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State of Washington

Cannabis Laboratory Accreditation Recommendations

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Cannabis Laboratory Accreditation Recommendations

DRAFT

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Executive Summary

In 2018, the Washington State Legislature directed the Washington State Department of Ecology (Ecology) to research and develop preliminary recommendations for protocols and accreditation standards for cannabis[1] testing laboratories, as stipulated in Engrossed Substitute Senate Bill 6032:

> Section 302: For the Department of Ecology – Appropriations (FY 2019)
>
> (17) $98,000 of the dedicated marijuana account—state appropriation for fiscal year 2019 is provided solely for the department to begin conducting research into appropriate protocols and accreditation standards for marijuana testing laboratories. By January 15, 2019, the department must report to the appropriate committees of the legislature with preliminary recommendations regarding laboratory accreditation standards that should be applied to marijuana testing laboratories.

Accreditation is formal recognition of conformity to a standard. An accredited laboratory is capable of providing accurate and defensible data according to established quality standards. Accreditation requires evaluation of a laboratory's quality system, staff, facilities and equipment, test methods, records, and reports (Ecology, 2010).

The Revised Code of Washington 69.50.345 charges Washington State Liquor and Cannabis Board (WSLCB), in consultation with Washington State Department of Agriculture (WSDA), to establish accreditation requirements for cannabis testing laboratories. The WSLCB or its designee accredit cannabis testing laboratories according to Chapter 314-55 WAC. Currently, cannabis testing laboratories are evaluated by a private accreditation provider under contract with the WSLCB.

In response to this legislative directive in ESSB 6032, Ecology researched current accreditation practices in Washington and reviewed other states' approaches. We found two main challenges:

- Current quality standards (methods, method validation protocols, and performance criteria) as outlined in Chapter 314-55 WAC are insufficient to support a robust, science-based cannabis laboratory accreditation program. Revisions are needed for analytical methods, method validation protocols, performance criteria, proficiency testing, and sampling and homogenization procedures.
- Widely accepted quality standards for testing cannabis and cannabis products do not yet exist.

Recommendations

To strengthen Washington's cannabis laboratory accreditation program, we recommend four critical actions:

(1) Develop appropriate quality standards. This includes further developing, adapting, or adopting methods, method validation protocols, and method performance criteria. We also suggest scoping a supplemental proficiency testing sample program and a process for laboratory fraud investigations. This work should be facilitated through a science-based workgroup (Cannabis Science Workgroup) consisting of experts in medicine, toxicology, chemistry, microbiology, and food- and agricultural-testing methods,

[1] The term "cannabis" is used throughout this document. "Marijuana" will be used in discussions where the referenced context requires this alterative term.

and including representatives from Washington State Department of Health (DOH), Washington State Department of Agriculture (WSDA), and Ecology.

(2) Adopt the new quality standards developed by the Cannabis Science Workgroup. This step will require revisions by WSLCB to Chapter 314-55 WAC.

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

(4) Designate Ecology's Laboratory Accreditation Unit (LAU) as the accreditation provider for Washington State cannabis testing laboratories. Laboratories will be evaluated using LAU's accreditation framework (Chapter 173-50 WAC) and revised cannabis-specific quality standards in Chapter 314-55 WAC. We recommend this because Ecology's existing environmental and drinking water laboratory accreditation programs are successful models, and experienced staff can provide technical assistance to laboratories for essential quality assurance practices.

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Introduction

In 2018, the Washington State Legislature directed the Washington State Department of Ecology (Ecology) to research and develop preliminary recommendations for protocols and accreditation standards for cannabis[2] testing laboratories, as stipulated in Engrossed Substitute Senate Bill 6032:

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The Revised Code of Washington 69.50.345 charges WSLCB, in consultation with WSDA, to establish accreditation requirements for cannabis testing laboratories. The WSLCB or its designee accredit cannabis testing laboratories according to Chapter 314-55 WAC.

Currently, cannabis testing laboratories are evaluated by a private accreditation provider under contract with the WSLCB. However, language within Chapter 314-55 WAC does not sufficiently detail cannabis-specific quality standards (methods, method validation protocols, and performance criteria) for laboratories to follow. Such quality standards are necessary for a robust, scientifically sound laboratory accreditation program.

What is Laboratory Accreditation?

Accreditation is the formal recognition that a laboratory is *capable* of producing accurate and defensible analytical data. An accredited laboratory possesses the technical competence to perform an identified scope of work through specified procedures and methods to meet defined quality standards. Accreditation requires evaluation of a laboratory's quality system, staff, facilities and equipment, test methods, records, and reports (Ecology, 2010).

Accreditation assessments are performed by independent entities. These entities must be separate from the laboratories they accredit. They must also be independent from those who establish, set, or authorize the quality standards and methodologies. This arrangement is designed to instill confidence in the laboratories and their results through impartial evaluation of a pre-determined quality system.

Accreditation does *not* prescribe particular procedures, methods, or performance criteria. It ensures that the required methods and standards established by others are practiced and applied appropriately.

Accreditation does *not* designate product standards or quality standards. However, these are necessary to support meaningful accreditation.

Accreditation alone does *not* eliminate the "human factor." It does *not* prevent laboratory personnel from performing short cuts, procedure deviations, and altering or forging measurements during daily use of an

[2] The term "cannabis" is used throughout this document. "Marijuana" will be used in discussions where the referenced context requires this alterative term.

accredited method or procedure. Such human errors may be a result of intentional fraud, incompetence, or inadvertent error.

Accreditation does *not* mean that any specific report or set of data originating in an accredited lab is accurate or defensible (Ecology, 2010).

Research

To comply with this legislative directive, Ecology gathered accreditation data, reviewed current Washington policies and practices, assessed policies and practices in other states, and developed preliminary recommendations.

The WSLCB, DOH, and WSDA provided information and data to support Ecology's research.

Most notably, Ecology obtained copies of comprehensive accreditation program records from the WSLCB-contracted accreditation provider, the RJ Lee Group. Records included initial application packages, lab-written standard operating procedures (SOPs), proficiency testing (PT) data, deficiency findings reports, and follow-up corrective action correspondence. Ecology used these records to assess the current accreditation process, review methods and protocols used by the cannabis testing laboratories, and identify challenges existing within the current cannabis testing system. Appendix A lists the laboratories for which Ecology obtained accreditation records.

To supplement our research, we investigated applied practices of organizations outside of Washington, including the following:

- Colorado Department of Public Health and Environment
- Maryland Medical Cannabis Commission
- New York Department of Health
- Oregon Health Authority and the Oregon Environmental Laboratory Accreditation Program
- Accreditation providers from non-governmental organizations
- Consensus standards organizations
- Proficiency testing sample providers

Additionally, our recommendations and discussions build upon some concepts originally delivered in the 2013 WSLCB-commissioned reports by BOTEC Analysis Corp.[3] The BOTEC papers presented a theoretical discussion of these concepts, while this report presents an observation-based synthesis.

[3] https://lcb.wa.gov/marijuana/botec_reports

Findings

Ecology's review of the current accreditation program, together with deeper evaluations of specific records and current procedures, revealed evidence of both real and potential areas of system failure. The Ecology team made an early determination that it was not appropriate to merely develop a new accreditation standard. It became apparent that Ecology needed to identify critical challenges that would be a barrier for any accreditation system to succeed. The following discussion presents these challenges, and in some cases, a potential path forward is provided. Some examples of other states' mitigation approaches to similar challenges are presented in Appendix B.

Current Quality Standards Are Insufficient

Current quality standards as outlined in Chapter 314-55 WAC are insufficient to support a robust, science-based cannabis laboratory accreditation program. Revisions are needed for methods of analysis; method validation protocols; performance criteria; proficiency testing; and sampling, homogenization, and preparation procedures.

The American Herbal Pharmacopeia 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.

However, the American Herbal Pharmacopeia (AHP) monograph is not a peer-reviewed, validated analytical method or compendium of said methods. Monographs exist as detailed written studies of a single specialized subject or an aspect of it, often by a single author and usually discussing a scholarly subject. Specifically, the cannabis APH monograph provides a substantial discussion of the various botanical attributes and qualities of the cannabis plant and further details topics such as best cultivation practices, history and use, and legality throughout the world. A very limited discussion of analytical approaches for identifying cannabis chemical constituents, both natural (e.g., cannabinoids) and from contamination (e.g., pesticides) is presented. However, this section does not explicitly detail analytical methods, require the use of any one validated method, or provide comprehensive analytical requirements to guide quality testing practices. The cannabinoids determination (potency) discussion covers nearly half of the 12-page analytical section. Also, it does not provide a comprehensive outline of analytical and critical quality assurance practices.[4]

There are some robust analytical methods referenced within the paper. These methods are simply suggested as *possible* for testing cannabis or cannabis products, based on their recognized effectiveness for testing other matrices. Examples include the Environmental Protection Agency (EPA) Residue Analytical Methods (RAM)[5] for testing food commodity products, the Food and Drug Administration's

[4] Missing critical elements: method validation protocols, quality control sample requirements, and other performance criteria to judge the accuracy and reliability of generated data.
[5] https://archive.epa.gov/pesticides/methods/rammethods/web/html/ram12b.html

(FDA) bacterial analytical manual (BAM),[6] and the United Nations Office of Drugs and Crime (UNODC) method for the identification of cannabis though the analytical determination and presence of cannabinoids.[7] However, in each case, the applicability of the analytical method is also noted as likely *limited* due to the lack of empirical evidence that they can appropriately be used to test cannabis or cannabis products. The document further attests that no single analytical method should be expected to test one chemical across all cannabis and cannabis product types.

Laboratory users of this document are left to design their own testing protocols that may or may not be suitable for their intended use, and which may not generate accurate data.

The Good Laboratory Practices Checklist

Currently, the Good Laboratory Practices (GLP) Checklist contained in WAC 314-55-103 is used to certify cannabis testing labs. The auditors use this general checklist to evaluate laboratory operations, quality systems, and laboratory-developed methods designed around insufficient quality standards. Specifically, for evaluations of testing methods, the auditors use the checklist to evaluate and hold laboratories accountable for the criteria the laboratories themselves wrote into their standard operating procedures (SOPs). With weak Chapter 314-55 WAC quality standards, the laboratories are not required to implement methods with specific quality assurance (QA) and quality control (QC) measures to ensure that quality data can be generated. Thus, the laboratories are allowed to design their own levels of QA/QC to be accredited to and regulated against. Cannabis laboratories are using different QA/QC measures, so accreditation is currently inconsistent among laboratories. This checklist does not ensure that only quality products are supplied for Washington consumers.

Proficiency Testing

Determination of a laboratory's capability to generate accurate and reliable data is challenging without augmentations to the current available proficiency testing (PT) system. WAC 314-55-1025 stipulates that the WSLCB or WSLCB's vendor is to determine the sufficiency of the PTs. The WAC further states that the WSLCB can waive PTs if PT samples or PT [vendor] programs are not available. Ecology asserts that PT evaluations are essential and are an integral part of laboratory accreditation.

A PT evaluation is a process where a known sample (PT sample) is provided for analysis, but the chemical constituents are unknown to the laboratory performing the analysis. Testing of PT samples provides laboratories unknown chemical constituents in a representative matrix. They are designed to ensure that there is appropriate implementation and use of laboratory methods. PT evaluation providers use results from all participating laboratories to establish and assess proficiency of (score) each individual participant.

Participation in PT evaluations is required for pre-accreditation and ongoing assessments of competency for all major testing programs to support environmental and public health regulations. These include EPA environmental and drinking water testing programs,[8] food and feed programs[9] in the United States

[6] https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006949.htm
[7] https://www.unodc.org/documents/scientific/ST-NAR-40-Ebook_1.pdf
[8] http://www.nelac-institute.org/content/NEPTP/ptproviders.php
[9] https://www.aphl.org/programs/food_safety/laboratory-accreditation/Documents/Proficiency-Testing-Provider-List.pdf

Department of Agriculture (USDA), and the Clinical Laboratory Improvement Amendments (CLIA) programs.[10] For these well-established programs a wide variety of material and matrix-specific appropriate PT samples are available. PT samples are available for drinking water, and for numerous types of wastes, soils, foods, feeds, pharmaceutical, geological, and mined materials. These PT evaluation samples may be obtainable from the organizations that established the consensus methods, by the regulatory oversite program, or by independent, private for-profit companies.

As with many other state cannabis testing programs, appropriate PT samples are not currently available to laboratories for cannabis testing in Washington State. Two PT providers[11,12] currently offer a selection of a "surrogate" PT samples in matrices such as hops, safflower oil, hemp oil, hemp bud, and solvent-based matrices. These PT sample matrix selections do not cover the breadth of actual cannabis products that require testing (for potency and contaminants) in Washington. Further, for the hemp oil and hemp bud PT sample matrices offered from some producers, availability may be limited should the federal Drug Enforcement Agency (DEA) begin to enforce the gray-area interpretation around interstate distribution. Regardless, these PT samples do not match the levels of constituent(s) (e.g., cannabinoids[13]), matrix, or complexities needed to replicate those observed in the products being tested on a daily basis.

Specifically notable, pesticide detection and quantification in the presence of low or no concentrations of cannabinoids is drastically different from that of pesticides testing in the presence of cannabinoid interferences. Additionally, those provided in a solvent matrix are essentially "analytically ready" and thus do not follow the preparation path and handling of a real non-solvent matrix sample, i.e., homogenization and preparation steps.

It may be practical to establish round robin or interlaboratory comparisons using cannabis and cannabis products for laboratories to participate. Under the current legal restrictions, the cannabis and cannabis products matrix materials appropriate to serve as relevant PT samples would need to come from inside the state. This would be most suitable for assessing potency amongst the laboratories. Contaminant testing comparison studies would need to source one or more samples[14] that contain appreciable levels of the current regulated contaminants. Product(s) containing contaminants may be difficult to obtain from within state stock.

Alternatively, a state program or private company under advisement of the state might source products (within the state) and then spike cannabis and cannabis products with contaminants at various concentrations to replicate actual samples. Currently, Colorado implements a state-run PT program, and Oregon uses a private company to ensure all chemical (and contaminant) constituents are present.[15]

[10] United States Centers for Medicare and Medicaid CLIA PT providers: https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Proficiency_Testing_Providers.html
[11] http://nsi-es.com/proficiency-testing.aspx
[12] https://emeraldscientific.com/
[13] Component containing DEA-restricted constituents.
[14] For all defined appropriate product types, e.g., cannabis flower/trim, edible product(s), pharmaceuticals, inhalants, concentrates, and other intermediates.
[15] For some PT program studies, PT samples may not cover all contaminates, because PT studies often purposely omit a few constituents as a part of the test design.

Cannabis Sampling and Sample Homogenization Procedures

The current cannabis sampling protocol and the lack of detailed sample homogenization criteria are additional challenges. Absence of guidance and properly employed techniques may generate biased samples. Biased samples entering into an accredited analytical testing system will always result in biased reported results. As with analytical methods for testing cannabis, there are no nationally or internationally recognized standard methods for cannabis sampling and sample homogenization.

Cannabis Sampling

The current WSLCB rule describes a basic process for cannabis sampling that permits the licensed producer or processer to collect samples (WAC 314-55-101). Untrained samplers may lack the technical knowledge to collect representative, consistent samples without introducing error and bias into collected samples. Bias introduced at sample collection will persist through all stages of preparation and analysis, resulting in the generation of biased data. Protocols should comprehensively describe approved sampling procedures to include matrix- or product-specific sampling approaches, use of sampling devices, and QA/QC. Sampling activities are not assessed as a part of accreditation. Assessments are restricted to laboratory processes and activities performed by laboratory personnel.

Sample Homogenization

Sample homogenization procedures are defined at the discretion of the laboratory and may lack required protocols or mechanisms to ensure quality criteria. Inefficient and inadequate homogenization practices will lead to variable, non-representative lab testing results. Preparation and pre-preparation methods are not normally evaluated in accreditation activities, unless they are included in the analysis method or in a preparation SOP. These could be assessed as a part of accreditation activities, provided that there is an established procedure and set performance requirements.

Widely Accepted Quality Standards Do Not Exist

The challenge remains that nationally or internationally "recognized," "standard," or "approved" methods validated specifically for the preparation and analysis of cannabis and cannabis products largely do not exist. This is partially due to the infancy of the industry and patchy legal and policy frameworks. Also, the production of validated methods is a demanding undertaking.

In fact, production of validated methods usually requires many months to years of development, rounds of intralaboratory (single) and interlaboratory (multiple) validation studies, and method peer-review, even with established method development protocol, such as those employed by the EPA[16] or the Association of Official Analytical Chemists (AOAC).[17] Method development is further complicated with the need to test drastically differently structured products types, like those in the cannabis industry, such as foods, drinks, pharmaceuticals, and various plant materials, to name a few. Additionally, within each product type, there also may be multiple matrices further necessitating development of distinct matrix-specific protocols.

[16] https://www.epa.gov/measurements-modeling/method-validation-and-peer-review-policies-and-guidelines
[17] http://www.aoac.org/aoac_prod_imis/AOAC/Publications/Official_Methods_of_Analysis/AOAC_Member/Pubs/OMA/AOAC_Official_Methods_of_Analysis.aspx?hkey=5142c478-ab50-4856-8939-a7a491756f48

It may be practical to adopt (and adapt) analytical methods used in other testing programs, including USDA or Food and Drug Administration (FDA) approved methodologies[18] that currently are not recognized for use on cannabis. Other regional cannabis-specific published methods from states,[19] countries,[20] instrument manufacturers, or by the industry itself may additionally warrant further review for suitability to serve as approved methods. Adoption of federal government-authored methods, such as EPA methods, will not come with the same support or technical oversight as is available when they are practiced under their intended scope. Further performance criteria may still need to be added on top of adopted methods to accommodate specific method applications.

Alternatively, it may be practical to adopt or adapt performance criteria or validation protocols from specific testing methods or programs, such as AOAC protocols, to be used in conjunction with non-standard or laboratory-created methods, such as those for determining potency.

Ecology asserts that although the testing laboratories have valuable expertise, experience, and information to contribute to the discussion, it should not be left to each individual cannabis testing laboratories to determine the fundamental and essential critical items: most appropriate methods, method validation protocols, and method performance criteria. Those determinations should be made by regulators, in part to help instill public confidence in lab testing.

Consensus Standards Used Elsewhere

Established consensus quality standards, methods, and method validation criteria are necessary to set the expectations and requirements of doing business to deliver a specific product, for example, cannabis testing for quality assurance.

Industry-specific member-based organizations such as the NELAC Institute (TNI), United States Pharmacopeia (USP),[21] the Association of Public Health Laboratories (APHL) and other large member-based organizations such as ANSI, American Society for Testing Materials (ASTM),[22,23] and International Union of Pure and Applied Chemistry (IUPAC)[24] generate standards and guidance for a wide range of disciplines using a proficient fundamental framework. Regardless of industry or practice, each organizations' participating members donate their time and expertise to collectively drive the mission and objectives to help strengthen the practices, methods, and quality within their industry or discipline.

Generated consensus standards may facilitate government policy or may be developed out of a need to administer an activity to meet a set policy. In some cases, very specific methodologies, procedures, or practices must be developed to perform work to achieve required outputs or to meet policy. Where this is the case methodologies, procedures, and practices are deliberately developed, practiced, perfected,

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[18] https://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/default.htm
[19] Or from within state, such as adopting methods already used within established agency programs (i.e., WSDA).
[20] Methods and practices are anticipated from Canada, due to recent legalization of cannabis nationally.
[21] Responsible for developing and disseminating public standards for medicines and other articles, and engaging in related public health programs. http://www.usp.org/sites/default/files/usp/document/about/convention-membership/2015-2020-bylaws.pdf.
[22] https://www.astm.org
[23] ASTM Committee D37 on Cannabis was formed in 2017 to develop standards for cannabis, its products, and processes: https://www.astm.org/COMMITTEE/D37.htm.
[24] https://iupac.org/who-we-are/strategic-plan.

validated, and peer-reviewed. Acceptance or adoption of these items is often contingent on issuance by governmental or authoritative bodies recognized as following best and appropriate science practices.

As an example, the EPA adopted TNI standards (2009) though implementation of the National Environmental Laboratory Accreditation Program (NELAP). TNI standards build upon International Organization for Standardization (ISO) concepts but are structured to facilitate best policy and practices and to harmonize accreditation specific for environmental analyses. The EPA has developed and validated a large volume of methods, but do also recognize methods developed by ASTM, AOAC, USGS, the American Water Works Association,[25] and a few others. NELAP-participating states administer laboratory accreditations to TNI standards, established program methods, and regulatory policy.

The ISO/IEC[26] 17025 Accreditation Standard Is Not Enough

The International Organization for Standardization (ISO) standards are developed though consensus by technical committees consisting of international members participating from 162 individual nations, including the United States. Participating members sit on technical committees that assist and guide in the development of international standards for processes, products, and personal certifications.

The ISO/IEC 17025[27] accreditation standard was developed by ISO in conjunction with the International Electrotechnical Commission (IEC). It presents the general requirements, specifications, and guidelines necessary to judge the competence of testing and calibration laboratories. The ISO/IEC 17025 standard builds upon the quality management system[28] assessment criteria and basic laboratory concepts. The ISO/IEC 17025 standard serves a broad array of laboratory disciplines by not incorporating explicit details that address any one specific industry's needs, such as application considerations, relevant technologies, or industry standards. Accreditation to the ISO/IEC 17025 standard alone does not distinguish a laboratory's capability to provide any particular laboratory services, such as a capability to test road materials versus cannabis products. An ISO /IEC 17025 accreditation remains vague and general, unless it is paired with established specifications or policy and adoption of other regulatory, industry, or consensus standards.

ISO provides this guidance regarding the use and applicability of the ISO/IEC 17025 standard:

> ISO/IEC 17025:2005 is for use by laboratories in developing their management system for quality, administrative and technical operations. Laboratory customers, regulatory authorities and accreditation bodies may also use it in confirming or recognizing the competence of laboratories. ISO/IEC 17025:2005 is not intended to be used as the basis for certification of laboratories. (ISO, 2005)

Accreditation Providers

[25] https://www.awwa.org/store/productdetail.aspx?productid=28493774
[26] International Organization for Standardization/International Electrotechnical Commission
[27] ISO/IEC 17025:2005 is the current recognized standard edition. In December of 2017 the ISO/IEC 17025:2017 edition was published as an update to the 2005 version. Conformity assessment bodies and testing laboratories are required to transition to the newer version by December 2020. (International Organization for Standardization)
[28] ISO 9001 Quality Management Systems – Requirements. International Standards Organization. Fifth edition. 9-15-2015.

Ecology's Laboratory Accreditation Unit

Within Ecology there is a small team of scientists that functions in a special role to serve as laboratory accreditation specialists. Ecology's Laboratory Accreditation Unit (LAU) is made up of three chemists, a microbiologist, a toxicologist, and an environmental specialist. The unit implements the Washington State Environmental Laboratory Accreditation Program established under provisions of RCW 43.21A.230[29] and satisfies the intent of RCW 43.20.050.[30]

Ecology's LAU accredits to Chapter 173-50 WAC, *Accreditation of Environmental Laboratories*.[31] The WAC in itself does not require environmental laboratories to be accredited; those requirements are specified in other state, federal, or regulatory rules. In 2002 the WAC scope was broadened when Ecology assumed the responsibility of certification of drinking water laboratories to fulfill the federal Safe Drinking Water Act (SDWA) laboratory certifications requirements. A Memorandum of Understanding (MOU) was established by the DOH and Ecology, moving authority to administer accreditation activities to Ecology. The MOU further stipulates that all certifications, decertifications, and provisional certifications taken upon a laboratory shall be the responsibility of Ecology (DOH, 2002).

LAU's program administers both initial accreditations and continuing accreditations for a broad range of categories, including general chemistry, trace metals, organics, microbiology, and toxicology. The first step to any accreditation is submission of a completed application[32] to LAU. The application is reviewed to assess the complexity of the laboratory and assign appropriate accreditation activities and their associated fees. At that time, the laboratory must also submit its Quality Assurance (QA) manual or any changes to an existing QA manual. The QA manual is where a laboratory outlines its policies, organization, objectives, functional activities, and QA and quality control (QC) activities designed to achieve its quality goals. Drinking water laboratories must meet additional drinking water QA plan requirements. An approved QA manual is one by which the laboratory adequately documents its plan to ensure that quality results are generated and reported.

LAU accreditations are to the parameter, or a combination of an analyte and an analytical method, for a specific matrix.[33] Laboratory-generated standard operating procedures (SOPs) are required for all the specific tasks the laboratory implements for each parameter. Some methods (SOPs) can encompass multiple analytes (and/or matrices), for instance, more than one metal by a single determinative analytical method. The scope, applicability, and level of modification, if any, that can made by an end user to a method is defined within the cited original method. For environmental and drinking water laboratories, accredited parameter SOPs are to be generated from approved pre-established published methods.[34,35] Some methods, such as EPA drinking water methods, are prescriptive, and modifications are not permitted. LAU performs SOP document reviews to assess deviations from cited methods and to look for calculation errors and other mistakes.

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[29] http://app.leg.wa.gov/RCW/default.aspx?cite=43.21A.230
[30] http://app.leg.wa.gov/RCW/default.aspx?cite=43.20.050
[31] http://apps.leg.wa.gov/WAC/default.aspx?cite=173-50
[32] https://fortress.wa.gov/ecy/publications/SummaryPages/ECY07004.html
[33] Official scopes of accreditation granted under four matrices: 1) drinking water, 2) non-potable water, 3) solids and chemical materials, and 4) air and emissions.
[34] https://www.epa.gov/sites/production/files/2015-03/documents/testmeth.pdf
[35] Use of alternate methods limited; requiring scrutiny by client, oversight program and/or EPA.

For accreditation, a laboratory's procedures are assessed through review of SOPs, along with data packages displaying initial demonstrations of capabilities (IDCs) and method detection limits (MDLs) or lower limits of quantitation (LLOQs). For continuing accreditations, example client data packages are additionally reviewed to evaluate whether the generated data is reported accurately and appropriately.

Deeper reviews into a laboratory's practices may occur at various stages during accreditation activities. This may include looking further into a laboratory's QA/QC practices to ensure data quality, such as the appropriate implementation of QC samples, calibrations, control charts, corrective action processes, data management, and record keeping. Other scrutiny may be warranted out of review of unexpected or incomplete data generated within the IDCs, MDLs, or LLOQs. Discussions surrounding a laboratory's use of validation techniques to develop a procedure (and SOP) may be necessary to ensure that all method performance characteristics (such as determinations of selectivity, sensitivity, linearity, reproducibility, robustness, and precision and bias) are addressed. Some discussions are requested by laboratories themselves, sometimes outside of accreditation activities, where LAU may be able to provide technical assistance, troubleshooting, or QA training opportunities for the laboratories.

Passing PT results are mandatory to satisfy laboratory accreditation requirements. One recent set of PT results are required for each applicable parameter during the initial application process. Two PT studies must be completed each accreditation year thereafter, with the exception of microbiological and bioassay parameters, where only one PT study is required. PT samples must be acquired from an approved PT provider.[36]

The final requirement for accreditation is an on-site audit to fully determine if a laboratory is capable of producing accurate and defensible data. On-site audits are required at initial accreditations and used as a tool for periodic assessment for maintaining accreditation. The auditor reviews and verifies the accuracy of the information provided in the QA manual and further reviews documentation and other evidence, including personnel training and experience, facility features, sample handling procedures, QA/QC procedures, analytical procedures, and data management practices. Audits may take one or more day depending on the required scope of accreditation. Audit reports are issued following the audit. The report describes findings and actions required in response, and as appropriate, makes recommendations about resolutions of findings (Ecology, 2010). Reconciliation of identified deficient or negative findings is necessary to attain accreditation.

For the laboratories participating in the Washington State Environmental Laboratory Accreditation Program, LAU holds authority to grant, revoke, or suspend accreditations. Additionally, LAU has mechanisms in place to provide interim and provisional accreditation for certain circumstances. LAU may further recognize other accrediting authority of an environmental laboratory located in Washington or out-of-state.

Other Accreditation Providers

In the United States, there are eight recognized accreditation providers of the ISO/IEC 17025 accreditation standard. They are signatories to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA); the ILAC is an impartial organization that operates in

[36] https://ecology.wa.gov/Regulations-Permits/Permits-certifications/Laboratory-Accreditation/Proficiency-testing-providers

conformance to the ISO/IEC 17011 standard.[37] Although they each operate and do business separately, the eight ILAC MRA members jointly agree to facilitate ISO accreditations with a mutually agreed standard process for consistency. ILAC MRA accreditation bodies currently provide ISO 17025 certification services to both non-governmental and governmental organizations under various laboratory disciplines. Only four of the eight ILAC MRA accreditation bodies are likely to provide services for accreditation of ISO/IEC 17025 for the cannabis industry in Washington State:

- American Association of Laboratory Accreditation (A2LA),[38] a nonprofit public membership society.
- ANSI-ASQ National Accreditation Board (ANAB).[39] ANAB is a non-governmental organization that provides accreditation services to public- and private-sector organizations and is jointly owned by the American National Standards Institute (ANSI) and the American Society for Quality (ASQ). ANSI serves as the official U.S. representative and participating member of ISO.
- International Accreditation Service (IAS),[40] a nonprofit, public-benefit corporation.
- Perry Johnson Laboratory Accreditation (PJLA),[41] a privately owned organization.

Washington State Agencies as Laboratory Science Resources

Washington State Department of Agriculture

The WSDA Chemical and Hop Laboratory currently operates as an established program to support investigations of alleged pesticide misuse, monitor pesticide residues in foods, carry out physical grading and chemical analysis of hops, and validate that accurate labeling is implemented for fertilizers. This laboratory ultimately supports USDA, EPA, and FDA regulatory requirements.

In August 2016, the WSLCB and WSDA entered into an interagency agreement (IAA) for the WSDA to develop methods and conduct testing for pesticide residues in cannabis and cannabis concentrates.

For cannabis, the WSDA adapted United States Department of Agriculture (USDA)–recognized methods (Anastassiades et. al, 2003; FDA, 1999, 2002) and validated those methods using USDA Pesticide Data Program (PDP) practices and guidelines (USDA, 2018).[42] Drawing from the WSDA's experience in testing pesticides in other crop plants, two analysis procedures were developed for the analysis of pesticides in cannabis. The WSDA developed two analytical procedures, each utilizing a separate analytical instrument,[43] to fully encompass a comprehensive list of pesticides. Additionally, the WSDA

[37] ISO/IEC 17011: Conformity assessment – Requirements for accreditation bodies accrediting conformity assessment bodies.
[38] http://www.a2la.org/
[39] https://www.anab.org/
[40] https://www.iasonline.org/services/
[41] http://www.pjlabs.com/
[42] USDA Pesticide Data Program's *Chemical Compounds, PDP Commodity Grouping, Method Validation and Quality Control* guidance does not include cannabis in its scope because is not recognized federally as a commodity (USDA 2017).
[43] One procedure calls for a gas chromatography tandem mass spectrometer (GC-MS/MS) and the other a liquid chromatography tandem mass spectrometer (LC-MS/MS).

developed two mill-processing procedures for sample homogenization and one cannabis sample preparation procedure to use in conjunction with their analytical procedures.

Collectively the two WSDA analytical pesticide procedures are capable of screening more than 200 pesticides in cannabis and cannabis concentrates, including a range of pesticides not permitted for use on cannabis crops and pesticides recognized as having a high potential of misuse. This includes the current WAC 314-55-108 action limit list of 59 pesticides, as well as pyrethrins and piperonyl butoxide.

In May 2017, the WSDA received an ISO/IEC 17025 accreditation through A2LA. The accreditation overlays the A2LA Food Testing Program Requirements. These additional requirements contain the 2015 *AOAC International Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals*, which are required by agricultural and food safety regulating authorities. The issued certificate shows the WSDA lab as accredited for three methods to test pesticides, two combustion test methods, and one spectroscopy method. The certificate identifies one accredited pesticide methods as for use with "cannabis and other matrixes." Individual pesticides are not specifically listed in their certification.

The WSDA also developed a cannabis potency procedure based on the AHP monograph. This method was also validated using the PDP practice and guidelines, similar to the process used to validate their cannabis pesticide procedures. The potency procedure is not currently being implemented and is not included in the scope of their current ISO/IEC 17025 accreditation issued in 2017. Their current accreditation runs through July 2019.

Additionally, the WSDA runs a Food Safety and Consumer Services (FSCS) Laboratory. The FSCS implements several programs with grants from the FDA, including but not limited to the Food Emergency Response Network (FERN) and Manufactured Food Regulatory Program Standards (MFRPS).[44]

Collectively the WSDA FSCS runs four laboratory divisions, currently testing milk, milk products, ready-to-eat products such as salads and sandwiches, and other deli items for pathogens, including *Escherichia coli* (*E. coli*) and *Salmonella*. They also test for water activity.[45] Grains and other commodities are analyzed for aflatoxins and other mycotoxins under the WSDA's Animal Feed Program. These pathogens and toxins are currently required for testing in cannabis and cannabis intermediate products.

The FSCS Laboratories are ISO/IEC 17025–accredited and follow the MFRPS, Association of American Feed Control Officials (AAFCO) Quality Assurance/Quality Control guidelines for Feed Laboratories,[46] and AOAC methodologies.

Washington State Department of Health

The DOH does not currently test any cannabis or cannabis products, including edibles or other products designed for a medical use.

The DOH operates its own laboratory divisions, collectively known as the Public Health Laboratories (PHL), which provides public health testing[47] for chemistry parameters,[48] shellfish biotoxins,

[44] https://www.fda.gov/Food/NewsEvents/ConstituentUpdates/ucm523145.htm
[45] *E. coli*, *Salmonella*, and water activity also exist as required tests for cannabis and cannabis products.
[46] https://www.aafco.org/Publications/QA-QC-Guidelines-for-Feed-Laboratories
[47] https://www.doh.wa.gov/Portals/1/Documents/Pubs/301-016-PHLDirectoryServices.pdf
[48] Not currently providing production testing for inorganic chemistry parameters (as of August 2018).

radiochemical, and food microbiology. PHL chemist and microbiologists also provide newborn screening, public health microbiology, to include enteric pathogens, mycobacteriology, parasitology, virology to meet a wide array of public health testing objectives. As with the WSDA, the PHL also participates in FERN, as well as USDA and FDA food safety programs, using AOAC and FDA analytical methods.

The PHL holds seven separate certifications to cover the breadth of their testing capabilities, including a CLIA certification, FDA certificate for food and shellfish, and a Washington State accreditation for copper and lead in drinking water issued by Ecology's LAU.

Cannabis Laboratory Accreditation Models Evaluated

Ecology evaluated four potential scenarios for cannabis accreditation. We settled on the first model (Model One) as the best for development of a defensible cannabis accreditation program in Washington. The other models were examined, but we do not recommend them.

Model One

Ecology's Laboratory Accreditation Unit (LAU) assumes the role of accreditation provider. Laboratories are evaluated using LAU's accreditation framework (Chapter 173-50 WAC) and **revised** cannabis-specific quality standards in Chapter 314-55 WAC.

This model is our recommended approach. Ecology's LAU currently accredits over 450 environmental and drinking water laboratories in Washington. Our staff have decades of experience in evaluating laboratories and supporting them with reliable technical assistance.

This model requires revisions by WSLCB to language in the following WACs:

- Laboratory certification and accreditation requirements (WAC 314-55-0995)
- Quality assurances sampling protocols (WAC 314-55-101)
- Quality assurance testing (WAC 314-55-102)
- Proficiency testing (WAC 314-55-1025)
- Good Laboratory Practices Checklist (removal of WAC 314-55-103)
- Laboratory certification – suspension and revocation (314-55-1035)

This model *may* require revision by WSLCB to language in the following WACs:

- Sections within marijuana product compliance (WAC 314-55-107 and Chapter 246-70 WAC)
- Pesticide action levels (WAC 314-55-108)

Additionally, this model requires the establishment of a Cannabis Science Workgroup (CSW) to collaborate on development of science-based quality standards (methods, method validation protocols, and performance criteria). The CSW should facilitate the WAC updates to ensure a robust, scientifically sound laboratory accreditation program.

Advantages

- ✓ Ecology's staff is well versed in the use of LAU's accreditation framework.
- ✓ Minimal procedural changes to the LAU framework are projected. Thus, LAU accreditation can be implemented quickly once quality standards are set.

- ✓ LAU auditors are capable of providing additional technical assistance to laboratories for fundamental quality assurance practices.
- ✓ LAU auditors will have the subject-matter expertise for evaluation of cannabis-specific laboratory work (e.g., organic chemists, microbiologists, etc.).
- ✓ Detailed audits will include rigorous review of methods, method validation, and performance criteria.
- ✓ Increases public confidence that labs are producing credible, unbiased data.
- ✓ Increases public confidence that product potency is as labeled and products do not contain contaminants.

Disadvantages

- × WAC content revisions require further identification, research, and adoption of scientific principles and practices. This process may be slow and challenging.
- × Participation by Washington State Liquor and Cannabis Board (WSLCB), Washington State Department of Health (DOH), and Washington State Department of Agriculture (WSDA) is essential.
- × Cannabis testing laboratories will need to adapt to a new style of accreditation.

Model Two (evaluated but not recommended)

An International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Agreement (MRA) accreditation provider accredits to an ISO/IEC 17025 accreditation and the **revised** cannabis-specific quality standards in Chapter 314-55 WAC.

This model requires revisions by WSLCB to language in the following WACs:

- Laboratory certification and accreditation requirements (WAC 314-55-0995)
- Quality assurances sampling protocols (WAC 314-55-101)
- Quality assurance testing (WAC 314-55-102)
- Proficiency testing (WAC 314-55-1025)
- Good Laboratory Practices Checklist (removal of WAC 314-55-103)
- Laboratory certification – suspension and revocation (314-55-1035)

This model *may* require revision by WSLCB to language in the following WACs:

- Sections within marijuana product compliance (314-55-107 WAC and Chapter 246-70 WAC)
- Pesticide action levels (WAC 314-55-108)

This model requires the establishment of a Cannabis Science Workgroup (CSW) to collaborate on development of science-based quality standards (methods, method validation protocols, and performance criteria). The CSW should facilitate the WAC updates to ensure a robust, scientifically sound laboratory accreditation program.

In addition, this model:

- Requires utilization of one identified ILAC MRA provider.

- May require collaboration with the ILAC MRA provider to ensure accreditation meets Washington's revised WAC requirements (dependent on provider's level of customizable services).

Advantages

- ✓ Fulfills industry desire for an ISO accreditation.
- ✓ This widely recognized international standard has good name recognition. It may increase public confidence that labs are producing credible, unbiased data, and thus increase public confidence that product potency is as labeled and products do not contain contaminants.
- ✓ Laboratories can market that their accreditation is to the internationally known ISO name.

Disadvantages

- × WAC content revisions require further identification, research, and adoption of scientific principles and practices. This process may be slow and challenging.
- × Participation by WSLCB, DOH, and WSDA is essential.
- × Cannabis testing laboratories will need to adapt to a new style of accreditation.
- × Expected increased costs associated with ISO accreditation.
- × Provider may lack ability to provide technical oversight and assistance.
- × Auditors may not have the subject-matter expertise for evaluation of cannabis-specific laboratory work (e.g., organic chemists, microbiologists, etc.).
- × ISO accreditation uses broad, general systems audits, which may not include detailed review of methods, method validation, and performance criteria.

Model Three (evaluated but not recommended)

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

This model requires revision by WSLCB to language in the following WACs:

- GLP Checklist (WAC 314-55-103)
- Laboratory certification and accreditation requirements (WAC 314-55-0995)

This model *may* require revision by WSLCB to language in the following WACs:

- Quality assurances sampling protocols (WAC 314-55-101)
- Proficiency testing (WAC 314-55-1025)
- Laboratory certification – suspension and revocation (314-55-1035)
- Pesticide action levels (WAC 314-55-108)
- Sections within Marijuana product compliance (314-55-107 WAC and Chapter 246-70 WAC)

This model requires the establishment of a Cannabis Science Workgroup (CSW) to collaborate on updating the GLP Checklist. The CSW should also consult on science-based quality standards (methods, method validation protocols, and performance criteria). The CSW should facilitate future WAC updates to ensure a robust, scientifically sound laboratory accreditation program.

Advantages

- ✓ Possible interim option.
- ✓ Best option to move towards Model One.
- ✓ Revisions to checklist and accreditation requirements may help to reconcile perceived and actual data quality issues.
- ✓ Cannabis laboratories are already accustomed to accreditation to the GLP checklist.

Disadvantages

- × WAC content revisions require further identification, research, and adoption of scientific principles and practices. This process may be slow and challenging.
- × Participation by WSLCB, DOH, and WSDA is essential.
- × Lacks revised quality standards.
- × Accreditation to the revised GLP checklist will not sufficiently overcome the lack of established quality standards.
- × Not a long-term solution.
- × Challenging for LAU to accredit to weak quality standards.
- × Does not increase public confidence that labs are producing credible, unbiased data.
- × Does not increase public confidence that product potency is as labeled or that products do not contain select contaminants.

Model Four (evaluated but not recommended)

Ecology's LAU assumes the role of the accreditation provider, and cannabis testing laboratories are evaluated using LAU's accreditation framework (Chapter 173-50 WAC) and the current "as is" Good Laboratory Practice (GLP) Checklist in WAC 314-55-103.

Advantages

- ✓ Lower implementation costs.
- ✓ Little or no rule-making.
- ✓ Quickest to implement.

Disadvantages

- × Lacks revised quality standards.
- × Accreditation program remains weak due to the lack of cannabis-specific quality standards (methods, validation protocols and performance criteria).
- × Not a long-term solution.
- × Challenging for LAU to accredit to weak standards.
- × Does not increase public confidence that labs are producing credible, unbiased data.
- × Does not increase public confidence that product potency is as labeled or that products do not contain select contaminants.
- × Does not provide a mechanism to correct all perceived and actual data quality issues.
- × Maintains status quo that testing labs do not want.

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Recommendations

To strengthen Washington's cannabis laboratory accreditation program, we recommend four changes:

(1) Develop appropriate quality standards.

The primary challenge to developing a solid accreditation program for Washington State is lack of established quality standards. Quality standards should include determination and establishment of appropriate methods for sampling, preparation, and analysis; method validation protocols; and method performance criteria specific to the established methods.

Cannabis Science Workgroup

Ecology recommends establishment of a Cannabis Science Workgroup to collaborate on development of appropriate quality standards. The CSW would provide science-based recommendations to update language in the WAC sections regarding quality assurance (QA), sampling and homogenization protocols, QA testing, proficiency testing, good laboratory practices, action limits, and product compliance specification with relevant and appropriate scientific practices. Functions of this workgroup should include, but not be limited to:

- defining appropriate applicable methods (approved methods).
- adopting or establishing method validation protocols.
- defining performance criteria.
- assessing appropriateness of emerging testing methods developed by other states programs, countries, or recognized consensus bodies.
- advancing an in-state proficiency testing program.
- scoping an investigations division to detect and prevent sample adulteration and laboratory fraud.

This workgroup should be composed of scientists from multiple disciplines, such as medical doctors, toxicologists, chemists, and microbiologists, with expertise in public health and food- and agriculture-testing methods. CSW should including representatives from the DOH, WSDA, and Ecology. We also recommend the inclusion of cannabis industry non-governmental scientists. The level of non-governmental scientist participation would be based on workgroup mission and scope.

(2) Adopt the new quality standards developed by the Cannabis Science Workgroup.

New quality standards will require revisions by WSLCB to language in the following WACs:

- Laboratory certification and accreditation requirements (WAC 314-55-0995)
- Quality assurances sampling protocols (WAC 314-55-101)
- Quality assurance testing (WAC 314-55-102)
- Proficiency testing (WAC 314-55-1025)
- Good Laboratory Practices Checklist (removal of WAC 314-55-103)
- Laboratory certification – suspension and revocation (314-55-1035)
- Sections within marijuana product compliance (WAC 314-55-107 and Chapter 246-70 WAC)

Additionally, this may require revision of language in pesticide action levels (WAC 314-55-108).

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

(4) Designate Ecology's Laboratory Accreditation Unit as the accreditation provider for Washington State cannabis testing laboratories.

Laboratories will be evaluated using LAU's accreditation framework (Chapter 173-50 WAC) and revised cannabis-specific quality standards in Chapter 314-55 WAC. We recommend this because Ecology's existing environmental and drinking water accreditation programs are successful models, and experienced staff can provide technical assistance to laboratories for essential quality assurance practices.

This recommendation is based on examination of current accreditation practices, review of other states' approaches, and Ecology's experience with scientific methodologies, good laboratory practices, and laboratory accreditation.

Conclusion

Based on our research and findings, multiple actions must take place to establish a robust and defensible cannabis laboratory accreditation program implemented by the Washington Department of Ecology.

The primary challenge to developing a solid accreditation program for Washington State cannabis laboratories is the lack of established quality standards. Moving accreditation to Ecology will require the creation of a Cannabis Science Workgroup to collaborate on the development of appropriate quality standards. The Department of Ecology, the Department of Health, the Department of Agriculture, and the Washington Liquor and Cannabis Board should collaborate to ensure this workgroup has the appropriate expertise. The Cannabis Science Workgroup should inform future WAC updates, which may require revision of language in at least five WACs as outlined in this report. The current accreditation process should remain intact while quality standards for cannabis testing and products are developed and WACs are revised. Finally, once quality standards are adopted into regulation, designate Washington State Department of Ecology as the accreditation provider for Washington cannabis testing laboratories.

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Definitions

Accreditation – (WAC 173-55 definition) The formal recognition by the department (Ecology) that an environmental laboratory is capable of producing accurate and defensible analytical data. This recognition is signified by the issuance of a written certificate, accompanied by a scope of accreditation indicating the parameters for which the laboratory is accredited. The term "accredit" as used in this chapter is intended to have the same meaning as the term "certify" as used in RCW 43.21A.230.

Accuracy – A measure of the closeness of an individual measurement or the average of a number of measurements to the true value. Accuracy includes a combination of random error (precision) and systematic error (bias), components that are due to sampling and analytical operations (EPA, 2005).

Analyte – The constituent or property of a sample measured by an analytical method.

Approved methods – Standard methods or other methods recognized by an entity (oversight program, government body) as applicable for use within a defined system.

Audit – A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives (EPA, 2001).

Audit (technical systems) – A thorough, systematic, on-site, qualitative audit of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a system (EPA, 2001).

Bias – The difference between the population mean and the true value. Bias usually describes a systematic difference reproducible over time, and it is characteristic of both the measurement system and the analyte(s) being measured.

Critical elements – Items that are necessary for consistent generation of accurate and defensible data. These elements are the subject of intense scrutiny throughout the accreditation process.

Certification – Used to mean the same as accreditation in this report. Certification and accreditation may be defined in other systems as separate or unique concepts.

Comparability – The qualitative term that expresses the confidence that two data sets can contribute to common interpretation and analysis of the parameter or matrix of interest.

Completeness – A measure of the amount of usable data obtained from a measurement system, expressed as a percentage of the number of measurements that should have been collected according to the study design.

Data quality indicator – The quantitative statistics and qualitative descriptors that are used to interpret the degree of acceptability or utility of data to the user. The principal indicators of data quality are precision, bias, accuracy, representativeness, comparability, completeness, and sensitivity (EPA, 2005).

Initial demonstration of capability (IDC) – Before analyzing compliance samples, an analytical team must demonstrate acceptable precision, accuracy, sensitivity, and specificity for the method to be used (EPA, 2005).

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Intralaboratory Comparison – A study of an analytical method for which repeatability and reproducibility are measured within a single laboratory.

Interlaboratory Comparison – A collaborative study of an analytical method for which repeatability and reproducibility are measured in at least two laboratories.

Limit of quantitation (LOQ) – The smallest measured amount of analyte in a sample that can be reliably quantified with a specified degree of precision.

Lower limit of quantitation (LLOQ) - defined as the lowest point of quantitation, which, in most cases, is the lowest concentration in the calibration curve. The LLOQ is verified periodically with blank spikes, also known as laboratory control samples (LCSs) using lab-specific statistically based recovery limits, or project limits (EPA, 2005).

Matrix (*pl.* matrices) – The material or compound in which an analyte is retained.

Method – A formalized group of procedures and techniques for performing an activity, systematically presented in the order in which they are to be executed.

Method detection limit (MDL) – The minimum amount or concentration of analyte in the test sample that can be reliably distinguished from zero. MDL is dependent on sensitivity, instrumental noise, blank variability, sample matrix variability, and dilution factor (FDA, 2015b).

Method validation – The process of demonstrating that an analytical method is suitable for its intended use. It involves conducting a variety of studies to evaluate method performance under defined conditions (EPA, 2006).

Method verification – The process of demonstrating that a laboratory is capable of replicating a validated method with an acceptable level of performance (FDA, 2015b).

Parameter – A descriptor of a specific analyte coupled with a specific analytical method.

Peer review – a documented critical review of work by qualified individuals (or organizations) who are independent of those who performed the work, but are collectively equivalent in technical expertise. A peer review is conducted to ensure that activities are technically adequate, competently performed, properly documented, and satisfy established technical and quality requirements. The peer review is an in-depth assessment of the assumptions, calculations, extrapolations, alternate interpretations, methodology, acceptance criteria, and conclusions pertaining to specific work and of the documentation that supports them (EPA, 2001).

Performance criteria – Defined, measurable performance characteristics of an analytical method or process-specific requirements for accuracy, precision, recovery, specificity (selectivity), sensitivity (limits of detection), inclusivity, exclusivity, linearity, range, and scope of application. Criteria may also be set by defining process, i.e., method validation protocols.

Precision – A measure of variability in the results of replicate measurements caused by random error. Also referred to as imprecision. Precision is usually measured as the standard deviation, relative standard deviation, or relative percent difference (Ecology, 2010).

Proficiency testing sample (PT sample) – A sample provided to a laboratory for the purpose of demonstrating that the laboratory can successfully analyze the sample within acceptance limits specified

in the regulations. The qualitative and/or quantitative composition of the reference material is unknown to the laboratory at the time of the analysis (EPA, 2005).

Quality assurance (QA) – An integrated system of management activities involving planning, implementation, documentation, assessment, reporting, and quality improvement to ensure that a process, item, or service is of the type and quality needed and expected by the client (EPA, 2001).

Quality control (QC) – The overall system of technical activities that measures the attributes and performance of a process, item, or service against defined standards to verify that they meet the stated requirements established by the customer; operational techniques and activities that are used to fulfill requirements for quality (EPA, 2001).

QA manual – A document describing the policies, organization, objectives, and specific QA and QC practices within a laboratory.

Repeatability – The measure of variability derived under specified repeatability conditions, such that independent test results are obtained with the same method on identical test items in the same laboratory by the same analyst using the same equipment, batch chemicals and media, and tested in a short period of time.

Reproducibility – The measure of precision derived under reproducibility conditions, such that test results are obtained with the same method on identical test items in different laboratories with different operators using different equipment. A valid statement of reproducibility requires specification of the conditions used.

Robustness – The measure of an analytical method's capacity to remain unaffected by small but deliberate variations in method parameters. This provides an indication of its reliability during normal usage (FDA, 2015b).

Selectivity – The change in instrument response that corresponds to a change in the measured quantity (e.g., analyte concentration). Selectivity is commonly defined as the gradient of the response curve or slope of the calibration curve at a level near the LOQ (FDA, 2015b).

Sensitivity – The ability to detect small changes in the concentration of an analyte in a sample.

Specificity – In quantitative analysis, specificity is the ability of a method to measure an analyte in the presence of components that may be expected to be present. The term *selectivity* is generally preferred over *specificity* (FDA, 2015b).

Standard Methods – Methodology from a government publication or peer-reviewed literature, usually widely accepted based on use of rigorous method validation protocols used during development.

Standard operating procedure (SOP) – A written document that details the method for an operation, analysis, or action with thoroughly prescribed techniques and steps, and that is officially approved as the method for performing certain routine or repetitive tasks (EPA, 2001).

Validated methods – The methods that have undergone validation.

Validation (method) – The process of demonstrating or confirming the performance characteristics through assessments of data quality indicators for a method of analysis.

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Acronyms and Abbreviations

A2LA – American Analytical Laboratory Accreditation

AHP – American Herbal Pharmacopeia

ANSI – American National Standards Institute

AOAC – Association of Official Analytical Chemists

APHL – Association of Public Health Laboratories

ASTM- American Society for Testing and Materials

BAM – Microbiological Methods and Bacteriological Analytical Manual

CAA - Clean Air Act

CDPHE – Colorado Department of Public Health and Environment

CWA - Clean Water Act

DEA – United States Drug Enforcement Agency

DOH – Washington State Department of Health

Ecology – Washington State Department of Ecology

EPA – United States Environmental Protection Agency

EPTAVU - Environmental Proficiency Testing and Validation Unit

FDA – United States Food and Drug Administration

FERN – Food Emergency Response Network

FSCS – Food Safety and Consumer Services

IEC - International Electrotechnical Commission

ILAC - International Laboratory Accreditation Cooperation

ISO – International Organization for Standardization

IUPAC – International Union of Pure and Applied Chemistry

LAU – Ecology Laboratory Accreditation Unit

MFRPS – Manufactured Food Regulatory Program Standards

MRA - Mutual Recognition Agreement

NELAP – National Environmental Laboratory Accreditation Program

NYSDOH – New York State Department of Health

OHA - Oregon Health Authority

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ORELAP – Oregon Environmental Laboratory Accreditation Program

PAM – Pesticide Analytical Manual

PDP – USDA Pesticides Data Program

PJLA – Perry Johnson Laboratory Accreditation

RCRA - Resource Conservation and Recovery Act

SDWA - Safe Drinking Water Act

TNI – The NELAC Institute

USDA – United States Department of Agriculture

WSDA – Washington State Department of Agriculture

WSLCB – Washington State Liquor and Cannabis Board\

UNODC – United Nations Office of Drugs and Crime

USP – United States Pharmacopeia

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Appendix A. Cannabis Laboratories for Which Ecology Received Accreditation Records

Lab Name	City	Status	Initial Certification Date
Steep Hill Labs	Tukwila	Active	8/20/2014
Confidence Analytics	Redmond	Active	6/18/2014
HD Analytics	Lake Stevens	Withdrawn	2/2016
Analytical 360, LLC.	Yakima	Active	5/27/2014
True Northwest, Inc.	Olympia	Active	7/10/2014
Testing Technologies, Inc.	Poulsbo	Active	10/26/2016
G.O.A.T. Labs	Vancouver	Active	7/23/2014
Integrity Labs	Olympia	Active	8/19/2014
Anatek Labs	Spokane	Active	8/20/2014
Green Grower Labs	Spokane	Active	9/23/2014
Dragon Analytical Laboratory	Olympia	Suspended	1/9/2015
Trace Analytics	Spokane	Active	3/4/2015
Medicine Creek Analytics	Fife	Active	5/25/2016
Molecular Testing Labs	Vancouver	Active	9/23/2016
Praxis Laboratory	Centralia	Active	11/2/2017
Treeline Analytics, LLC.	Bellingham	Active	8/17/2018
Capitol Analysis	Lacey	Active	11/9/2016
Peak Analytics Lab Testing Services	Bellingham	Suspended	11/17/2015

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Appendix B. Cannabis Laboratory Accreditation in Other States

Oregon

The Oregon Health Authority (OHA) accredits[49] cannabis testing laboratories under their existing Oregon Laboratory Accreditation Program (ORELAP). ORELAP functions as a federally recognized state body that has been authorized to provide accreditation of environmental laboratories under the National Environmental Laboratory Accreditation Program (NELAP) using TNI:2009 standards. Oregon's ORELAP accreditation program provides laboratory certification for EPA regulatory programs that include testing in support of the Clean Air Act (CAA), the Clean Water Act (CWA), Safe Drinking Water Act (SDWA), and Resource Conservation and Recovery Act (RCRA). NELAP permits Oregon to define specific ORELAP criteria to meet OHA needs to implement their program. The scope of accreditation, the type of laboratory included under the state's program (including the regulatory or voluntary nature of the program itself), the assessment of fees, and the use of third party assessors are all options of the state (NELAP n.d.).

Oregon's existing ORELAP program is a framework for their cannabis lab accreditation extension. OHA has further authored their own standard methods for sampling marijuana,[50] for use by testing laboratories. NELAP does not recognize these methods nor require their use. To further reinforce best sampling practices by qualified personnel, Oregon requires that all cannabis sampling must be performed by trained[51] personnel employed by an ORELAP-accredited laboratory.

Oregon utilizes the same available producers of "surrogate" PT samples as does many states, including Washington. However to fill the lack of relevant in-matrix PT samples, OHA has begun to collaborate with one PT program provider, PHENOVA, to design PT samples using a cannabis flower/trim matrix. Currently only the cannabis flower/trim matrix PT samples are available for testing for pesticides and potency. Oregon's statutes and logistical problems of sourcing (amount and location) and preparing material has impacted the robustness of this program. This currently limits the production of in-matrix PT samples to those made for testing potency (cannabinoids) and for those most affected by the presence of cannabinoids (pesticides). For in-matrix PT samples, once the cannabis is sourced, PHENOVA works in a host laboratory located within Oregon to complete the preparation of the PT samples. The prepared PT samples are delivered to or picked up by laboratories to begin testing.

PHENOVA also provides "surrogate" matrix PTs for testing water activity and moisture, heavy metals, microbiologics, and aflatoxins. Their selection of "surrogate" PTs[52] are produced at their Colorado

[49] https://www.oregon.gov/oha/PH/LABORATORYSERVICES/ENVIRONMENTALLABORATORYACCREDITATION/Pages/cannabis-info.aspx

[50] https://www.oregon.gov/oha/PH/LABORATORYSERVICES/ENVIRONMENTALLABORATORYACCREDITATION/Pages/Sampling.aspx

[51] Training includes an initial 8 hours of classroom training, including principles, procedures, and policies of sampling; field or on-on-the job training in sampling; and an annual 8-hour refresher training.

[52] PHENOVA does not use hemp, because their company has chosen to acknowledge all DEA gray-area restrictions on shipment of hemp.

headquarters. Currently, there is no requirement specifying that when an in-matrix cannabis flower/trim PT sample is available it must be used.

New York

The New York State Department of Health (NYSDOH) Environmental Laboratory Approval Program (ELAP), a separate independent program in the NYSDOH, serves as the accrediting authority over laboratories participating in their medical marijuana testing program. Since its inception in 1984, ELAP has been responsible for certifying states within New York for air quality and emissions, drinking water (SDWA), non-potable water, and solid and chemical materials/wastes (RCRA) to the NELAP TNI:2009 standard.

The NYSDOH adapted their existing environmental accreditation framework for accrediting cannabis laboratories. Cannabis testing laboratories are required to meet the standards set forth in the ELAP Quality System Standards (NYSDOH, 2002) and use specified department-written analytical methods and protocols.[53] The NYSDOH developed and published 21 cannabis-specific method protocols to cover preparation and analysis techniques for cannabinoids, microbiologics, mycotoxins, metals, and pesticides to fill the void of validated standard methods. These methods were based on EPA and USP consensus methods by department scientists experienced with these methodologies. This strategy allows for complete control of methods and method validation protocol, and ensures the all laboratories are accredited to the same methods and performance criteria specific to cannabis.

The NYSDOH also houses an ISO/IEC 17043– and ISO/IEC 17025–accredited and NELAP-recognized entity that provides environmental proficiency testing (PT) samples nationally. The NYDOH Environmental Proficiency Testing and Validation Unit (EPTAVU) is comprised of several state health and environmental laboratories that collaborate to produce and validate PT samples for various testing schemes covering the common environmental parameters. Although a robust PT program design framework exists, currently the EPTAVU does not manufacture cannabis-specific proficiency samples for use by New York marijuana testing labs.

Colorado

Regulation of retail marijuana in Colorado is by the Department of Revenue's Marijuana Enforcement Division, and regulation of medical marijuana is through the Colorado Department of Public Health and Environment (CDPHE). The State Marijuana Laboratory Sciences division, a program within the CDPHE, was granted authority for implementing the statewide marijuana (retail and medicinal) testing laboratory certification program.

The CDPHE provided consultation for all of the scientific aspects of the state's marijuana program. Currently the department fills several roles in the state's cannabis program, in addition to running the marijuana laboratory accreditation program. As a multidisciplinary department, the CDPHE is comprised of many types of science professionals, including chemists, toxicologists, medical doctors, and a variety of other public health specialists. Collectively the CDPHE oversees and facilitates routine duties for protection of public health; technical assistance on laboratory and quality assurance; studies on cannabis

[53] https://www.wadsworth.org/regulatory/elap/medical-marijuana

use, trends, and impacts; and food safety and waste disposal programs. For marijuana sciences, they served and continue to serve as the authority on marijuana laboratory science and practices.

In response to the lack of a standard testing model and concern for the variability in the initial data generated from testing laboratories, the CDPHE developed an approved methods reference library in 2015. The reference library houses CDPHE-approved validated analytical methods and authoritative approaches for the testing laboratories to draw from. With exception to the potency determination, several methods are listed as available to select from for each field of testing. Vetted methods include those employed in government programs or developed by consensus organizations, following method development and validation protocols and policy. Several AOAC, FDA, ASTM, USP methodologies are listed as permissible for use when all applicable controls are incorporated. For the potency analysis, no one method is validated to a level CDPHE recognizes as a validated standard method. For potency, the laboratories are permitted to develop their own protocol from journal articles, papers, or application notes, provided they follow validation protocols from an approved governmental or consensus method program.

To fill the gap in the lack of in-matrix PT samples for potency, the CDPHE established a state PT program, handled by their Health Division, whereby they source cannabis and cannabis products from within their state to manufacture potency PT samples. Their program sources three matrix types from alternating growers and producers to use as PT samples: flower, edibles, and concentrates. Upon agreement with all certified laboratories during stakeholder advisory sessions, the sourced material is brought by a Colorado health scientist to a certified laboratory for processing. Each testing laboratory serves as a host for this process. The Colorado Health scientist homogenizes and subsamples the material for the certified laboratories to then pick-up themselves. Since there is no true value assigned to the material at distribution, Colorado uses the individual test results to generate a robustisized mean, to which each laboratory's test result is then tested against.

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