

# Our webinar will begin soon

## Connecting to Audio: 3 Options

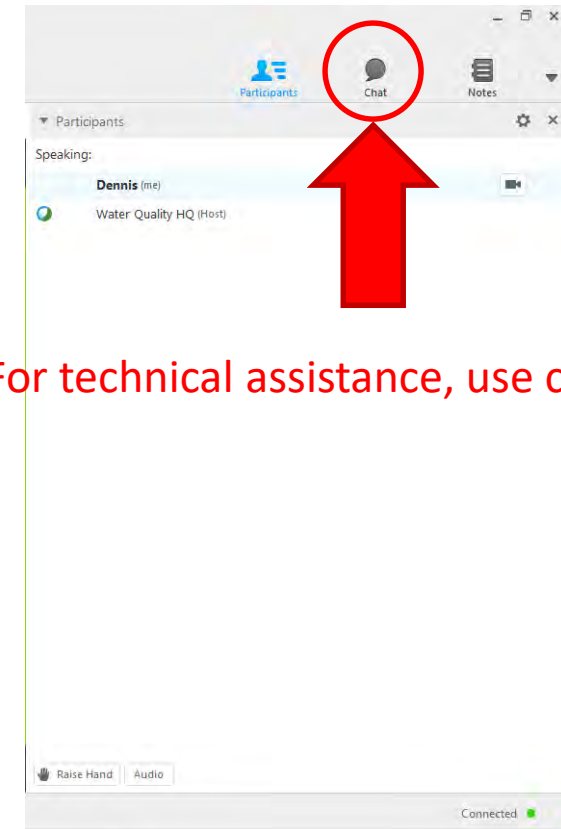
### Phone (best sound quality)

1. Select "Call Me"
  - o Enter your phone number
  - o You will be called back
2. Or select "I Will Call In" and dial the number provided
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# Use chat for technical help

- Our webinar is now beginning.
- Use should be able to hear us now.
- Use chat for assistance.



For technical assistance, use chat.



# Facilitators

Camille St. Onge & Ruth Froese  
Communications

# Presenter

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# Author

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# Webinar Format

- All attendees are in listen only mode.
- The presentation will be made available on Ecology's website.
- Ecology will hold a feedback session on October 29.



# LEGISLATIVE ASSIGNMENT & REPORT PROCESS

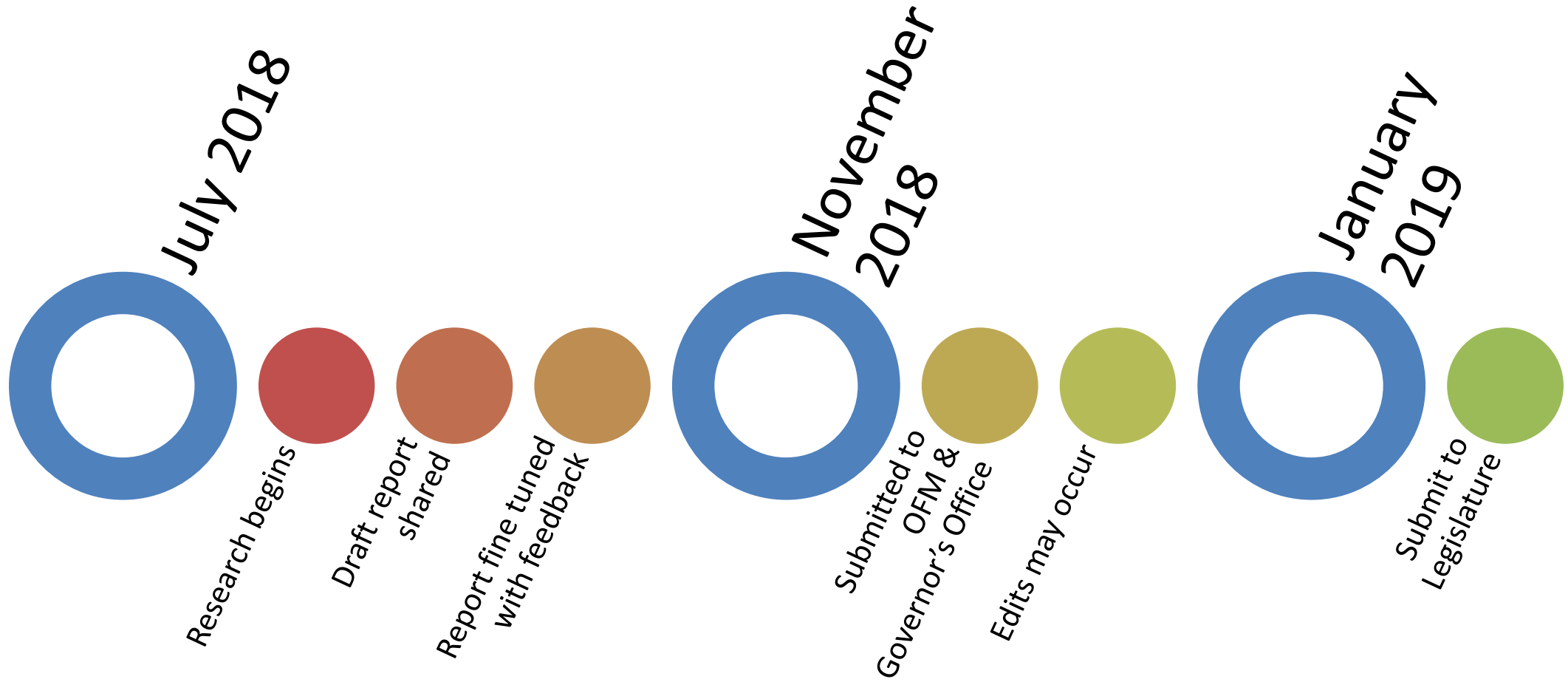
# Senate Bill 6032

## PRELIMINARY RECOMMENDATIONS

Begin conducting research and developing preliminary recommendations for protocols and accreditation standards for cannabis testing laboratories.



# Report process



# Legislative Report Cannabis Lab Accreditation

Jessica Archer

Section Manager, Environmental Assessment Program





# ACCREDITATION & ECOLOGY'S ROLE

# What is accreditation?

- Accreditation is the formal recognition that a laboratory has the technical competence and the systems in place to perform an identified scope of work, defined by regulations, and is therefore capable of producing accurate and defensible analytical data.



# Ecology's role in accreditation



- Accredits ~500 laboratories
- Provides initial and continuing accreditation
- Accredits to the parameter
- Ecology grants, revokes, or suspends accreditation



Report scope and initial research

# **DRAFT REPORT**

# Scope

Begin conducting research and developing preliminary recommendations for protocols and accreditation standards for cannabis testing laboratories.



# Problems with Scope

	Environmental Samples	Drinking Water	Recreational Cannabis	Medical Use Cannabis	Report Focus Areas
Federal Policy	✓	✓	Illegal - schedule I drug	Restricted - schedule I drug; limited Fed. approved research-use only purposes	
Federal Program Oversight	✓	✓	DEA*	DEA, FDA, DINA (Natl. Institute on Drug Abuse)*	
State Regulatory Authority	✓	✓	✓	✓	✓
State Accreditation Program	✓	✓	✓	✓	✓
Federal Accreditation Std	✓	✓			
State Accreditation Std	✓	✓	✓	✓	✓
Other Accred. Authorities	✓	✓	Not currently used in WA	Not currently used in WA	✓
State Program Meets Federal Std.	✓	✓			
Validated Methods	✓	✓	User discretion AHP C&L monograph doc. Monograph cites some validated methods.		Recommendations for next steps only.
Analyte /Matrix Specific Methods Available	✓	✓	Limited, varies by <u>analyte</u> and matrix		Recommendations for next steps only.
Method Validation	✓	✓	User discretion, some validation protocols attached to specific validated methods		Recommendations for next steps only.
Proficiency testing	✓	✓	Limited availability, some surrogate types avail.		Recommendations for next steps only.



# Research



- Gathered accreditation data
- Reviewed current policies and practices
- Looked to other states
- Developed preliminary recommendations



**CRITICAL CHALLENGES MUST BE  
ADDRESSED**



# Critical Analytical Gaps & Challenges

- Methods of analysis
- Method validation
- Performance criteria
- Proficiency testing
- Sampling
- Homogenization
- Preparation procedures



# Cannabis Science Workgroup

- Cannabis Science Workgroup:
  - Doctors, toxicologists, chemists, microbiologists, public health experts, food & ag testing methods, DOH and WSDA, industry non-governmental scientists
  - Determine methods, protocols, quality standards
  - Science-based updates to language in WAC regarding QA, sampling, homogenization, QA testing, PT, lab practices, action limits, product compliance,



# American Herbal Pharmacopoeia Monograph

According to WAC 314-55-0995,

- Certified labs must follow the analytical requirements [in the] most current version of the *Cannabis Inflorescence and Leaf Monograph* published by the *American Herbal Pharmacopoeia* or notify the WSLCB or its designee what alternative scientifically valid testing methodology the lab is following for each quality assurance test.



# The Good Laboratory Practices Checklist

- Evaluate to weak and insufficient quality standards
- Labs accredited to criteria in SOPs that they wrote themselves.
- Labs not required to implement specific QA/QC due to weak WAC quality standards.
- Not an effective accreditation mechanism



# Proficiency Testing

- Integral part of laboratory accreditation
- Required pre-accreditation in all major testing programs
- Appropriate PT providers not available in WA
- Round Robin interlab comparisons may be appropriate
- State program or private company could source and spike product



# Sample Procedures

- Lack of guidance may lead to biased samples
- No nationally or internationally recognized standard methods
- Insufficient process in WAC 314-55-101
- Bias introduced at this stage will persist through process
- Sampling protocols needed
- Not assessed as part of laboratory accreditation



# Sample Homogenization

- Left to laboratory discretion
- May lead to variable, non-representative results
- Not normally part of accreditation activities unless part of analysis method or in a prep SOP



# Widely Accepted Protocols & Methods Do Not Exist

- Validating & developing methods take months – years to develop
- Multiple matrices, each requiring different protocols





# Options for Protocols & Methods

- Adopt (and adapt) methods from other testing programs
- Use methods from other states, countries, instrument manufacturers, or the industry
- Adopt (or adapt) performance criteria or validation protocols to use with non-standard lab methods
- Canada



# MODELS OF ACCREDITATION EVALUATED

# Model 1

- Ecology's Laboratory Accreditation Unit (LAU) assumes the role of accrediting body, and laboratories are evaluated using approved methods, established performance criteria, and other critical elements necessary to assess competency and ability to generate consistently accurate and defensible data



# Model 2

- An **ISO/IEC 17025 accreditation** by a selected International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA) provider



# The ISO/IEC 17025 Accreditation Standard Is Not Enough

- General requirements, specifications, and guidelines
- Serves broad array of disciplines by not incorporating specific details
- Vague and general unless paired with specifications or policy and adoption of other regulatory, industry, or consensus standards



# Model 3

- Ecology's LAU assumes the role as the accreditation body and accredit cannabis testing laboratories to a **revised** version of the GLP Checklist (WAC 314-55-103) and **revised** laboratory certification and accreditation requirements (WAC 314-55-0995), at a minimum



# Model 4

- Ecology's Laboratory Accreditation Unit (LAU) assumes the role as the accreditation body and accredits cannabis testing laboratories to the current "as is" Good Laboratory Practice (GLP) Checklist in Washington Administrative Code (WAC) 314-55-103.



# RECOMMENDATIONS



# (1) Develop protocols and quality standards to achieve established product standards.

- Cannabis Science Workgroup:
  - Doctors, toxicologists, chemists, microbiologists, public health experts, food & ag testing methods, DOH and WSDA, industry non-governmental scientists
  - Determine methods, protocols, quality standards
  - Science-based updates to language in WAC regarding QA, sampling, homogenization, QA testing, PT, lab practices, action limits, product compliance,



## (2) Revise Chapter 314-55 WAC to adopt the new protocols and quality standards.

- Laboratory certification and accreditation requirements (WAC 314-55-0995)
- Quality assurance testing (WAC 314-55-102)
- Quality assurance sampling protocols (WAC 314-55-101)
- Proficiency testing (WAC 314-55-1025)
- Laboratory certification – suspension and revocation (314-55-1035)
- Sections within marijuana product compliance (WAC 314-55-107 and Chapter 246-70 WAC)
- Additionally, this option may require revision of language in pesticide action levels (WAC 314-55-108)



**(3) Maintain the current private accreditation provider until the new protocols and quality standards are in place.**



## (4) Adopt a new accreditation provider after new standards are in place.

- Designate Ecology's Laboratory Accreditation Unit as the accreditation provider for Washington cannabis testing laboratories.



# Next steps

See draft report at  
[ecology.wa.gov/cannalabs](http://ecology.wa.gov/cannalabs)

## Feedback session

October 29

3 – 4 p.m.

Ecology Headquarters

300 Desmond Drive

