TO: Cannabis Laboratory Standards Stakeholders

Thank you for reviewing and responding to our draft rules of the Cannabis Laboratory Analysis Standards Program. We have reviewed the questions and comments sent in and have modified our rules to address many of them. Please take the time to review the responses below and the updated draft of the rules and give us your feedback by Friday, July 28th.

As you review the rule, please keep the following two questions in the front of your mind:

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

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

Below, we have taken each question or comment received and put it with like questions from other stakeholders. Some of the concerns received similar or same responses but we wanted to list each stakeholders response so they knew they were heard. We also took out the quality control testing limits from each of the testing rule requirements and referred to WAC 314-55-102 instead.

Three of the key concerns heard included personnel qualifications, standardized methods, and sample matrix. For personnel qualifications, we reviewed both federal and state educational requirements for same or similar responsibilities and feel we came up with an acceptable solution. To hopefully address some of the method comments, the standardized methods selected by the Cannabis Science Task Force are in the process of being edited to focus specifically on cannabis testing. These should be available for review in a couple of weeks. As to standards in matrix, this is a topic that continues to cause the most challenges and is one that multiple agencies are attempting to address. Even though there isn't a perfect solution available we are working with the best options we have at the moment.

Thank you again for your time and contribution to this process. We recognize the importance of your input as we develop standards for this industry.

Respectfully,
David Michaelsen
CLASP Coordinator

GENERAL

ITEM 1: General - The current lack of a Traceability system and regulations requiring accurate representative QAQC samples be collected must be considered. Without rule changes to address this most basic scientific principle (objective, unbiased, representative sampling), the proposed rules will have no benefit to consumer information and protection.

We understand your feedback, however, we do not have regulatory authority over sample collection. We do believe that creating standards that ensure laboratories follow the same processes for the samples they test will improve consumer protection.

ITEM 2: General - It is unclear if Producer/Processors (P/P) will have the resources to pay the much higher cost of compliance testing. It is our experience that many P/P are unable to afford required testing at the current lower rates. This may force more P/P to close, which would reduce sales and revenue for the laboratories.

Businesses will have to consider the best options to cover any costs related to meeting new standards. It is our intent to modify as many components of the rule as possible in order to minimize negative cost impacts wherever possible, while simultaneously improving testing standards. It will be up to businesses to identify where costs may be passed on to customers.

ITEM 3: General - The complexity of the matrices received will make matrix blanks and matrix spikes requirements extremely difficult, time consuming and expensive. Clear guidelines and definitions to determine what product types are included in a "matrix group" must be defined. For example, does a juice with xanthan gum added fall into the same matrix category as a juice with no emulsifier?

Matrix issues are very complex in cannabis testing and must be considered for quality testing. Any extraction or significant modification of the specimen before testing must be evaluated for efficiency. We are working to better define matrix group and matrix requirements to figure out a way to maintain testing integrity and minimize the complexity of spiking controls in matrix.

ITEM 4: General - NY Code 300 only evaluates 2 types of matrix extensions – metered dose inhalers, and chewables. Laboratories receive cannabis products in a wide variety of matrices, often with unique properties and formulations, it is unclear if these methods will be accurate across existing and future product types.

The methods that we have listed for Cannabinoid Concentration (Potency), Heavy Metals, and Residual Solvents are all Methods recommended by the Cannabis Science Task Force and some weren't designed specifically for cannabis matrices, but rather to be adapted to cannabis and cannabis products. Each lab should use the basis behind the method and make any adjustments necessary for specific cannabis products and validate them for performance.

ITEM 5: The requirement of using acetonitrile accounts for approximately 25% of the estimated cost of compliance. Acetonitrile routinely experiences global shortages. The demand for acetonitrile is predicted to continue to increase globally with a concomitant decrease in global production.

The current cost of acetonitrile is approximately 10x that of methanol, which is superior for cannabinoid analysis.

The prescribed mobile phase solvent in this cannabis concentration method does include acetonitrile. However, the laboratory is allowed to make changes to the mobile phases composition and gradient should they choose.

ITEM 6: Ultimately, the industry will have to deal with other long-term shortages (e.g., Helium). This is an additional reason to allow for multiple accepted methods, and/or provide validation requirements to meet on any method chosen.

It is true that there are some industry challenges like helium, however, these high complexity methods must have the specificity, sensitivity, and robustness to identify the necessary analytes for compliance. Historical results have shown the need to standardize a select few methods to obtain the necessary consistency of those tests.

DEFINITIONS

ITEM 7: Definitions - 82. "Testing Personnel" means those qualified on the basis of appropriate education, training, experience and demonstrated skills to perform analytical testing on cannabis, cannabis concentrates, and cannabis infused products.

It'd be good to get a better definition here. Most of us use lab assistants who are not bachelor level analysts, for portions of the sample prep procedures. If AGR wants to disallow that, it needs to be specified.

We have modified the requirements in the Personnel section to allow lab assistants to perform some testing and create opportunities for long term employees who have received their experience outside of a formal educational setting.

PERSONNEL

ITEM 8: Personnel - We are also extremely concerned with the employee qualification requirements which appear to be more stringent than required by the current WSDOE Lab Accreditation Program. Requiring a minimum of 24 semester hours of undefined “testing personnel” will create a hardship for laboratories not located near science/tech/academic hubs (Seattle). The pool of candidates is much smaller once you leave these areas and will provide a competitive advantage to laboratories based on geography. The pool of qualified candidates is already reduced due to the (unfounded) stigma of working for a cannabis lab. This rule may require the termination of employees that have performed extremely well and are reliable.

We have included additional rules to clarify our personnel requirements and have separated out testing by complexity to allow for non-degreed personnel to perform lower complexity methods.

ITEM 9: Personnel - The rules should be modified to include on the job training hours equivalents and/or change requirement from a prerequisite to a corequisite (e.g., require 1 to 2 classes a year while working or require continuing education credits in their field of testing).

We have included additional rules to clarify our personnel requirements and have separated out testing by complexity to allow for non-degreed personnel to perform lower complexity methods.

ITEM 10: Personnel - (6) d. copies of transcripts: Are these college/post-graduate transcripts?

We have removed transcript requirements from the rules.

Will this be checked during an audit?

Personnel files will be checked at audits. This file is used to show the education, training, and competence of each analyst and which methods they are approved to perform by the lab director. Usually, it will be just a representation of those working that will be reviewed and not all the employees but the auditors will have the option to choose who they look at. It is common that whoever performed the testing of the data being review at the audit will have their personnel files reviewed as part of the process.

Personal opinion is that I feel references are more useful than transcripts and don't request them.
Would this only apply to new hires after this goes into effect? I trust my current staff's skills and don't need transcripts to convince me they can do their job.

The requirement will be to have a personnel file on all employees since employees need documentation of their training and competencies. The need for transcripts has been removed. Should any testing be challenged and go to trial, it makes it easier to show that the employee met the requirements of the regulations.

ITEM 11: Personnel - (6) f. Documentation of continuing education: Is there a requirement for CE? if so, what constitutes CE? Recommend clarification.

The Scientific Director would set requirements for CE if any. CE is usually encouraged in the scientific community. Continuing education can be anything, but most CE is either required by the laboratory as part of the competency program or suggested by the Scientific Director. Some can be through presentations, workshops, conferences or reading of publications with a summary written up by the employee showing they understood what the topic was about. I would imagine that much of it would be about cannabis and cannabis advances in testing, but it doesn't have to be.

ITEM 12: Personnel - (12) Testing personnel must be qualified…..lists a bunch of requirements.

- Does everyone doing any type of labwork have to have a scientific degree? "testing personnel" should be defined better.
- I can envision situations where this would be overkill and unnecessary. Such as….
    - Are 'foreign matter' tests included? what about water activity? you don't have to have a degree in chemistry to perform these tests.
    - what about weighing samples or performing extraction or sample preparation steps but not analyzing data or making decisions about quantitation?

- If everyone touching cannabis for analytical quantitation needs to have a scientific degree, this will be a significant cost (1 or more full-time positions at minimum $60K salary plus benefits per year, with no improvement in scientific quality). I would also probably have to get rid of the person doing this job now.

We have included additional rules to clarify our personnel requirements and have separated out testing by complexity to allow for non-degreed personnel to perform lower complexity methods.

ITEM 13: Personnel - *(6) d. copies of transcripts*

(6) f. Documentation of continuing education

(12) Qualifications of testing personnel

- Do we need copies of every employee's college transcript? That is not the policy at our company. And unless we are hiring for an upper-level position we don't ask for copies of diplomas, etc.

We have removed transcript requirements from the rules.

- Many of our positions are often filled by non-college graduates. Can you clarify who must have a degree?

We have included additional rules to clarify our personnel requirements and have separated out testing by complexity to allow for non-degreed personnel to perform lower complexity methods.

- What constitutes CE and what is the requirement?

The Scientific Director would set requirements for CE if any. It is usually encouraged in the scientific community. Continuing education can be anything, but most CE is either required by the laboratory as part of the competency program or suggested by the Scientific Director. Some can be through presentations, workshops, conferences or reading of publications with a summary written up by the employee showing they understood what the topic was about. I would imagine that much of it would be about cannabis and cannabis advances in testing, but it doesn't have to be.

- Hiring all college grads and adding additional CE would be a significant cost addition.
- 1-3 Full time employees will need to be hired to meet all the new testing requirements and if all are required to be have degrees that will be somewhere in the range of 60-70K per year per employee.

We have included additional rules to clarify our personnel requirements and have separated out testing by complexity to allow for non-degreed personnel to perform lower complexity methods.

ITEM 14: Personnel – Scientific Director qualifications - I think adding physical sciences is appropriate at this point. Is there any reason to exclude physicists?

The Scientific Director's requirements focus on chemistry and microbiology since the laboratory performs complex chemical and microbiological testing. A physicist could qualify if they have the appropriate classes completed as a high complexity analyst along with the appropriate lab experience.

ITEM 15: Personnel – LIMS - Is this a requirement of a LIMS? I don't see any other reference to a LIMS besides this section.

The Laboratory Information Management System refers to any computer or software that manages the data and reports of the laboratory as defined in #1 of the Laboratory Computers and Information Systems section. The Lab Director must have good knowledge of the limitations and functions of their systems even if they employ an IT staff to maintain it.

ITEM 16: Personnel – (10) If the laboratory performs microbiological testing then at least one member of laboratory staff must have a Bachelor's degree in a biological or clinical laboratory science or medical technology . . . Does a chemist with bio experience count here? Does this mean we must have a degreed chemist and a degreed biologist?

A laboratory testing for microbes should at minimum have one biologist or microbiologist on staff capable of creating, implementing, or revising methods, as well as reviewing data for quality assurance. A chemist with extensive biological experience could potentially meet this qualification.

ITEM 17: Personnel – (12) Testing personnel must . . . (c) Have education and training equivalents that includes. . . How will experience be evaluated? Many of us have lab assistants that perform low level tasks but do not have degrees. Some of these analysts have years of experience.

The employees' personnel folder containing their education, training, competency reviews, continuing education etc. will be used to help evaluate testing personnel.

ITEM 18: Personnel – (13) Laboratory testing personnel must have adequate supervision by persons familiar with test methods and procedures.

Not to be overly detailed here, but what is adequate supervision? Isn't this why we have SOP's and DOC's? If we are also adding a degree to the requirements in place for "testing personnel", i'm confused as to what "adequate supervision" would mean. Aren't these individuals required to be familiar with the test methods and procedures already?

Each laboratory must have a qualified person to contact either on-site or by phone who can answer questions, resolve concerns, and review the final data when necessary. This could be performed by the scientific director or another qualified individual.

STANDARD OPERATING PROCEDURES

No questions or concerns identified by labs for this category at this time.

SAMPLING & HOMOGINIZATION

ITEM 19: Sampling - (1) a. each sample package must have a transportation manifest accompanying it. Current rules allow for private citizens or medical patients to test what they purchase off the

shelves or products they make for medical use. These samples do not have a transport manifest. Will this no longer be allowed?

Transport manifests apply to compliance samples only.

Currently, WAC 314-55-102 stipulates what testing labs can perform under their rules.
(8) Certified labs are not limited in the amount of useable cannabis and cannabis products they may have on their premises at any given time, but a certified lab must have records proving all cannabis and cannabis-infused products in the certified lab's possession are held only for the testing purposes described in this chapter.

The tribe would be very opposed to not allowing private citizens/medical patients to test their products for dosing and/or safety. Suggest revising to specify "each COMPLIANCE sample package must have a transportation manifest"

The definition of sample has been changed in the rules to specify compliance samples.

ITEM 20: Sampling - (12). Automated liquid handling – is a multi-channel pipet considered an 'automated liquid handling equipment'? or is another type of equipment required here?

We have changed the requirement to include both manual and automated pipetting.

ITEM 21: Sampling - (15). Minimum sample size tables:

- With very limited exceptions for some edible products, cannabis products are not frozen or refrigerated during harvest/cure/processing/selling and the cost to purchase and maintain large refrigerators would be significant. (~$10,000+) Similarly, -30C for pesticide sample storage is overkill. These freezers are very expensive ($25,000+) and require specialized electrical hookups to run and additional energy costs to run them constantly. Again, no improvement in scientific quality for large increase in cost and reduction in energy efficiency.

Laboratories will be required to establish storage requirements for each type of sample and standard and must support stability with analytical data.

The requirement on the freezer temp was established by the Cannabis Science Task Force to maximize the stability of pesticide standards. The original suggestion was -40C and the group compromised at -30C. Due to cost concerns, the minimum temperature has been changed to -20C but lab directors will have to monitor pesticide standards and samples closely for potential degradation.

ITEM 22: Sampling - The 0.5 gram for cannabinoid would increase the use of solvent by 2.5x and increase the cost of waste disposal accordingly.

Laboratories will be required to establish specimen requirements for each type of sample and test and must support it with analytical data.

ITEM 23: Sampling - Would like clarification on "hold times". Is this how many days we have to start the extraction? I assume it's from the moment we receive the sample (since we don't have any control over temperature or timing of harvest of sample at original facility)

Hold times were suggested as a means to establish a stability timeframe for each analyte tested in case the laboratory didn't perform testing the day of receipt or shortly thereafter. Instead, laboratories will be required to establish stability and storage requirements for each type of sample and support it with analytical data.

ITEM 24: Sampling - The 0.5 grams for cannabinoids in concentrates would both increase cost by using **10x** as much solvent and/OR **significantly increase uncertainty** if we can adjust dilutions to only a **5X solvent increase**. Similar to above comments, there is associated increased waste disposal costs as well as solvents.

Laboratories will be required to establish specimen requirements for each type of sample and test and must support it with analytical data.

ITEM 25: Sampling - The 0.5 grams for residual solvents would also require a lot of re-weighing and re-prepping (increased cost of analyst time and consumables) because this will cause many signals to be over the calibration curve if a spiked matrix is required.

Laboratories will be required to establish specimen requirements for each type of sample and test and must support it with analytical data.

ITEM 26: Sampling - The 0.5 g for water activity is not how our method works – the amount used is the amount necessary to fill the sample cup in the instrument (less than 0.5 g). Too much or too little sample gives invalid results.

Laboratories will be required to establish specimen requirements for each type of sample and test and must support it with analytical data.

ITEM 27: Sampling - If all of these suggested changes are required, a method re-validation will need to occur for all these methods, resulting in at least $8,000 cost for method review by accrediting bodies. Additionally, it will be very difficult to validate new methods on instrumentation and maintain current methods / sample volume.

Laboratories will be required to establish specimen requirements for each type of sample and test if they haven't already and must support it with analytical data. If current lab sample requirements meet final rules then additional validations, other than yearly revalidations, will not be required.

ITEM 28: Sample - *Section 5. The laboratory must establish a minimum volume/weight to conduct all testing requested and any additional tests.*

The weight of sample provided to the laboratory is written into the WAC and is based on the size of the sample lot. A bigger lot requires more sample to have a representative sample. Are you having the current WAC stricken and the labs are to determine sample size? Is the lot size representative sample being removed as a requirement.

This requirement is actually for the individual methods and not the total amount the P/P send to the lab for testing.

ITEM 29: Sample - *Section 11. Aliquots must be labeled with a unique identifier assigned to the sample either with a barcode and in human readable form or just human readable form.*

I am assuming you are referring to flower samples having a Whole Flower Aliquot and a Homogenized Flower aliquot and that you are not referring to each separate subsampling used for extracting each separate test.

Each sample and aliquot must be properly labeled throughout the testing process.

ITEM 30: Sample - *Section 12. Automated Liquid Handling*
What constitutes automated liquid handling?

We have changed the requirement to include both manual and automated pipetting.

ITEM 31: Sample - Section 15 Laboratories must use no less than the minimum sample size, use no more than the homogenization size, store the samples at the appropriate conditions, and analyze the samples within the appropriate hold times for each testing procedure listed below:

MATRICES - There are only 3 matrices in Cannabis. Flower products, concentrates and edibles. To have to validate a method for Food Grade Solvents (a concentrate) and then to have to repeat the exact same validation on Hydrocarbon concentrate is redundant. These products are treated identically in the processes by the laboratories.

We realize that all concentrates are not made equal and those differences are important in relation to matrix effects and possible extraction efficiencies. Equating a food grade solvent concentrate with 40% THC to an isolate with 99% THC concentration doesn't always work. We are happy to work with the labs on matrix requirements to figure out a way to maintain testing integrity and minimize the complexity of spiking controls in matrix.

ITEM 32: Sample - SAMPLE SIZE - The minimum sample size required is too large for cannabinoid concentration and residual solvents. A 0.5g Sample size for cannabinoid concentration testing would either need a much higher dilution factor which would drastically increase the error in testing (the larger the dilution the larger the corresponding error) or a big increase in solvent use and hazardous waste generated. This sample size would cause a 2–4-time increase in solvent use and correspondingly hazardous waste generated. If the samples are being homogenized, then why would we need such a large sample size? Annual Addition Cost $10,000 per year in addition solvent cost and additional waste disposal.

Laboratories will be required to establish specimen requirements for each type of sample and test and must support it with analytical data.

ITEM 33: Sample - A 0.25g Sample size for residual solvent would result in too many samples having to be reweighed at a lower weight and retested. There is already a high percentage of samples that need reweighing and retesting at our current weight of 0.1g. This will cause an increase in analyst work and prep technician work.

Laboratories will be required to establish specimen requirements for each type of sample and test and must support it with analytical data.

ITEM 34: Sample - The proper sample size for water activity is the amount that properly fills the sample cup. Too much or too little sample leads to erroneous results.

Laboratories will be required to establish specimen requirements for each type of sample and test and must support it with analytical data. The sample size for water activity should be based on the manufacture's recommendations.

ITEM 35: Samples - Storage Requirements - Currently we store samples at room temperature. Storing concentrate samples at 8C, especially in a syringe, makes them unmanageable and they must sit out and reach room temperature before the concentrate is able to be weighed. You actually do not rid yourself of the volatilization of residual solvents issue.

Laboratory Refrigerator Fisherbrand™ Isotemp™ General Purpose Laboratory Refrigerators 6850 +Tax $7535.

You would need 2 of these, one for samples and one for cannabinoid extracts. $15,070

-30 Freezer Thermo Scientific™ Jewett™ High-Performance Lab Freezers (this is for a mini-freezer) $9223+Tax=10148

You would need 2 of these (1 for Pesticide Sample Aliquots, and 1 for Pesticide Standards) Total =$20296

Infrastructure Electrical Upgrade for -30 freezers $2500(This is just a guess on my part based on electrical panel upgrades I needed done at my home)

Specimen storage is based off of specimen integrity. Laboratories will only need to store samples under longer-term appropriate conditions, when they are not testing in the standard testing time frames due to repeat or follow-up testing or other concerns depending on the product. Laboratories will be required to establish specimen storage requirements for each type of sample and must support it with analytical data.

ITEM 36: Samples – HOLDING TIMES -A 3-day hold time for pesticides would be difficult to manage. This would require a weekend crew 52 weeks a year. Crews would have to come in to check on pesticides runs over holidays. If QC fails or the run fails to complete due to instrumentation error or power outage, there would be no time for rerunning samples. This would lead to costly delays for the labs and their customers. Labs would have to contact customers for resubmittal of samples. This short hold time would give a huge competitive advantage to labs in Eastern Washington for the outdoor cannabis grow market. These samples typically come via courier, which often takes up to 2 days. This would then require immediate response from laboratories with zero margin for error.

Hold times are periods of time when the lab can't test the sample for whatever reason i.e. instrument down time, weekends or holidays. The lab must establish the conditions the sample must be kept at i.e. room temperature, refrigerated, or frozen, and the time frame the sample can be stored for to maintain sample integrity for future testing. Laboratories will be required to establish specimen storage requirements for each type of sample and must support it with analytical data.

ITEM 37: Sampling – (12) When multi-well plates are used, the laboratory must use automated liquid handling equipment that ensures the correct sample is aliquoted into the correct plate well and maps the location of each sample on the page.

This requirement will add a significant cost to biological testing. Do any labs currently have automated liquid handling equipment? I don't know of any.

We have changed the requirement to include both manual and automated pipetting.

QUALITY CONTROL & ASSURANCE

ITEM 38: QA/QC - ITEM (3) positive control every day for every assay;

- Will increase cost of standards by ~10x each year, minimum **~$50,000 /year additional cost across all tests.**
- Also, matrix spiking for cannabinoids is very difficult and VERY expensive (arguably not feasible) because of the relatively low concentration standards we have access to. This would result in probably **$50-$100,000K per year of additional analytical standards**.

Positive and negative controls are a must for every assay. Without them laboratories cannot verify that a method is working properly. We are working to better define matrix group and matrix requirements to figure out a way to maintain testing integrity and minimize the complexity of spiking controls in matrix.

ITEM 39: QA/QC - (16) The laboratory's Quality Assurance plan must measure meaningful data throughout laboratory processes that establish thresholds or limits for the indicators to trigger evaluation of the services if not met. Meaningful indicators established within the laboratory can be qualitative or quantitative and may be related to structure, processes or outcome of the service involved.

- I don't know what this gray section 16 means or what it's referring to. Some clarification would be appreciated.

Quality indicators would include failed runs, quality control summaries, customer complaints, proficiency testing scores, corrective actions etc. Anything that the laboratory can track to help them make improvements to their services.

ITEM 40: QA/QC – (3) *The laboratory must use controls that evaluate the performance of the sample prep and analytical instrument(s) each day of testing that include:*

a) A negative or blank control to demonstrate the assay(s) ability to perform without interference or contamination.

b) A positive or spiked control below the cutoff or decision point but above the limit of quantitation for each matrix of sample.

c) A positive or spiked control above the cutoff or decision point but below the upper limit of linearity for each matrix of sample.

d) A matrix spiked duplicate at least every 20 samples per matrix.

These will be required for high and possibly moderate complexity testing depending on method limitations .

ITEM 41: QA/QC – Matrix spikes are not feasible for Cannabinoid Concentration Batches. Let us spike our 0.5g sample with 100ul and add 10ml of Methanol. Solution concentration of 100ug/ml. To avoid running the flower sample multiple times, I dilute it 50X so the THCA levels are on scale. Solution concentration put on the instrument is 2ug/ml. So low, the information is useless. If I do not dilute the spiked sample so that the concentrations are in the upper region of my curve, then the THCA concentration will be at approximately 10,000ug/ml, 40X above my highest standard. It would be even worse for concentrates that are approximately 75% delta 9 THC. The highest concentration standard available on the market is Restek Catalog # 34067, Catalog # 34111, Catalog # 34011, Catalog # 34094 at 1000ug/ml. Cost $464 plus tax plus shipping($100) $610. Annual Cost for Matrix Spikes $183 per batch. 3 Batches (1 batch for each of the 3 matrices) per day. $549/day $2745/week $142,740/annually for spiking cannabinoids.

A Matrix spike can be as simple as spiking a specimen that was tested the previous day and comparing the new concentration to the addition spike concentration expectation.

ITEM 42: QA/QC - *(6) Laboratories must establish acceptance limits for each method based on statistical evaluation of the data generated by the analysis of quality control check samples.*

(8) Quality control acceptance criteria for analysis must be within ± 20% of established value unless specific acceptance limits are established by rule

These two seem to be at odds. Are you saying use 20% as a guide until your own limits are established or are you saying establish your own limits but if they are above 20% use a 20% default.

Removed requirment QA/QC #6

FACILITIES, EQUIPMENT & MAINTENANCE

ITEM 43: Facilities, Equipment, and Maintenance - *The laboratory must comply with the scheduled maintenance and function checks recommended by the manufacturer and perform preventive maintenance and check critical operating characteristics of each instrument used in the testing process. Records must be retained for all instruments and equipment.* Every instrument manufacturer recommends annual preventative maintenance requirement. Following this would require a PM contract on each piece of equipment.

Shimadzu HPLC X2 $6800
Shimadzu GC/MS & Headspace Analyzer$10897
Meter Group Water Activity Meter $1200
Perkin Elmer Pesticide LC-MS-MS $30,000
Annual Cost $48,897

Most maintenance and daily/weekly/monthly function checks can be performed by qualified analysts

but there will be some maintenance that can only be performed by an external service when necessary**.**

METHOD PERFORMANCE

ITEM 44: Method Performance - (3) Laboratories must test samples on an 'as is' basis

- This seems to contradict the requirement that we refrigerate/freeze samples.
- Recommend clarifying if this is referring to drying samples (i.e. "Laboratories are not allowed to dry samples or 'dry weight correct' when calculating cannabinoid concentration")

Properly storing samples before testing is important to minimize degradation. An 'as is' or 'as received' basis means the labs should test the sample that they received and not modify it in such a way that it would alter any analyte they are testing for. i.e. Can not dry down flower as part of the sample prep before testing it for cannabinoids. Storage should not be altering the sample.

ITEM 45: Method Performance - *(3) Laboratories must test samples on an "as is" or "as received" basis.*

I think we need to clarify what "as is" or "as received" basis means. If we are grinding them through a tissue grinder we are not testing them "as is" or "as received".

Homogenization does not change the product under this description.

WATER ACTIVITY

ITEM 46: Water Activity – (2) One sample must be run in duplicate with difference in values of 20% or less per batch of up to 20 samples as a quality control specimen.

Are we supposed to establish our own limits or are you providing them?

The rule has been modified for clarification and establishes the range of acceptability.

ITEM 47: Water Activity – (4) The laboratory must run two continuing calibration verifications at levels bracketing the target concentration at the beginning of each day of testing

Why do you need to run a low standard since there is no lower failure limit for this test?

This requirement is according to manufacturer's recommendations.

ITEM 48: Water Activity - *The laboratory must calibrate the aw instrument when:*

a) The instrument hasn't been calibrated in the last seven days.

If the standards are passing why do you have to recalibrate?

This requirement has been removed.

CANNABINOID CONCENTRATION

ITEM 49: Cannabinoid Concentration - Not enough time was given to read the CLASP methods provided

at the last minute.

No response required.

ITEM 50: Cannabinoid Concentration – (3) c. Produce all data required from the validation.

This criteria is important to know so that we can get started validating now. Nobody wants to use the NY state method, from the conversations I've had.

The NY method is used as a recommendation of the Task Force but must be adapted by the laboratory to meet the needs of the different cannabis products and our proposed rules.

ITEM 51: NY Code 300 requires 9 cannabinoids but only 4 are reported to CCRS. CBGA not included, which is one of the most common cannabinoids.

The method itself can test for additional cannabinoids to include CBGA, however, the specific cannabinoids required for compliance testing is limited to was is currently listed in WAC 314-55-102.

ITEM 52: The CLASP methods from NY are currently utilized for sampling that requires 1 sample be taken for an unspecified harvest size of multiple strains. There are few similarities to the I502 industry and may not translate well. We suggest adding additional methods that are more appropriate (e.g., ASTM, AOAC)

The NY method is used as a recommendation of the Task Force but must be adapted by the laboratory to meet the needs of the different cannabis products and our proposed rules.

ITEM 53: Matrix spike requirements are cumbersome due to multiple matrices being included in each run with each sample containing multiple cannabinoids. Matrix blank used in NY Code 300 is MCT oil, which is not an appropriate matrix blank for most cannabis products.

Matrix issues are very complex in cannabis testing and must be considered for quality testing. We are happy to work with the labs on matrix requirements to figure out a way to maintain testing integrity and minimize the complexity of spiking controls in matrix.

FOREIGN MATTER

ITEM 54: Foreign Matter -The requirement to photo document each foreign matter inspection, whether passing or failing, at high and low resolution, is at minimum one full-time job and it is expected to delay flower testing by 24 hours. This requirement increases per sample cost and may also create an opportunity for sample contamination.

The Foreign Matter requirement is one of the methods that is performed by observation only. The analyst documents their observations and transposes the results to their report. Unfortunately, there isn't any printed results from an instrument to obtain an accurate record. Taking a quick picture is the only way to create an accurate record in case a result was to be challenged. There are several options available to evaluate and photograph the sample for under $500 should a lab not already have the equipment to meet this standard.

ITEM 55: Foreign Matter – (1) and (3) need some clarification.

- The table on page 13 says 'full sample' for minimum sample size - seems to be contradictory?

Removed table. Laboratories will be required to establish specimen requirements for each type of sample and test and must support it with analytical data.

- also this seems difficult to determine - are we supposed to look at a full 1/3 of the entire sample under a microscope? If lot sizes stay the same, that could be ~13 grams (a very large amount) of dried flower.

The laboratory should be inspecting a representative amount of sample. The larger the lot size the more sample there is. Just looking at a small amount does not provide an adequate inspection or meet the intent of this rule.

- "low and high-power" should be clarified. Are we supposed to record a microscope photograph for each sample? or just a photograph of the overall sample/container?

Removed requirement of two different powers. Each overall sample will need to be photographed outside of the sample container.

ITEM 56: Foreign Matter - *The laboratory must use a microscope with both low and high-power magnification with photographic capabilities to assess foreign matter*

- Motic AE2000 Microscope and Camera Bundle Cost $6000+Tax or $6600

Modified to " …microscope with photographic capabilities or a camera with magnification to assess foreign matter."

ITEM 57: Foreign Matter - The *laboratory must document a detailed description of the foreign matter inspection and photograph the sample supporting the report.*

- This is a much more extensive inspection
  10minutes/sample includes photo, written description archiving photo.
  24 samples a day 4 hours/day.
  We would have to hire a new technician.
  $25/hour plus benefits Annual Cost of $65,000

The Foreign Matter requirement is one of the methods that is performed by observation only. The analyst documents their observations and transposes the results to their report. Unfortunately, there isn't any printed results from an instrument to obtain an accurate record. Taking a quick picture is the only way to create an accurate record in case a result was to be challenged. There are several options available to evaluate and photograph the sample for under $500 should a lab not already have the equipment to meet this standard.

MICROBIOLOGY

ITEM 58: Microbiological - *The laboratory must have a procedure for shipping and receiving bacterial*

enrichments, organisms, or presumptive positive samples. Biohazardous shipping and receiving training must be documented.

I could not find the cost for this class. I assume it is an annual cost.

OSHA and Washington State Dept of Labor & Industry provide information for training requirements and any cost associated with them, typically free training videos are available.

RESIDUAL SOLVENTS

ITEM 59: Residual Solvents - Suggested methods are designed to test for 1 or 2 specific solvents at a time. Labs are required to test for many more.

Laboratories are expected to adapt the procedure for cannabis and cannabis products, so they are given flexibility to modify them to meet the cannabis testing requirements.

ITEM 60: Residual Solvents - Methods do not include some of the most common solvents detected: butane, propane, isobutane and pentanes.

Laboratories are expected to adapt these methods for cannabis and cannabis products which would include adding the common solvents required for compliance testing.

ITEM 61: Residual Solvents - Cannabinoid extracts do not dissolve in water as the method requires.

That particular part of the method was for other types of samples so only the extraction that works on cannabis products needs to be used.

ITEM 62: Residual Solvents - Suggested methods require water and/or methanol dilutant, but methanol is a target compound.

In Method 3585, the term "Appropriate Solvent" must be defined and understood as, "An organic solvent that is capable of accomplishing the dilution of the sample while still able to meet the quality control requirements of this method, the proceeding analytical method, and regulatory requirements, and is NOT a required analyte per WAC 314-55-102." The selected solvent must be specifically cited in a lab's standard operating procedure(s).

ITEM 63: Residual Solvents - Sample container requiring no headspace for extracts is not possible for several matrices (e.g., diamonds, shatter)

Residual solvents screening is especially important in extracts and the goal is to minimize the evaporation of solvents from the product due to inappropriate packaging prior to testing. The goal of this rule is to protect the sample prior to testing.

ITEM 64: Residual Solvents - A modified USP 467 may be a more appropriate method.

USP method 467 lacks any mention of quality control or method performance criteria so it wasn't included as an option.

ITEM 65: Residual Solvents - Benzene Limit is listed in 1 significant figure. Is this how you would like this compound reported?

- Chloroform Limit is listed in 1 significant figure. Is this how you would like this compound reported?
- Cyclohexane The failure limit is 3 significant figures, but we have been told only to report to two. Please modify the failure limit.
- Xylenes (Sum of Isomers) The failure limit is 3 significant figures, but we have been told only to report to two. Please modify the failure limit.

The table has been and requirements are referred to in WAC 314-55-102.

ITEM 66: Residual Solvents - *The lab must analyze 0.25 grams of sample per residual solvents analysis.*

- Too big of a sample size leads to too many repreps at lower weights and reanalysis

Laboratories will be required to establish specimen requirements of each type of sample and test and must support it with analytical data.

ITEM 67: Residual Solvents - *Samples must be stored at < 8°C and must be analyzed within 14 days of receipt.*

- Date of receipt or date sampled?

Date of receipt.

MYCOTOXIN

ITEM 68: Mycotoxin Screening - Required sample size is not consistent ELISA kits protocols. Language should be included to allow manufacturer instructions to be followed.

Laboratories will be required to establish specimen requirements for each type of sample and test and must support it with analytical data.

ITEM 69: Mycotoxins - *To ensure the quality of data for an immunoassay method, the laboratory must: g. Use an internal standard to minimize errors caused by evaporation of solvents and injection errors or discrepancies;*

- You cannot use an internal standard with an immunoassay test.

Removed and placed under mass spectrometry.

ITEM 70: Mycotoxins - *Have a detailed procedure for the manual integration of peaks, including the review of automated integration and adjustments;*

- There is no manual integration for an immunoassay test. The detector gives a UV absorbance.

Removed and placed under mass spectrometry.

ITEM 71: Mycotoxins - *Report results below the limit of detection with a qualitative indicator such as "trace" or "not detected".*

- Results below the "Limit of Detection" should be reported as not detected not trace.

It has been changed to only "negative" or "not detected".

ITEM 72: Mycotoxins - *Include matrix spike controls in each batch of samples, performed at a minimum frequency of 1 in 20 samples per matrix;*

f. Analyze matrix spike duplicates or laboratory duplicates at a frequency of 1 in 20 samples per matrix, per sample extraction or preparation method, to measure repeatability and precision of the mycotoxin assay(s);

- Restek Mycotoxin Standards Catalog # 34121 & 34122 Cost $406 plus Tax so $450
- 1Batch a Day Assuming combining Flowers and Concentrated in Batch 300ul a day 1500ul a week. So, 1.5 ampules per week or $15,600 annually. If you require flower and concentrate batches to be run separately them $31,200 Annually

Labs can use either a matrix standard or spike a previously tested sample.

PESTICIDES

ITEM 73: Pesticides - (10) a. and b.

- Clarification: Does this mean every analyte needs to be spiked at least every other batch?
- If so, this will increase the cost of standards by an additional ~$10,000/year.

The goal is to test as many pesticides as possible as control spikes. Breaking them up into groups is the easiest way to keep the cost down and still meet quality control requirements. We are still trying to find a balance for this method in the way of controls due to the number and cost of the standards.

ITEM 74: Pesticides - *Storage of analytical standards: c. Access to the freezers and refrigerators shall be controlled and standards usage documented through the use of appropriate records (e.g., log books). These records shall contain at a minimum: standard name and/or unique code, date and time removed, initials of person removing standard, date and time returned, initials of person returning standard.*

- Standards do not need to be monitored to this degree.

The requirement on the freezer temp was established by the Cannabis Science Task Force to maximize the stability of pesticide standards. The original suggestion was -40C and the group compromised at -30C. Due to cost concerns, the minimum temperature has been changed to -20C but lab directors will have to monitor pesticide standards and samples closely for potential degradation.

ITEM 75: Pesticides - *Standard Checking:*

a. Stock solutions of neat pesticide standards not previously prepared or not currently in use in the laboratory shall be prepared in duplicate and the two standards compared to each other. Responses for standards of comparable concentrations must match within 15% relative percent difference (RPD).

i. If standards do not match, potential sources of variation should be reviewed, and a third standard shall be made and compared. This process shall be continued until two matching standards are prepared.

b. New stock solutions that are prepared from neat pesticides currently used in the laboratory shall be compared to the old stock solution. The two standards must match within 15% RPD. If the two standards do not match, the problem must be identified and solved before the standard is used for quantitation.

c. Documentation of the standard checking process shall be kept through appropriate records (i.e. logs). Chromatograms of all standards shall be kept indicating the standard comparisons of old and new standards and the calculated difference.

- Again, this seems excessive. If you are running second source check standards, which you are required to do, then there does not seem to be a need to check your original stock against itself.

Removed

ITEM 76: Pesticides - 10 Multi-residue Screening

a. A laboratory may choose to rotate spike mixtures between analytical sets or spike all compounds analyzed, as long as each extraction/detection system is adequately represented within each set.
b. If the laboratory chooses to rotate spike mixtures they must spike no less than 50% of the analytes and all analytes must be spiked between two concurrent sets.

Item 5 of the Quality Assurance section requires spiking of all compounds. This contradicts that section.

Removed

ITEM 77: Pesticides - *Samples analyzed by each extraction/detection system shall include the analysis of a process control compound. More than one process control may be required. The laboratory shall make every effort to choose a compound that is not expected to be an incurred residue .*

Please define the term “incurred residue” I am not familiar with this term..

Incurred residue means a pesticide that is in the sample or matrix. A PT provider will use 'incurred residue’ to say that they applied a pesticide to a growing plant, rather than spike the pesticide onto the matrix in the lab to make a PT.

ITEM 78: Pesticides – (18) GC/MS and LC/MS Confirmation Criteria.

We currently do not use mass spec for pesticides and confirm via other methods, ie multiple columns/detectors per injection. It would cost a significant amount of money to upgrade now.

This is only for those who are using GC/MS and LC/MS for pesticide testing.

HEAVY METALS

No questions or concerns identified by labs for this category at this time.

OTHER ANALYTES

ITEM 79: Other Analytes - 1.a. says "non-regulated tests may not be used for any labeling or marketing purposes."

- Does this include ALL cannabinoids except THCA, THC, CBDA and CBD?

We have removed this rule.

- will the accrediting body be willing to accredit any additional cannabinoids? If they won't, it will be problematic for many WA licensees and us regarding reporting out. - suggest changing language to "non-accredited tests"?

The accrediting body can only accredit those analytes which the LCB has included in their rules. We have updated our reporting criteria for "non-regulated" or additional tests on the COA. The WSDA is still investigating what part "non-regulated" tests will have in the certification process.

- What about terpenes? if those are a "non-regulated" test, will the accrediting body be willing to review and accredit us?

The accrediting body can only accredit those analytes which the LCB has included in their rules. We have updated our reporting criteria for "non-regulated" or additional tests on the COA. The WSDA is still investigating what part "non-regulated" tests will have in the certification process.

ITEM 80: Other Analytes - 2.b. When can we expect to see a draft of the "Method Validation (WAC xx-xx) document?

The "Method Validation (WAC xx-xx)" document referred to is actual the "Method Validation" section in these rules. Currently, there isn't an assigned WAC number yet so "(WAC xx-xx)" is just a place holder for that number once assigned.

LAB COMPUTERS

ITEM 81: Lab Computers – (1) The laboratory must have computer systems and software adequate for sample tracking throughout the laboratory's possession from receipt of the samples, through testing, reporting and disposal.

I recommend requiring a 3rd party LIMS. Tracking changes made to sample parameters such as sample mass could give LCB better data during investigations. It also makes fraud riskier, which won't eliminate it but will make it more difficult.

It is possible that a laboratory may choose a 3rd party LIMS, but we will leave this up to the laboratory how they will meet this requirement.

ITEM 82: Lab Computers – (9) The laboratory must have a signed contract/agreement with external service providers that include the priority elements of physical, technical, and administrative safeguards to protect their systems and data.

This point was confusing. Do I need to hire a third party company to protect my data?

The rule just requires that any third-party service the laboratory obtains must have a signed contract or agreement for those services. This contract should address issues brought up in the rules. i.e. a contract with a LIMS provider should have wording regarding security, confidentiality etc.

METHOD VALIDATIONS

No questions or concerns identified by labs for this category at this time.

PROFICIENCY TESTING

ITEM 83: Proficiency testing - Compliance with proficiency testing rules may not be possible with the currently approved PT providers. Spiking of PT samples is still required for some fields of testing. After an initial increase, the options for PT providers have decreased, and some have been shown to be unreliable.

Proficiency testing will continue to be a challenge for many reasons. By standardizing some methods, especially standardizing sample prep, we should be able to give better feedback to PT providers to help them create viable samples.

ITEM 84: Proficiency testing - Most PT providers use MCT oil, olive oil or hemp seed oil as a surrogate for cannabinoid extracts. The chemical characteristics of a lipid-based oil are not similar to an oil consisting of cannabinoids and should not be used.

Creating appropriate proficiency samples continues to be a challenge. We hope that input from the labs will help move the industry forward to provide better surrogates.

REPORTS

ITEM 85: Reports – (2) Laboratories must report the numeric concentrations of the required analytes tested.

Currently many labs are artificially setting the LOQ to the action level set forth by the wac and anything less is being reported not as a number but a non-detect or below MRL. Is this an acceptable practice moving forward? would giving LOQ/LOD a better mathematical definition (I realize there are a few, just pick one) help to resolve this, or is this a non-issue?

There are problems with setting the LOQ to the action level. Laboratories must be able to distinguish between the action level and values below them. The LOQ should be at a concentration of no more than 75% of the action level allowing below cutoff controls to be distinguished quantitatively from the

decision point. The LOD could be artificially set at the LOQ should the laboratory choose since distinguishing between the two in the cannabis industry doesn't require any action. The LOQ and LOD must be determined with analytical data not calculated theoretically from baseline noise.

PROCUREMENT CONTROLS

No questions or concerns identified by labs for this category at this time.

SUBCONTRACTING

No questions or concerns identified by labs for this category at this time.

GENERAL COMMENTS BY STAKEHOLDERS

There are multiple factors that may lead to decreased sales and revenue as a direct or indirect result of these rules being implemented in this current form. Laboratories will be unable to process the current number of samples per week (and year), therefore sample price must be increased to cover fixed costs. The proposed methods unnecessarily require the use of expensive reagents and high volumes of standards. Additional employees and labor will be required to process each sample, which will further increase the cost.

Several of the rules have been modify to address many of these concerns.

The rules changes implemented in April 2022 increased the compliance testing cost to P/P. Due to the low margins in these businesses, P/P are incentivized to maximize their value of testing by submitting the largest lots possible to spread the cost. Thus, the sample volume seen by the labs has artificially decreased to levels lower than projected. These rule changes will further exaggerate the lower sample volumes, which will impact laboratories and the public safety of the industry.

We hope the modifications we have made to the first draft will minimize the impact.

All of these economic estimates do not include the additional cost of having to comply with a completely new cannabinoid concentration method and/or proving our current method is 'sufficient' or 'better' than the required method. I would request clarification on the "written procedure" to get a new method approved and some understanding of how burdensome that process might be. Labs have yet to review this guidance document, so I have not included any additional costs (and they will be significant) to comply with those new rules.

Unfortunately, standardization of methods does come with a cost, but this was a standard that both the laboratories and agencies agreed needed to happen to improve the industry.