BARBADOS MEDICINAL CANNABIS LICENSING AUTHORITY

LABORATORY LICENSE GUIDE

Let's Grow Together

The Barbados Medicinal Cannabis Industry Act, 2019, (the Act) establishes that an application for a license must be filed with the regulatory body, the Barbados Medicinal Cannabis Licensing Authority (BMCLA), in the form and manner specified by the Act and the Barbados Medicinal Cannabis Industry Regulations, 2020 (the Regulations) and must include all the information required.

This Laboratory Guide provides general terms and conditions for the operation of a Laboratory License within the medicinal cannabis industry.

This Guide should be read in conjunction with the Act, the Regulations and the General License Guide. This Laboratory Guide is intended to supplement the provisions of the Regulations.

It is the responsibility of the applicant to ensure that they are familiar with these guidelines and the Regulations. Your application may be denied, or your operations delayed, suspended or your license revoked if you fail to meet the requirements outlined.

The BMCLA is committed to protecting personal information as well as confidential business information that is under its possession. Ensuring the confidentiality, integrity, and availability of information is essential to the regulator's decision making and the delivery of services. The BMCLA recognizes that the protection of this information is an essential element in maintaining public trust.

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Disclaimer
This document is a living document, which may be updated and changed by the BMCLA as it sees fit. Users are advised to ensure they are using the most recent version.

In the case of any discrepancies between this document and the Act and the Regulations, please seek direction from the BMCLA.

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LET'S GROW TOGETHER

FOREWORD

The Barbados Medicinal Cannabis Industry Act, 2019 (the Act) was proclaimed on September 30, 2020. It establishes the conditions under which the Medicinal Cannabis Industry in Barbados will operate. Provisions for the licensing regime, patient access to medicinal cannabis and the establishment of the regulating Authority, the Barbados Medicinal Cannabis Licensing Authority (herein referred to as the BMCLA) and its Board are all found within the Act. Further, the Act is supported by the Barbados Medicinal Cannabis Industry Regulations, 2020 (the Regulations).

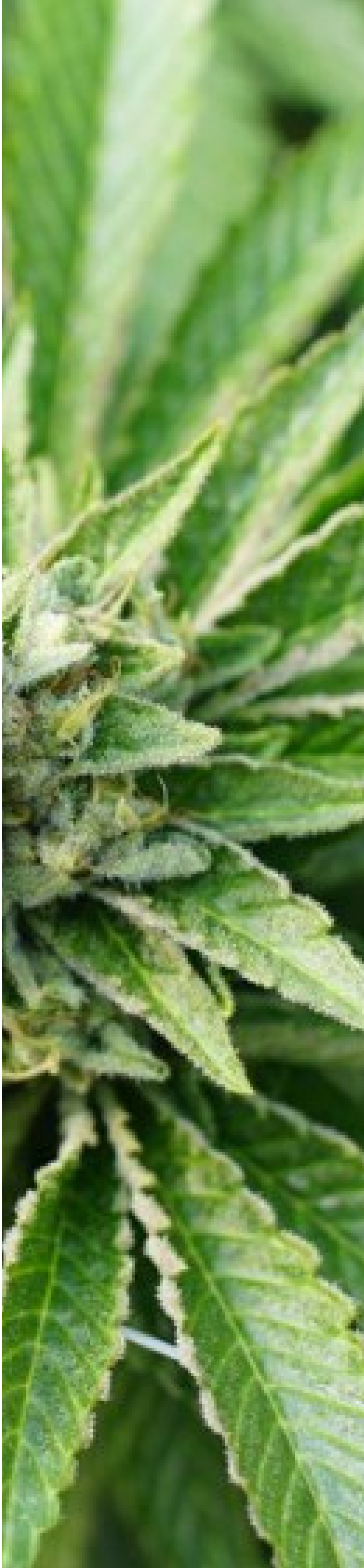
This guidance document should be read with reference to both the Act and the Regulations. The intent is to provide further direction to the applicant based on the provisions established in the aforementioned documents. It also sets out the rules and regulations for a Laboratory License.

Section 4 (1) of the Act provides for the BMCLA to develop policies, procedures and guidelines for the industry. Additionally, section 4 (2) of the Regulations also provides the BMCLA with the right to request any additional information that pertains to the licensee, its agents or directors and that is necessary to consider the application. It is the responsibility of all applicants to make sure that they are aware of all rules, regulations and policies which pertain to their application and operations.

The BMCLA is not responsible for any circumstance in which an applicant or licensee might find themselves non-compliant due to lack of awareness of the necessary requirements.

This document, while aimed at being comprehensive, may not contain every answer an individual may need. In those cases, it is suggested that the applicants contact the BMCLA at clo@bmcla.bb or visit the BMCLA's website www.bmcla.bb.

The overall intent of the regulatory framework, including all guidelines governing the Barbados Medicinal Cannabis Industry, is to ensure patient safety and the administration of an orderly and efficient industry.



GLOSSARY

Certificates of Analysis
A Certificate of Analysis (COA) is a document issued by a laboratory to confirm whether a regulated product meets the quality specifications.

ISO/IEC 17025
This is the general requirements/standards for the competence of testing and calibration in laboratories.

Laboratory Quality Assurance (LQA) programme
The purpose of the quality assurance program is to assure that all laboratory testing is performed according to the principles of current Good Laboratory Practice (GLP).

Limit of Detection (LoD)
Limit of Detection (Lod) is the lowest concentration level that can be determined to be statistically different from a blank (99% confidence). Limits of detection are matrix, method and analyte-specific.

Limit of Quantitation (LoQ)
Limit of Quantification or lower limit of quantification is the level above which quantitative results may be obtained with a specified degree of confidence. Limits of quantification are matric, method and analyte-specific

Standard Operating Procedures (SOPs)
These are Standard Operating Procedures which are collated into a document consisting of step by step instructions on how to complete a particular job or procedure within the licensed activities.

BACKGROUND

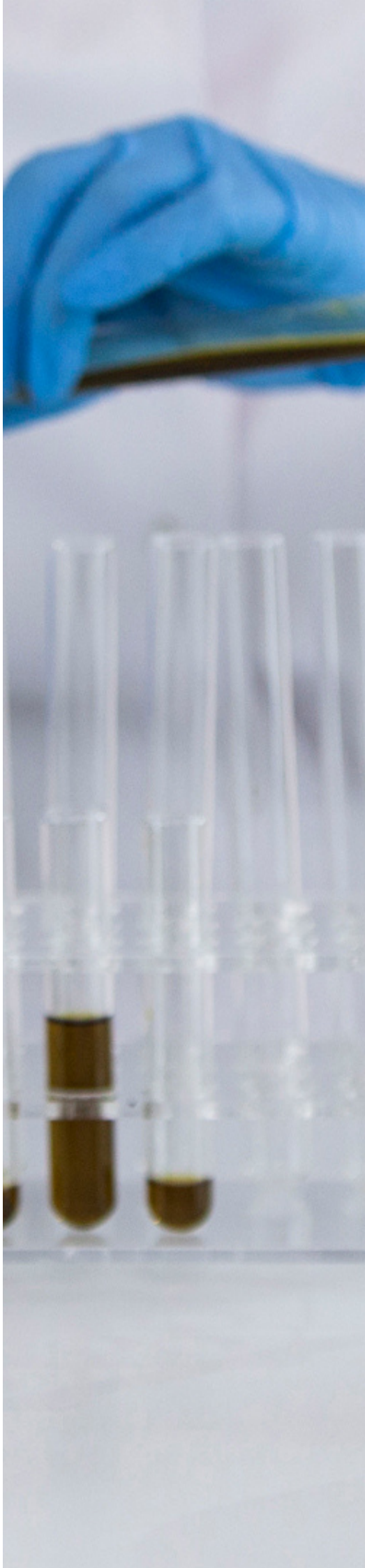
The Barbados Medicinal Cannabis Industry Act, 2019 (the Act) and the Barbados Medicinal Cannabis Industry Regulations, 2020 (the Regulations) provide, among other things, the framework for legal access to medicinal cannabis, control and regulation of medicinal cannabis use and commercial engagement in Barbados. It in no way makes legal the use in the production, manufacturing and handling of cultivation or production of cannabis for any purpose other than that as stated under the Act. The Act lays out the allowance under which persons can engage in medicinal cannabis within the jurisdiction of the Barbados Government.

The Act speaks to the establishment of the BMCLA, the allowance for the use of cannabis for medicinal purposes, which must be prescribed by a doctor and dispensed by a licensed pharmacist (as defined under the Pharmacy Act, Cap. 372D). The Act also makes provision for the establishment, licensing, regulation, monitoring, control and enforcement of the medicinal cannabis industry by the BMCLA. It established eight (8) different types of licenses and tiers and gives the BMCLA the sole right and responsibility for the importation, cultivation, processing, exportation, transportation, analyzing as well as research and development of cannabis for medicinal purposes.

Under this framework, a person is required to obtain a license issued by the BMCLA in order to conduct various activities with cannabis. Applicants and license holders are responsible for compliance with the Act and the Regulations as well as compliance with other applicable laws, as made by the Government of Barbados.

The Act establishes that an application for a license must be submitted to the BMCLA in the form and manner specified by the Regulations and must include all requested information and supplemental documentation as requested. This guide sets out the application process including the form and manner for submitting an application and the information that is required.

The BMCLA will publish other guidance documents and information as needed on its website (www.bmcla.bb) that may be used in conjunction with this document to assist applicants in preparing their applications. In order to maintain consistency and transparency, this guide, as well as other guidance documents and information, will be updated, as required, to reflect changes to policies and/or operations.



GENERAL REQUIREMENTS

1. Licensed Activities

1.1. Laboratory License shall be issued to allow for the conduct of testing and analytical services associated with improving or further developing medicinal cannabis.

1.2. Entities with a Laboratory license are permitted to engage in the commercial activity of conducting testing and analytical services associated with medicinal cannabis.

This is not internal testing, whereby a licensee may test their own product, internal testing does not require a Laboratory license.

If at any time a Licensee attempts to test the product of another license this becomes a commercial activity and requires a license.

1.3. All testing and analytical services of medicinal cannabis must be for entities licensed by the BMCLA.

1.4. Laboratory Licensees will automatically receive an import and an export licence as specified in section 31 (2) (a) of the Act.

However, the import and export licenses may only relate to the specified laboratory activities. In other words, the import and export license granted with the Laboratory license cannot be used for purposes outside of those relating to imports and exports for the purposes of analytical testing.

2. Premises

2.1. All Laboratory Licensees must be able to show the following designated areas within their premise plans:

- office area;
- laboratory;
- chemicals storage and usage areas;
- hazardous chemical storage;
- chemical emergency areas;
- secured areas for the storage of medicinal cannabis materials and products in all forms used for testing; and
- secured areas for the storage of medicinal cannabis meant for disposal and disposal areas.

3. Testing

3.1. All laboratories are required to issue Certificates of Analysis (COA) for every sample they are contracted/engaged to test.

3.2. On this COA, the laboratory should include the results of all tests performed and include a findings report/comments, explaining the results of each test.

3.3. All laboratories are required to upload a copy of all COA to the BMCLA's Track-and-Trace system, simultaneously to the results being given to the contracting party.

4. Certificate of Analysis

4.1. All COAs must carry at a minimum the following details:

- laboratory's name and BMCLA licensed name, address, and license number;
- batch number of the batch from which the sample was obtained,
- sample identifying details including unique sample identifiers;
- sample history, harvest or production date, including the date the sample was received by the laboratory and date of analysis;
- for dried flower samples, the total weight of the batch, in grams, and the weight of the sample;
- in the case of medicinal cannabis product, the total unit count of both the representative sample and total batch size
- the analytical methods, analytical instruments and the corresponding limits of detection (LOD) and limits of quantitation (LOQ- the highest concentration of the substance detected);
- a pass or fail grade for each test performed
- when reporting results for any analytes detected the following method should be used:
  - <LOD - Lowest quantity which can be detected
  - <LOQ - Highest concentration of analytes detected
  - ND - None Detected
  - NT - Not Tested

5. Remediation & Re-testing

5.1. The licensed cultivator or processor may engage in the remediation of any batch which fails testing standards.

5.2. The batch must then be re-tested and may only be sold if it successfully passes the retesting.

5.3. If the batch fails retesting, it must be destroyed.

5.4. Any batch which is not remediated or reprocessed must be destroyed.

6. Post testing sample retention

6.1. Any portion of a sample not used in the testing process may only be kept for a period of 30 business days after having been received.

6.2. The sample must then be destroyed via the processes in keeping with the disposal guidelines and the disposal plan the laboratory previously submitted.

7. Standards

7.1. All laboratories are required to keep all testing equipment in good working order.

7.2. All laboratories are required to operate at a peer-reviewed level and be in an active movement towards achieving ISO 17025 standard.

7.3. All laboratories are required to show the BMCLA proof of achieving ISO/IEC 17025 certification.

7.4. Licensees are required to develop, maintain and follow a Quality Management System with activities to establish and control the work processes from preanalytical through post-analytical processes, manage resources, conduct evaluations, and make continual improvements to ensure consistent quality results.

8. Laboratory Audits

8.1. All laboratories shall conduct an internal audit annually or in accordance with the ISO/IEC 17025 requirements.

8.2. The internal audit should include all the aspects required under ISO/IEC 17025 certification.

8.3. Within one (1) week of the completion of the audit the laboratory should furnish the BMCLA with a copy of the report.

8.4. The BMCLA may at its discretion audit any laboratory procedures and processes and may do so using internal or external experts.

8.5. Per provision 24 (d) of the Regulations, any laboratory that has not successfully achieved ISO/IEC 17025 certification within the two-year timeline, must write to the authority, advising them as to:

- the reason for the delay,
- the steps the laboratory is taking to rectify the problem,
- the timeline within which the laboratory will achieve the certification, and
- requesting an extension.

9. Laboratory Quality Assurance (LQA) programme

9.1. The laboratory must develop and have available upon request a written LQA programme to assure the reliability and the validity of the analytical data produced by the laboratory.

The LQA programme shall, at a minimum include a written LQA manual that addresses the following:

- Quality control procedures;
- Laboratory organization and employee training and responsibilities, including good laboratory practice;
- LQA objectives for measurement data;
- Traceability of data and analytical results;
- Instrument maintenance, calibration procedures and frequency;
- Performance and system audits;
- Corrective action procedures;
- Steps to change processes when necessary;
- Record retention and document control;
- Test procedure standardization; and
- Method validation

9.2. The supervisory or management laboratory employee shall annually review, amend if necessary, and approve both the LQA programme and manual when they are created and when there is a change in methods, laboratory equipment or the supervisory or management laboratory employee.

10. Laboratory Quality Control (LQC) Samples

10.1. The Laboratory shall be allowed to purchase and keep LQC samples and adhere to Good Laboratory Practices (GLP) in the performance of each analysis according to the following specifications:

- The laboratory shall analyze LQC samples in the same manner as the laboratory analyzes medicinal cannabis samples.

- The laboratory shall use at least one negative control, one positive control and one laboratory replicate sample in each analytical batch for each target organism during microbial testing. If one of the controls produces unexpected results, the samples shall be re-prepped and re-analyzed with a new set of controls.

- If the results of the microbial analyses are outside the specified acceptance criteria in the following table, the laboratory shall determine the cause and take steps to remedy the problem until the results are within the specified acceptance criteria:

Laboratory Quality Control Sample	Acceptance Criteria	Corrective Action
Method Blank Sample	Not to Exceed LOQ	Reanalyze the entire analytical batch, once. If the method blank is still greater than the LOQ for any analyte, locate the source of contamination then re-prep samples and reanalyze.
LCS	Percent recovery 70% to 130%	Reanalyze the entire analytical batch, once. If problem persists, re-prep samples and reanalyze or re-run the initial calibration curve.
Laboratory replicate sample	RPD ≤ 30%	Reanalyze sample and associated replicate samples once. If problem persists re-prep samples and re-analyze
Matrix Spike Samples	Percent recovery between 70% to 130%	Reanalyze sample and associated matrix spike sample once. If problem persists re-prep samples and re-analyze
CCV	Percent recovery between 70% to 130%	Reanalyze all samples that followed the last CCV that met the acceptance criteria. If CCV still fails, re-run the initial calibration curve and all samples in analytical sequence.

10.2. If any analyte is detected above any action level, as described in this part, the sample shall be re-prepped and reanalyzed in replicate within another analytical batch:

- For quantitative analyses, the re-prepped sample and its associated replicate shall meet the acceptance criteria of RPD ⩽30 %.

- For qualitative analyses, the re-prepped sample and its associated replicate results shall concur.

10.3. If any LOC sample produces a result outside of the acceptance criteria, the laboratory cannot report the result and the entire batch cannot be released for sale. The laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.

10.4. If the Laboratory determines that the result is a false-positive or a false-negative, the BMCLA may request the laboratory to re-sample or re-test.

10.5. The laboratory shall compile and generate one LQC sample report for each analytical batch that includes LQC acceptance criteria, measurements, analysis date and matrix.

11. Limits of detection (LOD) and Limits of Quantitation (LOQ) for Qualitative Analyses

11.1. The laboratory shall calculate the LOD for the chemical method analyses according to any of the following methods:

- A signal-to-noise ratio of between 3:1 and 2:1; and
- The standard deviation of the response and the slope of the calibration curve using a minimum of seven (7) spiked blank samples calculated as follows:
  - LOD = (3.3 x standard deviation of the response) / slope of the calibration curve;

11.2. The laboratory shall calculate the LOQ for chemical method analyses according to any of the following methods:

- Signal-to-noise of 10:1, at a minimum;

- The standard deviation of the response and the slope of the calibration curve using a minimum of seven (7) spiked blank samples calculated as follows:
    - LOD = (3.3 x standard deviation of the response)/slope of the calibration curve.

11.3. The laboratory shall calculate the LOQ for chemical method analyses according to any of the following methods:

- Signal-to-noise of 10:1, at a minimum; and
- The standard deviation of the response and the slope using a minimum of seven (7) spiked blank samples calculated as follows:
    - LOQ = (10 x standard deviation of the response)/slope of the calibration curve.

12. Personnel

12.1. A holder of a license for analytical testing must retain the services of one individual as the head of the laboratory, who must work at the site set out in the license and who is responsible for the testing.

12.2. The head of the laboratory must have sufficient knowledge of the provisions of the Act and the Regulations that apply to the holder of the license for analytical testing. S/he must also have knowledge and experience related to the duties of the position and possess a degree awarded by a University and recognised by the Barbados Accreditation Council in a science-related field in conjunction to the work to be carried out.

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WE ARE HERE TO HELP!

For further information on the Barbados Medicinal Cannabis Licensing Authority (BMCLA) or the Barbados Medicinal Cannabis Industry, please contact us:

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