STATE OF WASHINGTON

DEPARTMENT OF AGRICULTURE

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Concise Explanatory Statement
for amendments to
Chapter 16-309 WAC
Cannabis Laboratory Accreditation Standards Program

On December 28, 2023, the Washington State Department of Agriculture (Department) held an initial hearing remotely to accept testimony on the proposed rule language that would be used to establish chapter 16-309 WAC.

Based on the comments that were received at that public hearing, the Department decided to incorporate a significant amount of the feedback that stakeholders provided into the proposed rule language and file a supplemental CR-102. On April 9, 2024, another hearing was held remotely to accept testimony on its second version of proposed rule language to establish chapter 16-309 WAC.

The proposed rule language includes the following elements:

1. Creating education and training requirements for laboratory personnel, which depend on position, or testing responsibilities (WAC 16-309-050 through WAC 16-309-080).
2. Requiring standard operating procedure (SOP) criteria for all laboratory testing (WAC 16-309-090).
3. Requiring sampling and homogenization protocols for sample preparation (WAC 16-309-100).
4. Requiring security and safety protocols for the laboratory and for the laboratory staff (WAC 16-309-110).
5. Requiring the use of quality control and assurance protocols for laboratory testing (WAC 16-309-120).
6. Establishing facilities and equipment maintenance criteria for the laboratory (WAC 16-130).
7. Establishing method performance criteria for laboratory testing (WAC 16-309-140).
8. Establishing quality control and method performance criteria specific to each required test: water activity testing; cannabinoid concentration analysis; foreign matter inspection; microbiological testing; residual solvent testing; mycotoxin testing; pesticide testing; and heavy metals testing (WAC 16-309-140 through WAC 16-309-210).
9. Establishing required standardized testing procedures for cannabinoid concentration analysis, residual solvents testing, and heavy metals testing. (WAC 16-309-160, WAC 16-309-190, and WAC 16-309-220).
10. Establishing quality control and method performance criteria for analyte testing outside of product testing requirements as established by the LCB (WAC 16-309-230).
11. Creating laboratory computers and information system requirements (WAC 16-309-240).
12. Establishing method validation criteria for laboratory testing (WAC 16-309-2640).
13. Establishing a process by which laboratories can submit their own methods for approval. (WAC 16-309-250)

April 16, 2024

14. Establishing minimum proficiency testing standards for laboratories (WAC 16-309-270).
15. Establishing certificate of analysis (CoA) report requirements (WAC 16-309-280).
16. Establishing procurement protocols for the selection and purchasing of services and supplies for the laboratory (WAC 16-309-290).
17. Establishing sample subcontracting requirements for third party services (WAC 16-309-300).

Reasons for Adopting the Rule

This proposed rule is intended to replace and expand upon the laboratory quality standards first created by the Washington State Liquor and Cannabis Board (WSLCB) as required by House Bill 1859 (HB 1859).

HB 1859 created an interagency coordination team for cannabis laboratory quality standards. The team consists of the Department of Agriculture, the WSLCB, and the Department of Health (DOH). The Department is designated lead agency for the team and must provide all necessary administrative support. The Department must establish and maintain cannabis testing laboratory quality standards by rule. The bill requires the cannabis testing laboratory quality standards to include but are not limited to: approved methods for testing cannabis for compliance with product standards established by rule by the WSLCB or the DOH; method validation protocols; and performance measures and criteria applied to testing of cannabis products.

Summary of Comments and the Department's Response

The initial public comment period ran from November 20, 2024, until the close of business on December 28, 2023. During that time, four written comments and seven oral comments were received.

The supplemental public comment period for the second version of the proposed rule language ran from February 21, 2024, until the close of business on April 9, 2024. During that time, two written comments and one oral were received regarding the proposed rule language.

Due to the volume and length of the comments received throughout this rule making process, a summary of the testimony received for both versions of the proposed rule language and the Department's responses are attached below.

Differences Between the Proposed and Adopted Rule

There were two minor changes made from the proposed to the adopted rule. References to WAC 314-55-102 were replaced with references to chapter 314-55 WAC in response to feedback received from the WSLCB. The term "iCAL" which Jay Burns referred to as undefined in his written comments was replaced by the full term, Initial Calibration.

Chapter 16-309 WAC, Cannabis Laboratory Accreditation Standards Program
Public Comment Summary – Initial Proposed Rule Language Filed November 2023

Topic	Comments	Source
RULE LANGUAGE		
16-309-020	• Analytical Batch: The definition states that it is "...a group of samples, standards, and blanks…"Suggest changing the verbiage to "...a group of samples, controls, and blanks…" because standards can also refer to reference standards. *Response:* Standards include calibrators and controls. Changing it to controls will eliminate calibrators, so we are retaining the definition to maintain the inclusivity. • Cross check reference: this control is the same as an initial calibration verification (ICV), which is a common term in methods and it should be mentioned in this definition. Although not entirely necessary, we also recommend that initial calibration verification be added to the list of definitions. *Response:* Added ICV definition into rules. • Cut-off concentration: WAC 314-55 uses "limit," not cut-off concentration, though we do see the term cut-off used in the CLASP methods. Suggest adding limit for consistency and adding limit to the list of definitions. *Response:* Added limit definition into rules. • Repeatability (RSDr): "MLV reports" is used in this definition (as well as in "Reproducibility (RSDR)"). We did not find any definition of this acronym. Please add. *Response:* Change "MLV report" to method validation report and added "Method Validation Report" definition into rules. • Matrix spiked duplicate, ICV, and ICB are used in the Draft Rules, but do not appear in Section WAC 16-309-020 Definitions. Meanwhile, several control types that are defined in Section WAC 16-309-020 do not appear anywhere else in the Draft Rules. Please unify terminology related to controls, ensuring all used terms are defined and all defined terms are used. *Response:* Added Matrix spiked duplicate, ICV and ICB to definitions.	Confidence Analytics 12.28.23
16-309-030(4)	States that "...labs must report quality control test results both to the customer and directly to the board…" The use of "quality control" is confusing. Although we believe "quality control" in this statement refers to the results for the submitted sample, it is confusing as to whether it refers to the results for the analytical controls run in the sample batch (e.g. CCV, matrix spike, etc.) or both analytical controls and compliance samples. *Response:* We changed the use of quality control in this context to refer to the sample results that report out to the COA.	Confidence Analytics 12.28.23
16-309-040	How easy will it be to get a waiver? If waivers are allowed why even have these qualifications included? *Response:* The laboratory will have to document the employees training and competencies, and they will be interviewed by the accrediting authority during an audit to insure they have the skills to perform the tasks they are assigned, if an employee meets these requirements, then the educational requirement would be waived by the accrediting authority.	Treeline Analytics 01.04.24

16-309-090	The requirement in this section regarding to refrigeration of samples is contradictory to other section by stating that the samples only need to be refrigerated if they are not analyzed within 7 days. Section -190 says they must always be stored below 8C and the Residual Solvents Method document says that sample must be stored below 6C. *Response:* We removed the refrigeration requirement.	Medicine Creek Analytics 12.27.23
16-309-100	This section states that the laboratory must assure that the sample meets the minimum requirements in WAC 314-55. Under current rules, the laboratory is not provided the parent lot size so will not be able to determine if the submitted sample meets the minimum requirement. *Response:* We removed the reference to WAC 314-55 and made it clear that labs need to make sure they have enough sample to do the test that is requested. Laboratories must establish the minimum sample size that they need to test to meet the sensitivity limits of their methods. Laboratories must not settle for any amount but must set sample size requirements if they are not already established in rule.	Confidence Analytics 12.28.23
16-309-100	Must have manifest. It was said in the meeting that this allows for medical testing. The WSLCB has historically not allowed labs to test outside of the i-502 market due to potentially aiding and abetting a criminal enterprise. *Response:* Chapter 16-309 WAC is intended to provide standards for laboratories conducting compliance testing for the I-502 system. The WSDA does not have regulatory authority to limit the scope of a laboratory's customers, if other agencies have that authority, that must be discussed with them.	Treeline Analytics 01.04.24
16-309-100(6)	Residual solvent containers that 'minimize evaporation of solvents' – vague and unhelpful language. *Response:* The intention is to provide laboratories flexibility to use a variety of closed containers with the aim of minimizing evaporation, so we have retained the rule language.	Medicine Creek Analytics 12.27.23
16-309-100(6)	"All samples received for residual solvent testing must have an aliquot placed in an enclosed container that minimizes the evaporation of any solvents that may be present as soon as possible upon receipt." Our procedure is to subsample for residual solvents as soon as possible upon receipt. The addition of an aliquot step would only result in increased risk of solvent loss. Please reword to specify some time delay in subsampling that would require sequestering an aliquot of sample for residual solvents testing. *Response:* The procedure you just described will meet the same requirement.	Confidence Analytics 12.28.23
16-309-100 (6)	This CLASP mentions RS only needs to be refrigerated after 14 days without testing. WAC 16-309-100 6) says 7 days. And section 16-309-190 5e) days samples must be stored at <8ºC and must be analyzed within 14 days. This differs from the 6ºC in the CLASP method. This is confusing because it seems there are multiple regulations that differ on all sections for the storage and testing requirements. Contradictory references. *Response:* We have removed the refrigeration requirement in 16-309-100(6), 16-309-190 (5)(e), along with the Residual Solvent method and indicated that laboratories must establish storage requirements for all sample types.	Treeline Analytics 01.04.24

16-309-110(8)	Requires the laboratory to maintain hardcopy records for all samples. We believe electronic copies with appropriate back-up measures are sufficient. Electronic copies are more sustainable as laboratories doing 1500 samples per month would print out approximately 3000 pages if hardcopies are required. *Response:* This is not a requirement to maintain everything in a hardcopy, but rather any documents that are created in the laboratory as a hard copy must be maintained. The word "original" was added to rules to better define the documents transcribed or scanned.	Confidence Analytics 12.28.23
16-309-120	What are all these mentions of cutoff/decision point? Are the cutoffs for solvents and pesticides the action limit? Is there no decision point for potency because it is all positive? *Response:* From our definitions: "Cut-off concentration" means, in qualitative analysis, the concentration of the analyte that is either statistically lower than the level of concern (for limit tests) or at which positive identification ceases (for confirmation of identity methods). - This is the same as action limit. "Decision point" means the level of concern, cutoff, or target level for an analyte that must be reliably identified or quantified to be considered positive in a sample. There is a decision point for cannabinoid concentration, which is the lower limit of quantitation upon which cannabinoid concentrations must be reported.	Treeline Analytics 01.04.24
16-309-120(1)	States that the QC program "...involved concurrent analysis of calibrators and controls with samples…" Does this mean that calibrators must be run with every batch? We agree that some test methods/instruments require frequent calibration (e.g. Heavy Metals), other test methods/instruments are quite stable (e.g. cannabinoids HPLC-PDA) and historical calibrations can be used as long as batch controls verify the accuracy of the calibration curve. WAC 16-309-140 allows use of historical calibrations. *Response:* We have amended the language in 16-309-120 and referenced "a calibration" instead of "appropriate calibrator" allowing historical calibration so it doesn't seem to conflict with 16-309-140.	Confidence Analytics 12.28.23
16-309-120(2)	States that "Laboratories must use appropriate calibrators and controls in each analytical batch." Similar to number 1 above, we believe that the laboratory should be allowed to use historical calibrations. *Response:* We have amended the language in 16-309-120 and referenced "a calibration" instead of "appropriate calibrator" allowing historical calibration so it doesn't seem to conflict with 16-309-140.	Confidence Analytics 12.28.23
16-309-120(3)	Numbers 3b and 3c: While we understand the reasons behind requiring spiked controls both above and below the cutoff, this requirement would be costly both in time and materials due to the variability of cutoff/decision points of compounds in a single test method and standard mixtures that are commercially available. ○ For example, the limit for residual solvents ranges from 2 ppm to 5000 ppm (three orders of magnitude!) depending on the compound. ○ Mixtures available from the vendors do not necessarily scale concentration with action limits/cut-off concentrations so it may take several different spike levels to meet this requirement. *Response:* The standard to have a positive or spiked control below the cutoff or decision point but above LOQ has been replaced with "Instruments that use a multipoint curve must be calibrated using a minimum of a four-	Confidence Analytics 12.28.23

	point curve with the first calibrator at the LOQ." This requirement now supports the below cutoff linearity range that the previous below the cutoff control did. ○ Adding a minimum of two controls for each matrix type analyzed further increases the number of controls necessary. Matrix types are evaluated during the validation process and if matrix-matched cals/controls are necessary, the lab will implement them. If it is observed that matrix-type has little effect on the data, "universal" cals and controls can be utilized across multiple/all matrix types. *Response:* Calibrators are not required to be made in-matrix. CLASP pesticide documents now clarify that if the laboratories wish to make their calibrators in-matrix, they are allowed to do so. The "per matrix" requirement has been removed from subsection (b) and (c). How are "matrix types" going to be grouped? Some of the CLASP methods refer to them as "commodity groups." *Response:* We have removed references to matrix types and acknowledge that the CLASP team will need to work with labs, the LCB, and other I-502 stakeholders to further define matrix types. ○ We ask that the language in WAC 16-309-120 Quality control and assurance be updated to remove the "per matrix" requirements and to remove the requirement for dual-level controls based on each analyte's action limit. As an alternative, we propose requiring that every batch contain at least one control that is within +/-50% of each analyte's action limit. *Response:* The" per matrix" requirement has been removed from subsection (b) and (c). Laboratories are expected to validate that they can accurately quantify sample analysis results at or near the analyte's action limit by using a calibrator at the LOQ.	
16-309-120(4)	Requires controls to be "processed in the same manner and included with the test sample batches through the entire testing process" without exception to the control type. ○ The CCV, however, being defined as "one of the primary calibration standards" cannot meet this requirement except in cases where the calibrators are also processed as samples, which is not practical/possible for all of the analytical methods. *Response:* The proposed rules have been revised to clarify that the CCV is excluded from this requirement. ○ ICV/CCR and CCV are typically not required to be processed as samples, as their purpose is simply to verify the accuracy of the calibration. *Response:* In general, positive controls are required to be processed as samples and must be processed as such through preparation and analysis. We have clarified in rules that the ICV and CCV do not have to be processed as samples. ○ Spiking standards into extraction tubes on the same scale as samples requires a large volume of costly standards. *Response:* The process of spiking standards into extraction tubes is required when using positive controls such as a matrix spike, matrix spike duplicate, and laboratory control spike to measure the extraction efficiency of the sample preparation process. Laboratories are expected to use positive controls that encompass the entire preparation and analysis of their methods.	Confidence Analytics 12.28.23

	○ Additionally, it is valuable to analyze a variety of negative controls, some of which should be isolated from the sample prep procedures and not processed as samples in order to identify contaminants or interference from the instrumental systems. Please update the draft rules to indicate that the LCS is subject to this requirement and other control types such as ICV and CCV need not be processed as samples. *Response:* The proposed rules require the use of a negative or blank control to demonstrate the assay(s) ability to perform without interference or contamination. A LCS has the same requirements as a matrix spike and must be processed as a sample. ○ Within the regulatory text and the various CLASP methods there are discrepancies and variances regarding controls. Overall, please include universal guidelines in rule specifying for each method. ▪ The number and type of controls required for an analytical batch or calibration ▪ The nature/requirements for prep of each control type ▪ The acceptance criteria for each control type *Response:* The proposed rules have been updated to include the number, type, and acceptance criteria for controls.	
16-309-120(5)	Number 5 requires controls to be prepared from a source different from the calibration standard source. ○ When a calibration curve is analyzed, the accuracy of the calibration curve is verified using a second source standard (ICV). There is no reason that other batch controls must be from a second source if the initial accuracy is already verified using a second source. *Response:* Calibration curves must be verified from a second source lot to include but not limited to an ICV, so if the initial accuracy is verified using a second source then that is sufficient. Laboratories may choose which source the other controls are made from. ○ The definition of different source contradicts Section WAC 16-309-020 Definitions which describes the "Cross check reference standard (CCR)" as a control prepared from an independent source and in this case a different source is defined as "independent vendor, independent lot, or independent preparation" which is a more flexible definition. Please clarify and correct conflicting definitions for what constitutes a separate source of standards. In cases where a separate lot is not readily available, allow independent preparation as a separate source. *Response:* When labs are searching for a second source of standards, first labs should seek an independent manufacturer, if that is unavailable, then they could use a separate lot from their current manufacturer, and if that is unavailable then create their own standard from the same source. We have removed "Cross check reference standard (CCR)" from rules to eliminate this confusion. ○ Furthermore, many - if not all of the CLASP methods state that controls must be prepared from the same source as the calibration standard, which is unnecessarily restrictive. *Response:* We have updated the adapted methods to be consistent with rules. ○ It is our scientific opinion that once the calibration has been validated by a second source (different manufacturer or different lot from same manufacturer), there is no reason to restrict the source for controls,	Confidence Analytics 12.28.23

	including CCV. If a control fails, appropriate investigations and corrective actions will be implemented, including (but not limited to) checking standards and re-calibration. Please update draft rules for which control types must be prepared from a different source of standards from the calibration. Only the CCR/ICV should be subject to this requirement, as is stated in the CLASP methods. *Response:* We changed the rule language to make it clear that the calibration must be verified from a second source, they can use controls from a second source, or an initial calibration verification control (ICV) from a second source. However, the CCV by definition must be made from the same source as the calibrators.	
16-309-120 (5)	Control lots must be different – Laboratories are limited in their access to standards and it may not be possible to use this multitude of different lots. The cost of this has the potential to increase standard costs significantly. Cannabis laboratories cannot be held to a higher standard than those who supply standards to us. Could labs do one additional lot of verification standards instead of 3? Either daily or for the calibration table? Two different lots should be enough to verify. *Response:* Only two lots are required.	Treeline Analytics 01.04.24
16-309-120(8)	Defines the acceptance criteria as ±20%. Industry standard has historically been ±30%. The Cannabis Science Task Force's December 2021 report to the legislature specifies a range of ±30% by incorporation of the NY Method for Cannabinoids and METHOD 8260D for Volatile Organic Compounds, among others. We propose keeping this acceptance range as recommended by the CSTF. *Response:* We have changed the acceptance criteria for controls to 30% for pesticides, residual solvents and heavy metals and left spiked standards at 20% for cannabinoids.	Confidence Analytics 12.28.23
16-309-120(11)	Requires quality control results to be reviewed by an analyst performing the test. Many labs separate sample preparation and data review. Analysts actually preparing the samples and performing the test are not trained in data review. We suggest a change to "quality control results must be reviewed by qualified personnel appropriately trained on and familiar with the test method" or something similar. *Response:* We removed the language "performing the test" to acknowledge that the person reviewing results may not be the same person that is performing the test. We have clarified the language to include that the person reviewing the results must be qualified to do so.	Confidence Analytics 12.28.23
16-309-120 (20)	CLASP RS and potency do not mention any sort of R2 calibration curve requirements. WAC 16-309 says everything must be R2 >0.995. Pesticide method mentions R2 0.990. Inconsistent across CLASP methods. *Response:* We have clarified the language in rule to set R2>0.995 as the standard unless otherwise specified in an approved method. CLASP methods have also been updated to be consistent with rules.	Treeline Analytics 01.04.24
16-309-130 (10)	Laboratory must comply with manufacturer PM specifications – PM on some of the machinery is used more frequently than manufacturer recommended. Laboratory should define their own maintenance procedures. *Response:* We have clarified "at minimum" to make it clear that laboratories can certainly do more PM than the manufacturers recommendations.	Treeline Analytics 01.04.24

16-309-130(12)	Requires "Each (pipette) must be rechecked at least every six months." Please clarify if internal checks are sufficient or if the device must be sent out for official calibration. We check our pipettes quarterly and send them out annually. We believe an annual calibration is sufficient and every six months would be disruptive to the workflow. *Response*: Your internal checks would meet the requirement as long as it verifies the accuracy of the pipette.	Confidence Analytics 12.28.23
16-309-140	What is a 'decision point' for potency? Is it the 1000 minimum in the WAC 314-55? All samples will have some cannabinoids. *Response:* Yes – the decision point for potency is the lower limit of quantification, per 314-55.	Treeline Analytics 01.04.24
16-309-140(3)	Limits the use of a calibration The rule has been curve to 30 days, after which a new calibration must be run. We agree some instruments/test methods do require frequent calibration (e.g. pesticide analysis by LC-MS/MS.) However, other instruments/test methods are very stable (e.g. cannabinoid analysis by LC-PDA) and instrument drift is minimal. Quality control samples are analyzed with every batch and would catch any instrument drift. Therefore, it is suggested that labs may use historical calibrations and recalibrate as needed to meet quality criteria, when major instrument maintenance requires, or after six months, whichever comes first. *Response:* Yes, we are allowing historical curves, but have limited the length to not greater than 30 days.	Confidence Analytics 12.28.23
16-309-160(3)	This needs clarification or a better description of what the process might be to "seek approval from department" for using a different cannabinoid method. a. Is there an estimated timeline for the department to complete these reviews and will there be any forms or rubrics to document their decision process? *Response:* The proposed rule has been amended to add a section that details the method approval process, including the timeline required for method review and approval.	Medicine Creek Analytics 12.27.23
16-309-170	There will be increased cost to laboratories for photography capabilities. *Response:* We understand there will be costs associated with the labor and equipment involved in taking a picture and storing it, however as documentation is currently required, this could potentially be a cost saving alternative to the current documentation requirement. This requirement can be satisfied with a low-price digital camera and photo storage system. We clarified that a camera with the resolution to identify foreign matter would be sufficient to meet this requirement. A description from a lab tech is very subjective where a photograph would be more objective.	Treeline Analytics 01.04.24
16-309-170(3)	Do we need to use a magnification method to inspect a full 30% of the sample? Does the photograph need to be magnified? Will any magnified image of the sample be sufficient for this requirement? This section's language is vague and difficult to comply with. *Response:* We have changed the word "assess" to "document," and clarified that a camera would need the resolution to identify foreign matter. The photograph wouldn't necessarily need to be magnified as long as the photograph can easily show any foreign matter if present.	Medicine Creek Analytics 12.27.23

16-309-180 (4)	Says methods that deviate from CLASP “adaptations must supersede or be used in conjunction with the minimum method requirements as appropriate” What are the minimum method requirements and what is appropriate? *Response:* This language was removed because we have changed the rule to allow for labs to submit methods for approval and have provided criteria for method approval.	Treeline Analytics 01.04.24
16-309-190 (5e)	Inconsistent temperature and storage requirements with CLASP. *Response:* We removed the temperature requirement.	Treeline Analytics 01.04.24
16-309-190(5)	• (5)(c) requires labs to analyze at least 0.2 g of sample for residual solvents. Analyzing 0.2 g of sample would require extraction and dilution steps to measure concentrations at the action limits, but still within the instrument linear range. This handling of the sample results in a high probability of evaporation for any solvents that may be present. Evaporation during handling may result in passing a sample that actually contains residual solvents at a level that exceeds the action limits stated in WAC 314-55-102. This potential evaporation was discussed at length in the CSTF and unanimously agreed that handling the sample prior to analysis (mixing, agitating, etc.) is not preferable due to the likely loss of target analytes. Instead, as discussed in the CSTF Workgroups and Steering Committee, it is preferred that the residual solvent subsample be deducted from the sample before homogenization and be placed immediately in a headspace vial and sealed with no mixing. To accomplish this without popping the vial due to overpressurization during incubation or going above the ULOL, the subsample mass must be less than 100mg. *Response:* We are maintaining this standard. We have determined a need for larger sample sizes in order to better capture residual solvents. Laboratories can use a dilution factor should some samples test above the ULOL. • (5)(d) requires that, “When headspace is encountered, laboratories must either reject the sample, or flag the data as having biased results due to headspace.” This requirement is poorly-defined and unreasonable, as products on retail shelves often are subject to some volume of headspace in their containers. Please remove this language. *Response:* In acknowledgement that laboratories do not have control over how producers and processors send their samples, we have removed this requirement. • (5)(e) states, “Samples must be stored at < 8°C and must be analyzed within 14 days of receipt.” The cold storage requirement presents a hardship for labs and does not represent the storage or handling of products in warehouses, at retail, or in possession of consumers. We request a common sense approach that is representative of how products are commonly stored - at room temperature and inside sealed jars or syringes. Testing will more closely match consumer exposure if the samples are stored in conditions that replicate conditions in the retail shops. It should also be noted that samples are typically analyzed within 24 hours of receipt due to customer requirements so it is extremely rare that samples are stored at ambient temperature exceeding this time window.	Confidence Analytics 12.28.23

	Response: We have removed this requirement, understanding that some matrices would not benefit from refrigeration.	
16-309-190(5)(d)	Requires a "hard sealable container or syringe". We disagree with this language as well as the refrigeration requirement for the following reasons: b. When you chill a distillate, it becomes solid. If it's in a syringe, it needs to be warmed up to get the sample out, thus defeating the purpose of refrigerating them. Moreover, no one in the cannabis industry refrigerates their concentrates during processing, sale, or use at home, so the samples should be treated the same. c. The regulatory language sections are somewhat contradictory; -090 says samples need refrigerated if they're not analyzed within 7 days, but section -190 says they must always be stored below 8C. The Residual Solvents Methods document 973 says samples must be stored below 6C. Please align language across documents to be consistent. *Response:* In acknowledgement that laboratories do not have control over how producers and processors send their samples, we have removed this requirement. We have also removed the refrigeration requirement, understanding that some matrices would not benefit from cold temperatures.	Medicine Creek Analytics 12.27.23
16-309-200	First paragraph is not relevant to mycotoxins and seems to be copied/pasted mistakenly from the microbial section. Recommend fixing. *Response:* This was a typo, microorganisms has now been replaced with the word mycotoxin.	Medicine Creek Analytics 12.27.23
16-309-200(1)	States, "Mycotoxin screening is intended to accurately measure qualitative, semi-quantitative, or quantitate results, and report microorganisms incurred through the production and processing of cannabis and cannabis products." Qualitative methods are not appropriate for a test with a numerical action limit. Please update to specify quantitative methods only. In addition, the mycotoxin test does not report microorganisms, rather mycotoxins are toxic residues produced by some species of microorganisms. *Response:* In regard to the mycotoxin test reporting, this was a typo corrected, microorganisms was replaced with the word mycotoxin.	Confidence Analytics 12.28.23
16-309-200(2)	States, "For qualitative methods, all results must be reported as qualitative designations such as 'detected,' 'not detected,' 'positive,' or 'negative.'" Again, a qualitative method is not sufficient for a test with a numerical action limit. In order to pass proficiency testing, labs will be required to report numerical results for individual mycotoxins as well as for the sum of aflatoxins. *Response:* This was changed to allow semi-quantitative or qualitative methods when the laboratory is reporting negative results. Should a sample be positive, the laboratory would have to perform a confirmation test that would accurately quantitative the analyte.	Confidence Analytics 12.28.23
16-309-200(5)	Requires that labs perform a second-source calibration verification at the beginning of each day of testing. A second-source calibration verification should be analyzed before putting a calibration into production, but should not be required on each day of testing. CCV should be used on each day of testing to verify the calibration	Confidence Analytics 12.28.23

	accuracy has been maintained and need not be of a separate source. Please remove the daily second-source calibration verification requirement from Section WAC 16-309-200 Mycotoxin screening. *Response:* A second source control is required for each day of testing for high complexity testing even when a laboratory is using a historical curve.	
16-309-200 (5)	Does not encompass all mycotoxin testing. With pre-made kits, there is no second set of standards, it is what comes in the kit. Can pre-made kits and standard preparations be approved based on manufacturers QA? These kits do not use linear calibration curves but are accepted for use for mycotoxin testing. Will we be allowed to use this methodology moving forward? *Response:* We do not have enough information about the pre-made kit you are referring to, to know whether or not it would meet the standard. We'd be happy to discuss this with you further. Section 4c) - Why is this where the mention of recycling solvents goes? Seems like that should be a general rule, not only in the mycotoxin section. *Response:* We have moved this to the facilities, equipment, and maintenance section to note that it is a general rule.	Treeline Analytics 01.04.24
16-309-230	Will labs be able to be certified for the additional analytes that are not on the list? *Response:* No, at this time labs will only be accredited for required analytes.	Treeline Anlaytics 01.04.24
16-309-230(1-2)	State that for any analytes not required in WAC 314-55 or WAC 246-70 (referred to as "non-required analytes"), these analytes must be reported separately from the required analytes on the COA and the results must be identified as analytes outside the scope of accreditation. ○ We would like to point out that the prescribed cannabinoid method, 976-CLASP, includes two analytes that are not required in WAC 314-55 or WAC 246-70 (delta-8-THC and CBN) ○ Listing non-required analytes separately can make for a lengthy, confusing, and cumbersome COA that is less valuable to our clients and also to retailers and consumers. ○ For labs that have these analytes included in their ISO 17025 scope of accreditation, identifying non-required analytes as outside the scope of state accreditation but a part of ISO accreditation is extremely confusing, especially for individuals who do not understand laboratory regulations and accreditation. ○ We suggest that non-required analytes do NOT have to be reported separately on the COA. However, if these analytes are not in the laboratory's scope of accreditation by either the state accrediting agency or ISO 17025 accreditation, then non-required analytes should be identified as outside the scope of accreditation. *Response:* The WSDA has determined that accreditation standards will start with the analytes required by the LCB and DOH, and that any additional analytes must be distinguished on the COA. However, we have removed the requirement to list them separately in order to create ease in the structure and design of the Certificate of	Confidence Analytics 12.28.23

	Analysis. Laboratories will still have to identify analytes outside the scope of accreditation on their COA with a written statement.	
16-309-230 (3-4)	State that non-required analytes test requirements and method validation must meet the testing and validation standards outlined in WAC 16-309 and the CLASP methods. If the state accrediting body is verifying that the analytes meet the testing standards and method validation criteria as required analytes, we believe that the accrediting body should allow these analytes to be included in the scope of accreditation. *Response:* The department aims to increase the standardization of results that are being commonly reported, however the state is currently only accrediting for required analytes.	Confidence Analytics 12.28.23
16-309-230(2)	Will WSDA be accrediting any other cannabinoids beyond the 4 required in current WAC? Will they be accrediting terpenes? *Response:* The state is currently only accrediting for required analytes.	Medicine Creek Analytics 12.27.23
16-309-250	Precision in section 7 is 20 results total, then section 15 matrix effects are 10 different lots. Can this be the same validation? *Response:* You can use the same data, but you will have to document both for precision and matrix effects separately.	Treeline Analytics 01.04.24
16-309-250(1)	States that a full method validation is required prior to "...implementing a standardized method." If the lab is issued a standardized method, that method would have been previously validated. The lab should do a method transfer/performance verification of appropriate method characteristics (LOD/LOQ, linearity/dynamic range, precision and accuracy) but we believe it is not necessary to perform a full validation. Number 25 does outline criteria for an "abbreviated instrument validation" when obtaining an instrument of the same make/model. We believe these requirements also pertain to transfer of standardized methods which have been previously validated. *Response:* Since all labs have different instruments, consumables, reagents, building infrastructure, and personnel, laboratories must complete a full method validation prior to implementing a method. We have also modified our incorporation of methods into the rule, labs will be allowed to utilize a list of pre-approved methods, or submit their own methods or edits for approval. Because of an increase in variance between methods, validation prior to implementation is important and will be maintained.	Confidence Analytics 12.28.23
16-309-250(3)	States that annual reverification studies are required and these studies "...are designed to verify LOD, LOQ, ULOL values are still valid." Calibration curves include the LOQ and ULOL. LOD can be estimated/calculated using the LOQ data. Proficiency testing is required at least annually. We believe that these requirements continually monitor method performance and verify that the characteristics of the method remain valid. If any of the data from these experiments are out of acceptance range, an investigation is performed and appropriate corrective action implemented. Are calibration curves and proficiency testing results adequate to meet the reverification requirement?	Confidence Analytics 12.28.23

	Response: Proficiency testing isn't designed for the purpose of verifying method performance, and therefore we are maintaining this requirement to ensure that methods and instruments are being verified yearly beyond the context of proficiency testing.	
16-309-250(11)	Requires labs to "characterize the ULOL of a method by a series of replicates with increasing concentrations (i.e., a minimum of five replicates at each concentration)." Assuming a valid calibration range which spans each analyte's action limit for each limit test, it is not necessary to experimentally determine the ULOL. Please remove this requirement or create an allowance where it is not necessary if a validation is able to demonstrate linear range above the action limit. *Response:* It is important that laboratories know the limit of linearity for each of their methods and at what point their results are no longer accurate. We are maintaining this standard; however we are reducing the number of replicates from 5 to 3, decreasing the cost to validate.	Confidence Analytics 12.28.23
16-309-250 (18)	There are no negative potency samples. A clear definition of and examples of representative negative potency samples should be provided. *Response:* Subsection 18 refers to qualitative testing. Cannabinoid concentration, is a purely quantitative test and therefore this standard does not apply to cannabinoid concentration.	Treeline Analytics 01.04.24
16-309-250 (19)	How would we determine extraction efficiency for potency if there is no standard to compare it against? Also, there are no negative potency samples. *Response:* You would have to perform multiple extractions on the same sample to determine the efficiency from the initial extraction to the secondary or tertiary extractions.	Treeline Analytics 01.04.24
16-309-250(22)	States that the original validation study records be maintained "...for an indefinite period." What if a test method is replaced? Most records in this rule have a retention period of 5 years. We believe this 5-yr period should apply to validation records for methods that have been retired. *Response:* We have modified the rule language to allow for a 5-year period for retired methods.	Confidence Analytics 12.28.23
16-309-250 (23f)	What are positive and negative sample differentiation studies. *Response:* Use negative controls and positive controls above the cutoff, to show that your method can distinguish accuracy and precision around the cutoff.	Treeline Analytics 01.04.24
16-309-250(25)	Outlines requirements for an abbreviated instrument validation for implementing methods on additional instruments of the same make/model as the instrument on which the method was validated. Based upon our 5 years of experience transferring methods to multiple instruments, carryover, interferences, and matrix effects for the additional instruments would be the same as the original instrument and should not be required. Parallel comparison studies with a validated instrument would identify any performance issues. *Response:* Parallel studies alone will not verify instrument performance adequately. We have retained subs a, b, and c, maintaining instrument specific requirements, but have removed the method specific requirement of interference studies.	Confidence Analytics 12.28.23

16-309-270(4)	Requires dilution of a sample that is above the established ULOL to obtain a quantitative value. For tests with cut-off concentrations/action limits, it is not necessary to obtain an actual quantitative value for a sample that will fail regardless. *Response:* We are maintaining this standard as quantitative results are valuable, especially when determining the severity of contamination as it impacts public and environmental health.	Confidence Analytics 12.28.23
16-309-270(6)(h)	Requires inclusion of the driver's name and contact information on the COA. COAs are considered public information and can be easily accessed by anyone. Including a driver's name and contact information on such a public document is, in our opinion, an invasion of the individual's privacy and opens up potential liability to both the company and regulatory agencies. *Response:* We have eliminated these from the COA requirement.	Confidence Analytics 12.28.23
16-309-270 (6)	• Comments: Section (f, h, and k) This data is captured on the manifest that all samples are required to have when they arrive at the lab. This data is reported to the LCB via the manifest data entered into CCRS and should not be included on a lab certificate of analysis. *Response:* We have eliminated the date of transport and driver's information from the COA requirement. We are maintaining the amount of sample received on the COA requirement to ensure the minimum lot size sampling has been achieved when I-502 products are transferred between I-502 producer/processors and I-5102 retail.	Green Grower Labs 01.04.24
16-309-270(6f) & (6)(h)	Requirement to include the date of transport and driver's information on the COA: this seems unnecessary to include on the COA, particularly Driver's contact information, there's already a 'date received' on the report, which should be good enough if the lab doesn't harvest or transport the sample. The transport manifest is linked to the samples both publicly and within our LIMs system, so this information remains tied to the samples, but we shouldn't have to add these onto the COA. *Response:* We have eliminated the date of transport and driver's information from the COA requirement.	Medicine Creek Analytics 12.27.23
METHODS		
475 CLASP Heavy Metals by ICP-MS	● Sect 6.3.5 We request the flexibility to follow our own quarterly pipette verification procedures, as outlined in our SOPs. *Response:* This section has been revised from "quarterly" verifications to "at least every six months", to maintain consistency with the proposed rules. Laboratories may perform verifications more often if they wish. Laboratories may submit a modified method if they wish to verify their pipettes using a different procedure. ● Sect 7.0, Table 4 - If method performance can be established without the use of gold (Au) matrix modifier, please accept its exclusion. *Response:* This method has been validated using gold (Au) as a stabilizer for mercury. If the laboratories wish to use another substance to stabilize mercury, then they may submit a modified method or their own for approval. ● Sect 8.0 Preparation of Reagents, Solutions, and Standards - We request the flexibility to scale the volumes of standards and other solutions to meet our needs based on the volume of testing. *Response:* Laboratories may scale the volumes of standards and other solutions to meet testing needs.	ConfidenceAnalytics 01.07.24

	○ Please allow the creation or purchase of mixed standards/solutions containing Hg, as long as stability can be demonstrated and corrective actions taken in cases of degradation. *Response:* The mention of trade names or commercial products in method is for illustrative purposes only and does not constitute a CLASP endorsement or exclusive recommendation for use. Laboratories may purchase or create mixed standards/solutions, as long as they meet the technical component described in the method. ○ Please allow the laboratory to determine the expiration date of each solution based on the manufacturer expiration dates of standards and reagents, in conjunction with ISO standards for assigning expiration based on solution constituents (aqueous, acidified aqueous, etc), as long as stability can be demonstrated. Solutions containing heavy metals are difficult and expensive to dispose of, and we would like to reduce our generation of such hazardous waste wherever feasible. We do not find it necessary to prepare Hg calibration/control solutions daily. To discard previous solutions on each day of analysis would unnecessarily generate a larger volume of hazardous waste. *Response:* This method was validated with the expiration dates as described. Laboratories may submit a modified method or their own method for approval if they wish to establish their own expiration dates. ● Sect 10.1 Please allow the use of glass inserts for digestion vessels. *Response:* This method allows for the use of glass inserts. ● Sect 10.3 Please allow the use of a microwave digester in place of hot block digestions. *Response:* This method was validated using hot block digestions. Laboratories may submit a modified method or their own method for approval if they wish to use microwave digestion instead. ● Sect 12.1 Please do not require LOD/LOQ study to be performed for each matrix. The analysis of a matrix spike should be sufficient to verify comparable recovery when different matrices are analyzed. *Response:* Section 8 has been revised to not require the LOD/LOQ study be performed in matrix. However, laboratories are expected to investigate matrix interference effects for the products they intend to test as part of their validation work. ○ 12.1.4 Since calibration is performed on each day of analysis and the calibrated range should include the LOQ for each element, we do not find it necessary to perform a quarterly verification of the LOQ. *Response:* This section has been revised to yearly verification of LOQ to maintain consistency with the proposed rules. ● Sect 12.3 Quality Control Standards - Consistent with previous feedback, we would prefer control criteria to be published in WAC 16-309 for each method. We would appreciate more consistent criteria across the different control types and fear it may be difficult to maintain +/-10% for ICV/CCV. We are willing to make method changes to improve our accuracy, but feel +/-10% may be too strict, especially in cases where samples show no detections. *Response:* We are modifying this standard for ICV/CCV to +/- 30% for heavy metals and pesticides.	

	● Sect 15.3 Assuming the LDR spans above the action limit, it should not be necessary to dilute and reanalyze a sample with a detection above the LDR, as it has already been determined to exceed the action limit and has failed quality assurance testing. *Response:* We are maintaining this standard as quantitative results are valuable, especially when determining the severity of contamination as it impacts public and environmental health.	
972 CLASP Residual Solvents by GC-FID	• Section 6.5 – Syringes. This should be more broad-autosamplers may not use the same syringes. For example, our HS autosampler uses a 1 mL gas tight syringe. *Response:* The mention of trade names or commercial products in method is for illustrative purposes only and does not constitute a CLASP endorsement or exclusive recommendation for use. • Section 6.7 – Why 4 decimal places on a balance? CLASP 973 mentions to weigh the sample to the nearest 0.01 g. This does not require 4 decimal places. This would require the purchase and continued calibration of new balances within the laboratory. *Response*: We have removed the specifics of a 4 decimal place balance however; laboratories would have to verify that their 2 decimal place balance meets the requirement of +/- 0.01g variance. • Section 7.6 – Inconsistent regulation - Standards should not be prepared in methanol due to that being a required testing compound. This also goes against WAC 16-309-190. *Response*: Standards shouldn't be prepared in a solvent that is being tested. We have updated this method to remind laboratories not to use standards prepared in methanol. • that states to not use solvents as diluent that we are testing for. • It would be more useful to do standards in DMSO, DMA,TMB. Spiking solution is a good idea, but the spikes should be with appropriate standards. • Section 7.8 – Surrogate compounds may be unstable due to the inherent volatility in residual solvents. • Section 9.6 – What is a "Clean Matrix"? Will that be a, for example, distillate sample that has previously tested with no solvents? *Response*: Yes, that would be one example. • Section 9.7.2. "If expected to contain target analytes…" – All samples should be expected to contain a target analyte. If a lab anticipates none but then some is found, does the test have to be re-performed with second QA? (e.g. a CO2 sample that was then winterized and has ethanol in it). *Response*: The section allows for the flexibility of running duplicate samples when a lab has seen consistency one way or the other with a specific product. • Section 11.3.2 External Standard Calibration – Currently required 4 calibration points, this is increasing it to 5? No mention of R2 values. There are multi-component mixes available for all cannabis state residual solvent analyses in DMSO, DMA, or TMB. Single component analyses are not applicable to the industry	ConfidenceAnalytics 01.07.24

	as we must screen each solvents sample for 25 unique compounds. How to calibrate using the multi-component mixes, in addition to single-component analyses, should be addressed. *Response*: Rules indicate that labs use a minimum of 4 calibration points, This method uses 5 which would then allow a laboratory to drop one if they had an issue with it. Other standards like R2 values are mandated in rules when not specifically pointed out in a method. Labs should address other issues in their methods even if they are not included in a standard method available through the WSDA. • Section 11.5 – Volatility in RS standards is well known. It may be prudent to have a >20% RSD allowed due to the amount of compounds that will have to be performed on this QA check. Response: Allowing too much variance in calibration standards is not a wise idea. We are keeping calibrations ≤ 20% while allowing controls at ≤30%. We understand that labs may have to modify their handling • Section 11.6.1 The sequence ends when the set of samples has been injected or when retention time and/or % difference QC criteria are exceeded – Great QA expectation. • What if there are not enough samples for a 12 hour shift? E.g. only 2 residual solvents. Does there still need to be verification checks? *Response*: Anytime a test is run, there needs to be a verification check. • What is the difference between a solvent blank and a method blank? *Response*: Sometimes they are the same thing. However, a solvent blank doesn't necessarily have everything in it that a method blank has. • Section 11.6.3 – It is nice to see guidance on how to deal with different interference issues as these complex matrices are not cut and dry (e.g. terpenes). *Response:* This above method was removed from rules to reflect the addition of a new method approval process, the criteria for approved methods has been detailed in section 16-309-250	
972 CLASP Residual Solvents by GC-FID	972-CLASP Method: Residual Solvents by GC-FID ● Due to the low action limits of some compounds (e.g. benzene and chloroform) and non-specific nature of FID, we do not recommend GC-FID for residual solvent analysis. *Response:* We agree that benzene and chloroform may be problematic to test on GC-FID, however we will not be restricting a laboratory's use of GC-FID for this analysis as long as they can properly validate it. ● Sect 3.0 says to "Refer to EPA SW-846 chapter of terms and acronyms for potentially applicable definitions." The EPA SW-846 compendium contains multiple documents, and we did not find a chapter of terms and acronyms. There is a glossary in Chapter 1 (Quality Control.) Please provide more guidance of where to find the terms and acronyms or reference the glossary in Chapter 1 if that is the appropriate list. *Response:* Removed reference to EPA definitions in method. ● Sect 4.2 mentions trip blank. We do not believe that this control is necessary or relevant to our operation. Also, water is not a GC-friendly solvent and if a trip blank is required, we believe that the laboratory should be able to choose an appropriate solvent to use.	ConfidenceAnalytics 01.07.24

	Response: Removed mention of trip blank in method. ● Sect 4.3 discusses carryover and contamination. ○ It states "Whenever an unusually concentrated sample is encountered, it should be followed by an injection of a solvent blank…" Samples are batched up and injected automatically. It is not possible to know if a sample will contain a high level of target analyte so it is not possible to inject a solvent blank after the "high concentration" sample. It is prudent to investigate any detections of the "high concentration" compound in subsequent samples and reanalyze if necessary. *Response:* Modified statement to clarify when to investigate "high concentration" samples and potential carryover effects. ○ These sections also require rinsing of syringes or autosamplers between samples. For liquid injection analysis, syringes can be rinsed between samples. However, in headspace analysis, it is not possible to rinse syringes/needles/sample loops between samples. *Response:* Headspace is addressed in a separate method, 973 CLASP Method – Residual Solvents by Head Space Analysis. ● Sect 6.1 says that the required system includes a "..gas chromatograph suitable for solvent injections, direct aqueous injections, headspace, and…" It sounds like the system is required to accommodate all those sample introduction techniques. However, the system should only be required to accommodate the sample introduction technique that the lab chooses to use. For example, if a lab is using headspace sampling, it is not necessary for the system to be able to perform solvent injections or direct aqueous injections. *Response:* Method language has been clarified. This method allows for several different sample injection options; it does not require the use of all sample injection options. ● Sect 7.4 states that the "...aqueous calibration standards will bracket the working range.." As previously mentioned, water is not a GC-friendly solvent so we avoid water as much as possible. The calibration standards should be prepared in an appropriate solvent. *Response:* Method language has been modified to remove 'aqueous' and to allow for the use of other solvents. ● Sect 7.6 also says to prepare the spike solutions in water. See comment above (Sect 7.4) regarding using water in GC analysis. It also makes a comment regarding "...methanol content of the original standard." Methanol is included in the residual solvent list in WAC 314-55-102; therefore, labs should not use reference standards prepared in methanol. Several other appropriate solvents are commercially available (e.g. solvents in triacetin, dimethylacetamide). *Response:* Method language has been modified from 'in water' to 'in solution'. ● Sect 11.3.2.1 States that the standards must be prepared in organic-free reagent water. As mentioned, water is not very GC-friendly. Furthermore, the majority of cannabis products are not water-based (with the obvious exception of beverages.) We suggest that the standards be prepared in "an appropriate solvent." *Response:* Method language has been modified to remove references to "organic-free reagent water", added references to "reagent grade solvent" in place.	

973 CLASP Residual Solvents by Headspace	●Sect 1.2 says "This method describes… of volatile organic compounds (VOCs) in cannabis concentrates…" We recommend that "cannabis concentrates" be changed to "cannabis concentrates or extracts" to be consistent with WAC 314-55. *Response:* Method language updated to include "or extracts". ● Sect 1.7 advises that analysts "...consult the disclaimer statement at the front of the manual and the information in Chapter Two…" Please clarify "manual" and "Chapter Two." *Response:* Section has been removed from method. ● Sect 2.3 states that the vial is pressurized with helium. Other inert gases (e.g. nitrogen, argon) can be used to pressurize the vials. We recommend "appropriate gas" be used instead of specifying helium. *Response:* Removed "with helium" from method to allow use of other inert gases. ● Sect 3.1 says to "Refer to each method…and to Chapter Four…" Please clarify "Chapter Four." *Response:* Reference to "Chapter Four" has been removed. ● Sect 3.3 refers to a trip blank. Is this control a recommendation or requirement? *Response:* Removed mention of "trip blank" from method. ● Sect 6.3.1 states to prepare the spike solutions in water. We recommend that the spike solutions be prepared in an appropriate solvent because 1) water is not GC-friendly; and 2) most cannabis products are not water-based. This section also states that "...the linearity of the calibration is not affected by the methanol content." It is unclear why there is methanol. Also, methanol is on the residual solvent list so should not be used as a diluent. *Response:* Modified method language from "solutions in water" to "solutions in solvent". Modified "methanol content" to "solvent content". ● Sect 6.4 States to add 10 mL of matrix modifying solution to a headspace vial for the blank preparation. Ten milliliters is a very large amount of solution, as we typically add 20-80µL of solution. The matrix modifying solution is also aqueous, so not a very GC-friendly solution at any volume. Also, as previously mentioned, most cannabis products are not water-based. We recommend that the laboratory choose an appropriate solvent/liquid for the blank. As an alternative to the 10 mL of matrix modifying solution is adding 0.2 grams of solid matrix blank to a headspace vial. Again, 0.2 g is a large mass to be adding as we typically use <50 mg. *Response:* Removed 10mL requirement from method language. 0.2 gram requirement is maintained. Method language modified to allow for use of internal standard or surrogate. ● Sect 6.6 outlines the preparation of the matrix modifying solution and uses water. We believe that a matrix modifying solution is not necessary and laboratories should choose a solvent/solution appropriate for their method. Furthermore, this section again states that 10 mL should be analyzed, which is an extremely large volume for current analytical instrumentation. *Response:* We are maintaining this section in the method. Laboratories may submit their own methods to CLASP for approval if they wish to not use this method.	ConfidenceAnalytics 01.07.24

	● Sect 7.2.1 requires that samples be stored at ≤6℃. We do not believe that storing at these low temperatures is necessary because 1) it will incur additional costs for additional refrigeration; and 2) these temperatures are not representative of product storage at the production facility or retail shop. *Response:* This method was validated using these parameters so we are maintaining this section in the method. Laboratories may submit their own methods to CLASP for approval if they wish to not use this method. ● Sect 8.1 states that the QC criteria in the rules take precedence over chapter QC criteria. The rules state that the acceptance range for controls is ±20%. With the volatility of some solvents, consistently meeting this range without cracking a fresh standard ampule each time would be very difficult. Using a fresh ampule each time would be very costly. We have already recommended that 16-309 change the acceptance range for controls to ±30% unless otherwise specified in the method documents. Additionally, we propose that the acceptance range be increased for the following highly volatile compounds - propanes, butanes, pentanes, and hexanes. Some states (e.g. AZ) have an increased acceptance range for these compounds. We propose ±40%. *Response:* Method language has been modified to remove mention of QC criteria precedence. Rules language has been updated from ±20% to ±30% for residual solvents. ● Sect 8.8 refers to the “data user.” We could not find a definition for this term; please clarify. *Response:* Method language modified to replace “data user” with CLASP. ● Sect 10.1 says that standard solutions should not be added to a sealed vial by using a syringe and puncturing the septum. It continues to recommend the caps exchanged if they are punctured using a syringe. Changing caps will increase loss of volatile solvents. In our experience, using a syringe to add standard solutions through the septum and into the sealed vial provides the best results and minimal loss of analytes. *Response:* Method language allows flexibility to use screwcaps, crimping caps, septum, etc. to seal residual solvent vials. Laboratories are required to validate methods before use; laboratories must investigate the laboratory’s preferred method of sample preparation as part of the validation work. ● Sect 10.1.1.1 again states to use 10 mL of the matrix modifying solutions. As previously stated, 10 mL is a very large volume which would have severe impact on the method and instrument, especially as this solution is aqueous. *Response:* Removed 10mL requirement and replaced with 2mL requirement in method language. ● Sect 10.3.1.1 says to prepare a headspace vial with extraction solvent. 795 CLASP method does outline liquid extraction but it is not required. It is also unclear exactly what this vial is, as it references tuning agent. *Response:* Section removed from method. ● Sect 10.3.2.1 states to mix samples for 2 min prior to loading onto the autosampler carousel. This step is not necessary if vials are shaken in the headspace oven. *Response:* Requirement to mix samples on “a rotor or shaker” removed to reflect that instrumentation may include a mixing mechanism. ● Sect 10.4.2 states to transfer 0.25 g of sample into a vial containing 10 mL of solvent. These values are extremely large. We recommend 20-50 mg of sample (the equivalent if using a liquid extraction.)	

	Response: Language modified from "0.25g" to "0.2g". We are maintaining the 0.2g standard. ● Sect 10.4.3 also states to have 10 mL of extraction insolvent in the headspace vial. See previous comments regarding this large volume. *Response:* Removed 10mL requirement and replaced is 2mL requirement in method language. ● Sect 12.1 "Pollution prevention encompasses any technique that reduces or eliminates the quantity and/or toxicity of waste at the point of generation . . . Whenever feasible, laboratory personnel should use pollution prevention techniques to address their waste generation." The clearest way to reduce waste generation when analyzing residual solvents is to reduce consumption of solvents and materials in sample prep and to maintain a calibrated range that does not necessitate a large number of repreps. It is feasible to conduct residual solvent testing while generating minimal waste, without sacrificing the quality of the analysis. For this reason, in addition to previously-expressed concerns of evaporative loss, we encourage the use of methods that do not require extraction or dilution of the sample. Promptly weighing and sealing a small subsample (20.0 - 50.0 mg) into a headspace vial for direct analysis is the most environmentally friendly and economical procedure and presents the lowest risk of evaporative loss through handling. *Response:* Language modified from "0.25g" to "0.2g". We are maintaining the 0.2g standard. The decrease in sample mass required will lead to reduced consumption of solvents and materials.	
973 CLASP Residual Solvents by Headspace	Sample refrigeration requirement of 6C is contradictory to requirements in the rule language. See above notes on sections -090 & -190. *Response:* Removed refrigeration requirement from the proposed rules. Sample storage requirements, including refrigeration, are maintained in the method since it was validated using those parameters. Laboratories may submit a modified method or their own method for approval if they wish. Are all the individual hexane isomers a requirement to add to our method and separate? Hexane is rarely/never seen in cannabis processing and this would vastly change our method parameters. *Response:* The requirement to report the sum of hexane isomers as required in LCB the proposed rules has not changed. The requirement for a 50 min. heated incubation time is excessive –we are in the process of producing data to compare our method's signal at 30 minutes (our current incubation time) and 50 minutes to submit to the regulatory body. This will drastically increase the cost of helium gas and create a bottleneck for this method to run given the much longer time requirement with no increase in scientific validity. *Response:* The heat time of 50 minutes was what the method was validated with. You will need to submit a modified method or your own method for approval to lessen the requirement. Laboratories may submit a modified method or their own method for approval if they wish. Res. Solvent Doc 973, 3.3) is a 'trip blank' requirement really necessary? Or feasible for the lab to enforce? This is just more disposable packaging and sample that will ultimately get wasted/thrown away. The document	Medicine Creek Analytics 12.27.23

	references some risk to Methylene chloride cross-contamination, but it's unclear where that could be a risk anywhere for cannabis products. Recommend removing this requirement. *Response:* The 'trip blank' requirement has been removed from method. What is a LOQ check standard and when should it be run? It's not listed in the required QC injection list in section 8.5 *Response:* Limit of Quantitation Check Standard requirement has been removed from method. In general, the 973 document needs to be brought into line with appropriate cannabis matrix situations. Additionally, suggest removing section 10.4 'high-concentration' sample prep as all cannabis samples can be considered 'low-concentration' situations. *Response:* Revised section heading from "High-Concentration Method" to "Dilution for High Concentration Samples" for clarity.	
973 CLASP Residual Solvents by Headspace	• Section 1.0 - Thank you for suggesting surrogates. Some of these surrogates are potentially used as diluent in standards. Trimethylbenzene *Response:* Thank you for your feedback. • Are we allowed to do a screening and estimating sample results without quantitation under these methods? This was not allowed before, everything needed to be quantified. *Response:* This method does not allow you to screen and estimate sample results without reporting final quantitative results. This method allows you to screen samples for the presence or absence of target analytes before performing a quantitative confirmation analysis on positive samples. • Water/salt diluent – the sample will not become homogenous in a water mixture as the extracts are not water soluble. Is the purpose of this to take up more headspace or make a homogenous mixture? In a side-by side comparison against our method, and we had significantly less recovery of solvents when the water/salt diluent was used vs our normal method. It was observed that the cannabis extract did not go into solution, and was just covered by the water, suppressing the solvent release. The hard part of the calibration is that there are many compounds with a limit of5,000 ppm, but also compounds with a limit of 2ppm. To get all of these compounds in one run, suppression is not desirable. *Response:* The salt solution decreases the solubility of polar organic solvents promoting a higher transfer into headspace. The magnitude of its effect is not the same in all matrixes. Laboratories will need to validate their method by determining the efficiency of their headspace analysis. Laboratories may submit a modified method or their own method for approval if they wish. • Section 2.1 – It is not possible to add matrix modifying solution at sampling stage as labs have little oversight of sampling procedures. It must be added to the laboratory. It will also be impossible to ensure that the sample touches the matrix modifying solution if it is already present in the vial due to the sample not being soluble in matrix modifier and the need for subsampling within the lab.	Treeline Analytics 01.04.24

<table>
<tr><td></td><td>Response: Removed “during sampling” from method language to reflect that laboratories do not have oversight of sampling procedures.
• Section 2.2-2.3 – All headspace autosamplers are not the same. The heating/pressurizing is not necessary to this method. This section should be a method that defines the requirements that the analyzer must hit. Labs may have to buy a new headspace autosampler to fit these requirements$20,000-50,000.
Response: Headspace analysis of volatiles requires a heat source but not necessarily pressurizing. However, this method was validated using both. Laboratories may submit a modified method or their own method for approval if they wish.
• Section 3.6 – We have never identified any methylene chloride in a sample due to contamination. Why is this important?
Response: This section has been removed from method.
• Section 6.2 – Must use “pesticide” grade reagents for residual solvents – This implies Mass Spec grade and will be costly to the labs. Also, there is no extraction step in the headspace. Could we just use any reagent that has shown to be “solventless”? And in 6.1 it says must use “reagent grade” chemicals. Which is correct? Inconsistent regulation.
Response: Method language has been modified to “reagent grade” chemicals.
• Section 6.4 – Does this mean we use matrix modifier or a matrix blank in each run? Can we not use matrix modifier if the method is acceptable without, and a matrix blank is present?
Response: The matrix modifier will only be required for specific matrixes. Laboratories may submit a modified method or their own method for approval if they wish.
• Section 6.6 – refrigeration is generally classified as 2-8ºC. Is there a reason to choose 6ºC?
Response: This is the requirement of the method by the EPA as recommended by the Cannabis Science Task Force. We are maintaining this requirement in this method because it was validated using this temperature. Laboratories may submit a modified method or their own method for approval if they wish.
• Section 7.2 – Great sample storage and analysis timelines for storage. This section mentions freezing - do you mean refrigeration as the rest of this SOP mentions refrigeration temperatures.
Response: This section is a recommendation for storage; it is recommended only to not freeze cannabis samples in VOA vials with no headspace. We are maintaining the freezing language, to allow for subsamples added to prepared headspace vials be stored frozen. Laboratories are expected to validate their storage parameters for samples, standards, etc. as part of their method validation work.</td><td></td></tr>
<tr><td>795 CLASP Residual Solvents</td><td>We would like to start by saying that we are against any liquid extraction for residual solvents as it could result in significant loss of any residual solvents present in the sample.
● The footer starting on page 2 says “Liquid Extraction for Residual Solvents by ICP-MS;” ICP-MS should be replaced by the appropriate term(s) (GC-MS and/or GC-FID).</td><td>ConfidenceAnalytics 01.07.24</td></tr>
</table>

Liquid Extractions	*Response:* Method language has been corrected. ● Sect 2 states to weigh 1 g of sample end extract in 2-10 mL. We recommend using a smaller subsample mass (0.100-0.250 g) and less extraction solvent. By reducing these two parameters, a smaller tube/vial - which has less headspace - can be used for extraction and minimize potential solvent loss. Furthermore, these smaller sizes will reduce the environmental impact (less solvent waste, less plastic/glass waste) of the sample preparation. *Response:* Method language changed to 2mL. 0.2g sample mass requirement is being maintained. ● Sect 3.1 specifies “Pyrex® wool plug should be placed into the injection port liner.” The type of wool should not be limited to the Pyrex brand. It is also possible to get liners that already contain glass wool. We suggest changing the verbiage to “A liner that contains glass wool should be used.” or similar statement that encompasses all available products that meet the scientific need. *Response:* Method language added to clarify laboratories are not limited to Pyrex. ● Sect 3.2 states “The solvent used for waste dilution may contain…” We suspect that the intended sentence is “...solvent used for ***sample*** dilution…” *Response*: The sentence has been updated to “sample dilution.” ● Sect 4.7 limits glass wool to Pyrex. *Response:* Method language added to clarify laboratories are not limited to Pyrex. ● Sect 4.9 references and HP part number for the liner and requires the user to add wool. HP no longer manufactures scientific consumables, though it does appear Agilent (formerly HP) has this part number. Also, as stated above, there are many liners available that already contain glass wool and it would be more consistent to purchase liners containing wool rather than adding it. Possible products are Phenomenex AG0-4659 or AG2-4800, Restek 23300 or 23472. Liner type will depend on make and model of the GC. *Response:* Parts and references to manufacturers were included with the method from the EPA. Laboratories have the flexibility of using parts and manufacturers as they see fit for their instruments. ● Sect 7.3 states to weigh 1 g of sample to the nearest 0.1 g. With the capabilities of analytical balances, the weight should be recorded to the nearest 0.001 g - or even 0.0001 g, which is preferred. Also see the statement above on Sect 2 regarding the large sub-sample mass and extraction solvent volume. *Response:* Method language updated to clarify sample mass and analytical scale balance requirements. ● Sect 8.3 mentions “field duplicates” but this term is never defined. It also does not explain how many are required to be collected, how many must be analyzed, or acceptance criteria. Because the laboratory does not perform sample collection, we recommend any reference to field duplicate be omitted. *Response:* We have removed “field duplicates” in methods. We are addressing any possible contradictions between CLASP methods and rules. Laboratories will be able to submit their methods for approval by the WSDA. The criteria for method approval is detailed in section 16-309-250.	
975 CLASP Residual	Sect 4.2 specifies “preparation and analysis should be physically separated from laboratory areas where target solvents are used. Air supply for the volatiles area should provide positive pressure relative to other laboratory	ConfidenceAnalytics 01.07.24

Solvents by GC/MS	areas." As long as method blanks are prepared for residual solvents in the same areas where samples are prepared, we do not see a need to restrict which areas of the laboratory are suitable for preparation and analysis. *Response:* Method language provides a recommended best practice. Adjusting air supply to create positive pressure in certain restricted areas is a common laboratory practice. Laboratories must assure that samples are not being contaminated by solvents in the laboratory. ● Sect 7.9 requires the CCV to be prepared from the same source of standards as the calibration. As stated in previous feedback, we request the flexibility to prepare CCV controls from any acceptable source of standard that contains all the analytes. *Response:* This requirement is maintained. Preparing the CCV from the same source of standards used to create the calibration is the scientific standard. A secondary source may be used for other types of controls, such as ICV. ○ 7.9.1 requires five concentration levels for linear and average response factor (RF) calibrations and six concentration levels for quadratic models. WAC 16-309-120 Quality control and assurance section 20 specifies that linear regression must be used, which is in conflict with 975-CLASP. We believe a quadratic model should be allowed where appropriate, and request the draft rules be updated to include this allowance. *Response:* Language about quadratic model use removed from method. Method language updated to not be in conflict with the proposed rules. ○ 7.10 requires the Matrix Spike and LCS to be prepared from the same source of standards as the calibration. Similar to the CCV, we do not believe the standard source for the MS and LCS should be restricted. *Response:* This EPA method requires that the matrix spike and LCS be made from the same standard to minimize variation of recovery. Laboratories may submit their own methods to CLASP for approval if they wish to not use this method. ● Sect 8.2 requires samples to be stored separately from "other samples expected to contain significantly different concentrations of volatile compounds," however we don't necessarily know the residual solvent profiles of any samples until after they have been analyzed. *Response:* Residual solvents are only required on concentrates which allows you to make sure they are packaged and stored in such a way to minimize the potential of contamination of other concentrates. Separate residual solvent sample storage to reduce potential cross-contamination is the scientific standard and common laboratory practice. ● Sect 9.2.2 along with Table 3 (page 26) indicate calibrations are to be acquired prior to analyzing samples and as needed to meet performance criteria. We find this to be the appropriate rule for required frequency of calibrations, allowing labs to save time and costs as long as performance and quality criteria are maintained. We request that this guidance be reflected in the WAC draft rules in place of the current language in WAC 16-309-120 Quality control and assurance which seems to require calibration with each sample batch (sections 1 and 2) and WAC 16-309-140 Method performance criteria which states "historical calibrations can not extend past 30 days" (section 3).	

	Response: Initial calibration (ICAL) must be performed prior to sample analysis AND as needed, not either/or. We are maintaining the standard to limit historical calibrations to 30 days. ● Sect 9.4.2 -9.4.5 In cases where analyte concentrations are measured at similar area/concentration in a sample and in the blank, we do not find it appropriate to report the suspect concentration in the sample. Even in cases where the analyte concentration is well below the action limit, suspected contamination on the part of the laboratory should not be reported as a result on the CoA nor to the Cannabis Central Reporting System (CCRS). As an alternative, we propose that labs may establish LOQs or reporting limits which are high enough to prevent the reporting of concentrations that may be due to contamination as long as the LOQ or reporting limit is ≤50% of the WA State action limit. It appears that Sect 11.3.5.1 already allows for this, "An accurate estimate of background contamination is necessary to set method reporting limits for method analytes when blank levels are problematic." *Response:* Suspected contamination is not to be reported on a COA but investigated prior to publishing results. Laboratories are allowed to establish their LOQ but are not required to report results below the action limit. ● Sect 9.8 describes a procedure for an annual LOQ verification. Since the LOQ shall be included in the calibration range, sensitivity and accuracy at the LOQ will be verified with each calibration event. For this reason we do not find it necessary to perform a separate verification, as calibrations will certainly be performed more often than annually in order to maintain performance. Also in Sect 9.8, we find this sentence to be highly problematic, "Optimally, the LOQ should be less than the desired decision level or regulatory action level based on the stated DQOs." Please revise to specify that the LOQ for each analyte must be maintained below its WA State action limit. *Response:* Clarified LOQ language in this section. Laboratories are allowed to establish their LOQs. ● Sect 9.8.1.2 states "LOQ verification is prepared by spiking a clean control material with analyte(s) of interest at 0.5-2 times the LOQ concentration…" We strongly believe that where LOQ verification is required, the verification should occur **at** (or below) the LOQ concentration. *Response:* Removed section from method. ● Sect 11.3.4-11.3.6 define a number of quality criteria and corrective actions for calibration curves: ○ 11.3.4.2 The RSD should be ≤20% for each target analyte. (Referring to the RSD of response factors.) ○ 11.3.5.2 "If more than 10% of the compounds included with the ICAL exceed the 20% RSD limit and do not meet the coefficient of determination criterion (r2≥0.995 or relative standard error (RSE) ≤20%) for alternate curve fits, then the chromatographic system is considered too imprecise for analysis to begin . . . If compounds fail to meet these criteria, the associated concentrations may still be determined but they must be reported as estimated." We do not find it appropriate to report estimated concentrations in conducting compliance testing. We request rules requiring all analytes to meet criteria for linearity/fit before reporting sample measurements and that criteria for r2 of the curve and accuracy of each calibration point be defined in WAC 16-309 for all methods. If Mean RF models are also considered acceptable (along with Linear and Quadratic) this should also be stated in the WAC 16-309.	

	Response: The proposed method was revised from five-point calibration curve to four-point calibration curve. Removed use of quadratic RF model from method and reporting estimates. ○ 11.3.6 Re: ICV, "Suggested acceptance criteria for the analyte concentrations in this standard are 70- 130% of the expected analyte concentration(s)." Please define (preferably in WAC) a required acceptance criteria for the ICV of 70- 130%. *Response:* ICV has been defined in definitions. ● Sect 11.4 CCV "A CCV standard must be analyzed at the beginning of each twelve-hour analytical period prior to any sample analysis." We propose a CCV to be required at the beginning and the end of an analytical batch as well as bracketing every set of 10 samples within the batch. We request this requirement be set in WAC for all analytical methods. *Response:* The proposed rules already contain the minimum QC requirements specific to each analytical method. Laboratories may perform QC control checks more frequently if they choose. ○ 11.4.1 Again, we believe any acceptable source of standards containing all required analytes should be allowed for use in CCV. *Response:* This requirement is maintained. Preparing the CCV from the same source of standards used to create the calibration is the scientific standard. A secondary source may be used for other types of controls, such as ICV. ○ 11.4.2 CCV standard criteria - Accuracy criteria for the CCV is stated as ±20%, but with many quality exceptions possible. Per our previous feedback, we propose an acceptance range of ±30%, which is consistent with the recommendations in The Cannabis Science Task Force's December 2021 report. Additionally, we find too many quality exceptions in this section and we are concerned for the risk to data quality and consumer safety that is represented here. *Response:* We are maintaining the ±20% CCV standard for cannabinoids. The purpose of the CCV is to verify the accuracy of the calibration using calibrator materials. Expanding the acceptable range beyond 20% does not sufficiently verify accuracy of the calibration. Standards like CCVs are typically prepared in solution without matrix interference, so it reasonable to expect less variation from the expected value. We have expanded it for Pesticides, Residual Solvents, Mycotoxins, and Heavy Metals. 11.4.2.2 Requires only 80% of analytes to meet the CCV accuracy range. Even if this standard is not met (fewer than 80% of analytes within accuracy range) the lab is still allowed to report concentrations of non-conforming analytes if they are "qualified appropriately." While we acknowledge the difficulties in analyzing such volatiles, we find these criteria too loose and propose the following alternative criteria (preferably to be written in WAC): ● CCV accuracy within ±30% must be met in order to report detections in samples. ● CCV accuracy within ±40% for propanes, butanes, pentanes, and hexanes. This expanded acceptance range is due to the volatility of these compounds in the reference standard. ● CCV accuracy of at least 50% *or* a demonstration of sensitivity at (or below) the analyte's LOQ within the analysis batch must be met in order to report non-detects in samples.	

	Response: We are maintaining the ±20% CCV standard for cannabinoids. The purpose of the CCV is to verify the accuracy of the calibration using calibrator materials. Expanding the acceptable range beyond 20% does not sufficiently verify accuracy of the calibration. Standards like CCVs are typically prepared in solution without matrix interference, so it reasonable to expect less variation from the expected value. We have expanded it for Pesticides, Residual Solvents, Mycotoxins, and Heavy Metals. ○ 11.5.4 "When screening results indicate high levels of target analytes and/or interferences, or if analyte concentrations are measured above the calibration range, prepare and analyze an appropriate dilution of the sample(s), or choose a preparation method that is more amenable to making dilutions. Dilutions should be targeted so the response of the major constituents (previously saturated peaks) falls near the middle of the calibration range." We oppose dilution procedures in analysis of residual solvents due to the high likelihood of analyte loss during handling. For this reason, we also oppose the minimum 0.2 g subsample requirement stated in the proposed WAC, as this would require a dilution step in sample prep or would make it impossible to calibrate many of the analytes at/above their action limits. If a smaller subsample is allowed, the calibrations should be designed to span below and at/above each analyte's action limit. Therefore we propose: ■ If the calibration range spans at/above the action limit and a target analyte is measured above the calibration range, it is not required to dilute and reanalyze the sample as it is already determined to exceed the action limit. *Response:* We are maintaining the 0.2g standard for this method. Laboratories may submit a modified method or their own method for approval if they wish to use less sample material for residual solvents screening. We are maintaining the quantitative reporting standard as quantitative results are valuable, especially when determining the severity of contamination as it impacts public and environmental health. ● Sect 14.1 "Pollution prevention encompasses any technique that reduces or eliminates the quantity and/or toxicity of waste at the point of generation . . . Whenever feasible, laboratory personnel should use pollution prevention techniques to address their waste generation." The clearest way to reduce waste generation when analyzing residual solvents is to reduce consumption of solvents and materials in sample prep and to maintain a calibrated range that does not necessitate a large number of repreps. It is feasible to conduct residual solvent testing while generating minimal waste, without sacrificing the quality of the analysis. For this reason, in addition to previously-expressed concerns of evaporative loss, we encourage the use of methods that do not require extraction or dilution of the sample. Promptly weighing and sealing a small subsample (20.0 - 50.0 mg) into a headspace vial for direct analysis is the most environmentally friendly and economical procedure and presents the lowest risk of evaporative loss through handling. *Response:* Language modified from "0.25g" to "0.2g". We are maintaining the 0.2g standard. The decrease in sample mass required will lead to reduced consumption of solvents and materials. Laboratories may submit a modified method or their own method for approval if they wish to use less sample material for residual solvents screening. ● Sect 18	

<table>
<tr><td></td><td>○ Table 1 - The lab requests flexibility to choose the target and reference m/z for each analyte which has been found to perform the best in validation and production.
Table 2 - The lab requests flexibility to choose alternative internal standards based on cost, availability, and performance.
○ Table 3 - If QC criteria will be maintained in this method document, please update the column header from “Suggested Acceptance Criteria” to “Acceptance Criteria.” As previously stated, we request that acceptance criteria across analytical methods be simplified, unified, and published in the WAC. Specific concerns noted in Table 3:
■ For a calibration to be considered valid, all target analytes should be required to meet acceptance criteria.
■ Previous feedback for improving CCV criteria applies here as well. We do not find it acceptable to allow up to 20% of analytes to fail CCV criteria.
■ Please specify acceptance criteria for the LCS, Matrix Spike, and Lab Replicate or Matrix Spike Duplicate - Preferably in the WAC and consistent across methods. The current language in Table 3 appears to allow each lab to set their own acceptance criteria for these control types.
Response: Removed “Suggested” from “Suggested Acceptance Criteria”. Laboratories may submit their own method or modify this method for approval by CLASP. The proposed rules set minimum QC requirements. Laboratories may use additional QCs if they wish. We have revised the calibration model criteria for clarity.</td><td></td></tr>
<tr><td>976 CLASP Cannabinoid Concentration Analysis</td><td>• Great that you added D8! Does this mean all the cannabinoids on this list will be required for QA testing? We suggest CBG and CBGA are also important cannabinoids to be tested They elute closely with CBDs in many methods, and CBG/CBGA are often present.
Response: Laboratory accreditation can only accredit cannabinoid analytes defined in LCB and DOH rules. The addition of Δ8-THC and CBN in the method are for quality control purposes. It is a typical scientific standard to analyze compounds with similar chemical characteristics for quality control.
• Potency testing is done on every sample that enters the laboratory. Most HPLCs will be allotted for cannabinoid testing only. All samples for potency will be positive for at least one analyte. It will be next to impossible to find actual blank matrix, and to perform prescribed spikes in blank matrices. There are many mentions of if there is no analyte present. If there is no analyte present there is probably a different issue with the sample or machinery.
Response: We have modified section 11.8 “MS and MSD” to include the use of a laboratory sample duplicate.
• Section 1.2 - MCT is not representative of the cannabis matrix, not flower nor extracts. We suggest to not require matrix blanks but maybe a reagent blank/preparation blank to ensure cleanliness.
Response: “MCT” was removed from method language.
• Inconsistent regulation– Section 1.0 has LOQ of matrix as 1000 ug/mL. Section 2.0 has LOQ of 100ug/mL. Can we define an LLOQ (lower limit of quantification/lowest calibration point) and HLOQ (high limit of quantification/highest calibration point).</td><td>Treeline Analytics
01.04.24</td></tr>
</table>

Response: Section 2.0 has been revised from 100µg/mL to 1000µg/mL to maintain consistent regulation.

- Section 3.9 – Laboratory Control Sample - there is no “clean matrix” for cannabinoids.

Response: Method language has been revised to include “respective matrix”. We understand that there is no true “clean matrix” for cannabinoids; QC requirements at batch level are described in the proposed rules and must be followed.

- Section 7.2-7.4 - pentylphenyl 4- methybenzoate (surrogate)– checked for pricing. Is out of stock at first 5 vendors. US and UK and Canada. Fisher has it by customer request only. The Sigma Aldrich product code defined in this section has been discontinued. Can surrogate and/or internal standards be something from the AHP like diazepam, or other common internal standards such as caffeine, diphenhydramine, or ibuprofen?

Response: The list provided in method is not a fully inclusive list, and substitutions may be made if the criteria described in section 7.2.2 of the method are met. However, we were able to find both from vendors.

- Section 8.1.3 – Mentions other standards preparations can be used as long as it “meets requirements detailed herein”. Which requirements are important “herein”? Is it the calibration levels? Is it the cannabinoids required?

Response: Calibration level and target analyte preparation both must meet general requirements described in method.

- Section 8.9.3.1 -Hempseed oil is not a representative matrix. Hemp is also not a representative matrix of cannabis. Can we use our best professional judgement on representative matrices? How can you do LOD/LOQ/MS/MSD with samples that will already have analytes in them.

Response: Hemp and hempseed oil have been provided as representative matrices. Proficiency testing samples are typically tested in hemp matrix and hempseed oil matrix; laboratories are expected to be able to test on these matrices. Laboratories may submit a modified method or their own method for approval if they wish to not use hemp and hempseed oil.

- Section 9.2.2 - 6ºC refrigeration mentioned. Can it be 2-8ºC? Refrigeration of samples may cause moisture absorption, mold and mildew growth, and the sample will no longer be representative. Samples may be held in similar ways to how they would be stored at the grow, which is room temperature for flower, and room temperature or refrigeration for concentrates and edibles. There was a study done “The Stability of Cannabis and its preparations on storage” which found cannabis is reasonably stable for 1-2 years in a dark room at room temperature.

Response: Laboratories are responsible for maintaining the integrity of target analytes in compliance samples prior to testing by utilizing proper storage techniques. This method is a chemical analysis method; samples, standards, etc. must be stored at ≤6°C to reduce analyte degradation. Laboratories may submit a modified method or their own method for approval if they wish to not store their cannabinoid materials at ≤6°C.

	• Section 9.4 - HPLC Conditions – Each column will have a different need for the chromatographic conditions as far as mobile phase flow rates and percents. Mobile phases should not be dictated in this CLASP. We tried this method against our in-house. At this point, we have not been able to resolve 14cannabinoids comparable with our extended run (CBGA & CBDA coelution is an issue). The run does not need to be 30 minutes long. The cannabinoids it resolves are through the column in about 12 minutes. We performed this CLASP method with acetonitrile and methanol, three different columns as well as the acetonitrile vs methanol-. All performed chromatographically differently. Methanol had better separation on every column on the 14 cannabinoids that were tried. *Response:* EPA has validated this method under the HPLC conditions described in method. Any alterations to the method will require validation by laboratory. Laboratories may submit a modified method or their own method if they wish to change HPLC conditions. • Section 9.5 – Nobody should have to re-test samples after one month. Laboratories should be able to define their own retainer times. Sample retainers assume a significant amount of space and resources. Laboratories should be able to ask for additional sample for re-tests if sample has already been disposed. Other methods allow labs to dictate their own retainer times. Having inconsistent retainer times for each test is not appropriate. *Response:* Sample extract storage section has been removed from the method. We do not regulate sample retention times in chapter rule. • Section 10.0 – Unnecessary to define how calibration standards are prepared as long as accurate calibration curves are achieved. *Response:* This section is a recommendation, not a requirement. These settings serve as guidelines and may be adjusted for optimization of integration. Laboratories will need to define standard preparation in methods. • Section 10.3.2 - Does not mention R2 but has R of .9975. Can we have an R2 value, or can this all be.990? Inconsistent across methods. *Response:* We are maintaining this standard. R value of 0.9975 is equivalent to an $r2 \geq 0.995$. All methods should now be consistent. • Section 10.3.3 - Can error rates be mathematically determined to be different than 10%? This may be difficult for 0.45 ppm reading. An option is allowing a higher limit calibration table or letting the machinery dictate its calibration capabilities experimentally. *Response:* Calibration standards described in method cannot be lowered. A modified method or laboratory-provided method that lowers these standards will not be accepted for approval. • Section 11.8.1 – Matrix spike – are target analytes to be spiked all compounds that can potentially be quantified? Including compounds already present?	

	Response: We have modified section 11.8 "MS and MSD" to include the use of a laboratory sample duplicate. Target analytes as defined in the LCB current rules are required to be included in matrix spikes as part of QC. • Section 13.1.1 - HPLC relative retention times being within 2% - Labs should have done method robustness studies for the validation which can give method specific acceptable retention time shifts. Changing columns may change retention times more than 2%, changing mobile phase will change retention times >2% (Mobile phases should also be getting changed more than once a month), temperature in laboratory will cause >2% changes, pressure increasing in the column may cause >2%changes. Why was 2% chosen? It appears as though that is the general error as temperature in the column increases, not for a whole run. It is prudent to do a robustness study to see the impact that the time shifts have on results. Is this 2% from the beginning of the run QA Checks or from the calibration table? *Response:* The HPLC relative retention time being within 2% is the scientific standard for chromatography methods. Any shift beyond the 2% time window indicates an issue that labs need to address. Usually, instrument software will be set to flag retention times greater than 2%. • Inconsistent with section 13.2.2), .3) says retention time windows used to make identifications should be based upon measurements of action retention time variations over the course of a sequence. This contrasts with 13.1.1 and 13.2.3 that say it can only be 2%. Appendix also mentions not 2% retention time windows. *Response:* This section is maintained because it is not a contradiction. Retention time windows are the area of time the analytical instrument software will 'look' for a peak in signal on a chromatogram. The retention time is the expected time that peaks will appear on a chromatogram. These are two different types of analytical tools and therefore have different requirements. Section 11.9.1 - Tailing Factor – We are testing for a vast array of compounds with this method. Some compounds may come out perfectly with this PFG and TF, and some may not. If methods will be accepted by WSDA, would you be able to see the chromatography to verify and not need this requirement? This is not a requirement for other chromatographic methods included in this law. *Response:* We are maintaining this standard. Methods submitted for approval that do not include either Peak Gaussian Factor or Tailing Factor to determine chromatographic performance are unlikely to be approved. If another proposed chromatographic performance metric is offered, it will need to be reviewed by CLASP. As discussed in the Cannabis Science Task Force, laboratories may use Peak Gaussian Factor or Tailing Factor to determine chromatographic performance, depending on currently available instrumentation capabilities. • We have all been passing proficiency tests for multiple years by now. Is there really a reason to micromanage only the potency method when all proficiency tests show all labs are about the same? *Response:* Historical data demonstrate that we cannot assume all laboratories are performing proficiency testing the same.	

	• Section 11.9.2.2 - Maintenance requirements occur on different timelines than yearly even within the same machinery due to volume and type of sample injected. Instead of mandating yearly PM, have laboratories define their own maintenance requirements and frequency. *Response:* Method language clarified to "preventive maintenance (PM) must be performed once a year or at the manufacturer's specification, whichever is more frequent." Instruments must be maintained to meet the testing standards. • Section 13.1.7 – 2 hour startup requirement is unnecessary. Cleaning out the column after injections is just a good laboratory practice. Instead of saying "2 hour startup" maybe say "end preparation batch run with 100% solvent mobile phase". That is less daunting. *Response:* A period of 2 hours prior to startup is a recommendation, not a requirement. • Section 13.3.1.1 – Software may not be able to calculate all QA as defined in CLASP. Are spreadsheets okay to use? *Response:* Software typically calculates QA requirements. However, if current instrumentation does not allow for calculation, alternative software may be used ONLY if security controls are in place to protect the confidentiality, integrity, and availability of the system and its information. (WAC 16-309-240) • Section 14.3 – Do we no longer have an R2 Value for potency calibration curves? *Response:* We are maintaining the standard that a laboratory maintains either an R value of ≥0.9975 or an R2 value of ≥ 0.995. Both are equivalent. • Section 14.10.2 It will be extremely rare to have no target analytes detected in the batch for potency. *Response:* Section removed from method. • Appendix Page 31 Figure 2–CBDA and CBGA, and CBD and CBG are co-eluting and do not have baseline resolution. For THCA, peak fronting is visible. This chromatogram would not pass your QA checks as defined in this CLASP. *Response:* This chromatogram is included in the method as an example and meets the resolution expectation of >1. • Table 1 Page 32 – mentions again that the 2% acceptance and will vary over the course of the column/different columns. Taking out this 2% acceptance limit, and/or allowing labs to define their own acceptance limits will rectify this issue. Inconsistent regulation – this requirement is only mentioned for potency and is not mentioned for RS or Pesticides. *Response:* The HPLC relative retention time being within 2% is the scientific standard for chromatography methods A large retention time (>2%) shift indicate system issues and must be investigated.	
976 CLASP Cannabinoid Concentration Analysis	• Section 3.14 should be removed. What data supports setting the sample limit at 20 samples? This arbitrary limitation is not practical for commercial labs and has no correlation to testing accuracy exhibited by the equipment used to perform the test.	Green Grower Labs 01.04.24

	Response: The limitation of batch size to a certain number of samples is to ensure minimum variability in sample preparation and extraction. Most federal standards (EPA) utilize 20 samples as a batch maximum, as do California and NY in their cannabis lab standards, so we will be maintaining this in alignment with other agencies. • Sections 3.11 and 3.12 should be removed. Matrix studies are carried out during the method validation. Once it is determined that the matrix does not contribute bias to sample results, there is no further need for reproduction at each run. If a novel matrix is encountered, then a matrix spike may be carried out, but is still not required for each analytical run. *Response:* This standard is being maintained. The use of matrix spike samples (MS) and matrix spike sample duplicates (MSD) are typical quality controls and are intended to be used to monitor potential variability in the sample preparation and extraction process in high-complexity testing. • In section 8.9.3.1 the listed representative commodities to use for the method blank are listed as Hemp, hemp seed oil, and baked goods. Hemp and hemp seed oil will contain CBD which is one of the target analytes. Therefore, the requirement for method blanks should be removed, unless a novel matrix is encountered for an edible. *Response:* “Method Blank” in definitions revised to “Matrix Blank”. Section 8.9.3.1 is being maintained; this section refers to matrix blanks, not method blanks. The purpose of a matrix blank is to determine potential signal interference during analysis. Industrial hemp typically has a very low cannabinoid concentration (<1%) and may be used as a matrix blank. • Remove all requirements for internal standards. Internal standards are not warranted. If a surrogate compound is used to ensure and monitor sample preparation, then internal standards are redundant. For example, the surrogate compound will show if significant evaporation occurs during sample prep and/or analysis. Instrument performance is monitored using QC samples spaced evenly throughout the run. The addition of internal standards merely adds another dilution step to standards and samples, thereby increasing variance and decreasing the accuracy of the analytical method. *Response:* The use of an internal standard is only required when there is an interfering component present in the sample. It is not required to use when there is no interfering component present. Not all cannabis products include interfering components, so the use of an internal standard is not always necessary. This method requires the use of a surrogate standard. It is typical to use internal standards as quality control for long sample batch runs on instrumentation.	
976 CLASP Cannabinoid Concentration Analysis	Table 1 includes two analytes which are not required by WAC 314-55 or WAC 246-70, so according to the draft rules these would be reported separately on the CoA and qualified as not within the accreditation scope. We believe any/all analytes which are validated and meet quality criteria be included on the scope of accreditation and that no analytes which are validated under a single test method be required to report separately on the CoA.	Confidence Analytics 12.28.23

Response: Laboratory accreditation can only accredit cannabinoid analytes defined in LCB and DOH current rules. The addition of Δ8-THC and CBN in the method are for quality control purposes. It is a typical scientific standard to analyze compounds with similar chemical characteristics for quality control. Laboratories may submit a modified method or their own method for approval if they wish.

- Section 3.0 Definitions
  - 3.3 CCV is defined as one of the primary calibration standards, which conflicts with the draft rule that requires controls to be of a separate standard source and processed as samples. Since the purpose of the CCV is to verify the acceptability of an existing calibration, the CCV should not be required to be processed as a sample and any acceptable source of standard containing all the analytes should be allowed.

Response: CCV must come from the same source as calibrators. ICVs must come from a separate source. The definition of CCV in the method reflects the definition of CCV in the proposed rules.

  - 3.4 CCR - No issues with this definition, but request consistent terms be used for controls across all rules and method documents. We would like to suggest Initial Calibration Verification (ICV).

Response: “CCR” changed to “ICV” to ensure consistent terms are used for controls across documents.

  - 3.11-3.12 MSD and MS - Since the LCS is already required to be processed as a sample, please allow the MS and MSD to be spiked in-vial. This will drastically reduce the volume of standards needed to produce these controls.
    This standard is being maintained. The purpose of MS and MSDs is to monitor the efficiency of sample preparation and extraction of different types of matrices.
  - 3.14 Preparation Batch - Due to the low concentration of cannabinoid standards (which results in large volumes needed to prepare controls) in addition to their high costs, we request that preparation batches not be limited to 20 samples, as long as the samples in the batch are prepared and/or analyzed together with the same process and personnel, using the same lot(s) of reagents and are processed within the same 24-hour period. Additionally, please allow multiple matrices to be processed within one preparation batch for any method that has been validated to accommodate a variety of matrices. By utilizing additional injections of the control vials throughout the batch, it is possible to monitor instrument performance throughout a larger batch.

Response: The limitation of batch size to a certain number of samples is to ensure minimum variability in sample preparation and extraction. Most federal standards (EPA) utilize 20 samples as a batch maximum, as do California and NY in their cannabis lab standards, so we will be maintaining this in alignment with other agencies. Matrix spike and matrix spike duplicate requirements are being maintained. Multiple matrices are allowed to be processed within the same batch; however, the use of matrix spikes and matrix spike duplicates must be representative of matrix type. Batches with a variety of sample matrices being tested will need additional matrix spikes and matrix spike duplicates to ensure that all matrix types are being monitored.

- Section 5.0 Interferences

- 5.4 "After analysis of a sample containing high concentrations of analytes, one or more injections of solvent/mobile phase should be made to ensure that accurate values are obtained for the next sample." (Statement also appears in 977-CLASP.) Many samples contain high concentrations of analytes and it is not practical to inject one or more solvent blanks after each. A high-concentration control followed by a solvent blank should be sufficient to demonstrate the method parameters effectively prevent carryover. Please update the guidance in 976- and 977-CLASP accordingly.

Response: Section is being maintained. Laboratories must monitor and eliminate carryover effects to ensure accurate values are obtained. Laboratories that can demonstrate that one injection of solvent blank is enough to eliminate the carryover effect during their method validation work may be approved to do so.

- Section 8.0 Preparation of Reagents, Solutions, and Standards
  - This section contains very specific guidance as to prepared volumes and frequency of preparation for various standard/control/stock solutions as well as for mobile phases. We request labs have the flexibility to allow for more frequent preparation of stock solutions, calibration standards, and diluents, as needed. Also allow labs to scale the volumes of preparations to meet their needs based on the volume of testing conducted.

Response: Standard preparation steps are offered for guidance only. Alternate preparations, concentrations and stock mixtures may be utilized provided that they meet the requirements detailed within the method.

- Section 9.0 Shipping Conditions, Receiving, Preparation, Analysis, and Storage
  - 9.2.2 "Samples shall be stored at <6 °C until analysis in order to limit degradation of the analytes and further hinder sample biodegradation. Cannabis samples may be frozen." Please remove the requirement that samples be stored at <6 °C before cannabinoid analysis as specified in 976-CLASP, or specify some time delay in sample processing that would necessitate special storage requirements. To store all samples under refrigeration upon receipt presents a large burden on labs and does not represent product storage conditions at producer/processor facilities, at retail, or in consumer homes. Furthermore, 977-CLASP guidance conflicts by stating to follow the producer/processor's instructions regarding storage before analysis. Producer/processors do not provide such instructions to labs.

Response: EPA has validated this method under the conditions described in method. Any alterations to the method will require validation by laboratory. Laboratories may submit a modified method or their own method for approval if they wish to change storage conditions.

  - 9.5.1 " . . . After testing is completed, the remaining extracts are stored at ≤ -20 °C for one month for reanalysis if it is necessary." Please remove the one-month storage at ≤ -20 °C requirement for sample extracts. Over the course of one month, our lab would typically perform ~2000 extractions for cannabinoids. It is impractical and cost-prohibitive to maintain -20 C freezer space for this volume of extractions.

Response: Requirement for extraction storage has been removed.

- Section 10.0 Calibration

	○ 10.2 "The calibration curve standards are prepared monthly and stored at -20 °C for up to 2 months." This seems unnecessarily specific/restrictive. Please allow labs to prepare calibration curve standards as needed to maintain accurate calibrations on all instruments. *Response:* Laboratories are allowed to prepare new calibration curve standards as frequently as necessary. Laboratories are required to monitor their calibration curve standards and are expected to maintain their calibration curve standards. ○ 10.5.1.1 "The mid-level CCR must be within 85-115% of the known value for each analyte within the initial calibration." We request that all positive control criteria be consistent, simplified, and included in draft rule. Within 976-CLASP, four different accuracy ranges are listed for cannabinoid positive controls, with the CCR/ICV being completely unique in its accuracy requirement. *Response:* "CCR" has been changed to "ICV" to ensure consistent terms are used for controls across documents. This section describes comparing the ICV to the calibration at the percent level. Calibration controls and ICVs are typically prepared in solution, eliminating potential matrix interference. It is the scientific standard to have a tighter acceptance range at higher testing concentration levels. ○ 10.5.2 "For external calibration, a CCV is required at the beginning and end of each analytical batch. For internal standard calibration, a CCV is only required at the beginning of the analytical batch." We recommend that for all calibration types a CCV be required at the beginning, the end, and bracketing every 10 samples within an analytical batch. *Response:* The proposed rules already contain the minimum QC requirements specific to each analytical method. Laboratories may perform QC control checks more frequently if they choose. • Section 11.0 Quality Control and Assurance ○ 11.2.1 - 11.2.3 It appears there is a validation requirement to perform LOD and LOQ studies in each representative matrix. We believe the LOD and LOQ should be defined for each method (i.e. Cannabinoids) and challenged with a variety of matrices, rather than establishing a separate LOD/LOQ for each matrix. *Response:* In matrix requirement has been removed. Section has also been revised to indicate that LOQ may be the same as LOD to maintain consistency between method and the proposed rules. ○ 11.5.2 "The LCS must be spiked with all target analytes at a mid-level concentration in the curve." Due to the low concentration and high cost of cannabinoid standards, we request more flexibility on the spiking level of the LCS, which is spiked in the extraction tube, requiring a large volume of standards. If the CCV, which is spiked in-vial, meets the requirement of a mid-level control, then the LCS could be prepared at a lower concentration level. *Response:* As described in method, a matrix spike may be used in place of an LCS. This would allow the combination of the matrix along with the spike to be at a midrange concentration. The CCV cannot replace the LCS, and a control must be used to monitor sample preparation and extraction efficiency.	

	○ 11.8 MS and MSD - If the MS and MSD may be spiked in-vial rather than in the extraction tube, then meeting the mid-level concentration should not be a problem. Otherwise, we request some flexibility in spiking level for these controls. *Response:* Section revised to allow for MS and MSDs to be spiked at a concentration above the action limit, removing the mid-level concentration requirement. The standard of spiking concentration into extraction vessels is being maintained. The purpose of MS and MSDs is to monitor the efficiency of sample preparation and extraction of different types of matrices. ○ 11.8.1 Method specifications - Please provide some context for these tests. Are these to be performed in method validation? We also note there appear to be some missing references under Table 15. *Response:* The section refers to batch quality control requirements, not method validation. ○ Furthermore, many - if not all 0f the CLASP methods state that controls must be prepared from the same source as the calibration standard, which is unnecessarily restrictive. *Response:* CCV must be prepared from the same source as calibration standards. ICVs must be prepared from a second source. Other controls can use either source, as long as there is at least one control from a second source to verify the calibration.	
977 CLASP Cannabinoid Concentration Analysis	Much of the language (definitions, preparation batch size, LOD/LOQ studies, etc) is identical to 976-CLASP, so please consider our feedback for 976-CLASP wherever the same language appears in 977-CLASP. ● 2.1 "A portion of cannabis product, typically from 10 to 1200 mg, is weighed into a 50-mL centrifuge tube." To reduce both solvent and plastic waste, we request the flexibility to scale down extractions and extract some sample types in 15 mL centrifuge tubes. *Response:* Requirement to use 50mL centrifuge tube removed; laboratories will have flexibility on what size centrifuge tube they can use. ● 5.2 Contrary to the guidance in 976-CLASP section 5.2.1, which states to use lab SOP for cleaning for glassware, the instructions in 977-CLASP section 5.2.1 require a specific procedure. We request flexibility to use our own glassware cleaning SOP. *Response:* Language for specific cleaning procedure removed to maintain consistency between method documents. ● 8.3.4.4 Requires sample extracts be stored at ≤ -20°C until analysis is final. We find this a sensible guideline, preferable to the 30-day requirement states in 976-CLASP. *Response:* Sample extract storage requirements have been modified in 976-CLASP to remove the 30-day post-analysis requirement. ● 11.2 "Follow instructions provided by the licensed producer or processor for storage prior to sample extraction." Licensees do not provide such instructions to labs. We believe the lab's storage of sample materials before analysis should reflect the conditions under which the represented lots are held at the producer/processor facility and/or the environmental conditions under which the products are sold at retail.	Confidence Analytics 12.28.23

	Response: This section has been removed in acknowledgment that laboratories do not have control over licensees. ● 12.2 - 12.2.1 “Dispose of solvent waste in an appropriate solvent waste container, properly labeled” and “All other solvents are separated into two categories, chlorinated and non-chlorinated and are disposed of in red, 5-Gallon solvent cans.” We find this disposal requirement unnecessarily specific and request more general guidance, such as to dispose of solvent waste according to local and state regulations. *Response:* Section has been modified to clarify compliance requirement with local, state, and federal regulations.	
977 CLASP Cannabinoid Concentration Sample Preparation	Given that this method runs for much longer and the solvent is more expensive than what most labs in WA are using, the assumption is many--if not all--labs will submit a request to use a different method. Therefore, we recommend a document that lays out *method performance criteria* rather than a specific prescriptive method. This allows for flexibility for future molecules, changing regulations and innovation. *Response:* Method performance criteria will be defined in the proposed rules. Positive control (LCS) for cannabinoids – what is deemed as an “appropriate clean matrix?” (977 doc, 3.9-3.14) another plant like hops or oregano? Or will you accept additional cannabinoids spiked onto a ‘real’ cannabis sample (like standard addition) and use that recovery as the LCS? *Response:* The method includes a representative commodity by matrix table. Hemp/industrial hemp are suitable representative matrices. Hops and oregano are not suitable representative matrices. MS may be used in place of the LCS as long as the acceptance criteria are as stringent as for the LCS. a. The 976 document references an MCT matrix as a ‘model’ but this is not relevant to any type of product we test except for MCT-based tinctures (less than 1% of compliance testing samples). *Response:* MCT has been removed as a representative matrix from the representative commodity table and has been replaced with hempseed oil. Cannabinoid document 977 section 3.17: mentions requiring both a “surrogate” and an “internal standard”, both of which are spiked before the sample is processed. It’s unclear what the difference is between these two and the justification for requiring both? These are expensive additions given the high concentration needed and we don’t see the scientific reason for having two different QCs that measure the same quality parameter. *Response:* The use of an internal standard is only required when there is an interfering component present in the sample. It is not required to use when there is no interfering component present. Not all cannabis products include interfering components, so the use of an internal standard is not always necessary. This method requires the use of a surrogate standard. It is typical to use internal standards as quality control for long sample batch runs on instrumentation.	Medicine Creek Analytics 12.27.23
977 CLASP Cannabinoid Concentration	• Section 3.18 – Why dictate acetonitrile for SSD? It should be the diluent which is defined in 976 as methanol? This contrasts with section 5.6 that says samples and standards must be prepared in the same final solvent to allow for chromatographic comparability.	Treeline Analytics 01.04.24

Sample Preparation	*Response:* This method uses acetonitrile in mobile phase. It is a scientific standard to match a sample diluent to the mobile phase when performing chemical analysis. Laboratories may submit a modified method or their own method for approval if they wish to use a different diluent/mobile phase. • Section 4.0- The IS norgestrel is a suspected carcinogen and is known to be hazardous during pregnancy. Females of childbearing age perform science too, can we use a different IS? *Response:* Yes, you may use a different internal standard. The mention of trade names or commercial products in method is for illustrative purposes only and does not constitute a CLASP endorsement or exclusive recommendation for use. It is the laboratory's responsibility to maintain a Chemical Hygiene Plan that protects employees, including the use of PPE and environmental controls. • Section 9.1.4 - Mentions major changes to the method. Can you define major changes to the method? *Response:* Section has been revised to add clarity. Major changes to method are change of instrument, change of reagents and/or solvents, and any other changes that would change how analytical tests results are calculated. Major changes do not include change in personnel or change in lot of chemicals used. • Section 9.3- 20 samples is an arbitrary batch number. Samples should be allowed to continue processing until QA checks fail. This is also an inconsistent batch size with other CLASP methods. HPLC autosamplers are refrigerated and the amount of time samples sit in an autosampler should not be an issue. Preparation batch definition – why 20 chosen? Could we just do CCVs during the runs every 20 samples? This is going to be incredibly limiting to laboratories. Each sample that enters the lab for QA testing receives a potency test at minimum. *Response:* The limitation of batch size to a certain number of samples is to ensure minimum variability in sample preparation and extraction. Most federal standards (EPA) utilize 20 samples as a batch maximum, as do California and NY in their cannabis lab standards, so we will be maintaining this in alignment with other agencies. • Section 11.1 – Inconsistent regulations – other CLASP manuals require refrigeration or freezing of samples. This CLASP says, "follow instructions provided by licensed producer or processor for storage". These should be the guidelines for sample storage. *Response:* This section has been removed in acknowledgment that laboratories do not have control over licensees. • And 11.2 – extracts are stored in a deep freezer unless otherwise noted. This is inconsistent within the same section of the manual. Sample storage takes up a high volume of space and if that in its entirety has to be more temperature controlled than room temperature, that will add additional unanticipated costs to the laboratories. A one foot by one foot deep freezer (<20ºC) costs tens of thousands of dollars.	

	Response: These are the conditions that the New York Department of Health validated this method. Laboratories may submit a modified method or their own method for approval if they wish to store pre-analysis samples and sample extract at room temperature.	
980 CLASP Heavy Metals Sample Prep	Sect 2.0 Summary of the Method - Please allow for both the subsample mass and the final dilution volume to be scaled down to reduce use of consumables and the generation of waste (e.g. a 0.25 - 0.50 g sample diluted to 50 mL post-digestion). *Response:* This method was validated using 0.5 - 2g sample mass. Laboratories may submit their own modified method for approval if they wish to use less sample mass. ● Sect 6.2.3.2 One method blank per batch should be sufficient, consistent with other methods/rules. *Response:* This method was validated using two method blanks to verify the absence of contamination from sample vessels. Laboratories may submit their own modified method for approval if they wish to use fewer method blanks. ● Sect 6.3.2.9, Table 4 - We request the flexibility to use our own digestion programs, which are pre-loaded on our microwave digester. *Response:* This method was validated using the microwave digestion program described in Table 4. Laboratories may submit their own modified method if they wish to use a different microwave digestion program. ● Sect 7.4 Consistent with previous feedback, please simplify and unify where possible the control requirements and criteria for each method and publish these standards in WAC 16-309. *Response:* The proposed rules have been revised to include control requirements and criteria for each method. ● Sect 7.4.4 “Duplicate analytical portions are required for each product sample.” Please clarify if labs are required to analyze two aliquots for each sample. If so, we find this requirement to be excessive and suggest that only one lab replicate be required per batch. *Response:* Laboratories are not required to analyze two aliquots for each sample.	ConfidenceAnalytics 01.07.24
981 CLASP Pesticide Data Analysis	• This section is well done. All of the CLASP manuals should be written as this one is. Gives specific advice but not specific method instructions. *Response:* Thank you for the feedback.	Treeline Analytics 01.04.24
981 CLASP Pesticide Data Analysis	● 5.1.5 states that an LOD control must be ran with each batch. Given the number of analytes contained within the pesticide methods and the LOD values for each analyte are variable, it would require multiple preparations to create controls that targeted each individual LOD. If an LOD control is to be required, we recommend providing guidance to allow for targeting the highest LOD of an analyte within the method or targeting the largest possible number of analyte LODs with the control. *Response:* Requirement to run an LOD control with each batch has been removed. ● 4.2.5 states that if a result falls outside of the calibration curve, the sample must be diluted or the calibration extended. If a sample is above the fail threshold and the calibration range extends beyond the fail this is not necessary, as it does not change the pass/fail outcome of the sample/batch.	Confidence Analytics 12.28.23

	Response: We are maintaining this standard as quantitative results are valuable, especially when determining the severity of contamination as it impacts public and environmental health. ● 4.4.3 states that non-recovered pesticides may not be reported. This implies that it may be possible to report a pesticide result but exclude analytes with poor recovery. Please clarify, and if this is a correct interpretation, provide guidelines for when it is not appropriate to report pesticide results due to the number of analytes with poor recovery. *Response:* Non-recovered pesticides in the control standard indicate a failure in quality control. Any failure in quality control must be investigated. Laboratories are expected to prove that they are able to accurately recover and detect target analytes before reporting results. ● 5.2.1.1 and 5.2.1.2 discuss peak retention times for analytes and internal standards. Analyte peaks are given a 0.1 minute allowance for retention time, but then the internal standard used for an analyte must be within .01 minutes of the retention time of the analyte it is used on. Is this an error? Also, we recommend allowing a wider retention time window for internal standards and the analytes they apply to. There are a limited number of suitable internal standards available, often at high costs with long supplier lead times. This will make it difficult to find appropriate internal standards for all of the analytes within the method. *Response:* The retention time window compares the set expected retention time on the instrument with the sample. The relative retention time is comparing the actual retention of the calibrator with the sample. The actual retention time should be tighter than the set retention time window. ● 8.0 requires that the QA manager sign off and review all data packages. We recommend adding language to allow the QA manager or their designee(s). *Response:* Method language has been revised from "QA Manager" to "certifying scientist" to maintain consistency between CLASP documents and the proposed rules. The definition of "certifying scientist" has been revised to include that "no QA duties may be performed by any technical personnel directly involved with the conduct of the analytical findings or testing"	
981 CLASP Pesticide Data Analysis	● Sect 4.1 Calibration Integrity - We propose that calibration integrity is confirmed by analyzing a CCV at the beginning and end of each analytical batch and also bracketing every 10 samples within the batch. We request that control requirements and acceptance criteria be defined in the WAC, and standardized across all methods. We support accuracy criteria of ±30%, as recommended by The Cannabis Science Task Force's December 2021 report. *Response:* We have changed the acceptance criteria of the CCV to 30% for pesticides, explaining that acceptance criteria must be a value established within an approved method, cannot exceed plus or minus thirty percent. ● Sect 4.2.2 "If calibration curves are used for quantification, they shall be constructed using standards which bracket the expected range of residue concentration." We do not understand how pesticide residues could be quantified without the use of calibration curves. Please clarify or reword. Rather than require calibrations to	ConfidenceAnalytics 01.07.24

	bracket the expected range of residue concentration, please specify that calibration range for each analyte must span below and above its WA State action limit. This section describes calibration requirements for number of points, regression fit, weighting, etc. We request calibration characteristics/requirements be consistent across all methods and published instead in WAC 16-309. *Response:* Section language has been revised to clarify that calibration curves are required for this method. ● Sect 4.2.3 establishes acceptance criteria for the correlation coefficient as R2 > 0.990, which conflicts with the R2 > 0.995 that is stated both in the proposed WAC 16-309-120 and the established WAC 314-55-103. We request calibration acceptance criteria to be consistent across all methods and published in WAC 16-309. *Response:* This section has been revised from R2 > 0.990 to R2 > 0.9950 to maintain consistency between method and the proposed rules. ● Sect 4.2.5 "If results fall outside the calibration curve, the sample must be diluted or the calibration curve extended." Assuming a calibration that spans above each analyte's action limit, it should not be required to dilute and reanalyze the sample as it is already determined to exceed the action limit and fails quality assurance testing. *Response:* We are maintaining the quantitative reporting standard as quantitative results are valuable, especially when determining the severity of contamination as it impacts public and environmental health. ● Sect 4.4.3 "Pesticides not recovered shall not be reported." We agree that pesticides that do not meet acceptance criteria in calibrations or controls should not be reported, however WA State certified cannabis labs have a responsibility to screen and report results for all pesticides included in WAC 314-55-108. If any cannot be reported, then reanalysis must be performed after taking corrective action to meet quality criteria. Labs should not be allowed to exclude required analytes from their reports for compliance samples, and so all analytes listed in WAC 314-55-108 must meet quality/recovery criteria. *Response:* Pesticides not sufficiently recovered as described in the proposed rules from matrix spikes may not reported. Test results of target analyte concentration must pass QC checks prior to publication of results. ● Sect 5.1.1 "Uniform response" should instead be demonstrated by analyzing controls within the analytical batch and meeting accuracy requirements (i.e. 70-130% of assigned value). *Response:* This section refers to the calibration requirements, not the control requirements. Calibration accuracy requirements will be maintained at ±20% unless otherwise explicitly indicated in the method. ● Sect 5.1.4 Please instead specify in WAC the controls that are required in an analytical batch. If reinject or dilution data may be reported to the client and to CCRS, then these batches should require analysis of CCV at minimum. *Response:* Controls required for each analytical batch are specified in the draft rules. If the QCs for an analytical batch have passed, and the reinjection happens soon after the batch is run on the instrument it is not necessary to include a new QC for reinjections/dilutions. It is good laboratory practice to reinject a QC sample when reinjecting samples especially when time has elapsed between the completion of the run and the reinjection, but it is currently not a requirement.	

	● Sect 5.1.5 "A non-extracted LOD standard for each compound analyzed shall be run with each data set as a diagnostic tool" With highly variable LODs within the method, many vials would need to be prepared and analyzed to meet this requirement for each analyte. Please remove this requirement. Since each recalibration should include the LOQ, sensitivity and accuracy at the LOQ will be demonstrated with routine calibrations. This is sufficient to verify screening capabilities. *Response:* We have removed the LOD standard inclusion with each analytical batch requirement. This section has been removed. ● Sect 5.2.1.1 "If an **external** standard is used, the retention time (RT) of the compound of interest in the standard and the RT of the same compound in the sample shall be within 0.1 minutes." According to the proposed WAC 16-309-120, only **internal** standard calibration may be used for mass spectrometry methods. Please clarify, publishing all calibration requirements in the WAC and remove any conflicting language from the CLASP methods. *Response:* Section 16-309-120 in the proposed rule has been revised for clarity to include "internal or external standard". ● Sect 6.1 Raw Data Handling - Please update these sections to account for the use of all electronic records for bench sheets, logbooks, etc. *Response:* This section describes how to handle both hardcopy records and electronic raw data. The proposed rules have been revised to clarify that laboratories are not allowed to destroy original observations, regardless of if the observation is a hard copy record or electronic record. ● Sect 7.1.4 "Concentrations shall be reported to at least two significant figures in parts per million (ppm)." Please remove the words "at least" from this sentence, as WAC requires that labs report exactly two significant figures. *Response:* Section has been revised to remove the words "at least", to maintain consistency between CLASP document and the proposed rules. ● Sect 8.0 Data Review appears to require the QA Manager to personally review all data. Please allow QA Manager "or designee." *Response:* Method language has been revised from "QA Manager" to "certifying scientist" to maintain consistency between CLASP documents and the proposed rules. The definition of "certifying scientist" has been revised to include that "no QA duties may be performed by any technical personnel directly involved with the conduct of the analytical findings or testing".	
981 CLASP Pesticide Data Analysis	R^2 value does not match current WAC. Recommend editing to align. *Response:* Method has been revised from $R^2 > 0.990$ to $R^2 > 0.995$ to maintain consistency with the proposed rules.	Medicine Creek Analytics 01.07.24

982 CLASP Pesticide Residue Analysis QC	● Sect 3.1.4 Receipt of Analytical Standards requires assignment of a “unique code” upon receipt. We request the flexibility to design and use our own receiving/ identification procedures as long as traceability is maintained from neat materials to final dilutions. *Response:* This standard is being maintained. The use of unique identifiers such as codes is essential to maintain traceability in the laboratory. Analytical standards must be identifiable from neat to final dilution. This section has been revised to clarify the need for unique identifiers. ● Sect 3.1.5.1 - 3.1.5.2 describe specific (and differing) storage requirements for neat standards and stock solutions/dilutions. We request the flexibility to store standards in existing multi-use refrigerators and freezers as long as manufacturer recommendations are followed, materials are clearly labeled and organized, and cross-contamination is prevented. *Response:* Standards must be kept separate from samples. This standard is being maintained to reduce the possibility of sample contamination by standard as much as possible. This is especially important to maintain in small, enclosed areas such as freezers and refrigerators. ● Sect 3.1.8.1 Please specify when the duplicate preparation of stock standards is required for comparison. It is unclear to us if this is required only when using a new product (Manufacturer or Cat#) or when the lab is analyzing a specific pesticide for the first time. *Response:* This section has been modified for clarity. The duplicate preparation of stock standards has been removed and replaced with the use of an ICV control. ● Sect 3.1.8.2 Sometimes new stock solutions must be prepared due to degradation of the old stock solution. In these cases, the affected analyte(s) may not agree within 15% RPD. If this occurs, would documentation through a Non-Conformance report or Corrective and Preventive Action (CAPA) suffice? *Response:* This section has been modified for clarity. The duplicate preparation of stock standards has been removed and replaced with the use of an ICV control. Laboratories are expected to prepare new stock solutions that meet quality control minimums described in method. ● Sections 3.5 - 3.14 outline extensive validation requirements per each of the six commodity groups including establishment of a separate LOQ for each analyte/commodity combination. With 66 analytes (including isomers and DOH compounds) x 6 commodity groups, the lab must then validate, determine, and document 396 individual LOQs. We find it excessive to require validation studies per commodity group, as this represents a high cost in standards, materials, prep time, instrument run time, data review, and writeup labor for the laboratory. We propose instead that labs select a representative matrix for validation studies, including determination of LOD/LOQ. Once validated, the method may be used to analyze any cannabis product matrix as long as a sample spike of each unique matrix (aka commodity group) is analyzed within the batch to assess matrix effects, demonstrate comparable recovery, and verify method performance. *Response:* This standard is being maintained. Pesticide analysis is susceptible to substantial matrix interference, and laboratories are expected to investigate matrix interference effects for the products they intend to test as part of their validation work. Not all validation steps are required in matrix.	ConfidenceAnalytics 01.07.24

	● Sect 3.10 Verification of LODs/LOQs - Please clarify this section, as it appears that the same procedure used to verify LOD may be used to verify the LOQ and no accuracy requirements are stated. LOQ verification should include verification of accuracy at the LOQ within 70-130% of the nominal concentration. *Response:* Laboratories are allowed to set their LOD at their established LOQ. Laboratories are expected to investigate and establish the LOQ as part of their validation work. ●Sect 3.12 -3.13 We oppose the allowed use of "marker compounds" during validation of Quantitative Range, Accuracy, and Precision. These method characteristics should be evaluated and documented for every individual pesticide in the method, as many of the required compounds present complications that are unique, especially when challenged with real cannabis matrices. *Response:* Marker compounds in this method are defined as the pesticides analytes required in rule by the LCB and DOH. ● Sect 3.14.5 The phrase "Marginal Performing Analytes" is mentioned here, as well as in other sections of 982-CLASP. Please clarify the use of Marginal Performing Analytes as it relates to compliance testing of cannabis. As we understand it, all required analytes must meet performance criteria in order to be screened for WA State compliance. Similarly, the "Example narrative for a data package" includes language indicating the lab may drop analytes during method development due to difficulty in analysis. Please clarify to indicate that analytes required in the WAC may not be excluded from validation. *Response:* Recoveries may be low and/or erratic and rather than not including them in the laboratory's screening list, the laboratory may consult with WSDA to determine if marginal data may be preferable to no data. WSDA may designate analytes as a Marginal Performing Analyte on a case-by-case basis. The example narrative for a data package has been revised for clarity – laboratories may not drop analytes during method development. ● Sect 3.15.1 We do not believe a sample set should be limited in size, as long as all samples and QCs are exposed to the same reagents, equipment, and procedures and CCV is analyzed at least every 10 samples. Please consider limiting batches to 24 hour periods, or alternatively to a larger set such as a 40 sample batch size with CCVs every 10 samples. *Response:* Most federal standards (EPA) utilize 20 samples as a batch maximum, as do California and NY in their cannabis lab standards, so we will be maintaining this in alignment with other agencies. ● Sect 3.15.2 We oppose the use of distilled water as a reagent blank, as cannabis samples and extraction solvents do not typically contain a significant proportion of water. Instead, the reagent blank should be a vial of the extraction solvent that is used for samples and matrix blanks/spikes. *Response:* This section has been revised to assume that an "average" cannabis sample is 10% water. A reagent blank is intended to demonstrate glassware cleanliness and total system integrity with the use of all reagents during the extraction procedure. ● Sect 3.15.4 Matrix Spike - We oppose the allowed use of marker compounds in preparation of the matrix spike. Each required analyte should demonstrate recovery in the matrix spike (as well as CCV and other positive	

	controls). The requirement to spike at ~2x the LOQ or less may not be possible since some analytes will have very low LOQs and others (with higher action limits) may have significantly higher LOQs. Instead we propose that each analytical batch include at least one positive control that is below each analyte's action limit. *Response:* Marker compounds in this method are defined as pesticides analytes required by the LCB and DOH. The LOQ spike requirement has been revised to 5x or less. ● Sect 3.15.5 Verification of sensitivity at 2x the LOQ or less is effectively accomplished by analyzing routine calibrations, given that the calibration will include the LOQ for every analyte. We request this "Quarterly 2x LOQ Spikes" requirement be removed. *Response:* This section has been removed to maintain consistency between the method and the proposed rules. ● Sect 3.15.6 Process Control Spikes - We are unsure how to interpret this section. Does this section describe the use of a surrogate analyte to be spiked into each sample before extraction in order to verify recovery? If so, would not an internal standard accomplish a similar verification? *Response:* This section has been revised to clarify that a process control spike may either be a surrogate standard or an internal standard. ● Sect 3.16.1.3 Again, Marginal Performing Analytes should not be allowed if the analyte in question is required in the WAC. Sect 3.16.2.2 We understand and support flexibility in control limits, but only when a control is out of range in a way that doesn't pose a serious risk to sample data reporting, for example: ○ The control is >130% accuracy, but there are no detections in samples ○ The blank is contaminated, but there are no detections in samples *Response:* We are allowing for the possibility that in some cases, recording imperfect data may be preferable to recording no data. Recoveries may be low and/or erratic and rather than not including them in the laboratory's screening list, the laboratory may consult with WSDA to determine if marginal data may be preferable to no data. WSDA may designate analytes as a Marginal Performing Analyte on a case-by-case basis.	
982 CLASP Pesticide Residue Analysis	Document 982: "Priority compounds" Requesting more information and clarification as to why we're introducing the concept of "priority compounds" and the goal of this in the future. This type of language does not appear in current WAC and could vastly expand the list of compounds labs would need to include. It's also questionable if the current list of 59 WSLCB compounds (which are proposed to be "Priority 1") are really "commodity specific" to cannabis. Many of them are NEVER seen on cannabis. *Response:* This part of the standard method allows for potential future additions to the pesticides list. Section 3.1.2.3 has been modified to remove WSDA ability to designate priority 1 compounds. Priority 1 compounds may only be designated by the LCB or DOH. Section 3.16.1.2 and .3: "marginal performing analytes: Requesting clarification on this process – would this apply to current required WSLCB compounds such as Naled, which degrades into DDVP, which is also a listed compound which makes keeping standards and correct	Medicine Creek Analytics 01.07.24

	quantification difficult. Or would this be other types of compounds that aren't required i.e. priority 2-4 compounds in proposed document? *Response:* Recoveries may be low and/or erratic and rather than not including them in the laboratory's screening list, the laboratory may consult with WSDA to determine if marginal data may be preferable to no data. WSDA may designate analytes as a Marginal Performing Analyte on a case-by-case basis	
982 CLASP Pesticide Residue Analysis QC	● 3.16. 3.2 states that sample homogenate must be stored in a freezer. Similar to other comments we have made, we recommend removing this requirement. As long as storage conditions prevent degradation of sample homogenates, freezing is not necessary. *Response:* The USDA validated this method using those conditions. This method assumes that samples will be frozen after homogenization. It is the scientific standard to freeze pesticide sample homogenate if samples are to be stored prior to analysis. ● 3.15.2 outlines a reagent blank. Distilled water is called out as a surrogate matrix to take through the prep processes and that "...it shall be assumed that an "average" cannabis sample contains 80% water." Distilled water is a poor surrogate, as very few actual cannabis samples contain that much water. The matrix blank described in 3.15.2 performs this function more effectively. *Response:* This section has been revised from "80% water" to "10% water" to reflect that most cannabis samples are dried before submitted to laboratories. ● Multiple "#xLOQ" spiking versions are referenced for different controls throughout the method. Given the number of analytes contained within the pesticide methods and the LOD values for each analyte are variable, it would require multiple preparations to create controls that targeted each individual LOD. If an LOD control is to be required, we recommend providing guidance to allow for targeting the highest LOD of an analyte within the method or targeting the largest possible number of analyte LODs with the control. *Response:* Requirement to run an LOD control with each batch has been removed. Laboratories are expected to identify and verify the LOD of their methods as part of validation work. ● 3.1.2 describes various priority level compounds. 3.1.2.3 states that WSDA may also designate additional priority 1 compounds. This could result in required compounds that are not reflected in rule. Since priority 1 compounds are the required compounds, they should always only reflect the analytes that exist in the WSLCB and DOH regulations. *Response:* This part of the standard allows potential future additions to the pesticides list. This section has been modified to remove WSDA ability to designate priority 1 compounds. Priority 1 compounds may only be designated by the LCB or DOH. ● 3.12.6 describes a variety of method range extension scenarios and requirements. If a laboratory can quantify beyond the action limit, extending the method range is not necessary as they are able to accurately determine pass/fail.	Confidence Analytics 12.28.23

	This standard is being maintained. Laboratories are expected to provide quantitative results for quantitative tests. Laboratories are expected to establish calibration linearity ranges that are consistently capable of capturing the concentration of target analytes. ● 3.1.5.3 requires separate freezers for samples versus standard solutions. 3.1.7 allows for prep of solutions in the same area as long as contamination is prevented. The same should apply to freezer storage and samples and solutions should be allowed to be stored in the same area if contamination is prevented. This standard is being maintained to reduce the possibility of sample contamination by standard as much as possible. This is especially important to maintain in small, enclosed areas such as freezers.	
CLASP 983 Cannabis Pesticide Sample Processing	• Section 3.3 does not concur with section WAC 16-309: (14) Laboratories must ensure sample homogenization is appropriate for each test method performed. This section is redundant and should not be in the pesticide sample processing document. Most homogenizers use mechanical force through a ceramic ball to crush flower in a 50 mL tube. The resin on the flower ends up sticking to the side walls of the tube while leaving a pile of plant material at the bottom, not homogenized. Remove section 3.3. *Response:* Sample homogenization is an essential scientific standard. Laboratories are expected to homogenize samples before analysis. This document is being removed from rules and is available as a standard for labs to reference. Section 3.2.2 and 3.2.3 Remove these sections. Samples are normally set up within 24 hours after receipt in the lab. If not, the samples are stored at room temperature without any significant temperature changes. If a sample has been prepared for analysis, then the sample is put into an autosampler vial on the refrigerated instrument for potency or pesticides or put into an incubator for micro. The container that the sample was prepared in for analysis is not used for any further purpose. If a rerun of the original sample is necessary, then the sample is taken from the original container the sample was received in. With the sample size requirements, labs will always receive extra sample if additional testing is required. If contaminants or target cannabinoids in the cannabis sample degrade at room temperature, then they are degrading in the entire lot at the same rate because cannabis is commonly stored in bulk at room temperature. The refrigeration/freezer recommendation is in direct opposition to the necessity that the sample be kept in its native state at room temperature before performing micro-testing. *Response:* This standard is being maintained in this method. If pesticide samples are to be stored prior to analysis, they must be stored in a separate refrigerator/freezer from pesticide standards to avoid potential cross-contamination. Laboratories may sub-sample their compliance sample if they need samples for a variety of analyses that require different storage conditions.	Green Grower Labs 01.04.24
CLASP 983 Pesticide	• Section 3.2 – “Cannabis samples should be refrigerated for a period not to exceed 120 hours…” This is inconsistent with other CLASP storage rules. Samples will generally all get tested at the same time and very infrequently will a laboratory do, say, a residual solvents test for a product on Monday but not prepare the pesticide until Wednesday.	Treeline Analytics 01.04.24

	• *Response:* Laboratories are expected to establish their own testing schedules. Laboratories are expected to maintain the integrity of compliance samples prior to analysis. If the laboratory testing schedule does not allow for samples to be tested within the period described in the proposed rules or CLASP document, then laboratories are required to store samples prior to analysis as described in the proposed rules and/or CLASP document. This document is being removed from rules and is available as a standard for labs to reference. • Section 3.5 - These rules are inconsistent with the currently available methods of transportation. The laboratory has no say in how and when samples are stored or shipped to us. Just as laboratories have no say in how samples are stored at the p/p or in the vehicles. *Response:* This section has been revised to remove language regarding how samples are packaged and delivered to laboratories by producers and processors in acknowledgement that laboratories do not have control over how producers and processors send their samples. • Section 3.8 – "Reserve sample may be discarded at laboratory's defined timeline". Can this be for all reserve samples for all types of testing? This is inconsistent with other CLASP methods. *Response:* CLASP does not regulate the laboratory's timeline on discarding samples post-analysis. Laboratories are expected to develop their own sample/waste disposal procedures.	
983 CLASP Pesticide Sample Processing	Sect 3.2 Consistent with our previous feedback, we oppose the practice of storing samples frozen or under refrigeration prior to testing. Samples should be stored under conditions that reflect those at the producer/processor facility, the retail establishment, or the consumer's home. The samples we test are fully cured and ready for retail, therefore they do not require refrigeration, and to our knowledge manufacturer's refrigeration requirements are not allowed for products in the I-502 market. *Response:* This standard is being maintained for this method. If pesticide samples are to be stored prior to analysis, they must be stored in a separate refrigerator/freezer from pesticide standards to avoid potential cross-contamination. Laboratories may sub-sample their compliance sample if they need samples for a variety of analyses that require different storage conditions. ● Sect 3.3 We do not find it wise to homogenize the entire sample upon receipt, as in any case where a verification test is required, we prefer to access "untouched" material as it was received from the client and produce another homogenate for confirmation testing. By this practice we can demonstrate that we did not contaminate or mix up the sample during the homogenization process. We propose to require instead an approximate representative weight to be homogenized initially. In addition, pre-ground material would not be suitable for verification tests on volatile analytes such as terpenes. For this test, the sample must be freshly ground just prior to subsampling. *Response:* Sample homogenization is an essential scientific standard. The section has been revised to clarify that samples for pesticide analysis must be homogenized as part of sample preparation. This document is being removed from rules and is available as a standard for labs to reference.	Confidence Analytics 01.07.24

	● Sect 3.4 We do not agree with allowing the nominal target weight to be used in calculations for analysis. The actual weight for analysis should be recorded to the nearest 0.0001 g and this weight should be used in calculations. *Response:* This section has been revised to remove the use of nominal target weight in calculations. ● Sect 3.5 As cannabis products are required to be shelf stable, it is not necessary that they be shipped or stored under cooled conditions. *Response:* Laboratories are expected to maintain the stability of samples that have undergone sample preparation but not analysis. This extends to inter-laboratory sample shipping. ● Sect 3.6.2 It should be permissible to reserve some unhomogenized portion of a sample so fresh homogenates can be produced for confirmation testing. *Response:* This standard is being maintained. Homogenization of all pesticide samples is expected, including sample material used for confirmation testing. Producing fresh homogenate for confirmation testing will unnecessarily introduce additional variability to the sample.	
983 CLASP Pesticide Sample Processing	Document 983; section 3.2: refers to 'refrigerators and freezers' – which is it? Align language with other documents. As in previously-submitted comments on other proposed CLASP methods, we don't believe samples should have a frozen storage requirement – no cannabis products meant for sale are stored/shipped/purchased at frozen temps – everything is room temperature, so that's how our samples should be treated. If the compounds degrade ~that quickly~ from the matrix, it shouldn't be an issue for the end product if they're degraded by the time we run the test. If you want to make a temperature requirement, make a statement that they need to be stored at NO MORE than ~80oF or 24-27C. Lab environments are supposed to be kept below these conditions anyway. *Response:* The type of storage required depends on the material requiring storage. This method describes specifically the storage of sample homogenate and extracts, where the type of storage required is described. Section 3.3: Homogenization of 19+ grams of flower is quite cumbersome and creates expensive workflow challenges (manual labor to grind in multiple batches, clean grinder, etc.) multiple sample containers (increased cost and plastic waste). Recommend re-wording to include a representative sample will be taken depending on the size of flower sample received. *Response:* This standard does not require that the entirety of the sample submitted for compliance testing be used for pesticide analysis. This section refers to the portion of the sample to be analyzed for pesticides.	Medicine Creek Analytics 01.07.24
Small Business Economic Impact Statement (SBEIS)	It is our opinion that the SBEIS that was submitted with the CR102 failed to adequately address the requirements of RCW 19.85. All the businesses that are impacted are classified as small businesses. This means that an SBEIS must consider, *without limitation:* (a) Reducing, modifying, or eliminating substantive regulatory requirements; (b) Simplifying, reducing, or eliminating recordkeeping and reporting requirements; (c) Reducing the frequency of inspections; (d) Delaying compliance timetables;	Treeline Analytics 12.28.23

	(e) Reducing or modifying fine schedules for noncompliance; or (f) Any other mitigation techniques including those suggested by small businesses or small business advocates. The current SBEIS does not address each of these available options with rigor. *Response:* The department has thoroughly considered if any of the options listed above, intended to reduce costs on small businesses, are legal and feasible in meeting the stated objective of the statute upon which the rule is based and implemented those that met that criteria. When the department was not able to reduce costs, it has provided a clear statement as to how it made that determination, as required in RCW 19.85.030(5). The reduction, modification, or elimination of some of the recommendations of the CSTF must be considered and this information presented. For example, removal of the NY methods for cannabinoid analysis and replacing them with guidelines for QAQC that do not include potentially compounds that are potentially harmful to female employees, such as Norgestrel, and are reduced in scope to alleviate cost. *Response:* Based on feedback received from the original CR-102 and rule language that was proposed in November 2023, rules have been modified to allow laboratories to submit their own methods for approval or use a preapproved method. Those methods that meet the minimum requirements will be accepted. Removal of staff education requirements and field of testing complexity levels is an obvious portion of the rules that may be removed without impact on QAQC. At a minimum, a detailed cost/benefit analysis should be performed to demonstrate that these possible cost mitigations were examined and provide a clear explanation of why these obvious steps ought not be taken. *Response:* The purpose of these rules is to improve the laboratory standards due to many issues identified over the years since the cannabis testing rules were established by the Washington State Liquor & Cannabis Board. Improving lab standards includes staff training and competencies, which includes education. A technician's understanding of the acids, bases, and solvents they use every day is key to their safety along with the safety of others in the lab. Being trained in how to perform an extraction doesn't give the employee understanding of reasons for result failures, understanding chemical risks, understanding the science behind the testing etc. Scientific principles aren't picked up on easily nor quickly which is why laboratories rely on educated scientists and why this program is expecting a level of knowledge and education that supports the type of testing being performed. The department is not required to conduct a cost/benefit analysis, nor does it have the resources in which to do so. The proposed mitigations presented in Section 6 of the SBEIS fall short of any substantive reduction in cost.	

	Response: The Regulatory Fairness Act does not require that the department provide a substantive reduction in costs in order to comply with the rule. It requires the department to consider a variety of ways in which costs might be reduced as long as they are legal and feasible in meeting the stated objectives of the statute upon which the rule is based. Since the original drafting of the SBEIS, the department has received additional economic information from laboratories to better elaborate on costs related to compliance with the rule and has incorporated this information into the document. Finally, it must be stated that the enacting of the regulations will not have any effect on the safety or information of the cannabis consumer. There is no field of science that can increase the accuracy and precision of its data through increased rigor of laboratory analysis without having properly collected, random, representative samples. Currently, the I-502 cannabis market does not have this provision. In addition, there is not a fully functioning traceability system nor verifiable chain of custody. If these rules are enacted today, the increased cost to labs and Producer/Processors (through increased testing prices) will produce no benefit to the health and safety of cannabis consumers. This is a clear example of “putting the cart before the horse.” *Response:* It is well understood that the integrity of the sample is as important as the integrity of the testing, however, this rule set only has the authority to address the laboratory standards. RCW 19.85.030(2-5) states “Based upon the extent of disproportionate impact on small business identified in the statement prepared under RCW 19.85.040, the agency shall, ***where legal and feasible in meeting the stated objectives of the statutes upon which the rule is based,*** reduce the costs imposed by the rule on small businesses. The agency must ***consider***, without limitation, each of the following methods of reducing the impact of the proposed rule on small businesses: (a) Reducing, modifying, or eliminating substantive regulatory requirements; (b) Simplifying, reducing, or eliminating recordkeeping and reporting requirements; (c) Reducing the frequency of inspections; (d) Delaying compliance timetables; (e) Reducing or modifying fine schedules for noncompliance; or (f) Any other mitigation techniques including those suggested by small businesses or small business advocates. (3) If a proposed rule affects only small businesses, the proposing agency must consider all mitigation options defined in this chapter. (4) In the absence of sufficient data to calculate disproportionate impacts, an agency whose rule imposes more than minor costs must mitigate the costs to small businesses, **where legal and feasible**, as defined in this chapter.	

	(5) If the agency determines it cannot reduce the costs imposed by the rule on small businesses, the agency must provide a clear explanation of why it has made that determination and include that statement with its filing of the proposed rule pursuant to RCW 34.05.320." While the Regulatory Fairness Act does intend for state agencies to try to reduce costs on small businesses, it also recognizes that this is not always possible. Subsection (2) above states, "the agency shall, where legal and feasible in meeting state objectives of the statutes upon which the rule is based reduce costs imposed…". It also states that, "The agency must consider, without limitation, the list of methods provided as possible ways to reduce costs. The objective of the statute which requires the agency to develop and adopt these rules is to create a set of standards that all of the labs conducting this work must follow. The standards being adopted into rule are typical standards that are used by other industries who regulate laboratories. Through the multiple iterations of the rule language that were drafted prior to the filing of the CR-102, the agency reached out to stakeholders for feedback on how the rule would impact them. While the agency is not able to completely mitigate all costs to the laboratories that will be required to comply with this rule in order to establish a set of standards that is in line with the rest of the scientific industry, the agency has made a number of changes, that were legal and feasible to achieving the objective of the statute, to the original draft that would help mitigate the costs to small businesses, which are mentioned in the SBEIS. When the department was not able to reduce costs, it has provided a clear statement as to how it made that determination, as required in RCW 19.85.030(5).	
Questions, Summary, and Misc Feedback	Where there are contradictions between WAC 16-309 and WAC 314-55, please clarify which takes precedence. Where there are contradictions between WAC 16-309 and the CLASP methods and it has not been explicitly stated which takes precedence, please provide guidance in this situation as well. It is our hope that any/all contradictions in rule may be resolved before rules are finalized. *Response:* The proposed rules do not take precedence over another, unless otherwise explicitly stated in rule; for example, when the rules of a chapter explicitly defer to the rules of another chapter. WAC 314-55 and 16-309 are undergoing coordinated changes to avoid any possible contradictions. We would like to reiterate our request that rules related to preparation batch size allowance, number and nature of controls required, required calibration characteristics, and acceptance criteria for all controls and calibrators be unified and included in WAC 16-309, rather than described separately in each CLASP method. *Response:* Batch size along with quality control requirements are included in rules, along with acceptance criteria. Including these requirements in the WAC not only makes very clear what quality standards labs are held to but would provide guidance to labs when developing and validating methods. We are concerned that the current	Confidence Analytics 01.07.24

	guidelines, which vary significantly across the proposed WAC and the eleven CLASP method documents, result in conflicting quality standards that are unclear for labs and potentially unenforceable by regulators. *Response:* The requirements outlined in the rule language are the minimum requirements. Laboratories are required to utilize a method that has been approved by the department, which could include one of the pre-approved methods provided on the department's website or the lab could submit their own method for approval. Should conflicts exist between an approved method and the rule language, the method will be updated once the conflict is identified. We request that preparation batch sizes not be restricted, as long as the samples are prepared on the same day using the same reagents and equipment and a CCV is analyzed every ten samples. If batch sizes will be restricted, we request the batch size allowance be increased to 40 samples with a CCV analyzed every 10 samples. A calibration check will verify there is no instrument drift and that the calibration is stable. Most methods require five controls with each batch: method blank, laboratory control sample, matrix spike and a duplicate (matrix spike or sample), as well as a CCV. To prepare this single set of controls consumes $50-$800 in standards, depending on the method. For a lab analyzing 50-100 samples per day, limiting the batch size to 20 samples results in $150-$4000 **per method per day** in standards cost alone. Meaning just the cost of standards could be $40 per sample per test **.** Allowing larger batch sizes would reduce this cost substantially without compromising quality, as the CCV verifies calibration accuracy while the non-CCV control preparations account for other variables of sample preparation and method performance. *Response:* The limitation of batch size to a certain number of samples is to ensure minimum variability in sample preparation and extraction. Most federal standards (i.e., EPA) utilize 20 samples as a batch maximum, as do California and NY in their cannabis lab standards, so we will be maintaining this in alignment with other agencies. Additionally, we ask that WSDA take a close look at the current CLASP methods with the concern of potential future enforcement in mind. Many of the CLASP method documents describe quality exceptions which could be exploited by labs that are looking to cut corners and are willing to sacrifice quality. For example, some method documents permit the reporting of results even when controls are outside the acceptance criteria and even in cases where sample data may be similarly affected. If data qualifiers are to be allowed on certificates of analysis, then we ask that WSDA clearly define in the WAC what qualifiers are allowed, under what circumstances, and what qualifying language should appear on the CoA in these cases. Additionally, please explain how public health and safety will be maintained when data qualifiers are allowed especially considering the widespread problem of "potency inflation." Please consider and discuss how such allowances might impact all stakeholders – including labs who do not and will not employ such practices and consumers who frequently pay a premium for products labeled with fraudulently high concentrations of d9-THC.	

	Finally, in addition to reporting on a CoA, our data must be reported to the Cannabis Central Reporting System (CCRS) so we must ask how data qualifiers for non-conforming work should be relayed to the State reporting system if they are to be allowed. *Response:* Data qualifiers is a topic we plan to elaborate on in the Laboratory Manual set to publishing later this year. It is our intent to work with the laboratories in defining what is acceptable and what isn't.	

Chapter 16-309 WAC, Cannabis Laboratory Accreditation Standards Program
Public Comment Summary – Supplemental Proposed Rule Language Filed February 2024

Topic	Comment	Source
WAC 16-309-020 Definitions	Action Level definition is broad and may not be the correct terminology to be used across testing. Response: Our purpose was to have the definition be a little broader. Action levels, cutoffs, action points, etc. seem to be used interchangeably so we tried to use a broader definition for the scope of these rules. In general, they refer to the decision point limits set forth in chapter 314-55 WAC. Analytical batch defined but not used in 16-309. Response: That is correct, "Analytical batch" was not used in 16-309 other than in definitions. However, we felt it was important to include it. This is to differentiate between "analytical batch" and "preparation batch" so the two are not confused. There are many requirements for the preparation batch, and we wanted to avoid confusion with analytical batch. Cut-off concentration defined as qualitative. Unclear how a concentration determination can be qualitative. If qualitative is to be used in this way, a definition of quantitative and qualitative data should also be included. Response: Qualitative tests like the Romer Rapid Strips for Salmonella test positive or negative and have a sensitivity or cutoff level that is used. It is the cutoff that has a concentration, the actual result above which causes the reaction is qualitative. High Complexity testing defined as "due to high complexity". This is a circular definition and does not explain the concept and provides no utility. Response: High complexity testing is actually defined by the FDA. High complexity tests need well educated and trained technologists to perform and troubleshoot issues on these methods. The complexity of testing is determined by the method and the instrument. The seven categories for determining complexity are 1) knowledge required to perform the test, 2) training and experience required, 3) reagents and materials preparation, 4) characteristics of operational steps to perform the test, 5) calibration, quality control, and proficiency testing materials, 6) complexity of the test system and the knowledge, skills and abilities to troubleshoot and maintain the equipment, and 7) the complexity of interpretation and judgement. All lab developed tests (LDT) are considered high complexity. Further explanation will be found in the cannabis lab manual to come out later this year. These are general definitions in rules. Incubation definition only refers to microbes. Other incubations may occur in other fields of testing. Response: That is true, but our focus was on microbes for this definition.	Treeline Analytics 03/21/2024

Topic	Comment	Source
	Matrix not clearly defined. One of the most critical issues that needs to be addressed for the draft 16-309 rules to be effective is a clear and precise definition of matrix. Since labs will be under the regulation of WSDA, WDOH and WLCB, it must be clear to current and future auditors and agency staff what is the definition of matrix. Each agency may have a different interpretation of what qualifies as a unique matrix or matrix group. It is also possible that future auditors (not currently on WSDA staff) may interpret these rules differently, leaving the labs vulnerable to negative audit finding or citations through no fault of their own. A precise definition or grouping of matrices is required for fair and effective enforcement and compliance with these rules. As currently defined in this chapter; flower, trim and cannabis mix could all be unique matrices that require separate validation and matrix spikes during testing. This is not consistent with the reality of these sample types. The issue of matrix becomes more complex with concentrates, edibles and topicals. For example, can HCW, CO_2 oil, Live resin and rosin all be considered the same with regard to possible matrix effects? Edibles are also extremely complicated when you consider the diversity of products and product formulations (e.g., hard candy, pretzel, cookie, tincture, juice). Topicals provide an additional challenge considering the ingredients are not always accurately revealed to the labs, making it difficult to predict if an ingredient will impact analysis. It should also be noted that topicals often have the same ingredient profile as products considered to be edibles. The official designations in WAC 314-55-102 are high level and not clearly understood by P/P. For example, Hydrocarbon Wax designation is very broad and encompasses live resin, distillates, isolates, in addition to a normal hydrocarbon wax. Powder for making pills (edible) is often classified as Food grade solvent. Often, we are unable to determine the correct classification until some if not all of the testing is complete. This could require a complete rerunning of sample depending on how the definition of matrix is interpreted. Response: We agree that matrix is challenging. It is the department's intent to pull together lab directors, producers, processors, and agency scientists later this year to work on this very issue. Unfortunately, there wasn't enough time to resolve it prior to getting laboratory standards developed. Performance based method approach defined using "what" and "how". It is unclear why these terms are in quotes and what this means for the interpretation. Response: The quotes are for emphasis only. Performance based methods allow the laboratory to determine the "what" and "how" of the method as long as the method works by getting the correct results.	

Topic	Comment	Source
	"Parallel study "and "minor modification of method" require definition. Response: Both "Parallel study" and "minor modification of method" will be elaborated on in more detail in the Laboratory Manual coming out later this year to assist laboratories. A parallel study allows a laboratory to verify one method against a similar or even different method/instrument showing that it can perform appropriately and obtain equivalent results. All new instruments or methods must compare a set of sample results to the same samples run on the instrument/method the lab is already using for the same test parameter. This is a common laboratory practice, so we didn't feel we needed to put it in definitions. Minor modifications were too numerous to try and place in rules, but more information will be included in the Laboratory Manual. An example of a minor modification to a method would be: if a laboratory revises the temperature program in a GC-MS assay to resolve an interfering compound, interference studies would be required to document the ability to resolve the interference, but a precision/accuracy study would not be needed. Quantitative analysis. Estimated values would be semi-quantitative, also known as qualitative data expressed using numbers. What are some examples of estimation being utilized in quantitative analysis? Response: One example would be obtaining a result above the ULOL. It is an estimated result from a quantitative method. You still would have to dilute the sample and bring the result within the dynamic range to report out a quantitative number, but the method can potentially give both a numeric value and an estimated result. ICAL not defined. Response: We have replaced "ICAL" with "initial calibration". Positive control and positive control materials not defined. Response: "Control" is defined in definitions. The different positive controls are listed in WAC 16-309-120. Control materials will be defined as we deal with the issue of matrixes later this year.	
16-309-030	3(a) Record keeping requirement should be reduced to 3 years. COAs expire after 1 year, therefore it is unlikely to need data beyond 3 years.	Treeline Analytics 03/21/2024

Topic	Comment	Source

Topic	Comment	Source
	Response: Actually, WAC 314-55-102 (9) indicates that *"A certificate of analysis issued by a certified lab for any cannabis product subject to the requirements of this chapter that has not already been transferred to a retail location expires 12 calendar months after issuance."* Products much older than 1 year old can easily be on store shelves and purchased by consumers. Some issues take more time to be discovered. Data needs can easily extend beyond the 3-year period. Five years is common practice. (6) Audit schedule should be defined. Response: Audit scheduling is defined in chapter 16-310 WAC. It does not need to go in this rule. (7) Where can the checklist for internal audits be found? Will WAC 314-55-103 still be valid? Response: The department will supply a new checklist and cannabis lab manual that describes what each checklist question expects so that both the lab and the auditors know what is expected. We are hoping to release it by July 1st of this year.	
16-309-040	(d) Should be modified to state copy of diploma or transcripts Response: Based on the previous feedback from stakeholders, we had determined that transcripts may be too hard to obtain, so we dropped it as an option. However, if that is what a scientist wants to obtain to support their qualifications we will accept them. Whichever is easier. 3(a) Not all personnel will be conducting maintenance. Should say May include. Response: These are items that are included in the demonstration of competency. Personnel are only required to demonstrate competency for the items they will be performing. b) Could be more concise to convey the concept of "pass a proficiency test". Response: Testing personnel must be able to demonstrate their understanding of each aspect of what they are doing. Just passing a proficiency test doesn't mean laboratory personnel understand what they are doing, it just means they were able to get a result within the broad range of the PT vendor's expectations.	Treeline Analytics 03/21/2024
16-309-050	Qualifications for scientific director should be expanded to include PhD/MS/BS in biological, chemical, microbiological science or closely related fields. Biological scientific degrees require an extensive amount of chemistry classes, making these degrees well suited for the analysis of plant material. Chemistry degrees often have minimal biology requirements, making this degree well suited for laboratory analysis, but not	Treeline Analytics 03/21/2024

Topic	Comment	Source
	necessarily the understanding of the life history of plants which is often used in troubleshooting and experimental design. The current list of acceptable degrees is too limiting and does not reflect the pool of scientists that would be qualified. Response: Cannabis testing is primarily about chemistry and biology. Biology degrees require chemistry classes that usually qualify for a minor in chemistry. Chemistry degrees require biology classes which usually qualify for a minor in biology. This requirement assures that the scientific director is educated enough to deal with the scientific concerns of the cannabis laboratory. Other degrees are acceptable as long as they have the minimum requirements listed in rule.	
16-309-060 through -080	These requirements are too restrictive and cause an unnecessary burden and cost on labs. State labs do not have these regulations, so it is doubtful that this is based on "best science practices." A qualified Science director and QM will be able to provide the proper training and oversight to any employee they believe are suited for the position based on other traits. Classroom learning is not a substitute for on-the-job training. Most potential employees with a BS or MS will require substantial training that would be similar to an employee without a degree or course work. The ability to troubleshoot and recognize suspicious results comes with lab experience and cannot be gained in a classroom. Response: State laboratories like those under the Department of Ecology and Department of Agriculture hire only degreed scientists for positions performing high complexity testing. Detailed expectations are included in the posted job descriptions even though they are not addressed in regulations. The department has added in rules the opportunity for current employees to be grandfathered in if they meet specific conditions, however, future employees will need to qualify by rule. 24 credit hours would most likely consist of 100 and 200 level biology and chemistry classes. This level of education will not provide the training, knowledge, or background to develop methods, troubleshoot, or repair an instrument. Response: Credits from 100 and 200 level classes build general understanding of scientific principles, chemical reactions, understanding of atomic structures, knowledge of mixing acids and basis along with many others. It is many of these basic principles that help a scientist troubleshoot issues, maintain safety in the laboratory, and assure testing is performed properly.	Treeline Analytics 03/21/2024

Topic	Comment	Source
	Unclear how medical or clinical training is the "preferred" or stated education requirement. Should be biology or chemistry. Plant Physiology or Phytochemistry would make more sense, since it is not based on mammalian systems. There are numerous science degrees that will provide an extensive academic background in biology and/or chemistry. Response: We do not limit to specific degrees if they have the necessary chemistry and biology courses to give them the basic understanding of laboratory work in a cannabis lab. That is why we itemized the classwork for those that either graduated in a different science major or didn't graduate at all but took the necessary classes. Medical laboratory and clinical laboratory training focuses on the chemical principles of laboratory science. They take chemistry and biology one step further and apply basic principles directly into laboratory functions. It is ideal education and training for cannabis and other laboratories. It is important to consider that a clinical science degree may not include appropriate background. Clinical science is difficult to define as a field and covers broad areas of human health. For instance, a clinical scientist may have a background in epidemiology or behavioral research that may not provide the necessary academic and career experience to effectively run a lab performing research on a plant. Response: Other degrees do provide valuable education for various scientific areas. However, a cannabis laboratory deals with highly complex chemistry and chemical reactions along with dangerous microbials and mycotoxins. It is not just performing research on a plant. A proper education is necessary in these very specific areas. It is important that those who work in a cannabis laboratory have a good understanding of what they are doing not just the basic of how to do it.	
16-309-100	3) Receipt of Samples may be performed by non-scientific personnel, whose ability may be limited to verifying package integrity and sample identification/labeling. Other unacceptable conditions may not be determined to samples are handled by scientific personnel. If a sample is accepted on receipt, but later rejected by the laboratory, is this in compliance with this rule? Response: Rejecting packages that are damaged or unlabeled is the responsibility of the signee. This does not extend to only cannabis samples but is best practice for all goods received to be checked. Yes, a laboratory may reject a sample later once the technical personnel review the sample as well for technical issues.	Treeline Analytics 03/21/2024

Topic	Comment	Source
	(10) In the event of supply chain issues (pandemic, war), This rule would become unnecessarily cumbersome. It is important to note that supply chain issues still exist, and cannabis labs often have difficulty finding alternate sources. Response: Preventing cross contamination is extremely important. Non-disposable options are often available but require careful cleaning between samples thus costing much more. There is no requirement to use disposable devices. Disposable pipettes are designed for single use. If a laboratory is using a disposable pipette to aliquot a reagent into a tube, they can use it more than once as long as it does not get contaminated by the sample or any other reagent/chemical. Laboratories must be extremely careful about how they use disposable supplies. 11) Suggest simpler wording "human readable form. Barcodes may be added for internal laboratory use." Response: The term "human readable form" is a common phrase used in electronic information systems. Laboratories must know that if they use barcodes to label samples and vials, that it must also include identification in a "human readable form". The instruments may be able to read barcodes if they have barcode readers on them, but a readable identification is also required so a person can read and identify it.	
16-309-110	(5) and (6) Seems too restrictive and unnecessary. The labs are small with a limited number of employees. The majority, if not all, employees will be authorized to handle samples. We are not big corporate or state labs. We know each other very well. Response: This depends on the chain of custody and training utilized by the laboratory. For example, you could assign everyone access to everywhere, but then you will need to defend the reason and show documented training for everyone on proper handling of samples. Some laboratories have receptionists who check in samples when they arrive but don't assess the sample, prepare it for testing, or evaluate data for acceptability. Each person must be properly trained and have limited access to whatever they are not trained to do. If you have staff that perform only 2 of the tests, then they should have limited access to dealing with samples or testing for the other tests. Laboratories must establish criteria for each job description and training and must document what each employees' limits, if any, are.	Treeline Analytics 03/21/2024
16-309-120	Matrix spike requirements will be difficult and may be impossible in some instances. Standards are not always available at appropriate concentrations to make this feasible. For potency, due to DEA regulations,	Treeline Analytics 03/21/2024

Topic	Comment	Source
	labs are limited in the concentration of cannabinoids allowed to be purchased. It would make this nearly impossible to perform realistic spikes in some matrices from the start of testing. It is also unclear how effective and useful residual solvent matrix spikes will be, especially regarding propane and butane. In addition, matrix spikes are only surface level, and do not accurately mimic compounds biochemically produced inside plant material or incurred naturally during growth. It would be useful to require a spike of internal standard or surrogate to estimate extraction efficiency. Potential interference due to matrix could be determined by adding analyte spikes periodically. Response: Having matrix controls is of utmost importance to monitor samples through the testing process. Additional matrix discussions will be necessary to better define future requirements. Periodically adding matrix spikes doesn't allow the laboratory to evaluate all aspects of each run leaving questions as to the accuracy of the batch results that didn't have a spiked control. Controls are required at a preparation batch level. What does it mean that all reagents must be validated? A contaminated reagent would be easily detected based on daily observations. Response: To validate a reagent, before placing it in service, a laboratory would have to test it with a separate control that is placed on an already validated run. If the sample with the new reagent comes within its already validated parameters and doesn't show any interferences or other impurities, then the reagent is approved and signed off by the director or designee as being validated. Each new lot or manufacturer reagent will need to be validated before it can be placed into use. Laboratories must assure instruments, reagents, and chemicals will function appropriately before placing them into service to test cannabis samples. (d) If a matrix isn't available a representative matrix can be used? This is unclear and should be written more clearly. Response: The availability of different matrixes does need more input from producer/processors along with laboratory scientists and will develop over time in the industry. Currently for flower matrix, laboratories may use hemp or use any excess cannabis flower material they may have for matrix related controls. The department will continue to work with laboratories, producers, and processors to establish more detailed regulations for concentrates and edibles.	

Topic	Comment	Source
	(3) Positive control materials mentioned, but not defined or described how positive controls are used or prepared. No frequency discussed. How does it differ from a matrix spike. What would a positive control for potency look like? Are all target analytes required for positive control samples? Response: WAC 16-309-120 requires that the laboratory's quality control program involves concurrent analysis of calibrator and controls to demonstrate an analytical system is operating within defined tolerance limits and that random and systematic errors be identified in a timely manner. To do that, positive controls must be run with all batches. A positive control must be in the matrix and can be a sample re-tested from the day before or a matrix spike. All target analytes must be present in positive controls. For parameters like Pesticides that have multiple analytes, laboratories can use 2 or more controls samples to get all the analytes in. Control requirements are still unclear due to lacking and/or confusing definitions. Response: The control requirements as listed in 16-309-120 (2a-f) are: a negative or a blank; a CCV; a matrix spike; a laboratory control sample (when needed as defined in rule); a sample duplicate; or a matrix spike duplicate. Subsection (4) also indicates that a second source ICV must be used to verify the calibration curve. The department through the Cannabis Laboratory Manual will elaborate more on quality control, however, the laboratory director's responsibility is to know proper use of quality control for each method so they can forensically defend all testing results. The rules describe the minimum requirements.	
16-309-120	Expressed concern regarding the costs associated with subsection (2)(c) requiring matrix spikes and matrix spikes duplicates for every batch. What that means is we have to purchase these standards in order to spike onto a sample matrix at the beginning of the process at a very high concentration. And those standards are only available to us at relatively low concentrations and at very high prices. Response: Laboratories will not need to spike at high concentrations and should only need to spike 1mg/mL for the regulated analytes for matrix spikes. If laboratories use previously tested samples for their matrix spike or even a blank matrix then the addition of 1mg of cannabinoids can accurately be detectable. Laboratories are also allowed to use a sample duplicate rather than a spiked duplicate so only one matrix spike per batch would be necessary.	Medicine Creek Analytics 04/09/2024

Topic	Comment	Source
	Another concern is regarding section (6) that requires an internal standard for each batch, and that would give a good indication for recovery. While you know the in matrix method, validations should confirm any sort of matrix interferences that you might see from that compound and that matrix. So I just sort of want to go on record and say that that's gonna really increase the cost and if we could just do the internal standard and in matrix method validations that would be able to maintain current cost levels. Response: WAC 16-309-120 (6) requires that labs must use surrogate analytes or internal standards for all high complexity testing and WAC 16-309-120 (21) requires that labs must use internal or external standards on any mass spectrometry method. Relying strictly on the area under a curve to compare a sample against a calibration curve doesn't allow the normalization of the variables from a method or instrument even if automation is used to do both. Adjusting those variables against an internal standard or even the use of a surrogate is necessary to assure accurate results. Most labs are already using a surrogate for cannabinoid concentration and some type of internal standard for mass spec methods. We do not require that the internal standard be deuterated even though deuterated standards are usually the best. Scientific directors can determine which standard they will use but it must be one that has similar characteristics to the analytes being tested. For methods testing larger number of analytes like Pesticides, laboratories should use two or more internal standards that elute at different times and later in the run to normalize those later analytes.	
16-309-130	9) When is a biosafety cabinet used "as applicable"? Response: Biosafety cabinets must be used for storage of microbials and mycotoxin standards and positive bio-analyte samples. (13) Should specify that calibration check can be performed in-house. Are in-house repairs and calibration allowed? Response: Checks and repairs can be performed in-house. The rule only established that the check must be done and how often. There are a couple different instruments that help laboratories properly calibrate their pipettes like the Artel PCS®2 Pipette Calibration System. But no matter how the laboratory verifies calibration, it must be documented, and laboratories must either by maintaining a list of calibration dates or placing labels on the pipette showing when the pipette is up for recalibration and when the last time it was done.	Treeline Analytics 03/21/2024

Topic	Comment	Source
16-309-160	c) Retention shift of <2% is unreasonable for HPLC analysis. This could be as short as 1.2 seconds which is unreasonably restrictive and should be modified. If quality control samples are able to pass with regard to the monthly standard curve, and the control analyte RT are similar to sample analyte RT, this should be sufficient to verify accuracy of results. Response: If you have an analyte retention time shift of greater than 0.2 seconds in successive injections, then you have a problem with your HPLC. A shift of 2% should never be seen. Laboratories should evaluate their pumps, tubing, connections, and even the homogeneousness of their mobile phases if they have that much variation.	Treeline Analytics 03/21/2024
16-309-170	(5) What if foreign matter sample is not used for other testing? Does it still need to be examined in a “sanitary” fashion? Why would a lab collect analytical samples from a foreign matter sample? It would be logical to remove other samples first prior to risking contamination for foreign matter sampling. Is there any data on the number of samples that fail for foreign matter or are returned to retail stores for foreign matter complaints? Response: Standards aren’t necessarily based off the number of complaints but rather best practices. Foreign matter is only required on cannabis flower and cannabis mix, and both products can easily contaminate other samples if removed from their containers and placed on the same counter near each other, laboratories must handle them in such a way that minimizes that risk. This can be done by having a cleaning procedure on the counter it is exposed to, laying down clean sheets of examination paper, or similar processes. Multiple samples shouldn’t be laid out next to each other and processed for foreign matter simultaneously, unless the laboratory can show that their procedure protects each sample from contamination.	Treeline Analytics 03/21/2024
16-309-180	Define semi-quantitative. For example: qualitative data described using unverifiable or estimated numbers instead of using color, smell, shape etc. Response: Semi-quantitative tests are like qualitative tests in that they identify the presence of an analyte in solution. An example of a semi-quantitative test is a screening method which uses a test strip that changes colors depending on target analyte concentration, and the results of the test strip are determined using a reference color chart which lists different possible test color results to different levels of concentration. 4) If we buy PCR kits that are ready to use, do we have to do internal QC or is their QC guarantee sufficient?	Treeline Analytics 03/21/2024

Topic	Comment	Source

Topic	Comment	Source
	Response: Internal controls for PCR platforms are commonly included in kits in the form of a predetermined template and primers, which are included in the reaction "master mix" for all reactions. This requires an assay system capable of multiplexing at least to the level of two targets (assay target and internal control). Laboratories are expected to validate methods such as PCR platforms to determine that they are fit for purpose prior to their use on test samples. 4 b ii Limiting the number of cell divisions needs to be clearly defined, either by a range of estimated cell division or length of time. Can we instead verify microbes by using as positive controls or an identification method? E.g. API strips. What is the primary concern for cultures that is being addressed? Loss of enzymes? If the culture is being used for positive control of growth, this may not be a significant issue. However, if the culture is being used for a biochemical control, then this rule would be applicable. Response: The purpose of limiting the number of cell divisions is to ensure that positive controls maintain their ability to provide true control results. API strips must be validated by the laboratory to determine that they are fit for purpose prior to their use on test samples. 8b What is the scientific basis of 10 minutes? Response: The purpose of placing plates into incubation ovens within 10 minutes of inoculation is to prevent a false or otherwise inaccurate test result. Culture methods use live microorganisms, which will continue to grow, possibly unpredictably, while being handled in the laboratory unless strictly controlled. 9) For quantitative analysis, there is no calibration curve for Petrifilm. Limits are defined by media. Response: STEC and salmonella analyses do not require calibration curves, as they are qualitative tests. While not strictly considered as absolute quantification methods, due to the near impossibility of knowing the true amount of viable microorganisms in a sample, quantitative culture-based microbiological methods such as using Petrifilm for BTGN analysis have performance attributes and operational limits that are the same as, or are analogous to: specificity; sensitivity; precision; recovery; limit of detection; linearity and limit; and range of quantification. While it may not be possible to create a calibration curve in the same way one would for an analysis that used advanced instrumentation, laboratories are still expected to validate that they are able to quantify at different target CFU concentrations accurately and precisely, like they would when validating a calibration curve.	

Topic	Comment	Source
16-309-190	Replicates and spikes for solvents may not be able to pass the 20% RPD due to the volatility of compounds. Many samples are negative for all compounds. It may be difficult to obtain replicate data at this quality check level and this frequency due to the nature of the product. Response: It is important for laboratories to handle replicates and spikes in a sealed environment where there is little loss of volatile solvents. If their current method and vials have more than a 20% RPD then they need to modify their method or storage of standards. A better septum cap on the vial along with the use of a matrix modifier for volatile stability would be recommended. Many times manufacturers will have recommendations.	Treeline Analytics 03/21/2024
16-309-190	(8): The ICV must meet a minimum of 80-120 percent recovery for each analyte. We recommend changing this to 70-130 percent recovery. The light hydrocarbons propane, butane, and isobutane are volatile compounds. In our experience, it is possible to hit 80 to 120 percent recovery from an ICV standard, but only once after opening for the light hydrocarbons. Currently, we can use the ICV standard for two weeks and hit 70 to 130 percent recovery. After two weeks the light hydrocarbons have decreased below a value that would be within 70% of the target. Response: Laboratories will need to adjust their handling of standards to minimize evaporation of solvents. We know labs can maintain an 80-120 percent recovery for each analyte standard in residual solvent testing. There is an exponential relationship of the variability of chemical measurements with the concentration of the analytes, thus low percent/high ppm level analysis should have relatively low variability.	Green Growers Lab 04/03/2024
16-309-210	8a) For the 3 required ions, does this include a parent ion? For example, the 3 fragments are Parent ion, Q1, Q3. Response: Yes. One parent and two daughter ions giving two ion rations for identification and quantitative purposes.	Treeline Analytics 03/21/2024
16-309-230	Do these methods need to be approved by the department? Response: These methods do not need to be approved by the Department but will be reviewed at the audit.	Treeline Analytics 03/21/2024
16-309-250	5) What criteria would result in a method being denied?	Treeline Analytics

Topic	Comment	Source
	Response: Methods must be able to properly identify and quantitate the analytes of interest. If an extraction is not efficient enough, if chromatography peaks do not show proper separation, or other analytical inefficiencies, methods would be denied until laboratories corrected the issue(s). (6) It may not be possible to meet this requirement for all fields of testing. How can you have replicates below LOQ? Response: This question appears to be for 16-309-260 (6) and not 250. The decision point or cutoff should not be the laboratories LOQ. 260 (6) requires replicates below the cutoff not the LOQ. "(9) The laboratory must characterize the LOD of a method by a series of replicates with decreasing concentrations (i.e., a minimum of three replicates at each concentration). The LOD must be experimentally determined and supported by analytical data. The laboratory can choose to artificially set the LOD at the established LOQ if the LOQ is at least 25 percent below the decision point limit." L) This section provides requirements for collecting samples. We do not collect samples, they are collected by the customer and brought to us. Response: Methods must still describe the collection expectation. Laboratories must make sure that the samples they receive meet the regulated requirements. WAC 314-55-101 indicates that: "(1) All licensed cannabis processors, producers, certified labs, and certified lab employees must comply with the sampling procedures described in this section, consistent with RCW **69.50.348**. Noncompliance may result in disciplinary action as described in this chapter and applicable law. (2) **Sample collection.** All samples of cannabis, useable cannabis, or cannabis-infused products must be submitted to a certified lab for testing consistent with this chapter. (a) All samples must be deducted, stored, and transported in a way that prevents contamination and degradation. (b) To maximize sample integrity, samples must be placed in a sanitary container and stored in a location that prevents contamination and degradation. (c) Each quality control sample container must be clearly marked "quality control sample" and labeled with the following information: . . . ."	03/21/2024

Topic	Comment	Source
	Laboratories must reject specimens that don't meet these minimum requirements. This means laboratories must describe the requirements in their SOPs so that employees know and understand them and can recognize the criteria for their decision making. T) Are flow charts required or optional? Response: Flow charts aren't required, but if a laboratory uses flow charts they must be included in the SOP. Many times, flow charts are used in bench notes to abbreviate steps for techs to follow. Any bench notes must also be included in the SOP and show the scientific director's approval.	
16-309-260	No method is provided for mycotoxins. What is the appropriate path for validation of a required field of testing when no pre-authorized method is provided? Response: For methods that do not require pre-authorization, the laboratory's validation data will be reviewed at the next audit to assure the method has been properly validated. Validation protocol needs to be reorganized and flushed out to be clearer to follow. Response: These rules list the standard validation requirements and what the minimum expectation of data is to support the validation. Laboratories must establish protocols to meet these standards. The department is working on a Laboratory Manual to help laboratories understand these standards, elaborating on them to maintain consistency of expectation. Portions of the validation of potency will be limited due to all cannabis products containing some cannabinoids. This is also true of Mycotoxins since significant concentrations of mycotoxins have not been found in Washington cannabis. Response: Validations should be performed using positive standards that do contain the analytes of concern. All analytes are available as standards from a variety of sources. 4) Please define instrument parameters that are a major change to the method. Response: We will write more about modifications that affect the performance of a method in the accompanying lab manual. However, given the lengthy list of potential modifications a laboratory could make, trying to list all of these in rules would be challenging. If there is confusion about whether a change would affect performance or not, we strongly encourage a conversation with the Department.	Treeline Analytics 03/21/2024

Topic	Comment	Source
	One example of a major change would be if a laboratory replaces an electron multiplier on a GC-MS, requiring nearly a full re-validation. You wouldn't have to repeat the interference/specificity study but everything else would have to be repeated. (6) How can linearity be achieved in the analysis of samples? Should this read standards instead? Response: The word "sample" in this sentence reflects the use of spiked standards for validating linearity. (11) Should include "or utilizing the highest standard concentration available." Not all standards are available at concentrations that are beyond linearity. Response: Laboratories must analytically establish their ULOL for methods. They do not need to determine the highest value but one that works for them. It must be supported by data. The labs will need to decide on the balance between having longer calibration curves (more points on the curve) versus diluting more samples to place the concentrations within their calibration curves for reporting. (15) It is impossible to know all the components in cannabis samples. Cannabis science has not identified all the compounds or their frequency of presence in samples. Matrix has not been defined. Response: It is easy to determine if there is matrix effect by looking at the area under the curve values and comparing them to non-matrix standards or controls. If specific types of matrix cause suppression or enhancement, laboratories may need to modify their extraction procedure. Determining the specific compound or compounds that are causing the matrix effect is not necessary, just that matrices are having effects on the signal of analyte(s) and making adjustments for them. 16) Requirements of dilution studies seem redundant and unnecessary with other regulation regarding analysis of diluted samples. Can you provide a real-world example demonstrating this is a significant concern? Response: Proper dilution studies support a laboratory's ability to bring high concentrations within the dynamic range of the calibration curve. These rules are about best practices, and a laboratory must be able to show that their dilution procedure results in an accurate result. Given WAC 16-309-280 (4) labs will need to dilute samples above the ULOL.	

Topic	Comment	Source
	(19) How can extraction efficiency be determined besides utilization of spikes? Spikes are surface level additions and do not necessarily reflect the extraction of chemical internal to the plant material. Response: To determine extraction efficiency, laboratories will need to perform an initial extraction with a sample in matrix, remove the solvent, then perform an additional extraction to the original sample, remove it to a separate vial, and perform the same a third time. Each aliquot of solvent will be tested separately identifying the amount of an analyte present in each solvent extract. If the last extract still has analyte above the LOQ then an additional extraction is performed. Each extract concentration is compared to the total to determine efficiency. Many times, efficiency isn't the problem of the solvent, but rather the lack of proper sample preparation by the laboratory. If the sample is properly homogenized, then usually the first solvent extraction has an efficiency of 85% or greater. Changing from a less polar to a more polar solution or vice-versa may improve extraction efficiency of different analytes. Laboratories will need to know the limits of their method(s) and correct or modify them if their extraction efficiency is too low giving inaccurate results.	
16-309-280	(2) If results below the decision point cannot be reported does that mean, for example, 3000ppm butane would be reported as "pass". Response: That is correct. (4) (5) These rules seem out of place on the section. Response: We placed these two rules in the reporting section as a reminder to laboratories that they must only report values within the dynamic range of their methods. 6e) We do not know the date of sample collection as we do not perform sample collection. We will know the date the sample arrived at the laboratory. Response: According to 314-55-101 each sample must be labeled with . . . "the date the sample was collected. . .". Laboratories will need to add it to the sample COA if it is not already printed on it. (6) (m) Are cut-offs reported for quantitative data only? Is LOQ appropriate for this or should it be the values in WAC 314-55? Response: For cannabinoids the cutoff would be the LOQ, for all other parameters it will be the established limit or cutoff in 314-55.	Treeline Analytics 03/21/2024

Topic	Comment	Source
	(11) Does the COA need to have the identity of everyone analyzing the sample? Response: No, just the name of the certifying scientist who is reporting the results. Sometimes that will be the scientific director. Item 11 indicates that “all records must have the identity of personnel . . .” This refers to those who handle, prep, and analyze the samples must identify themselves on the documents they create or documents the action they participate in.	
Methods	In the method for Cannabinoid Concentration Sample Preparation We recommend removing the requirement for internal standards. As defined in the method: **The IS is also used to monitor instrument and extraction performance for each analysis and to correct for solvent evaporation during the analysis.** The use of internal standards is redundant and not necessary. Labs will already be using a surrogate compound to monitor extraction performance. If the surrogate compound measures within defined limits, then labs can confirm that the extraction process was acceptable and solvent evaporation was not a factor in analysis. Adding internal standards directly before samples go on to the instrument does nothing to monitor extraction performance. A typical method evaluation will determine if solvent evaporation is having a significant effect on sample results. On a daily basis, the Lab Control sample will monitor extraction performance. If solvent evaporation occurs the lab control sample will be out of range and the batch would have to be rejected. Response: Laboratories are allowed to use surrogate analytes OR internal standards for Cannabinoid Concentration testing. If you are already using a surrogate, then it will meet the requirements. The CLASP method that is posted on our website does call for both a surrogate and an internal standard. The internal standard allows a laboratory to normalize results if (and when) there are instrument variations. Surrogates are only used for monitoring purposes, and it is not appropriate to normalize results while using only a surrogate compound. We recognize that using both a surrogate and an internal standard can seem redundant. However, if a surrogate fails criteria and the internal standard passes this can point to spiking issues with the surrogate and helps rule out instrument or extraction problems.	Green Grower Labs 04/03/2024
	“Hi, yeah, this is Amber Wise calling from Medicine Creek Analytics, my last name is WISE.	Medicine Creek Analytics 04/09/2024

Topic	Comment	Source

	I'm the science director here and I just wanna just say, first of all, I very much appreciated all of the collaboration and working with the labs that State Department of AG has done during this rule making process. And I just wanted to sort of go on record with, excuse me one, one small section that I still am quite concerned about in terms of cost and with no real improvement in scientific quality, and that section 309120, And a section 2C requiring matrix spikes and matrix spikes duplicates for every batch. When that, what that means is we have to purchase these standards in order to spike onto a sample matrix at the beginning of the process at a very high concentration. And those standards are only available to us at relatively low concentrations and at very high prices. And so, umm, there's another section in that same our quality assurance Section 6, that requires an internal standard for each batch, and that would give a good indication for recovery. While you know the in matrix method, validations should confirm any sort of matrix interferences that you might see from that compound and that matrix. So I just sort of want to go on record and say that that's gonna really increase the cost and if we could just do the internal standard and in matrix method validations that would be able to maintain current current cost levels. So yeah, I think that's all I want to say and I'm looking forward to some, you know, new accreditation standards and all the labs hopefully being enforced and held to the same standards across the board." These responses are also located above for Medicine Creek. Response: Laboratories will not need to spike at high concentrations and should only need to spike 1mg/mL for the regulated analytes for matrix spikes. If laboratories use previously tested samples for their matrix spike or even a blank matrix then the addition of 1mg of cannabinoids can accurately be detectable. Laboratories are also allowed to use a sample duplicate rather than a spiked duplicate so only one spike per batch is necessary. Response: WAC 16-309-120 (6) requires that labs must use surrogate analytes or internal standards for all high complexity testing and WAC 16-309-120 (21) requires that labs must use internal or external standards on any mass spectrometry method. Relying strictly on the area under a curve to compare a sample against a calibration curve doesn't allow the normalization of the variables from a method or instrument even if automation is used to do both. Adjusting those variables against an internal standard or even the use of a	

Topic	Comment	Source
	surrogate is necessary to assure accurate results. Most labs are already using a surrogate for cannabinoid concentration and some type of internal standard for mass spec methods. We do not require that the internal standard be deuterated even though deuterated standards are usually the best. Scientific directors can determine which standard they will use but it must be one that has similar characteristics to the analytes being tested. For methods testing larger number of analytes like Pesticides, laboratories should use two or more internal standards that elute at different times and later in the run to normalize those later analytes.	