

# **Application for Initial Certification as a Third-Party Laboratory allowed to conduct required quality assurance tests under WAC 314-55-102 – V.1.0**

## **Overview**

An expectation of the Washington State Liquor Control Board (hereafter referred to as WSLCB or LCB) is that recreational marijuana be provided in a manner that protects the health and well-being of the public. You are applying for *initial* certification, from the WSLCB, to provide Quality Assurance Testing in support of I-502 as articulated in WAC 314-55-102 and supporting implementation documents. As such, please ensure you are using the most current version of the current WAC 314-55-102 requirements as well as those requirements found in the current Good Laboratory Practices checklist and the American Herbal Pharmacopoeia, *Cannabis Inflorescence* monograph. Out-of-date versions of, or references to any of these specifications will not be accepted.

Initial Application: There are two choices you can make concerning initial certification status requested; “Provisional” or “Non-Provisional”. The definition for each follows and must be carefully considered.

### *Provisional:*

The Laboratory applying:

- Is already operating as a business;
- Has a QA program in place;
- Has the right people and credentials in place;
- Has the necessary instrumentation/equipment and supporting procedures in place, and
- Can demonstrate acceptable performance through a combination of:
  - Existing certifications/certifications
  - Documented Demonstration of Capabilities
  - Documented performance through other certifications/certifications in relevant technical areas
  - Demonstration of capabilities through other means

A Laboratory designated and accepted as meeting *Provisional* status can be allowed to proceed with testing *provided* an initial assessment is scheduled within six months of application.

The Laboratory shall complete and submit this application, including related documents as specified, and pay an application fee to cover the costs of the review required to complete the application stage.

An On-Site Assessment will be scheduled as soon as practical but no later than three months following acceptance as meeting the requirements for *Provisional* status.

The Laboratory shall pay a fee for the On-Site Assessment that includes assessor time as well as all travel and per diem expenses.

*Non-Provisional:*

The Laboratory applying:

- Is an established business,
- The Laboratory does not have an established “track record” to demonstrate limited liability associated with “Provisional” status.
- The Laboratory applying has:
  - Hired staff, and
  - Secured necessary instrumentation/equipment, and
  - Developed QA and procedural practices but *cannot*
  - Demonstrate implementation of QA, resource and procedural practices.

A Laboratory designated and accepted as meeting *Non-Provisional* status will not be allowed to proceed with testing until an initial assessment is completed and the Laboratory is deemed competent to execute the work scope.

The Laboratory shall complete and submit this application, including related documents as specified, and pay a fee to cover the costs of the review required to complete the application stage.

An On-Site Assessment will be scheduled at a mutually agreed upon time following acceptance as meeting the requirements for *Non-Provisional* status. That is, the Laboratory shall identify a time for the assessment when the Laboratory believes it can demonstrate consistent application of the requirements of this Certification. The Laboratory shall pay a fee for the On-Site Assessment that includes assessor time as well as all travel and per diem expenses.

Following initial approval, each Laboratory will be required to submit an annual renewal application. In addition, an On-Site Assessment is required every two years following the initial Certification date, commensurate with demonstrating acceptable performance.

## **Instructions**

In order to complete the initial application process all forms included in this package must be completed. In addition, the following supporting documentation shall be provided along with this application.

1. An information only copy of the Laboratory’s QA Program. The QA Program may be one, stand-alone, document or a series of related documents.
2. Information only copies of Laboratory-developed Standard Operating Procedures (SOPs) for all tests required. If you are applying for optional tests then these applicable SOPs must also be submitted.
3. Demonstration of Capability results for tests performed in support of this certification if applying for Provisional Status.

## FORM 1: General Information

<p><b>Date:</b></p> <p><b>Washington State Business License Identification:</b></p>	<p><i>(Please check appropriate box)</i></p> <p><input type="checkbox"/> <b>Provisional</b></p> <p><input type="checkbox"/> <b>Non-Provisional</b></p>
<p><b>Laboratory Name:</b></p> <p><b>Laboratory ID#</b> <i>(if any):</i></p>	<p><b>WSLCB Point of Contact:</b></p> <p>MJ Examiner Program (360)-664-1614</p> <p>MJExaminer@lcb.wa.gov</p>
<p><b>Company Name</b> <i>(If different from laboratory name), indicate relationship of Laboratory to larger corporate entity (if any) :</i></p>	<p><b>Street Address and phone number:</b> <i>(i.e., physical location and number to be covered by this certification, P.O. Boxes not acceptable):</i></p>
<p><b>Owner(s)</b> <i>(If privately held) and Legal Status</i> <i>(e.g., "wholly owned subsidiary"):</i></p>	<p><b>Mailing Address</b> <i>(If different from street address, P.O. Boxes are acceptable):</i></p>
<p><b>Contact Name</b> <i>(Contact person for information regarding this application):</i></p> <p><i>Is this also the Primary contact for the laboratory? <input type="checkbox"/> yes <input type="checkbox"/> no</i></p>	<p><b>Billing Address</b> <i>(if different from street address):</i></p>
<p><b>Contact Person's Title:</b></p>	<p><b>Billing Contact Name</b> <i>(Person to contact regarding billing information):</i></p>
<p><b>Contact Person's Telephone Number:</b></p>	<p><b>Billing Contact Telephone Number:</b></p>
<p><b>Contact Person's Fax Number:</b></p>	<p><b>Billing Contact's Fax Number:</b></p>
<p><b>Contact Person's E-Mail Address:</b></p>	<p><b>Billing Contact E-Mail Address:</b></p>

**Is the laboratory currently under investigation or suspension by a governmental or private certification /certification agency?** *(Please check appropriate box)*

Yes                       No

If yes, attach a separate sheet describing the dates and circumstances of the investigation or suspension and discuss any applicable corrective actions.

**Check the laboratory type applies to this**

**application:** *(Please note that each laboratory/facility type requires a separate application).*

Fixed Site Laboratory

Mobile Laboratory

**Laboratory Certifications:** Is the laboratory accredited to ISO/IEC 17025 or another relevant standard by another accrediting body?  Yes                       No

**If yes, please indicate the accrediting body, certificate number, the programs for which this certification is held and how it is relevant to this scope of testing.**

## Form 2 Special Considerations for On-Site Assessment

<p>Please note any requirements that the Assessor should be aware of while arranging for your On-Site assessment. Some common special requirements are included, but not limited, to the list below. If there are any arrangements that the Assessor needs to make prior to the assessment or while on-site, please list them below. If there are any other special requirements not specifically listed, please describe them under "Other"</p>	
<b>Safety Requirements (e.g., training requirements)?</b>	
<b>Security Requirements (e.g., clearance levels, security check-in, and anticipated delays)?</b>	
<b>Can the assessor bring a laptop computer on-site? Can the assessor access the internet from on-site?</b>	
<b>Can the assessor park a car on-site? Any special parking arrangements?</b>	
<b>Should the assessor contact the laboratory before making lodging arrangements for special rates, etc.?</b>	
<b>Normal hours of operation? (e.g., 8am - 5pm, Monday - Friday)</b>	
<b>Other?</b>	

### Form 3 – Methods & Proficiency/Competency Participation Plan

Certification Parameter	Fields of Testing (FoT)	In-House Method No. (e.g., SOP-T01)	Published Reference Method	Demonstration of Competency or PT Participation Program	Scope Verification (to be checked by assessor)
Moisture <i>(Required)</i>	Gravimetric Automated Moisture Analyzer Other				
Foreign Matter <i>(Required)</i>	Visual Microscopic Sieving Other				
Potency <i>(Required)</i>	GC/FID LC/UV-VIS GC/MS LC/MS TLC (Screening Only) Other				
Residual Solvents <i>(Required)</i>	GC/MS: a) Headspace b) Purge & Trap c) Thermal desorption Other				
Microbial Analysis <i>(Required)</i>	qPCR identification Plating & Culturing Antibody method Other				

Certification Parameter	Fields of Testing (FoT)	In-House Method No. (e.g., SOP-T01)	Published Reference Method or In-House Method	Demonstration of Competency or PT Participation Program	Scope Verification (to be checked by assessor)
Terpenes <i>(Optional)</i>	GC/FID LC/UV-VIS GC/MS LC/MS Other				
Pesticides & Fungicides <i>(Optional)</i>	GC/MS GC/MS/MS LC/MS LC/MS/MS Plate Reader Assay Kits Other				
Metals <i>(Optional)</i>	ICP/OES ICP/MS AA CVAA (Mercury Only) CVAF (Mercury Only) Other				



## FORM 5 – MANAGEMENT/QUALITY MANAGER - DOCUMENTATION OF EXPERIENCE

**INSTRUCTIONS:** Complete this form for both the Scientific Director and Quality Manager listed on Form 4, "Management Summary". Do not attach a resume. All laboratories must comply with the Scientific Director and Quality Manager (QM) requirements in the Good Laboratory Practice requirements.

Name:		
Telephone No.	Fax No.	E-mail

### Educational Degrees

<input type="checkbox"/> BS/BA	Year Earned:	Institution:	Major:
<input type="checkbox"/> MS/MA	Year Earned:	Institution:	Major:
<input type="checkbox"/> PhD	Year Earned:	Institution:	Major:

### Certifications

Professional certifications? <input type="checkbox"/> Yes <input type="checkbox"/> No		
<i>If yes, specify:</i>		
Type of Certification:	Certification Body:	Certification Number, if applicable:
Type of Certification:	Certification Body:	Certification Number, if applicable:

Places of Employment	Dates of Employment	Duties and Responsibilities <small>(Categories of Analyses and/or Analytes; matrices; instruments used; Analyses vs. Management)</small>	% Classical Chemistry	% Organic	% Inorganic	% Other * <small>explain if relevant to scope of certification</small>

DUPLICATE PAGE AS NECESSARY.

### FORM 6 - ANALYSTS/TECHNICIANS

**INSTRUCTIONS:** List all analysts/technicians performing analyses pertinent to this application. Please enter the total number of years of experience for all laboratory work in the "Total Years Laboratory Experience" column and applicable years of relevant work experience in discipline specific categories as applicable.

Analyst/Technician Name	Job Function <i>(Please include "A" for Analyst or "T" for Technician)</i>	Highest Education Level and Degree Concentration <i>(e.g. high school, BS Chemistry)</i>	Total Years Laboratory Experience	Analyst/Technician Experience <i>(enter years of experience in each Scope Category)</i>		
				Classical Chemistry	Organic	Inorganic

**Explanatory Statement(s), if needed:**

**DUPLICATE THIS FORM AS NECESSARY.**

## FORM 7 - INSTRUMENTS AND EQUIPMENT

**INSTRUCTIONS:** Please indicate the number of instruments currently in use in the laboratory in the “Number In Use” column. Fill out this form completely, listing only those instruments that are applicable to the testing performed in support of WAC 314-55-102 for which the laboratory is applying. Please list additional equipment in the blank spaces below or add additional lines to the table as necessary to illustrate detector sub-types.

TYPE OF EQUIPMENT	NUMBER IN USE
Gas Chromatograph	
GC/MS	
AA, Flame	
AA, Graphite Furnace	
AA, Cold Vapor	
ICP	
ICP/MS	
Ion Chromatograph	
HPLC	
UV/VIS	
IR or Scanning IR	
X-ray Diffractometer	
PCM	
PLM	
TEM	
SEM	
XRF	
ISE	
Thermal Optical Analyzer	
ASV (Anodic Stripping Voltammeter)	
Optical Fluorimeter	
Balance(s)	
Compound Microscope with 1000x	
Fluorescence Microscope (Legionella)	
Class II Biological Safety Cabinet	
Autoclave/Steam Sterilizer	
Stereoscope	
Incubators ( <i>number in use and operating temperature</i> ):	
Other	

**FORM 8 - REGULATORY COMPLIANCE**

Certification of Compliance with Applicable Environmental, Health and Safety Standards

On behalf of \_\_\_\_\_,  
(Name of Laboratory)

I certify that, to the best of my knowledge:

1. The Laboratory mentioned above complies with all applicable federal, state, and local health, safety, and environmental standards; and
2. The Laboratory mentioned above maintains a waste management system for proper disposal of samples.

I also certify that I understand that the site assessment is not a safety inspection, has no safety related purpose, and that the sole purpose of the site assessment is to evaluate the ability of the laboratory to perform the analyses related to this certification program.

Printed Name:	Title:
Signed:	Date:

## FORM 9 - INDEMNIFICATION AND CERTIFICATIONS

### COMPLIANCE WITH REQUIREMENTS

NOTE: This section is to be signed by an authorized representative of the laboratory and returned as part of the application for certification.

On behalf of: \_\_\_\_\_  
(Name of Laboratory)

I certify that:

1. I have read the requirements for certification;
2. The laboratory above complies with the requirements;
3. The information contained in this application is correct;
4. The laboratory above agrees to notify the WSLCB within twenty (20) business days of any changes that significantly affect the laboratory's
  - a. legal, commercial or organizational status;
  - b. organization and management;
  - c. policies or procedures, where appropriate;
  - d. premises;
  - e. personnel, equipment, facilities, working environment or other resources;
  - f. authorized signatory;
  - g. any other matters that may affect the laboratory's capability, scope of certification, or compliance with requirements for certification;
5. Misrepresentations in this application may be grounds for withdrawal or denial of certification;
6. The laboratory mentioned above will not use its certification in such a manner as to bring the WSLCB or its agents into disrepute and will not make any statement relevant to its certification which the WSLCB may consider misleading or unauthorized;
7. Upon suspension or withdrawal of certification (however determined) the laboratory mentioned above will forthwith discontinue use of all advertising matter that contains any reference thereto and will return its certificate to the WSLCB;
8. The laboratory above will not use this certification to imply product approval by the WSLCB;
9. The laboratory above shall keep current on updates to WSLCB policies;

10. The laboratory mentioned above maintains impartiality and integrity in its dealings with clients requiring WSLCB licensing;
11. The laboratory mentioned above shall permit a WSLCB representative(s) to have access to the laboratory for the purposes of examining documentation, records and personnel, assessment of calibration and testing, reassessment, surveillance, resolution of complaints and any other issues necessary to verify compliance with the requirements for certification;
12. The laboratory mentioned above shall pay all fees according to the required schedule;
13. The laboratory mentioned above shall submit any and all necessary information to assess conformance to certification requirements;
14. The laboratory mentioned above shall continually commit to fulfill the requirements for certification set by the WSLCB for the areas where certification is sought or granted. This includes an agreement to adapt to changes in the requirements for certification;

\_\_\_\_\_ and its successors  
 (Name of Laboratory)

assigns, releases, indemnifies and holds the Washington State Liquor Control Board, its, site assessors, contractors, employees and representatives harmless from any and all claims, demands, suits and judgments by or on behalf

of \_\_\_\_\_, its employees and third persons  
 (Name of Laboratory)

by reason of any damage, death or injury resulting from accidents, exposure to or consumption of harmful substances, food or food products, and the unsafe operation of the laboratory facilities.

Printed Name:	Title:
Signed:	Date: