	-

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	FACILITIES AND EQUIPMENT	Document Reference	Y	N	NA	Comments
h.	The version and manufacturer of the software shall be documented.	-	-	-	-	-
i.	Commercially available software may be accepted as supplied by the vendor. For vendor supplied instrument control/data analysis software, acceptance testing may be performed by the laboratory.	-	-	-	-	-
((23.)) <u>24.</u>	Security.	-	-	-	-	-
a.	Written facility security procedures during operating and nonworking hours.	-	-	-	-	-
b.	Roles of personnel in security.	-	-	-	-	-
c.	SOP for controlled access areas and personnel who can access.	-	-	-	-	-
((d.	Secured areas for log-in of sample, and for short and long-term storage of samples.	-	-	-	1	-
24.)) 25.	Control of records.	Ξ	=	Ξ	Ξ	=
<u>a.</u>	The laboratory shall establish and maintain procedures for identification, collection, indexing, access, filing, storage, maintenance and disposal of quality and technical records.	Ξ	Ξ	Ξ	Ξ	Ξ
<u>b.</u>	All records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.	Ξ	=	Ξ	Ξ	=
<u>c.</u>	Records must be retained for a period of three years.	=	=	=	Ξ	=
<u>d.</u>	All records shall be held secure and in confidence.	=	=	=	Ξ	=
<u>e.</u>	The laboratory shall have procedures to protect and back-up records stored electronically and to prevent unauthorized access to or amendment of these records.	Ξ	=	Ξ	Ξ	Ξ
<u>f.</u>	The laboratory shall retain records of original observations, derived data and sufficient information to establish an audit trail, calibration records, staff records and a copy of each test report or calibration certificate issued, for a defined period.	Ξ	Ξ	Ξ	Ξ	=
g.	The records for each test or calibration shall contain sufficient information to facilitate, if possible, identification of factors affecting the uncertainty and to enable the test or calibration to be repeated under conditions as close as possible to the original.	Ē	Ξ	Ξ	=	=
<u>h.</u>	The records shall include the identity of personnel responsible for the sampling, performance of each test and/or calibration and checking of results.	Ξ	=	Ξ	=	=
<u>i.</u>	Observations, data and calculations shall be recorded at the time they are made and shall be identifiable to the specific task.	Ξ	=	=	Ξ	=
<u>j.</u>	When mistakes occur in records, each mistake shall be lined out, not erased or made illegible or deleted, and the correct value entered alongside.	Ξ	=	Ξ	Ξ	Ξ
<u>k.</u>	All such alterations or corrections to records shall be signed or initialed and dated by the person making the correction.	Ξ	=	Ξ	Ξ	=
<u>l.</u>	In the case of records stored electronically, equivalent measures shall be taken to avoid loss or change of original data.	Ξ	=	Ξ	Ξ	Ξ
<u>m.</u>	All entries to hard copy laboratory records shall be made using indelible ink. No correction fluid may be used on original laboratory data records.	Ξ	=	=	Ξ	=

	FACILITIES AND EQUIPMENT	Document Reference	Y	N	NA	Comments
<u>n.</u>	Laboratories shall establish and maintain a data review process beginning at sample receipt and extending through the report process. The data review process shall be an independent review, conducted by a qualified individual other than the analyst.	=	Ξ	Ξ	Ξ	=
<u>O.</u>	The review process shall be documented before data are reported.	Ξ	=	Ξ	Ξ	=
<u>26.</u>	Storage.	-	-	-	-	-
a.	Appropriate and adequate for sample storage over time. The laboratory shall monitor, control and record environmental conditions as required by the relevant specifications, methods and procedures or where they influence the quality of the results. Due attention shall be paid, for example, to biological sterility, dust, electromagnetic disturbances, humidity, electrical supply, temperature, and sound and vibration levels, as appropriate to the technical activities concerned.	-	-	-	-	-
b.	Adequate storage of chemical reference standards.	-	-	-	-	-
c.	Appropriate storage of any reagents: Fireproof cabinet, separate cabinet for storage of any acids.	-	-	-	-	-
d.	Appropriate safe and secure storage of documents etc., archiving, retrieval of, maintenance of and security of data for a period of three years.	-	-	-	-	-

		Document				
	QA PROGRAM AND TESTING	Reference	Y	N	NA	Comments
((25.)) <u>27.</u>	Sampling/sample protocols((±)) <u>must be consistent with chapter 314-55 WAC</u> , written and approved by the laboratory director, and must include documented training.	-	-	-	-	-
a.	Demonstrate adequacy of the chain-of-custody, <u>including:</u> <u>Tracking upon receipt of sample including all personnel handling the sample and documenting condition of the sample through a macroscopic and foreign matter inspection.</u>	-	-	-	-	-
b.	((Sampling method (representative of an entire batch) including, but not limited to, homogenization, weighing, labeling, sample identifier (source, lot), date and tracking.	-	-	-	-	-
e.	Condition of the sample:)) Macroscopic and foreign matter inspection - Fit for purpose test. Scientifically valid testing methodology: Either AHP monograph compliant((;)) or other third-party validation.	-	-	-	-	-
((d.)) <u>c.</u>	Failed inspection of product: Tracking and reporting.	-	-	-	-	-
((e.)) <u>d.</u>	Return of failed product documentation and tracking.	-	-	-	-	-
((f.)) <u>e.</u>	Disposal of used/unused samples documentation.	-	-	-	-	-
((g.)) <u>f.</u>	Sample preparation, extraction and dilution SOP.	-	-	-	-	-
((h.)) <u>g.</u>	Demonstration of recovery for samples in various matrices (SOPs):	-	-	-	-	-
i.	Plant material - Flower;	-	-	-	-	-
ii.	Edibles (solid and liquid meant to be consumed orally);	-	-	-	-	-
iii.	Topical;	-	-	-	-	-
iv.	Concentrates.	-	-	-	-	-
((26.)) <u>28.</u>	Data protocols.	-	-	-	_	-

	QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
a.	Calculations for quantification of cannabinoid content in various matrices - SOPs.	-	-	-	-	-
b.	Determination of the range for reporting the quantity (LOD/LOQ) data review or generation.	-	-	-	-	-
c.	Reporting of data: Certificates of analysis (CA) - Clear and standardized format for consumer reporting.	-	-	-	-	-
d.	Each test report shall include at least the following information, unless the laboratory has valid reasons for not doing so:	Ξ	=	=	Ξ	=
<u>i.</u>	A title (e.g., "Test Report" or "Certificate of Analysis");	=	=	=	=	=
<u>ii.</u>	The name and address of the laboratory, and the location where the tests were carried out, if different from the address of the laboratory;	Ξ	Ξ	Ξ	Ξ	=
<u>iii.</u>	Unique identification of the test report certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;	=	=	Ξ	=	=
<u>iv.</u>	The name and address of the customer;	Ξ	=	=	Ξ	=
<u>v.</u>	Identification of the method used;	Ξ	=	=	Ξ	=
<u>vi.</u>	A description of, the condition of, and unambiguous identification of the item(s) tested;	Ξ	=	Ξ	Ξ	=
vii.	The date of receipt of the test item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;	Ξ	=	Ξ	Ξ	Ξ
viii.	Reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;	Ξ	Ξ	Ξ	=	=
<u>ix.</u>	The test results with, where appropriate, the units of measurement;	Ξ	=	=	Ξ.	=
<u>X.</u>	The name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or certificate; and	Ξ	Ξ	Ξ	Ξ	=
<u>xi.</u>	Where relevant, a statement to the effect that the results relate only to the items tested or calibrated.	=	=	=	Ξ	=
<u>e.</u>	Material amendments to a test report or calibration certificate after issue shall be made only in the form of a further document, or data transfer, which includes the statement: "Supplement to Test Report (or Calibration Certificate), serial number (or as otherwise identified)," or an equivalent form of wording.	=	Ξ	Ξ	=	Ξ
<u>f.</u>	When it is necessary to issue a complete new test report or calibration certificate, this shall be uniquely identified and shall contain a reference to the original that it replaces.	Ξ	Ξ	Ξ	Ξ	=
<u>g.</u>	If the laboratory chooses to include a reference to their I-502 certification on their test report, any test results not covered under I-502 certification shall be clearly identified on the report.	Ξ	=	=	Ξ	=
<u>h.</u>	Documentation that the value reported in the CA is within the range and limitations of the analytical method.	-	-	_	-	-
((e .)) <u>i.</u>	Documentation that qualitative results (those below the LOQ but above the LOD) are reported as "trace," or with a nonspecific (numerical) designation.	-	-	-	-	-
((f.)) <u>j.</u>	Documentation that the methodology has the specificity for the degree of quantitation reported. Final reports are not quantitative to any tenths or hundredths of a percent.	-	-	-	-	-

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	QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
((g.)) <u>k.</u>	Use of appropriate "controls": Documentation of daily use of positive and negative controls that challenge the linearity of the curve; and/or an appropriate "matrix blank" and control with documentation of the performance for each calibration run.	-	-	-	-	-
((27.)) 29.	Chemical assay procedure/methodology.	-	-	-	-	-
((28.	Proficiency:	-	-	-	-	-))
<u>30.</u>	Quality Control (QC):	Ξ	=	=	=	Ξ.
a.	Documentation of use of an appropriate internal standard for any quantitative measurements as applicable to the method.	-	-	-	-	-
b.	Appropriate reference standards for quantification of analytes, performing and documenting a calibration curve with each analysis.	-	-	-	-	-
<u>i.</u>	Reference materials shall, where possible, be traceable to SI units of measurement, or to certified reference materials. Internal reference materials shall be checked for accuracy as far as is technically and economically practicable.	=	=	=	Ξ	Ξ
<u>ii.</u>	The laboratory shall create and follow procedures for safe handling, transport, storage and use of reference standards and reference materials in order to prevent contamination or deterioration and in order to protect their integrity.	=	=	=	Ξ	Ξ
<u>iii.</u>	Reference materials shall have a certificate of analysis that documents traceability to a primary standard or certified reference material and associated uncertainty, when possible. When applicable, the certificate must document the specific NIST SRM® or NMI certified reference material used for traceability.	=	=	Ξ	=	Ξ
c.	Demonstration of calibration curve r ² value of no less than 0.995 with a minimum of four points ((within)) which bracket the expected sample concentration range.	-	-	-	-	-
((d.	Documentation of any proficiency testing as it becomes available. Laboratory director must review, evaluate and report to the WSLCB any result that is outside the stated acceptable margin of error.	-	-	-	-	-))
<u>i.</u>	The calibration curve shall be verified by preparing an independently prepared calibration standard (from neat materials) or with a standard from an independent source. Acceptance criteria for the standard calibration curve and the independent calibration verification standard shall be documented.	Ξ	Ξ	Ξ	Ξ	=
<u>ii.</u>	Instrument calibration/standardization shall be verified each 24-hour period of use, or at each instrument start-up if the instrument is restarted during the 24-hour period, by analysis of a continuing calibration verification standard. Acceptance criteria shall be documented.	=	Ξ	Ξ	Ξ	=
<u>iii.</u>	Calibration or working quantification ranges shall encompass the concentrations reported by the laboratory. Continuing calibration verification standards and continuing calibration blanks shall be analyzed in accordance with the specified test methods. Acceptance criteria shall be documented.	Ξ	Ξ	=	Ξ	=
<u>d.</u>	Assuring the quality of test results.	Ξ	=	=	=	=
<u>i.</u>	The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken.	Ξ	Ξ	=	=	Ξ
<u>ii.</u>	The resulting data shall be recorded in such a way that trends are detectable and, where practicable, statistical techniques shall be applied to the reviewing of the results.	Ξ	=	=	=	Ξ

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	QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
<u>iii.</u>	This monitoring shall be planned and reviewed and may include, but not be limited to, the following:	=	=	Ξ	Ξ	=
<u>A.</u>	Regular use of certified reference materials and/or internal quality control using secondary reference materials;	Ξ	=	=	=	=
<u>B.</u>	Participation in interlaboratory comparison or proficiency- testing programs;	Ξ	Ξ	=	=	=
<u>C.</u>	Replicate tests or calibrations using the same or different methods;	=	=	=	Ξ	=
<u>D.</u>	Retesting or recalibration of retained items;	Ξ	=	=	=	=
<u>E.</u>	Correlation of results for different characteristics of an item.	=	=	=	=	=
<u>iv.</u>	Quality control data shall be analyzed and, where they are found to be outside predefined criteria, planned actions shall be taken to correct the problem and to prevent incorrect results from occurring.	Ξ	=	Ξ	Ξ	Ξ
<u>v.</u>	The laboratory shall determine, where feasible, the accuracy and precision of all analyses performed.	Ξ	=	=	Ξ	=
<u>vi.</u>	Acceptance limits for each method shall be established based on statistical evaluation of the data generated by the analysis of quality control check samples, unless specific acceptance limits are established by the method.	=	=	=	=	=
<u>vii.</u>	Control charts or quality control data bases shall be used to record quality control data and compare them with acceptance limits.	Ξ	Ξ	Ξ	=	=
<u>viii.</u>	Procedures shall be used to monitor trends and the validity of test results.	Ξ	=	=	Ξ	=
<u>31.</u>	Proficiency.	=	=	=	=	=
<u>a.</u>	Participation in approved PT programs for each field of testing.	Ξ	Ξ	Ξ	Ξ	=
<u>b.</u>	Passing PT results for two consecutive PTs.	=	=	=	=	=
<u>c.</u>	Documentation of investigation for all failed PTs.	Ξ	=	=	=	=
((29.)) <u>32.</u>	Method validation: Scientifically valid testing methodology: ((Either)) AHP monograph compliant, other third-party validation((\(\frac{1}{2}\))) or the current version of a standard method. The following requirements are applied to other third-party validation:	-	-	-	-	-
((30.	Level II validation of methodology used for quantification of THC, THCA and CBD for total cannabinoid content (if reporting other cannabinoids, the method must also be validated for those compounds):	-	-	-	-	-
a.	Single lab validation parameters are demonstrated for GC, HPLC data review:	-	-	-	-	-
i.	Linearity of reference standards;	-	_	-	-	-
ii.	Use of daily standard curve;		-	-	-	-
iii.	Accuracy;	-	_	-	-	-
iv.	Precision;	-	-	-	-	-
₩.	Recovery (5 determinations not less than 90%);	-	-	-	-	-
vi.	Reproducibility over time within a relative standard deviation of 5%.	-	-	-	-	-
b.	Dynamic range of the instrumentation: Limits of quantification (LOQ) and limits of detection (LOD).	-	-	-	-	-

	QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
e.)) <u>a.</u>	The laboratory shall validate nonstandard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and amplifications and modifications of standard methods to confirm that the methods are fit for the intended use.	=	Ξ	Ξ	Ξ	=
<u>b.</u>	The validation shall be as extensive as is necessary to meet the needs of a given application or field of application.	Ξ	=	=	Ξ	=
<u>c.</u>	The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to whether the method is fit for the intended use.	Ξ	=	=	=	=
<u>d.</u>	The customer shall be informed as to the method chosen.	=	=	=	Ξ	=
<u>e.</u>	The laboratory shall confirm that it can properly operate standard methods before introducing the tests or calibrations. If the standard method changes, the confirmation shall be repeated.	=	Ξ	Ξ	=	Ξ
<u>f.</u>	Deviation from test and calibration methods shall occur only if the deviation has been documented, technically justified, authorized, and accepted by the customer.	1	=	1	Ξ	=
<u>g.</u>	Validation shall be documented and include the following elements as applicable:	Ξ		=	Ξ	Ξ
<u>i.</u>	Minimum acceptance criteria;	Ξ	Ξ	=	Ξ	=
<u>ii.</u>	Analyte specificity;	Ξ	=	=	Ξ	=
<u>iii.</u>	Linearity;	Ξ	=	=	Ξ	=
<u>iv.</u>	Range;	Ξ	=	Ξ	1.1	Ξ
<u>v.</u>	Accuracy;	Ξ	=	=	Ξ	=
<u>vi.</u>	Precision;	Ξ	=	=	Ξ	Ξ
<u>vii.</u>	Detection limit;	Ξ	=	=	Ξ	Ξ
<u>viii.</u>	Quantification limit;	Ξ	=	=	Ξ	=
<u>ix.</u>	Stability of samples and reagents interlaboratory precision;	Ξ	=	=	Ξ	=
<u>X.</u>	Analysis robustness;	Ξ	=	=	Ξ	Ξ
<u>xi.</u>	Presence of QC samples;	Ξ	=	=	=	Ξ
<u>xii.</u>	Use of appropriate internal reference standard;	=	=	=	=	=
<u>xiii.</u>	Daily monitoring of the response of the instrument;	=	=	=	Ξ	=
<u>h.</u>	<u>Validation shall be performed for matrix extensions for each</u> type of product tested, <u>including</u> data review of recovery for:	-	-	-	-	-
i.	Solvent-based extract;	-	-	-	-	-
ii.	CO ₂ extraction or other "hash oil";	-	-	-	-	-
iii.	Extract made with food grade ethanol;	-	-	-	-	-
iv.	Extract made with food grade glycerin or propylene glycol;	-	-	-	-	-
v.	Infused liquids;	-	-	-	-	-
vi.	Infused solids;	-	-	-	-	-
vii.	Infused topical preparations;	-	-	-	-	-
viii.	Other oils, butter or fats.	-	-	-	-	-
((d.	Presence of QC samples and recording of daily testing.	_	-	-	-	-
e.	Appropriate use of an internal reference standard.	-	-	-	-	_
f.	Daily monitoring of the response of the instrument detection system.	-	-	-	-	-
31.)) 33.	Estimation of uncertainty of measurement.	Ξ	=	=	Ξ	Ξ

	QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
<u>a.</u>	Testing laboratories shall have and shall apply procedures for estimating uncertainty of measurement. The laboratory shall at least attempt to identify all the components of uncertainty and make a reasonable estimation, and shall ensure that the form of reporting of the result does not give a wrong impression of the uncertainty. Reasonable estimation shall be based on knowledge of the performance of the method and on the measurement scope and shall make use of, for example, previous experience and validation data.	Ξ	Ξ	Ξ	=	Ξ
<u>b.</u>	In those cases where a well-recognized test method specifies limits to the values of the major sources of uncertainty of measurement and specifies the form of presentation of calculated results, the laboratory is considered to have satisfied this clause by following the test method and reporting instructions.	Ξ	Ξ	=	Ξ	=
<u>c.</u>	When estimating the uncertainty of measurement, all uncertainty components which are of importance in the given situation shall be taken into account using appropriate methods of analysis.	Ξ	=	Ξ	Ξ	=
<u>d.</u>	Sources contributing to the uncertainty include, but are not necessarily limited to, the reference standards and reference materials used, methods and equipment used, environmental conditions, properties and condition of the item being tested or calibrated, and the operator.	=	=	Ξ	Ξ	=
<u>e.</u>	Test methods are classified as either qualitative or quantitative. Qualitative tests are defined as having nonnumerical results. Although estimation of measurement uncertainty is not needed for these tests, laboratories are expected to have an understanding of the contributors to variability of the results. For quantitative tests, laboratories shall determine measurement uncertainty using appropriate statistical techniques.	Ξ	Ξ	Ξ	Ξ	=
<u>f.</u>	<u>Laboratories shall make independent estimations of uncertainty for tests performed on samples with significantly different matrices.</u>	Ξ	Ξ	Ξ	Ξ	Ξ
<u>g.</u>	<u>Laboratories are required to re-estimate measurement</u> uncertainty when changes to their operations are made that may affect sources of uncertainty.	Ξ	Ξ	Ξ	Ξ	=
<u>h.</u>	When reporting measurement uncertainty, the test report shall include the coverage factor and confidence level used in the estimations (typically k = approximately 2 at the 95% confidence level).	Ξ	=	=	Ξ	=
<u>34.</u>	Other methods.	-	-	-	-	-
a.	<u>Validated microbiological methods fit for purpose.</u>	-	-		-	-
b.	Microbial contaminants within limits ((of those listed in the most recent AHP monograph and otherwise)) as directed by WSLCB.	-	-	-	-	-
c.	Moisture content testing fit for purpose. Scientifically valid testing methodology: ((Either)) AHP monograph compliant, or other third-party validation.	-	-	-	-	-
d.	Solvent residuals testing fit for purpose; solvent extracted products made with class 3 or other solvents used are not to exceed 500 parts per million (PPM) per one gram of solvent based product and are to be tested.	-	-	-	-	-
e.	Any other QA/QC methods is proven to be fit for purpose.	-	-	-	-	-
((32.)) <u>35.</u>	Laboratory ((notebooks)) <u>records</u> .	-	-	-	-	-
a.	Legible and in ink (or computerized system).	-	-	_	-	-

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	QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
b.	Signed and dated.	-	-	-	-	-
c.	Changes initialed and dated.	-	-	-	-	-
d.	((Periodically reviewed)) Evidence of periodic review and signed by a management representative.	-	-	-	-	-
((33.)) <u>36.</u>	Preventive/corrective action.	-	-	-	-	-
	The laboratory shall ((have a process in place to document quality affecting preventive/corrective actions through resolution)) establish a policy and procedure and shall designate appropriate authorities for implementing corrective action when nonconforming work or departures from the policies and procedures in the management system or technical operations are identified.	-	-	-	-	-
<u>a.</u>	The procedure for corrective action shall start with an investigation to determine the root cause(s) of the problem.	Ξ	=	=	=	Ξ
<u>b.</u>	Where corrective action is needed, the laboratory shall identify potential corrective actions. It shall select and implement the action(s) most likely to eliminate the problem and to prevent recurrence.	=	=	=	Ξ	=
<u>c.</u>	The laboratory shall document and implement any required changes resulting from corrective action investigations.	Ξ	=	=	Ξ	Ξ
<u>d.</u>	Any PT round that leads to the nonproficient status of a laboratory shall be addressed by the corrective action process.	Ξ	Ξ	Ξ	Ξ	Ξ
<u>e.</u>	The laboratory shall monitor the results to ensure that the corrective actions taken have been effective.	Ξ	=	Ξ	=	Ξ
<u>f.</u>	When improvement opportunities are identified or if preventive action is required, action plans shall be developed, implemented and monitored to reduce the likelihood of the occurrence of such nonconformities and to take advantage of the opportunities for improvement.	Ξ	=	=	Ξ	=
<u>37.</u>	Complaints.	=	=	=	=	=
<u>a.</u>	The laboratory shall have a policy and procedure for the resolution of complaints received from customers or other parties.	Ξ	=	Ξ	Ξ	=
<u>b.</u>	Records shall be maintained of all complaints and of the investigations and corrective actions taken by the laboratory.	Ξ	=	=	Ξ	Ξ
<u>c.</u>	<u>Test reports.</u>	=	=	=	=	=
<u>d.</u>	Each test report or calibration certificate shall include at least the following information, unless otherwise justified:	Ξ	=	Ξ	=	Ξ
<u>i.</u>	A title (e.g., "Test Report" or "Calibration Certificate");	=	=	=	Ξ	=
<u>ii.</u>	The name and address of the laboratory, and the location where the tests and/or calibrations were carried out, if different from the address of the laboratory;	=	Ξ	=	=	=
iii.	Unique identification of the test report or calibration certificate (such as the serial number), and on each page an identification in order to ensure that the page is recognized as a part of the test report or calibration certificate, and a clear identification of the end of the test report or calibration certificate;	Ξ	=	=	=	Ξ
<u>iv.</u>	The name and address of the customer;	=	=	=	Ξ	=
<u>v.</u>	Identification of the method used;	Ξ	=	=	=	=
<u>vi.</u>	A description of, the condition of, and unambiguous identification of the item(s) tested or calibrated;	Ξ	Ξ	Ξ	Ξ	Ξ

	QA PROGRAM AND TESTING	Document Reference	Y	N	NA	Comments
<u>vii.</u>	The date of receipt of the test or calibration item(s) where this is critical to the validity and application of the results, and the date(s) of performance of the test or calibration;	=	Ξ	Ξ	Ξ	1.1
<u>viii.</u>	Reference to the sampling plan and procedures used by the laboratory or other bodies where these are relevant to the validity or application of the results;	=	Ξ	Ξ	Ξ	=
<u>ix.</u>	The test or calibration results with, where appropriate, the units of measurement;	Ξ	=	=	Ξ	=
<u>X.</u>	The name(s), function(s) and signature(s) or equivalent identification of person(s) authorizing the test report or calibration certificate; and	=	Ξ	Ξ	Ξ	1.1
<u>xi.</u>	Where relevant, a statement to the effect that the results relate only to the items tested or calibrated.	Ξ	Ξ	=	Ξ	=
((34.)) <u>38.</u>	Periodic management review <u>and internal audit</u> .	-	-	-	-	-
<u>a.</u>	Laboratory management shall ((periodically)) annually review its quality system and associated procedures to evaluate continued adequacy. This review shall be documented.	-	-	-	-	-
<u>b.</u>	Periodically and in accordance with a predetermined schedule perform an internal audit of laboratory operations to verify compliance to the GLP checklist.	=	Ξ	Ξ	=	=

Notice of Permanent Rules for Lab Quality Assurance Testing Rules

This explanatory statement concerns the Washington State Liquor and Cannabis Board's adoption of rules for the Lab Quality Assurance Testing Rulemaking.

The Administrative Procedure Act (RCW 34.05.325(6)) requires agencies to complete a concise explanatory statement before filing adopted rules with the Office of the Code Reviser. This statement must be provided to anyone who gave comment about the proposed rulemaking.

The Washington State Liquor and Cannabis Board appreciates your involvement in the rule making process. If you have questions, please contact Joanna Eide, Policy and Rules Coordinator, at (360) 664-1622 or e-mail at rules@lcb.wa.gov.

Background and reasons for adopting this rule.

CR-101 – filed April 20, 2016, as WSR 16-09-117.

CR 102 – filed December 7, 2016, as WSR 16-24-094.

Public Hearing held January 11, 2017.

Supplemental CR-102 - filed March 17, 2017, as WSR 17-07-078

Public Hearing held May 3, 2017.

The Lab Quality Assurance (QA) Rulemaking and associated emergency rules are new rules and amendments to rules regarding laboratory certification requirements, proficiency testing (PT), pesticide action levels, requirements to promote lab accuracy and consistency, and quality assurance requirements.

Rule changes are needed to protect consumer safety through ensuring laboratories employ appropriate testing methodologies and achieve accurate testing results for marijuana. Creating proficiency testing requirements to achieve and maintain certification and parameters for laboratories will promote accuracy and accountability in marijuana testing by certified laboratories. Additionally, current permanent rules provide how a laboratory may be certified by the WSLCB, but do not contain provisions on what a laboratory must do to remain certified or how the WSLCB may suspend or revoke the certification of a laboratory. WSLCB needs the authority to suspend or revoke the certification of a laboratory that does not follow rule requirements for testing or for those laboratories that do not consistently achieve accurate testing results.

This rulemaking addresses the above issues, as well as significant improvements to QA testing requirements, the good laboratory practice checklist requirements, and pesticide action levels. These additional specific changes are summarized as follows:

- Adjustments to how potency is calculated to increase accurate reporting and labeling of potency levels. Specific direction on calculating potency, both THC and CBD, is included in the rule language.
- Moisture analysis and microbiological testing changes include testing and reporting for water activity rate, which is a more accurate indicator of the risk of growth of microbes, mold, etc.
- Microbiological screening was changed to test for enterobacteria. Many of these changes to when these tests are required are offset by the addition of testing for aflatoxins and ochratoxin (under mycotoxin screening).
- Adding mycotoxin screening as a required test for recreational products (already required for medical/compliant products).
- Added residual solvent testing requirements and action levels for failed QA tests mirrored after *United States Pharmacopea*, *USP 30 Chemical Tests / <467> -Residual Solvents* (USP <467>).
- Adjustments to when testing must be performed are proposed to allow for greater flexibility while still ensuring the proper tests are performed prior to products being sold at retail.
- Good Laboratory Practice Checklist adjusted to incorporate provisions of ISO 17025 5.4 in lieu of requiring ISO 17025 accreditation.

Timeline of development:

April 2016

- WSLCB passes emergency rules:
 - Recall procedures modeled from WSDA recall procedures in response to illegal uses of pesticides, and in preparation for possible future recalls due to rule violations.
 - Proficiency Testing (PT) is a system to determine the performance of individual laboratories for specific tests or measurements and is used to monitor laboratories' continuing performance. The rules require labs to conduct at least two rounds of PT per year as a condition of certification for each field of testing.
 - Laboratory Suspension and Revocations established a system for suspending and revoking lab certifications due to rule violations, and provided protocols for penalty escalation and administrative hearings.
- WSLCB works with Department of Health to evaluate pesticide action level for emergency rules in late May.
- QA Work Group is established to meet over several months for WSLCB to gain knowledge from representative stakeholder group of industry, state partner agency, and external members to inform staff.

 WSLCB begins rulemaking process for QA testing enhancements by filing a CR-101.

May 2016

- WSLCB adopts emergency rules establishing Pesticide Action Levels.
- QA Work Group meetings continue.

June 2016

- WSLCB permanent rules for sampling protocols (2015-initiated rulemaking) are effective:
 - WAC 314-55-101 established sampling protocols for marijuana producers and processors to address several issues around self-selection bias, hygiene, storage, and adulteration.
 - This is the first step in addressing issues related to collecting samples for Quality Assurance testing for marijuana.
- QA Work Group meetings continue.

July 2016

 QA Work Group meetings continue. Initial review of draft permanent rule changes for QA testing enhancements.

August 2016

- QA Work Group review and comment on draft permanent rule changes for QA testing enhancements continues.
- WSLCB renews emergency rules for Proficiency Testing and Laboratory Suspension and Revocation.
- Interagency Agreement signed August 23, 2016, between WSLCB and WSDA to conduct random and complaint driven pesticide testing. WSLCB transferred \$1.115 million to cover costs of equipment, personnel, and additional resources to conduct pesticide testing, with an addition \$300k annually to cover continual staff, supply, and service costs for the program.

September 2016

- WSLCB renews emergency rules for Pesticide Action Levels pending completion of permanent rulemaking for QA testing enhancements.
- Finalization of draft permanent rule changes (CR-102) for QA testing enhancements begins.

Update October 2016

- Final meeting of the QA Work group to review draft rules.
- Adjustments to rules identified.

November 2016

• Finalization of draft rules in preparation for CR-102.

December 2016

- CR-102 with proposed rules changes approved by the Board and filed with the Code Reviser.
- WSLCB renews emergency rules for Proficiency Testing and Laboratory Suspension and Revocation.

January 2017

- Public hearing held on proposed Lab QA rules.
- Written comment period ends.
- WSLCB indicates it will make changes and bring a Supplemental CR-102 due to volume of comments received, changes needed as identified by staff, and systems constraints.
- Renewal of emergency rules for Pesticide Action Levels while permanent rules are in progress.

February 2017

 WSLCB staff reviews comments received and makes adjustments to rules based on comments received, additional feedback from labs, our certifying vendor, and staff, and other adjustments needed due to traceability constraints.

March 2017

• Supplemental CR-102 filed with adjusted draft rules.

April 2017

Renewal of emergency rules in April 2017 while permanent rules are finalized.

May 2017

- Public hearing on Supplemental CR-102 held on May 3, 2017.
- Staff requests adoption of rule changes on May 31, 2017.
- WSLCB will continue considering whether to make additional changes over the coming year and monitor progress.

Summary of public comments received on this rule proposal.

Summary of Supplemental CR-102 Comments Received:

1. Concerns about high butane levels and solvents. Solvents are bad for humans at any level.

WSLCB response: The WSLCB received several comments related to concerns about butane levels. The action level to determine when a sample will fail was set at 5,000 ppm due to butane's listing as a class 3 solvent under federal standards for supplements and pharmaceuticals (USP <467>), among other product types including food. This is a ceiling and by no means a requirement. It determines when a sample will fail QA testing. We also heard concerns that consumers would taste the butane at close to the action level and reject it. If that is the case, then the market will control and products should be much lower than the residual solvent limits. We will continue to evaluate these levels as more research becomes available to determine whether they need to be adjusted.

Was this reflected in the final rule? No. The residual solvent level for butane was maintained mirroring federal standards.

2. Cannabis products need to be free from poison and hazards. People are using cannabis for health reasons and pain control.

WSLCB response: Thank you for your comments. We certainly agree with you. We understand that there are many product types on the market for people to choose from to match their preferences and/or needs.

Was this reflected in the final rule? N/A.

Concerns about the cost for tier one producers. Testing is needed but the
costs for tier one and two producers is too much. Every lab is different and
there is no common practice. The tier structure needs to be addressed not
testing cost increases.

WSLCB response: Many changes were made in the Supplemental CR-102 in this rulemaking in response to concerns about costs while still maintaining requirements that reflect science, general lab industry standards, and restrictions to address risks to consumers. While the final rules do increase costs, these costs due to changes in testing requirements are necessary to ensure scientific soundness, lab accuracy, accountability, and to mitigate risks to consumers.

The WSLCB is currently assessing proposals received related to the producer tier structure in a separate rulemaking.

Was this reflected in the final rule? Somewhat. The changes to language in the Supplemental CR-102 reduced the costs impacts to licensees comparative to the requirements proposed in the initial CR-102.

4. What scientific backing does LCB have to take ethanol off of the solvents list and add something like pentane?

WSLCB response: The residual solvents action levels are for QA testing purposes to indicate when a sample will fail QA testing and do not reflect allowed solvents. In fact, most of the solvents on the list are included as they are disallowed and may commonly be abused. There are limited solvents allowed for processing cannabis under current WSLCB rules: N-butane, isobutane, propane, and heptane and food grade glycerin, ethanol, and propylene glycol solvents to create extracts. Similar to how the pesticide action levels operate, if a disallowed residual solvent is detected at a level lower than the action levels, a licensee may still be subject to an administrative violation for using a disallowed solvent.

Ethanol was removed from the residual solvents list after conversations with licensees and other state regulators, such as Oregon. Oregon initially had a 5,000 ppm action level for ethanol reflective of its listing as a class 3 solvent by the federal government. Oregon removed that action level as they had little concern for health risks associated with ethanol and because those few who were failing QA tests for ethanol were only barely over the 5,000 ppm action level, which didn't seem to operate as it was envisioned. Due to this information, and due to the large volume of comments received that the ethanol action level should be significantly increased or removed altogether after the WSLCB proposed it at 2,500 ppm, we chose to remove it.

Was this reflected in the final rule? N/A. The comment was a question rather than a particular recommendation on language.

Concerns with allowing additives in extracts. Untested chemical additives are being imported and used to cut processors products with these flavoring agents.

WSLCB response: Thank you for your comments. We have heard concerns about additives and flavorings and previously proposed language to potentially restrict or prohibit their use in marijuana products. We are continuing to assess the issue to determine whether rule changes related to that issue are necessary.

Was this reflected in the final rule? No. This comment is out of scope with this current rulemaking but we will keep it in mind for future rulemakings.

6. Concerns with the new testing requirements. Which would cause bottlenecking due to the labs not being ready to take on such tests as mycotoxin since the labs are not ready to do these tests. These tests will also

put a horrible financial burden on small business owners. Now testing costs will be four times what they are now due to needing four samples.

WSLCB response: While you are correct that mycotoxin is a new required test for recreational cannabis, in many places where it is required it is taking the place of microbiological testing. WSLCB staff surveyed labs prior to the Supplemental CR-102 and the majority of them stated that they were either ready now or would soon be ready for mycotoxin testing. Further, they can reference (subcontract) for those tests to other labs if they are not yet certified for mycotoxin testing. With this information and flexibility, the WSLCB expects the labs will be prepared to meet the new requirements and we should be able to avoid any bottlenecking.

As for the four samples, we are actually simply reverting to the same language that is currently in effect in rule. The same thing is true for lot sizes. As required under current rules, the four samples must be taken from four quadrants of a 5 lb. lot and may be placed in a single container. That one sample is then used for testing purposes. Again, both of these requirements are simply reverting back to the requirements as they exist in current rules so there should be no impact there.

Was this reflected in the final rule? Somewhat. The WSLCB addressed other concerns related to costs through changes in the Supplemental CR-102 unrelated to mycotoxin testing.

7. Concerns with increasing residual solvents to 5,000 ppm for class three solvents (butane, propane). This raise my cause serious health issues for the customers.

WSLCB response: The rationale for the increase on those solvents is because they are deemed to be class 3 solvents with the least amount of risk associated with them. The levels are actually borrowed from USP 467 (United States Pharmacopeia). Those levels are used for supplements and pharmaceuticals and have been adopted by other states as well, such as Oregon. We will continue to evaluate these levels as more research becomes available to determine whether they need to be adjusted.

Was this reflected in the final rule? No. The residual solvent levels for solvents were unchanged in the final rules.

8. Concerns with water activity. Water Activity (AW) is THE critical moisture measurement in cannabis. Cultivators are able to jack up their THC content by sending in dry samples. An effective AW standard should apply from curing to packaging.

WSLCB response: Thank you for your comments. We agree that water activity is critical to determine potential for future microbiological growth on products, which is why we included it as a required test in these rules. We have heard similar concerns from others regarding a standard and dry samples to increase THC results. We will continue to evaluate this issue to evaluate whether additional rulemaking on the subject is necessary.

Was this reflected in the final rule? Water activity was maintained as a required QA test. The WSLCB did not create an additional standard for water activity in these rules.

9. It's good that proficiency testing is now required of labs and included in these rules, but proficiency testing twice a year to maintain certification will not keep labs from gaming the system and inflating potency results. Proficiency testing is expensive – it was \$800 the first year and now is \$4800 for the second year. We need more blind testing and enforcement.

WSLCB response: Thank you for your support of proficiency testing requirements for certified labs. We appreciate your concerns and are engaged in other activities outside of rulemaking (secret shopper programs, evaluating test results data in traceability, investigations, audits, etc.) that are aimed at addressing the concerns you raise. We hope that now that proficiency testing (PT) is required that more PT programs will soon become available and that may have an effect on costs. We will continue to gather information and look into ways that we may be able to reduce costs while meeting the goals and objectives of our mission and regulatory structure.

Was this reflected in the final rule? N/A. The recommendations do not require rulemaking to achieve. See above WSLCB response.

10. Labs aren't reporting cannabinoid results properly, and licensees are gaming the system to make total cannabinoid levels appear higher as labeled amounts are not matching up with lab results reporting. The rules are set up to encourage people to game the system.

WSLCB response: We have heard similar concerns and are engaged in other activities outside of rulemaking (secret shopper programs, evaluating test results data in traceability, investigations, audits, etc.) that are aimed at addressing the concerns you raise. We will continue to evaluate whether additional rulemaking may be necessary as we gather more information. We are also engaged in a rulemaking project related to packaging and labeling that may be able to address some of the issues surrounding how potency is labeled.

Was this reflected in the final rule? No. The comments received are directed at enforcement of the regulations and other activities outside of rulemaking, as well as

regulatory issues outside the scope of this rulemaking but addressed in a separate rules project.

11. Subsection (4) in the pesticide action levels rule is problematic and includes a segment of compounds inherent in the environment. The Board is holding licensees to a higher standard that they can hold themselves to. We've been on administrative hold with product for 8 weeks. The WSLCB has established action levels at 0.1 ppm for things that they themselves cannot test for.

WSLCB response: We have received numerous concerns about the pesticide action levels being too high or too low, as well as concerns about how pesticides issues are enforced. The WSLCB does take cross contamination and environmental conditions into account in investigations and consults with WSDA on these matters as well. The cannabis testing lab at WSDA can detect pesticides at very low levels and recently received ISO 17025 accreditation.

Was this reflected in the final rule? No. The pesticide action levels were not adjusted in the final rules. Concerns about issues with enforcement can be accomplished outside rulemaking. The WSLCB will continue to evaluate the pesticide action levels as more research and data becomes available.

12. We've been experiencing a financial hardship since being placed on administrative hold. We tested positive for diuron but that has never been identified on cannabis before, and we believe it's coming from the water or from WSDOT spraying on weeds on the roadside or some other source. It is present on live plants, but dissipates on dried material. Customer is purchasing the dried product. Focus on it being in the form the customer is consuming. All research shows that this level of this chemical is well below a public safety concern and other chemicals that are much more toxic are at higher levels on the pesticide action level chart in the rules. There needs to be some sort of mechanism or policy for adding or removing analytes from the list or for adjusting the levels.

WSLCB response: Adding, removing, or adjusting levels for analytes on the pesticide action levels list will be accomplished through rulemaking and is a similar approach to how other states have addressed or will address pesticide action levels. The WSLCB has been responsive to regulatory changes needed since the passage of I-502 and is constantly gathering information to determine whether changes are needed. The agency's approach to pesticides will not be any different. We also understand that information may develop over time that may make additions or changes to listed analytes and unlisted analytes in the future.

The WSLCB will look into the timing aspect for when samples are deducted on a policy/procedure level to see whether changes are needed at that level, but no rule change is needed to accomplish changes to the stage at which product is sampled.

We currently do take samples from other locations to determine where chemicals may be coming from as part of the investigation process on a case by case basis.

Was this reflected in the final rule? No. No rule changes are needed to accomplish this comment at this time.

13. Basis for a pesticide investigation is based on a complaint. Should be random based only. Complaints can be used as weapons. If a compound is slowing up from multiple tests for multiple producers that should be the focus.

WSLCB response: The WSLCB is approaching pesticide testing on both an investigation-based and random-based approach. We understand the potential for abuse that complaints hold, however were are confident that we proceed cautiously and with these risks in mind.

Was this reflected in the final rule? No rule changes are needed to address this comment. Changes to testing approaches can be done through the internal policy/procedure approach.

14.I was on the Quality Assurance Work Group and the outreach the WSLCB has been doing has been great. These are suitable rule revisions, but some concerns/challenges remain. RJ Lee has been great and is helping the good labs be better, but they are not enforcement.

WSLCB response: Thank you for your comments. We appreciate your participation and we understand that there is more work to be done. This is another step forward in an incremental process. We will continue to monitor whether additional changes that were walked back can be accomplished and if more changes are needed. We also understand that RJ Lee (WSLCB's lab certifying vendor) is not enforcement and have heard concerns about additional lab oversight in the form of enforcement.

Was this reflected in the final rule? No. Potential future rulemaking may address some of the general topics raised in the comment.

15. Action levels for the 57 analysts specified (disallowed) is concerning. 43 are not allowed for the use on tobacco. 42 of the levels exceed the levels for pyrolysis test required to see if they would be allowed. 7 are not allowed for use on any food crops. Allar was used on apples in the 80s and is not carcinogenic, but are of the metabolites is and it has a 1 ppm action level. Basis of the OHA report was on LOQs from testing labs. Pulled out of thin air. There is no basis for these levels. The levels are too high.

WSLCB response: The pesticide action levels were developed based on lab testing methodology and as put forward in a report by the Oregon Health Authority. We have heard concerns that some levels are too high, while other comments have

stated they fear the levels are too low. The WSLCB will continue to work with our state agency partners and fellow regulated cannabis states to evaluate the action levels as more data and research becomes available. Again, this is another incremental step forward in the process. We appreciate your participation and concern.

Was this reflected in the final rule? No changes to the pesticide action levels were made prior to requesting final adoption.

16. Proficiency testing is important but we need to have a mechanism to catch the cheaters. Random testing is needed for that. Percent moisture being required and adding water activity (Aw) is a little redundant as you can infer percentage moisture from Aw. Aw is more important. Good to add mycotoxins

WSLCB response: Thank you for your support of proficiency testing. The WSLCB currently engages in a "secret shopper" program for various testing, as well as random- and investigation-based testing for pesticides. We will continue to evaluate whether additional activities are needed. Thank you for your comments about the difference between moisture content screening and water activity (Aw). While we agree that much can be derived from Aw, we feel that maintaining both field of testing requirements is beneficial at this time. Thank you for your support of the addition of mycotoxins.

Was this reflected in the final rule? Some of the comment was rule-based and some was more policy/procedure based. No changes to the rules were made based on the comment, much of which was supportive of the proposed rule changes.

17. Action levels have already been established on non-allowed pesticides, however the new language suggests that even product below the action level could still be open to action and fines from the WSLCB. If product pesticide levels are under the pre-determined action level, it seems that no action should be taken against a producer or processor. Otherwise, what is the reason for the action level?

WSLCB response: The clarifying language that was included was intended to make it clear that the pesticide action levels do no negate the fact that a pesticide is not allowed for use on marijuana. If a test shows a disallowed pesticide was under the action level for that pesticide, the licensee may still be subject to a violation for the application of that disallowed pesticide even though the product may still be sold. No administrative hold or recall will apply unless the product tests above an action level. That does not absolve a licensee for applying a disallowed pesticide. There are action levels for a couple allowed pesticides as well. There are only 331 pesticides that have been listed as allowed for use on cannabis out of the over 13,000 pesticides registered for use in Washington State.

Was this reflected in the final rule? Some of the comment was rule-based and some was more policy/procedure based. No changes to the rules were made based on the comment, much of which was supportive of the proposed rule changes.

18. The SBEIS was one of the better I've seen –not perfect, but it was good. It shows a lot of outreach and questions were done.

WSLCB response: Thank you for your comments.

Was this reflected in the final rule? N/A.

19. The SBEIS was not good. I felt it was contradictory related to costs and relied too much on costs to producers/processors and not enough for labs.

WSLCB response: Multiple approaches were included in the SBEIS, including direct calculations based on information/feedback obtained from labs and industry members, as well as some quotes directly from labs and industry members (which were specified in the SBEIS). For these reasons, it may have appeared contradictory when in fact that was not the intent. The WSLCB wanted to make estimations but also acknowledge several viewpoints that may have not been aligned with the WSLCB's perspective, necessarily.

Was this reflected in the final rule? N/A.

20. I have concerns about costs associated with these changes. Every time we make a rule change we have to absorb costs. It's difficult on labs and licensees. Our lab had to reduce our costs to compete with labs committing fraud.

WSLCB response: Thank you for your concern. We attempted to reduce costs where practical and feasible, while still addressing our mission and goals and meeting state and federal legal and enforcement requirements. Many of the changes in the Supplemental CR-102 were made in direct response of concerns about costs, including reverting to a single potency test and retaining the 5 lb. lot size, among other changes. We understand that costs are a large factor and work to find balance between changes necessary for a well regulated industry and costs to that industry.

Was this reflected in the final rule? Somewhat given the changes from the CR-102 to the Supplemental CR-102. However, the WSLCB still received a lot of comments with concerns about costs even after the changes in the Supplemental CR-102 were proposed.

21. The changes to the good laboratory checklist are super important. But it won't get at everything. We need enforcement and investigation of the data stream we have in traceability. Proficiency testing is needed to determine accuracy but is not sufficient to ensure honesty on the part of the labs. Look at Jim McRae's blog for the labs he listed as good, bad, or indifferent. Most testing is

done by labs without regards to accuracy. Multiple tests for potency has no value if labs are inflating.

WSLCB response: We appreciate your support of the changes to the good laboratory practices checklist.

Was this reflected in the final rule? No specific rule changes were requested in the comment. Rather, it requested more or different enforcement activities for labs. This comment may be further addressed through current activities and additional future activities under the WSLCB's regulatory structure.

22.I don't like the remediation section in that I think if remediation techniques are needed, they should be required to disclose them on the label and not just supply upon request.

WSLCB response: The WSLCB tries to balance costs and requirements. Labeling issues have been raised by many licensees as being difficult to accommodate on the label. A current rulemaking project for packaging and labeling is currently underway and we can consider potential changes to rules as part of that rulemaking. However, this issue was discussed at length during the Quality Assurance Work Group and an agreement was made to require them to be provided upon request, similar to lab testing certificates. Further, remediation techniques must first be approved by the WSLCB prior to their use and would require additional testing. At this time, remediation techniques are limited in scope and no remediation techniques are known for pesticides yet.

Was this reflected in the final rule? No. The requirement to disclose remediation techniques upon request, similar to the requirements for lab testing certificates, was unchanged.

23. Mycotoxin testing requirements are great for safety, but I disagree with the asterisk to remove mycotoxin testing for concentrates. They should have to be tested.

WSLCB response: Thank you for your support of mycotoxin testing generally. Many concentrates are processed by heat or other measures that make it highly unlikely that mycotoxins would be present after processing. This issue was discussed at length during the Quality Assurance Work Group and with the labs to arrive at the language in the proposed rules. We can continue to receive feedback on this as we get data in from the tests once they are effective and see whether changes are needed.

Was this reflected in the final rule? No changes were made to the language referenced by the comment.

24. Scientific rationale should be provided for each change proposed. In some cases, I'm not sure why the rules are being put in place.

WSLCB response: The WSLCB is committed to transparency and attempts to include very robust rule documents and supplementary materials in its rulemakings. We are constantly looking for ways to engage with the industry and gather feedback, as well as communicate the rationale for the rule changes we propose. We will continue those efforts and look for ways in which we may be able to make improvements there. We hope that the information contained in this explanatory statement, coupled with the issue papers and other documents presented to the Board will assist in a clear understanding of the rationale for the rule changes.

Was this reflected in the final rule? N/A. See above response.

25. Solution is for unannounced stings to deal with lab fraud. They may be honest when you're looking. It's when you're not looking when labs cheat. Give producers and processors contaminated samples and do a sting that way. When is the state going to start enforcing against labs?

WSLCB response: Thank you for the recommendation. We do engage in multiple checks on licensees and labs through secret shopper programs for multiple testing requirements, as well as random- and investigation-based pesticide testing through our dedicated pesticide lab with WSDA. We will continue to see what activities may be beneficial in the future.

Was this reflected in the final rule? No. Rule changes were not specifically requested by this comment. This comment may be further addressed through current activities and additional future activities under the WSLCB's regulatory structure.

26. Requests LCB revisits its proposed non-listing of 3-(3,4-Dichlorophenyl)-1,1-dimethylurea, sold as Diuron. Since Diuron is not included in the subsection three, the default action level for Diuron is 0.1 ppm. LCB should include a policy mechanism in the rulemaking update to allow future action level listing of substances currently classified under WAC 314-55-108(4) as additional information becomes available.

WSLCB response: The pesticides listed in the levels specifically are listed due to their higher probability of abuse. There are over 13,000 pesticides listed for use in Washington State, so listing all of the prohibited pesticides would be cumbersome. Only 331 pesticides are allowed for use on cannabis. We will continue to look into this issue and discuss whether listing diuron may be necessary with WSDA, as well as the potential need to specifically list other analytes. WSLCB will handle any changes to the list by future rulemaking and intends to monitor these rule changes over the coming year to see whether additional changes are necessary or advisable.

Was the comments reflected in the rule? No. Diuron was not specifically listed in the pesticide action levels and the default level of 0.1 ppm remains in the rules.

Summary of Original CR-102 Comments Received:

Concerns about the "bottlenecking" in testing that will be a result if
mycotoxins are required to be tested since such tests can only be completed
in few facilities in the State. Currently Oregon is reviewing the same rules for
being too stringent.

WSLCB response: Many labs have confirmed that they are ready or will soon be ready for mycotoxin testing. Additionally, labs may "reference" or subcontract for mycotoxin screening to other labs that are able to perform those tests which should alleviate pressure. Screening for mycotoxins has shown to be an important measure and is already required for compliant (medical) product.

Was the comment reflected in the final rule? No. The WSLCB chose to maintain the mycotoxin screening requirement in the final version of the rules.

2. Please look at the effects Oregon had in their lab rules and don't make the same mistake as they almost shut down their entire marijuana industry. That is what is going to happen in WA if these are adopted.

WSLCB response: The WSLCB had several conversations with Oregon in regards to these rule proposals. We are confident that the changes that we are making are another incremental step forward in this developing industry and will contribute to increased protections for consumers as well as lab accuracy and accountability. The pesticide action levels that mirror Oregon's levels in rule have been in effect for a year already via emergency rule and no large issues have occurred.

Was the comment reflected in the final rule? No. We assume that the comment was requesting that we not adopt provisions similar to Oregon's. While some of the rules are similar to Oregon's, the WSLCB construct is different and we have a different length of time that labs have been operating in Washington.

3. Which labs will be doing the mycotoxin testing? Is this a temporary measure?

WSLCB response: At this time, we do not believe that mycotoxin testing will be a temporary measure. Of course, we will evaluate the requirement based on the data gathered from the testing and may change requirements or remove microbiological testing should it be shown that mycotoxins are sufficient. Several labs are already ready to perform these tests since mycotoxin screening is required for compliant

(medical) products. Becoming certified for mycotoxin testing is voluntary under these rules, but we expect that labs will advertise their capabilities on their websites and the WSLCB may look into listing the certifications for each lab on its website.

Was the comment reflected in the final rule? N/A.

4. Why would LCB require mycotoxin testing when such strict testing isn't required in other industries? This test is pre-mature and there is no medical proof that mycotoxins are a health hazard.

WSLCB response: Compliant marijuana products (medical) under DOH's rules must be screened for mycotoxins (as well as heavy metals and pesticides) before they can be deemed a compliant product. Mycotoxins have shown to be a potential risk for people with compromised immune systems, and are more comprehensive than microbial tests alone. Requiring that recreational marijuana be screened for mycotoxin aligns it at least partially with compliant products rules. Further, the WSLCB will monitor the data gathered after mycotoxin testing requirements become effective over time and assess whether changes to the requirements for this and/or microbial testing are advisable.

Was the comment reflected in the final rule? No. Mycotoxin testing requirements were maintained in the rules.

5. Not in support of this rule change as it will place an undue and harsh financial burden on the cannabis industry. This will cripple and bottle neck the entire testing process.

WSLCB response: Thank you for taking the time to express your concerns. Many changes to the initial proposal were made in the Supplemental CR-102 to address costs concerns. While we acknowledge that there will be some costs associated with these rule changes to enhance QA testing, the WSLCB has sought to reduce costs where it was practical. "Bottlenecking" should be mitigated by the ability of labs to reference tests to other labs that have certifications for fields of testing that other labs do not have. See other related responses in this explanatory document for more information.

Was the comment reflected in the final rule? Somewhat. Many concerns about costs made for the changes that were put forth in the Supplemental CR-102, which is the final version of the rules brought for adoption.

6. Requesting a delayed effective date because how it stands the effective date does not allow enough time for labs to adequately prepare for the requirements. The current effective date will bottleneck the testing process

and price gouging. Furthermore this will greatly impact the cost to the licensee and could force some licensee's out of business.

WSLCB response: This comment was received as part of the CR-102 comment timeframe, but remains relevant throughout this rulemaking. The changes made as a result of the Supplemental CR-102 addressed many of the "bottlenecking" and costs increases concerns. However, it should be noted that the changes in the rulemaking have been out for review for an extended period of time, even in advance of the initial CR-102 filing. We have heard from labs that many are ready to being mycotoxin testing now, and several are already certified for it due to its requirement for compliant products. Also, many labs stated that they would be ready for the new required testing within 2-3 months of the effective date of the new testing requirements. Under the rules, labs may also reference tests that they are not yet certified for to other labs certified for the field of testing. This is already occurring for mycotoxin, heavy metals, and pesticides testing for compliant products and has be successful thus far. Additionally, the effective date was delayed by the filing of a Supplemental CR-102, and the WSLCB is recommending a delayed effective date to allow time for the labs and licensees to prepare for the new testing requirements.

Was the comment reflected in the final rule? Somewhat. See above response.

7. Comments made to remove ethanol from the residual solvents limits table or revise its limit. Also make allowance for non-QA testing and do not set LOQs or LODs. Please acknowledge that mycotoxin testing is a temporary measure. We would be happy to see the formation and long-term support of an LCB advisory panel regarding testing rules.

WSLCB response: We received a lot of comments related to ethanol. For this reason, the Supplemental CR-102 removed ethanol from the residual solvents list. In consultation with our certifying vendor, we chose not to allow for testing other than that for QA testing by third party labs as that is not something that is done for labs that conduct QA tests in other industries. Further, the only testing allowed under law and rule is for QA testing. Nothing prohibits a licensee from using their own equipment on their own licensed premises to conduct testing for non-QA purposes or for research and development (R&D). Mycotoxin is being adopted not necessarily as a temporary measure, but as data from testing comes in the WSLCB will evaluate the need for mycotoxin testing in addition to microbial testing. The WSLCB has received similar comments about an ongoing forum for testing rules and is open to that in addition to the other stakeholder groups it has formed.

Was the comment reflected in the final rule? Ethanol was removed from the residual solvents list after discussion with our certifying vendor and with other

cannabis regulators. For the other items, please see the above response. Not all comments require a rule change to achieve.

8. QA Labs by necessity must extend credit to growers whom test with them. It is not uncommon for certain growers who use a lab and are not happy with the results of their testing, to refuse to pay the lab for their services. This practice creates a situation that encourages results to be adulterated. How will these rules address that? What does "chain of custody manifest" mean; are you referring to a BioTrack manifest? How will unused sample be returned to the licensee? Will the lab need to create a manifest to maintain traceability protocols?

WSLCB response: Issues relating to nonpayment of QA tests by licensees are civil in nature and between the lab and the licensee. If there are concerns, you would need to report those to enforcement. A chain of custody manifest in reference to labs being able to reference tests to other labs, means something done outside of the traceability system to show who was in possession and who did the tests.. Unused samples may be destroyed or returned to the licensee (as required in RCW/law).

Was the comment reflected in the final rule? Somewhat. See above response. Much of these comments are relative to rules that are not changing in the proposed rules or related to non-rule issues.

9. Concerns from labs that are being certified through RJ Lee in regards to licensees reaching out to the labs and are looking for the lab to deliver a "result" or "number" which would not be what the tests are actually showing. The licensee's then have threaten to go to a different lab that would show those requested "results" or "numbers." Labs are sure this is happening because once the threat has been made the licensees don't come back for any more testing.

WSLCB response: That is unfortunate to hear if it is occurring. We hope that these rule changes will help to improve the situation. We are also engaged in a separate rulemaking regarding packaging and labeling which also may address the ways in which potency is reported on the label to decrease issues with how licensees seek and report results.

Was the comment reflected in the final rule? This comment is related to issues outside this rulemaking, but may be considered through separate rulemaking and enforcement efforts.

10. Proposing changes to the Ethanol allowed limits to a much higher limit preferably no less than 5,000 ppm. Also proposing a new section WAC 314-55-

102 (5) Proficiency Testing: This section is "very vague." For instance, which entity exactly will be the "provider" of the standard samples? Also proposing new section WAS 314-55-099 (5) (b): suggest requiring HPLC (or a more advanced method if they are developed) for potency testing. Some additional suggestions are: Amend section to 314-55-102 (3) (b) to mandate pesticide screening for all producers. Restrict the use of "Pesticide Free" on labeling. Amend WAC 314-55-102 (9) to include marijuana extracts and concentrates meant for inhalation (LCB should follow the lead of other states such as OR and CA and ban the use of flavor additives in products).

WSLCB response: Ethanol was removed from the residual solvents table in response to concerns. The "provider" of the standard samples is the proficiency testing program provider. We will take the HPLC suggestion under advisement for potential future use. We considered mandatory pesticide testing for all marijuana, but instead decided that a random- and investigation-based route may be more of a deterrent at less cost and will continue to revisit the issue. Many are supportive of mandatory pesticide testing for all marijuana, and many are not in favor of that. The WSLCB contracted with the WSDA to purchase devoted equipment for pesticide testing for the WSLCB and for staff to run the tests. The use of "Pesticide Free" on the labels for products already may be handled under restrictions on false advertising, but we may also look into this issue in a separate, ongoing rulemaking on packaging and labeling. The WSLCB previously proposed the use of additives and flavorings, including hemp-based CBD oils, in previous rulemaking, but that was met with a lot of concern from the industry and was removed prior to adoption. We may reconsider this issue in upcoming rulemaking.

Was the comment reflected in the final rule? Somewhat. See above response. Ethanol issues were addressed in the final rules. Some other items are out of scope of this rulemaking and may be considered in other rulemaking.

11. Comments about increasing the lot size. Testing to 15 pounds is great but only using one test per 5 pounds will make smaller lots unprofitable. The market is already oversaturated with producer processors and smaller producers are unable to raise prices because retailers are not going to pay more when they can get product cheaper. This also will not reconcile the difference in test results seen between different labs.

WSLCB response: We received a lot of these comments with concerns about the initially proposed changes to lot size. We removed this proposal and reverted to current rule language in the Supplemental CR-102 due to these concerns and system restraints.

Was the comment reflected in the final rule? Yes. The final rules reverted the lot size back to current rule language.

12. The LCB should do away with any testing requirements and ban all pesticides. The medical industry has done fine without testing for years. The proposed new rules "could be the catastrophic last straw killing off more producer/processors and leaving only the giants, significantly higher retail prices and a flourishing black market."

WSLCB response: Thank you for your comments. Under RCW 69.50.342, the WSLCB is empowered with rulemaking authority to for methods of producing, processing, and packaging marijuana, useable marijuana, marijuana concentrates, and marijuana-infused products; conditions of sanitation; safe handling requirements; approved pesticides and pesticide testing requirements; and standards of ingredients, quality, and identity of marijuana, useable marijuana, marijuana concentrates, and marijuana-infused products produced, processed, packaged, or sold by licensees. Under this authority, for human health and safety reasons and to ensure consistency with state federal rules on pesticide use, these rules are necessary. Further, many medical marijuana patients have insisted upon the regulation and testing of pesticides on cannabis.

Was the comment reflected in the final rule? No. See above response.

13. Requiring 3 samples for potency will greatly affect the costs to licensees and still will not address the "inflation" that labs are doing without more strict rules on regulating the labs.

WSLCB response: Thank you for your comments. The initial proposal to require 3 separate potency tests and averaging those results for potency values, while scientifically sound, was reverted back to current rule requirements in the Supplemental CR-102.

Was the comment reflected in the final rule? Yes. Only one potency test is required in the final rules.

14. Smaller processors and producers will have a hard time affording the costs for these tests. Will LCB implement a new tiered licensing fee to offset the costs? Would testing smaller lots under 5lbs be an option for Tier 1 licensees?

WSLCB response: Due to similar concerns on costs, among other issues, the WSLCB reduced the amount of tests required in the initial CR-102 and reverted to the 5 lb. maximum lot size. Licensees may still test smaller lots. The WSLCB cannot

change the licensing fees through rule as those are set in statute (RCW), initially by I-502, and would take an act by the Legislature.

Was the comment reflected in the final rule? Yes, relative to the testing amounts and costs, as well as the lot size. See above response regarding license fees.

15. Why not focus rules that make the labs have stricter rules instead of economically hurting the Tier 1 producers?

WSLCB response: Thank you for your comments. These rules are designed to enhance accountability, accuracy, and reliability of the labs. Many concerns about costs to licensees prompted the changes seen in the Supplemental CR-102.

Was the comment reflected in the final rule? Somewhat. See above response.

16. LCB should be looking to reduce the amount of regulations it has on the marijuana industry instead of crippling a new industry when these rules go into effect it will shut the tier 1 processors and producers down.

WSLCB response: Thank you for your comments. The WSLCB is dedicated to ensuring it meets its mission and goals, as well as state laws and rules and federal enforcement guidelines, while not hindering this developing industry wherever feasible. Ensuring a well-regulated marijuana market is an important component in the continued operation of this developing market.

Was the comment reflected in the final rule? N/A.

17. THC testing will be a financial hardship for many licensees but microbial and pesticide testing will be a good source of information for public safety.

WSLCB response: Thank you for your support for the new testing requirements. We have endeavored to reduce costs when feasible and practical in these rules, which is reflected in the changes made in the Supplemental CR-102.

Was the comment reflected in the final rule? N/A.

18.THC testing for flower is unnecessary but should still be done for extracts and concentrates.

WSLCB response: Thank you for your comments. An interesting idea and one we have heard before, including when it comes to labeling.

Was the comment reflected in the final rule? No. Potency testing is maintained for all products at this time.

19. Residual ethanol testing is not appropriate for our product type.

WSLCB response: Thank you for your comments. Ethanol was removed from the residual solvents list in the Supplemental CR-102.

Was the comment reflected in the final rule? Yes. See above.

20. Overall the draft rules will help correct some of the issues we are currently seeing in the industry. Some things that might want to be considered are: Hiring a third party private lab with experience in cannabis testing, to "test the testers." Or have clear expectations that "secret shoppers" visit labs for "compliance checks." Later in the draft under the specific list of tests required there is no mention of water activity. The allowable limits for some of the residual solvents, specifically the limits for toluene and xylene should be reviewed. Rather than a licensee supplying samples to the state, the WSLCB or its designee should perform the sampling so as to eliminate any potential for bias or misconduct. Does the state intend to establish any requirement for minimum sample size?

WSLCB response: Thank you for your comments and support of the overall requirements. We do engage with WSDA to provide neutral testing for the WSLCB. We also engage in "secret shopper" activities. Water activity is required under the rules, but not in every category. We have heard suggestions about having the WSLCB conduct the sampling for QA tests. Unfortunately, that would require a lot of resources and is not practical at this time. Labs may choose to collect samples, but of course this would mean a cost to licensees that choose to do so.

Was the comment reflected in the final rule? See above response. The list of residual solvents was somewhat adjusted in the Supplemental CR-102.

21. Suggestion to maintain the current practice of testing moisture content, and eliminate water activity as a required test; it is time and labor intensive, and will not provide any increase of consumer safety. Potency testing favors labs that use HPLC over gas chromatography. Only edibles and topicals should be microbial tested. Instead of averaging the data for three tests why not homogenize the different samples and run the analysis one time?

WSLCB response: At this time, the WSLCB is maintaining the requirements for both moisture content and water activity as they indicate separate issues. As data from testing comes in, we will continue to evaluate whether both tests are needed.

Water activity tells us the likelihood that microbes will grow over time. Labs may use testing methodologies that have been reviewed, approved, and certified by our certifying vendor and so long as the technology allows for consistency and accuracy that allows the labs to be certified it may be used. The 3 separate tests and averaging for potency was reverted back to a single test from one sample homogenized from four separate quadrants from one lot (current rule requirements).

Was the comment reflected in the final rule? Microbial testing was not changed as a requirement, neither was moisture content and water activity. As for potency, yes, it was reflected in the final rule.

22. Will the rule list the required fields in which is required by the new rule change? How is LCB going to ensure there are enough labs with the correct accreditation to perform the tests that will be required with this rule change? Will labs be given a grace period between implementation and our next scheduled audit?

WSLCB response: Labs will be required to receive certification for fields of testing prior to being able to conduct QA testing. The same battery of tests required in current rules, with the addition of mycotoxin testing and water activity are all of the *required* tests. However, certification for mycotoxin, heavy metals, and pesticide testing is optional, but required for those labs that want to conduct those tests. The rules do detail this. Several labs are already certified in mycotoxin, and a couple are certified in pesticides. The rules allow labs to reference those tests they are not certified to conduct to labs that are certified. The WSLCB is recommending a delayed effective date to allow for licensees and labs to adjust to the new requirements and to apply for additional certification.

Was the comment reflected in the final rule? Yes, as to the required and options tests. For the other questions, no rule changes were needed.

23. Suggestions about using marijuana tax money to create public servant announcements about consuming illegal marijuana. This would educate the public that they want to consume legal marijuana due to the testing the state mandates. Also LCB should create "blind" testing so the labs are unaware of who the licensee is which should stop the push for falsifying results. LCB should subsidize testing by giving funds back to the farmers.

WSLCB response: Public announcements are unfortunately somewhat outside of this rulemaking. But this is an interesting idea and will be shared with DOH (the primary educational communicator for marijuana under the appropriations structure for excise tax funds). The WSLCB cannot subsidize the industry as this would be contrary to law and a gift of public funds. The WSLCB does engage in "secret

shopper" activities, and we have heard similar requests. We may consider whether this would be a viable activity under current resources.

Was the comment reflected in the final rule? No. The comment was primarily directed at activities outside of rule requirements.

24. If ELISA kits are utilized in the testing process then costs would not be so high. But any time you test at an accredited laboratory the cost would be higher due to the required QA/QC procedures.

WSLCB response: Thank you for your input – we appreciate the information about ELISA kits and took that into account in developing the requirements and SBEIS.

Was the comment reflected in the final rule? N/A.

25. Suggestion to not raise the cost of testing and instead to allow all tiers to be capped at 30,000 sq. ft.

WSLCB response: Thank you for your comments.

Was the comment reflected in the final rule? Somewhat. The Supplemental CR-102 addressed some of the concerns raised about the level of testing by reverting to a single potency test. Other testing requirements remain in place. Adjustments to tiers were outside the scope of this rulemaking.

26. Concerns regarding the language in the sampling procedures section 314-55-102 subsection 2, c and d. The misusing of sterile vs. sanitary is going to cost the industry a lot of money. If using sanitary procedures you would buy regular examination gloves and then sanitized frequently by spraying 70% isopropyl alcohol and rubbing the hands together. When the words sterile are used then it refers to everything being sterile and that is typically only used in an operation setting for doctors operating on people not testing marijuana. Sterile gloves are very expensive individually packaged hermetically sealed gloves that cost several dollars per pair which are used for surgery in the medical field.

WSLCB response: Thank you for your comments. The WSLCB solicited input from the labs and industry as it received several similar responses. The Supplemental CR-102 removed "sterile" and replaced it with "sanitary" where appropriate.

Was the comment reflected in the final rule? Yes. See above response.

27. The Department of Agriculture should be the ones doing the testing from several areas of the plant, to establish an average range of potency that can be expected on a plant. Then the labels should give the range of THC since it will vary from one location to another.

WSLCB response: Interesting idea and something we can look into for future rulemaking, as well as current ongoing rulemaking for packaging and labeling.

Was the comment reflected in the final rule? No. See above response.

28. It is proposed that the Department of Health and the LCB solicit direct input from no less than 6 lab directors and/or plant scientists for what they feel are realistic action levels on banned substances. It would make more sense to pay the labs to have a lab staff come out to collect the samples instead of having to send in more product and paying three times as much for the tests.

WSLCB response: The LCB did include our partner science agencies (WSDA, Ecology, DOH) as well as many lab directors and staff in addition to industry members on the Quality Assurance Work Group to gather information to develop these rules. The multiple potency tests were removed and the rules do allow for labs to come collect samples, but do not require it.

Was the comment reflected in the final rule? Somewhat, yes. See above response.

29. Concerns with having to test for residual ethanol in extracts made with ethanol (RSO).

WSLCB response: The WSLCB heard many concerns about ethanol on the residual solvents list and removed it in the Supplemental CR-102.

Was the comment reflected in the final rule? Yes. See above.

30. Concerns with the sample size for testing. One way to address this would be to just require a 1g samples per pound. Samples should also be taken from the retailer location to effectively test for pesticide levels.

WSLCB response: We have heard many concerns about the sample sizes. We changed the sample sizes initially proposed back to the current rule requirements in the Supplemental CR-102. The WSLCB does engage in "secret shopper" and random testing to ensure compliance and is evaluating activities.

Was the comment reflected in the final rule? Those comments that related to rule requirements and not to enforcement activities were reflected in the final rules. The sample sizes were not increased to 5g per 5 lb. lot and instead reverted to a 4 g. sample size per 5 lb. lot.

31. The penalty structure for sampling errors is too harsh. When an employee could make a simple mistake such as forgetting to wash their hands which would cause no harm to the consumer when violated but could result in a cancellation of the license.

WSLCB response: Thank you for communicating your concerns. The WSLCB endeavors to be reasonable in the application of penalties to licensees in this developing industry and is dedicated to educating licensees.

Was the comment reflected in the final rule? Somewhat. The penalty structure was not included in this rulemaking so no changes could be made there. Requiring the sanitary collection of samples is reasonable and much feedback was solicited on this issue as the WSLCB initially proposed sterile collection techniques and containers in the first CR-102 and changed to sanitary techniques in the Supplemental CR-102 due to similar concerns raised.

32. In full support of the rule change proposed it will help consumers ensure they product they are consuming will be properly tested for the things consumers ask most about.

WSLCB response: Thank you for your comments.

Was the comments reflected in the rule? N/A.

33. Concerns with lab results. When the same sample is sent to two different labs the results come back completely different. Where is the regulations for labs to test accurately? Once lab inaccuracies are addressed then we can look at these rules as a good thing currently they are a financial burden with the real possibility of forcing tier ones to close their businesses.

WSLCB response: We appreciate your concerns and have heard similar concerns. We are hopeful that many of the changes included in this rulemaking along with other current activities discussed in this Concise Explanatory Statement will help to address some of those concerns.

Was the comments reflected in the rule? No. Many of these concerns may be addressed outside rule changes.

WAC Changes from Proposed Rules (CR-102) to the Rules as Adopted:

All changes to rules from the CR-102 were done through the filing of a Supplemental CR-102. No changes were made to the rules from the Supplemental CR-102 filing to the adopted final version.

Date:	May 31, 2017		
То:	Jane Rushford, Board Chair Ollie Garrett, Board Member Russ Hauge, Board Member		
From:	Joanna Eide, Policy and Rule	es Coordinator	
Сору:	Rick Garza, Agency Director Peter Antolin, Deputy Director Justin Nordhorn, Chief of End Becky Smith, Licensing Director Karen McCall, Agency Rules Peter Corier, Marijuana Exar	or forcement ctor Coordinator	
Subject:	• •	103) for new and amended rule testing in Chapter 314-55 WA	
At the Board meeting on May 31, 2017, the Rules Coordinator requests that the Liquor and Cannabis Board approve the final rulemaking (CR 103) for new and amended rules related to labs and quality assurance testing in Chapter 314-55 WAC, Marijuana licenses, application process, requirements, and reporting.			
The Board was briefed on the rule making background and public comment for this rule making. An issue paper and text of the rules are attached. If approved, the Rules Coordinator will send an explanation of the rule making to all persons who submitted comments. After sending this explanation, the Rules Coordinator will file the rules with the Office of the Code Reviser. The effective date of the rules will be 60 days after filing, on August 1, 2017, to allow time for licensees and labs to adapt to changes.			
Appro	ove Disapprove	Jane Rushford, Chair	 Date

Attachments: Issue Paper, Rules, and CES

_ Approve

Approve

Disapprove

Disapprove

1

Ollie Garrett, Board Member

Russ Hauge, Board Member

Date

Date



PETITION FOR ADOPTION, AMENDMENT, OR REPEAL OF A STATE ADMINISTRATIVE RULE

In accordance with RCW 34.05.330, the Office of Financial Management (OFM) created this form for individuals or groups who wish to petition a state agency or institution of higher education to adopt, amend, or repeal an administrative rule. You may use this form to submit your request. You also may contact agencies using other formats, such as a letter or email.

The agency or institution will give full consideration to your petition and will respond to you within 60 days of receiving your petition. For more information on the rule petition process, see Chapter 82-05 of the Washington Administrative Code (WAC) at http://apps.leg.wa.gov/wac/default.aspx?cite=82-05.

CONTACT INFORMATION (please type or print)

Petitioner's Name: Kevin Oliver, Crystal Oliver, Eugene Flynn

Name of Organization: Washington State Affiliate of the National Association for the Reform

of Marijuana Laws (Washington NORML)



Mailing Address: 27315 North Monroe Rd

City Deer Park State WA

Zip Code: 99006

Telephone: 509-714-7407

Email: crystal@wanorml.org

1. NEW RULE - I am requesting the agency to adopt a new rule.

The subject (or purpose) of this rule is:

The purpose of the proposed rule is to prohibit processors in the state from importing CBD and THC from out of state (including overseas) and adding such imports to otherwise lawful cannabis products to be sold to consumers in Washington. Doing so will prohibit illegal trafficking of a Schedule I controlled substance, protect consumer safety, and support the rights of compliant cannabis producer/processors in Washington.

The rule is needed because:

There is reason to believe that some of the largest licensed producer/processors in this state are importing CBD (and possibly THC) from abroad and adding it to extracts for inhalation, topicals, edibles, and perhaps other types of cannabis products. This is allowing some processors to sell large amounts of product without purchasing Washington-grown cannabis from Washington farmers. There is no oversight regarding the purity of the source of this imported CBD and the Federal government and the Food and Drug Administration (FDA) have clearly communicated on several occasions that shipment of these products across state lines is not lawful.

Under a rule that took effect on January 13th, 2017, the Drug Enforcement Administration (DEA) clarified that CBD extract is included within the newly adopted drug code number 7350 (21 CFR 1308.11(d)(58)), defined to include all cannabis extracts. (See, *Establishment of a New Drug Code for Marijuana Extract*, DEA Rule, 81 FR 90194, December 14, 2016.) This change was thought necessary to clarify that CBD extracts are included in Schedule I controlled substances under the Controlled Substances Act, and to ensure compliance by the United States with its obligations under the 1961 Single Convention on Narcotic Drugs.

We believe such importation and use of the imported extracts are violative of both federal and state laws, and at a minimum puts Washington state's legalized cannabis program in disrepute. In a worst case, it could place the program in jeopardy of a federal shutdown.

As to purity issues, imported CBD oil from China is unregulated and untested for human consumption. It is thought to be high in heavy metals and other impurities, thereby putting consumer safety at risk. As CBD products are most commonly used for medical uses, the type of consumer most likely to be harmed is one using cannabis for pain relief or other therapeutic purposes. The WSLCB is tasked with protecting consumer safety, and this issue alone urges emergency action on the part of the agency.

Lastly, by allowing CBD extracts to be imported from out-of-state sources, compliant cannabis producer/processors in Washington are placed at a severe competitive disadvantage since they are unable to compete with such black market sources.

The new rule would affect the following people or groups:

Licensed cannabis producer/processors, medical patients, and general consumers

2. AMEND RULE - I am requesting the agency to change an existing rule. List rule number (WAC), if known:

WAC 314-55-105(8) [which is currently a blank item number and immediately precedes a section dealing with the prohibition against adulterating useable cannabis]

I am requesting the following change:

(8) A producer or processor may not add any CBD or THC extract derived from natural cannabis or hemp plants sourced outside the state of Washington, or any synthetic CBD or THC wherever sourced, to any cannabis product (including useable marijuana, marijuana-infused products, and marijuana concentrates). [NOTE: This language is intended to conform to the organization and terminology of the existing WAC, which is currently under active review by the WSLCB. The intent is to cover **all** cannabis products, e.g., topicals, tinctures, inhalants, etc.]

This change is needed because:

See the reasons stated under Section 1 of this form.

The effect of this rule change will be:

To discourage illegal trafficking of cannabis extracts, protect Washington consumers of medical and recreational products, and to support compliant cannabis producer/processors in Washington.

The rule is not clearly or simply stated:

No provision in WAC 314-55 addresses this issue.

REFERENCES

2015 Warning Letters and Test Results for Cannabidiol-Related Products https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm435591.htm

2016 Warning Letters and Test Results for Cannabidiol-Related Products https://www.fda.gov/NewsEvents/PublicHealthFocus/ucm484109.htm

DEA Rule: Establishment of a New Drug Code for Marijuana Extract https://www.federalregister.gov/documents/2016/12/14/2016-29941/establishment-of-a-new-drug-code-for-marihuana-extract

How Clean Is Your Cannabis Extract? (Excerpt)

August 4, 2015

https://dailydabs420.com/2015/08/04/how-clean-is-your-cannabis-extract/

Outsourcing CBD

One last concern specifically addresses CBD concentrates which are often manufactured from industrial hemp. As these concentrates have risen in popularity, China has begun exporting extracts made from Chinese hemp which could pose a health risk.

The New York Times and BBC recently published several articles covering how heavy metal runoff from mining operations has made its way into the food supply, skyrocketing cancer rates by as much as 500% (maybe more, its hard to determine exactly how bad things have gotten with a lack of reliable self-reporting from China).

It's been well established that plants like hemp readily absorb these heavy metals and that Chinese environmental authorities cannot be trusted for proper analysis or certification of such materials. Consumers must be cautious and make sure to only purchase extracts produced in countries with strong regulations like the U.S. and Canada.

So how clean is your cannabis concentrate? It's impossible to know without thorough independent chemical analysis. The extract industry has exploded largely unchecked and only now have we begun to realize that these concentrates pose a new set of concerns previously unknown with consuming the marijuana plant alone.

As places like Canada and Colorado begin to adopt policies that regulate the marijuana industry, there's no doubt we'll gain a better understanding of exactly how these substances actually affect our health.

HOW CLEAN IS YOUR CANNABIS? (Excerpt)

High Times Magazine, July 1, 2015 http://hightimes.com/culture/how-clean-is-your-cannabis/

Is Chinese hemp toxic?

Many plants—including cannabis—have been shown to absorb heavy-metal ions and other toxins from the soil or water. Precisely because of their capacity to hyper-accumulate toxic elements, these plants are used to clean up contaminated areas through a process known as photo-remediation. Plants also exchange air with the atmosphere, essentially breathing in any toxins that may be present. Fungicides and pesticides can leave residues as well.

A lack of strict environmental controls leads to contaminated soil. In the past six months, *The New York Times* has published two articles detailing how soil and water pollution in China have ended up in the food supply. Heavy-metal concentrations in plants grown in wastewater-irrigated soil were also significantly higher, exceeding the permissible limits set by the Environmental Protection Agency and the World Health Organization. The extent to which these toxic substances are accumulating in Chinese hemp—and especially the concentrates made from it—have yet to be determined.



PETITION FOR ADOPTION, AMENDMENT, OR REPEAL OF A STATE ADMINISTRATIVE RULE

Print Form

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CONTACT INFORMATION (please type or print)
Petitioner's Name JOHN WORTHINGTON
Name of Organization
Mailing Address 4500 SE 2nd PL
City RENTON State WA Zip Code 98059
Telephone 425-919-3910 Email Worthington two a Hotmail. com
COMPLETING AND SENDING PETITION FORM
Check all of the boxes that apply.
Provide relevant examples.
Include suggested language for a rule, if possible.
Attach additional pages, if needed.
 Send your petition to the agency with authority to adopt or administer the rule. Here is a list of agencies and their rules coordinators: http://www.leg.wa.gov/CodeReviser/Documents/RClist.htm.
INFORMATION ON RULE PETITION
Agency responsible for adopting or administering the rule:
1. NEW RULE - I am requesting the agency to adopt a new rule.
The subject (or purpose) of this rule is: Maritugna Seed breeding
The rule is needed because: (Uttings For maritauna should be Phased out-
The new rule would affect the following people or groups: Marituana Growers

2. AMEND RULE - I am requesting the agency to change an existing rule.	
List rule number (WAC), if known:	_
l am requesting the following change:	
This change is needed because:	
The effect of this rule change will be:	
The rule is not clearly or simply stated:	
3. REPEAL RULE - I am requesting the agency to eliminate an existing rule.	
List rule number (WAC), if known:	_
(Check one or more boxes)	
☐ It does not do what it was intended to do.	
It is no longer needed because:	
It imposes unreasonable costs:	
The agency has no authority to make this rule:	·
It is applied differently to public and private parties:	
it conflicts with another federal, state, or local law or rule. List conflicting law or rule, if known:	
It duplicates another federal, state or local law or rule. List duplicate law or rule, if known:	
Other (please explain):	

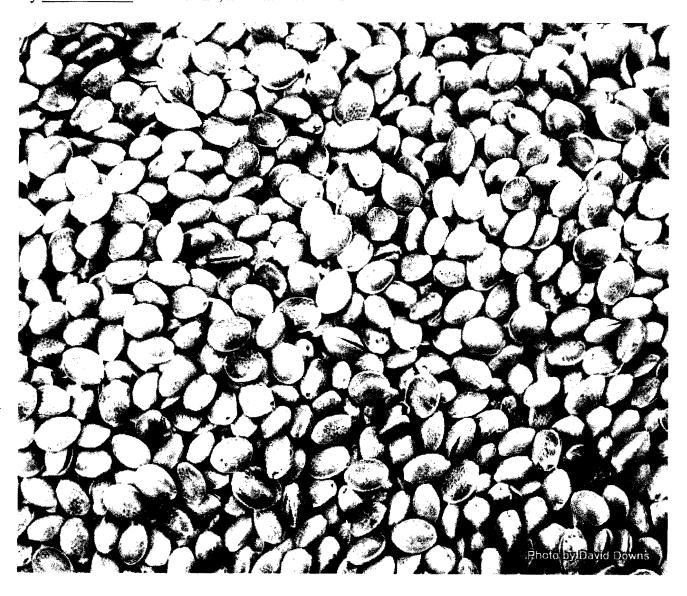
WSLCB and WSDA,

The use of marijuana cuttings should be phased out because the continued practice weakens the strain and makes it more susceptible to disease and requires more pesticide use. Furthermore, WSLCB and WSDA are starting to place administrative holds on marijuana found containing IAA, a chief ingredient in rooting hormone.

http://blog.sfgate.com/smellthetruth/2013/03/27/seeds-vs-clones/

Marijuana Seeds vs Clones

By alina Krukova on March 27, 2013 at 10:41 AM



These days it seems Cannabis growers only talk about using clones. A clone is a cutting from a 'mother plant' and according to Wikipedia any organism whose genetic information is identical to that of a parent organism from which it was created. Many medical marijuana dispensaries offer clones for sale as a service to their patients. The advantages would seem obvious, you know what strain it is, what you can expect for yield and strength. And for an indoor grower it shortens the entire cycle by a month or more.

However there are other growers that rarely use clones if at all. The anti-clone argument goes like this: Annual plants like cannabis were never "designed" to be maintained for years and years in order to maintain "clone only" varieties. Because these plants do not live for more than a year in natural conditions, perpetually fighting off environmental stresses, diseases and insects weakens the "vigor" of the genetics. The original plant from seed is capable of yielding more than a cloned offspring- the difference in yield only increases with time.

Cannabis plants grown from seed produce a Tap Root, cloned plants simply cannot-they produce a fibrous root system only. The Tap Root is a survival advantage in nature, as it is in any growing condition. A tap root not only more firmly anchors the plant down for better support, it is capable of driving downward to great depths in search of water and nutrients; an immeasurable advantage when growing outdoor crops in hot and dry conditions.

Indoor growers will tend to use clones more than outdoor growers for those reasons. Another advantage to seeds is a legal and practical one.

For medical cannabis plant providers in the USA, clones are a big legal risk. Maintaining over ninety-nine plants of any size can lead to Federal Prosecution that may involve lengthy mandatory minimum sentences. Besides that, they take up a lot of space, are perishable and require labor an electricity to maintain. Seeds can put a thousand plants in the palm of one's hand and allow for storage conditions of years with minimal space or inputs.

And then there is the issue of mono-culture within the Cannabis growing community, with the advent of clones does that means a decrease in variety, strength and more?

Clearly there is more "flavor" in the market when seeds are available versus medicinal markets that are dominated by clone-only plants. This gives people with illnesses that can be relived with cannabis more effective medicines to select from versus a "one type for all approach".

According to one seed distributor I spoke to almost all High Times Cannabis Cup Winners have been grown from seed and not from clone, his <u>collective</u> won the prestigious cup in 2012 in Amsterdam with <u>Rock Star Kush</u> and a further advantage to seed growing is "seeds allow growers to customize a strain for their growing environment and preferences-growing from clone only can be like trying to pound a square peg through a round hole. Because growers are selecting from similar but different plants when growing from hybrid or dihybrid regular seeds, they can select the variation that carries the genes necessary to produce the best yields and highest crop quality for the management the plant receives in that particular environment, as provided by the grower or the geographic region in the case of outdoor crops."

According to the cannabis seed expert Neville Schoenmaker the pioneer of Dutch Seed banks, "Cloned plants from commercial sources often carry pathogens and insects and even viruses. Seeds are always a clean and fresh start-helping to ensure that no harmful pesticides or fungicides will have ever been used in the production of medicinal cannabis."

The argument continues but after a large spike in clone usage over the last few years it appears that seeds, at least among the more serious Medical Cannabis growers, are making a comeback.

http://www.gardenculturemagazine.com/garden-inputs/propagation/is-seed-better-than-cuttings/



Tammy October 12, 2012 Propagation

There isn't really a straight yes or no answer here. It all depends on a number of things. You must be so much more vigilant on plant health in indoor gardening than you would with something like creating several more rosebushes from your favorite in the yard. Both methods will require you to monitor the new starters regularly to make sure their needs are met.

Obviously, plants grown from **cuttings** are going to mature faster than those started from **seed**. Still if the original plant has any traces of either pests or disease present, using it to start a new crop is going to give you great difficulties. Especially if the reintroduction to the growing space spreads the problem to all other plants you're growing. You might not always be able to discern there is a health issue brewing. So starting each new crop from **seed** is infinitely safer and make maintaining a healthy indoor garden easier at times.

There are times when starting new crops from **cuttings** is preferable to **seed** for other reasons. For hydroponic growers of some types of heirloom tomatoes on a larger scale, it makes their crop most cost effective with the **seed** being rather costly to purchase or hard to find. Another reason for choosing **cuttings** over **seed** would be if you find you have an unusually productive plant or one whose fruits are remarkably larger, a different color or better tasting than the others in your crop. This is how new plants comes onto the market, and if you only have one of them, then **cuttings** will be the only way to get more plants just like it.

By the way, cloning is the same as growing from cuttings. Depending on the plant you're trying to multiply in such a fashion, it can be much trickier than sowing a whole new crop. Seed is

generally very inexpensive and super simple to germinate. So, unless you have a super special reason to start new plants from **cuttings**, **seed** is the most popular choice.

Hello,

A follow up on the issue has revealed a problem in WSLCB and WSDA policy on marijuana.

The problem is the marijuana industry was founded on clones from existing genetics from available mother plants during an amnesty period. This process has created a clone dependent process that relies principally on the use of rooting hormones to propagate marijuana cuttings.

The chief ingredient in almost all rooting hormones is <u>indole-3-acetic acid</u> (IAA). Some use Indole-3-butyric acid.

Now the WSLCB and WSDA are placing administrative holds on marijuana crops that have been tested to show traces of IAA. This is problematic for many reasons.

First off, there are no known available sources of pesticides that contain IAA, except for pesticides used for killing Gypsy moths. Due to that unavailability it is highly doubtful that any Washington State marijuana grower has access to a pesticide containing IAA.

Furthermore, it is highly doubtful that an experiences marijuana grower would be using a pesticide for gypsy moths on marijuana... if...it was available to them.

It is disturbing to think that administrative holds could be placed on marijuana based on a rooting hormone whose use was required by the WSLCB rules and basic format. If the WSLCB were to test most marijuana available in Washington State they would most likely find traces of IAA. Those traces should be faint by the time the product has reached flower or end stage but it is conceivable that they are there.

I am suggesting two things.

- 1. The WSLCB and WSDA should confirm the use of rooting hormones in these cases and rule out any IAA source from a pesticide and immediately remove the administrative hold on marijuana that has been found to have IAA.
- 2. WSLCB and WSDA should immediately develop a rule allowing growers to breed marijuana seeds, even if it means altering strains, so the industry can make a mode shift from cuttings to feminized seeds.

My Petition for adoption Amendment and Repeal is attached.
Thank you
John Worthington