

BARBADOS MEDICINAL CANNABIS LICENSING AUTHORITY

CULTIVATOR LICENSE GUIDE

Let's Grow Together



The Barbados Medicinal Cannabis Industry Act, 2019 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 Barbados Medicinal Cannabis Industry Act, 2019, (the Act) and the Barbados Medicinal Cannabis Industry Regulations, 2020, (the Regulations) and must include all the information required.

This Cultivator License Guide provides general terms and conditions for the operation of a Cultivator License within the Barbados Medicinal Cannabis Industry.

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

It is the responsibility of the applicant to ensure that he/she is familiar with this Guide and the Regulations. Your application may be denied, or your operations delayed 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.

Publication Date: January 2021 © Barbados Medicinal Cannabis Licensing Authority (BMCLA)

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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. This document should be read in conjunction with relevant sections of the Act and the Regulations. 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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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 Cultivator 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 at 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

Area

For the purpose of this guide, area is defined as a space allocated for a specific cultivation purpose. Hence an area can be a growing bench (table), a shelf, multi-tier growing area, a field, greenhouse, or an indoor space of any size which is allocated to cultivation.

Agro-processing

For the purpose of this guide, agro-processing is defined as a set of activities carried out for the handling of cannabis plant material/biomass and to make it usable as industrial raw material or raw product. This may include cleaning, sorting, drying, curing, or packaging.

Certificates of Analysis (COA)

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

Integrated Pest Management (IPM)

Natural pests (ladybugs, bees and other specific "critters" are introduced to the crop in order to act as naturals predators for the possible infections of pests on the crop, which in turn minimizes the number of pesticides and chemicals that need to be used otherwise.

Irradiation

Irradiation is the application of gamma radiation for the sterilization of cannabis material. This eradicates any microorganisms and potential contaminants, thereby ensuring that the product is efficiently sterilized.

Responsible Person in Charge (RPIC)

This is the person with decision-making authority on the site and is also accountable for the activities taking place

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, 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 the production manufacture and handling of 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, regulating, 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 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 its 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 documents as requested. This guide sets out the 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. This license speaks to the cultivation of Medicinal Cannabis.Wider agricultural issues are regulated by the Ministry ofAgriculture and Food Security and issues such as pesticides andother resources are governed by the Ministry.

1.2. Acreage is calculated at 3000 plants (density) per acre. This calculation is the total number of plants **regardless of their stage of growth**. This includes:

- seedlings (propagation);
- vegetative state; and
- flowering or harvesting.

Hence, 3000 plants may be cultivated in any number of ways including:

- greenhouse;
- open door;
- vertical grow; or
- indoor growing

One (1) acre = 3,000 plants Five (5) acres = 15,000 plants Twenty-five (25) acres = 75,000 plants

2.2. A Licensee must cultivate only the area/acreage as authorized by the BMCLA.

A Licensee must seek approval from the BMCLA and follow the guidelines of the BMCLA if they wish to expand beyond their approved acreage. It may entail paying for a new category of license.

2.3. Each plant cultivated by a Licensee must be entered into the Track-and-Trace system as dictated by the BMCLA. Each plant must also be tagged with a unique identifier.

2.4. All cultivation activities must be completed and recorded in a batch mode or "batch record" within the approved Track-and-Trace system.

3. Good Agricultural and Collection Practices for Medicinal Plants (GACP)

3.1. All Licensees are required to follow the Good Agricultural and Collection Practices for Medicinal Plants (GACP) as the basic required standard and guidelines.

However, Licensees are advised to research the standards required by their intended final markets (E.U. GMP or other). Where those standards go above those provided under GACP, Licensees are advised to follow those standards.

No standards should fall below that required under GACP.

4. Batch Method

4.1. All licensed activities by cultivators (and processors) must be done using a batch method.

The batch method means that all cannabis material is separated into groupings called batches, and all activities must be completed and recorded under each specific batch record. This includes:

- planting;
- pruning;
- watering;
- application of pesticides, fertilizers, fungicides, herbicides, and/or Integrated Pest Management (IPM);
- harvesting;
- testing;
- processing; and
- all other activities

4.2. All batch activities will be recorded and documented using the Track-and-Trace system. (See more information in the Track-and-Trace Guide)

5. Fertilizers and Pesticides

5.1. All Licensees must use only fertilizers and pesticides as approved by the Ministry of Agriculture and Food Security.



6. Testing

6.1. All Licensees involved in the cultivation of cannabis must have their cannabis material analyzed according to the required tests (type and frequency) declared by the BMCLA. This analysis must occur prior to the sale of any harvested cannabis material and must be done in batches.

6.2. Each harvested batch must be sampled and tested separately.

6.3. As per the Regulation 27, which speaks to the need for testing, the BMCLA has determined that all licensees must use a third-party laboratory for testing all cannabis material for sale in order to fulfil the requirement of the Regulation.

6.4. All Licensees must keep a copy of all Certificates of Analysis (COAs) on file, whether digital or hard copy format; and must ensure that it can be produced upon request from the BMCLA.

6.5. All Licensees must send copies or instruct the testing facility to have copies of all COAs which do not meet testing standards to the BMCLA.

7. Quality Assurance

7.1. In keeping with the general quality assurance requirements, Cultivator Licensees are required to conduct quality assurance procedures before any distribution. This is to ensure that all handling, harvesting, testing and packaging and labelling requirements have been followed. All these steps need to be completed and approved by a designated Responsible Person In Charge (RPIC).

7.2. A cultivator Licenses must provide an official COA to all purchasers prior to the sale of any cannabis material (batch, or part thereof).

7.3. In fulfilling Regulation 27, Licensees may attempt irradiation of the particular batch of cannabis that has not met testing standards. After such irradiation, the cannabis is to be retested.

7.4. If the second round of testing passes testing standards, the Licensee will be allowed to sell the cannabis. However, where the material fails required standards, Licensees will be required to destroy the whole respective batch of cannabis material.



BARBADOS MEDICINAL CANNABIS LICENSING AUTHORITY

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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:



clo@bmcla.bb



246-421-4141



Concierge Desk Barbados Medicinal Cannabis Licensing Authority Warrens House, Warrens, St Michael. www.bmcla.bb