



## 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](mailto:rules@lcb.wa.gov).

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### 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.



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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.



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- 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.

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## **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.**



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**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.

### **3. 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.

**5. 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 bottleneaking 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**



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**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 bottlenecks.

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.**



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**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





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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.



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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 we 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



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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 not 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.



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**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**



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**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:**

- 1. 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



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(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 been 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



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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-**



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**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.



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**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



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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.



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**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.



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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



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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.



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**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.