MEDICINAL CULTIVATION REGULATIONS

ARRANGEMENT OF REGULATIONS

MEDICINAL CULTIVATION REGULATIONS

Citation

1. This Regulation may be cited as the Medicinal Cultivation Regulations.

Interpretation

2. In this Regulation –

"**Act**" means the Cannabis & Industrial Hemp Act, No. [] of 2024;

"authorized individuals" means employees of a holder of a cultivation license and includes outside vendors, contractors, or other individuals conducting business that requires access to the licensed premises.

"batch" or "**lot"** means a specific quantity of homogenous cannabis or cannabis product.

"batch or lot number" means an alphanumeric code or designation used for reference to a specific batch or lot;

"**cannabis regulations**" means all regulations under the Cannabis & Industrial Hemp Act, No. [] of 2024

"**cannabis**" has the same meaning as in the Cannabis & Industrial Hemp Act, No. [] of 2024

"**cannabis waste**" means any material intended for disposal that contains cannabis and may be hazardous cannabis waste and non-hazardous cannabis waste. It includes flowers, leaves, seeds of the plant as well as oils, the roots, non-viable seeds and mature stocks of the cannabis plant.

"**citizen**", in relation to a person making an application for a Traditional Cultivating License, means a citizen under the Citizenship of Saint Lucia Act, Cap. 1.04;

"**cultivation license**" means any of the following cannabis licenses –

(a) Traditional Cultivators Licence

(b) With regards to Outdoor Grows

i Traditional Cultivation License

ii Medical Tier One (Micro) License

iii Medical Tier Two (Small Scale Medical Cultivation) License

iv Medical Tier Three (Medium Scale Medical Cultivation) License

v Medical Tier Four (Large Scale Medical Cultivation) License

(c) With regards to Indoor Grows

i Traditional Cultivation License

ii Medical Tier One (Micro) License

iii Medical Tier Two (Small Scale Medical Cultivation) License

iv Medical Tier Three (Medium Scale Medical Cultivation) License

v Medical Tier Four (Large Scale Medical Cultivation) License

"**employee"** means any person directly employed by a holder of a cultivation license for wages, salary, barter, or trade. An employee cannot be an independent contractor, third party entity, or any other entity acting on behalf of the holder of the cultivation license; "**fresh cannabis**" means freshly harvest cannabis leaves, buds or flowers, but does not include plant material that can be used to propagate cannabis

"**hazardous cannabis waste**" means any material intended for disposal that contains cannabis flowers, leaves, seeds of the plant as well as oils. It excludes non-hazardous cannabis waste.

"**natural person**" means an individual human being and specifically excludes a company or corporate entity.

"**non-hazardous cannabis waste**" means any material intended for disposal that contains cannabis roots, non-viable seeds and mature stocks of the cannabis plant. It excludes hazardous cannabis waste.

"**operations area**" means an area of the site, other than a storage area, where cannabis is present as a result of any activities conducted under the specified license and includes grow area.

"**person**" has the same meaning as the Cannabis & Industrial Hemp Act, No. [] of 2024;

"**pesticide product**" means –

(a) a product, a substance or an organism that consists of contaminants and formulants as its active ingredients and is used as a means of directly or indirectly controlling, terminating, enticing, or repelling a pest or for mitigating or preventing its injurious, noxious or troublesome effects, and

(b) includes a product, a substance or an organism derived through biotechnology, or

(c) any other thing that is listed to be a pesticide product.

"**recall**" means any action taken by a cannabis license holder to correct or remove the cannabis or cannabis product from sale and distribution, and includes –

(a) the act of contacting persons within the cannabis supply chain in order to send the cannabis product back if a non-conformance is found with a requirement set out in the Cannabis Regulations;

(b) notifying the public of a problem or potential problem with the cannabis or cannabis product;

"**recognized laboratory**" means a laboratory that is recognized by the Minister of Health for cannabis testing as prescribed in the Act;

"**Regulated Substance Authority**" (RSA) means the Regulated Substances Authority established under the Regulated Substances Act, No. [26] of 2023;

"**Religious Organization**" has the same meaning as defined in the Public Consumption Space and Religious Cannabis Regulations.

"**seed-to-sale tracking system**" means a system that documents and tracks cannabis from a seed to its final product form.

"**site**" means an area that is used exclusively by the holder of a Cannabis License or Central Trading Entity Certificate that consists of at least one building, or one part of a building.

"**standard operating procedures**" (SOP) means a set of step-by-step instructions compiled by an organization that describes the activities necessary to complete tasks in accordance with industry standards, laws and regulations.

"**storage area**" means an area of the site where cannabis is stored.

"**system of auditing**" is an internal system that can be used to track any and all lots or batches of cannabis that are received, packaged, sold or distributed

Application

3. These Regulations apply to all applicants and holders of a Medicinal Cultivation License.

Non-application

4. These Regulations do not apply to industrial hemp or holders of industrial hemp licenses.

Criteria for a Traditional Cultivation License

5. A Traditional Cultivation License holder –

(a) must be a natural person or Religious Organization as established within the Religious Cannabis Regulations.

(b) In the case of a natural person is a Legacy Cannabis Operator

(c) is permitted to cultivate cannabis on 3 acres or less of land;

(d) may employ up to 10 persons to work under the license provided that they are listed on the license, and received the requisite security clearance;

Criteria for a Medical Tier One (Extra Small Scale Medical Cultivation) License

6. A Medical Tier One (Micro Scale Medical Cultivation) License holder –

(a) must be a natural or legal person;

(b) must intend to and will be permitted to cultivate cannabis less than one acre,

(c) Must intend to and will be permitted to employ up to 10 persons to work under the license, provided that they are listed on the license, and at least 40 % of the employees are Saint Lucian citizens.

(d) Must be able to obtain the requisite security clearance for all employees;

Criteria for a Medical Tier Two (Small Scale Medical Cultivation) License

7. A Medical Tier Two (Small Scale Medical Cultivation) License holder –

(a) must be a natural or legal person;

(b) must intend to and will be permitted to cultivate cannabis on greater than 1 but less than or equal to 5 acres of land;

(c) may employ more than 10 persons to work under the licence, provided that they are listed on the licence, and at least 40 %of the employees are Saint Lucian citizens. .

(d) Must be able to obtain the requisite security clearance for all employees;

Criteria for a Medical Tier Three (Medium Scale Medical Cultivation) License

8. A Medical Tier Three (Medium Scale Medical Cultivation) License holder –

(a) must be a natural or legal person;

(a) must intend to and will be permitted to cultivate cannabis on greater than 5 but less than or equal to 15 acres of land;

(b) may employ more than 15 persons to work under the licence, provided that they are listed on the licence, and at least 40 %of the employees are Saint Lucian citizens.

(c) Must be able to obtain the requisite security clearance for all employees;

Criteria for a Medical Tier Four (Large Scale Medical Cultivation) License

9. A Medical Tier Four (Large Scale Medical Cultivation) License holder –

(a) must be a natural or legal person;

(b) must intend to and will be permitted to cultivate cannabis on greater than 15 acres of land

(c) may employ more than 15 persons to work under the license, provided that they are listed on the license, and at least 40 % of the employees are Saint Lucian citizens.

(d) Must be able to obtain the requisite security clearance for all employees

MEDICINAL CULTIVATION regulations11

Authorized activities

10. –(1) A holder of a valid Cultivation License is authorized to conduct the following activities –

(a) possess cannabis at the approved cultivation site or space as specified under the Cultivation License;

(b) obtain dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds by cultivating, propagating and harvesting cannabis;

(c) to submit samples to a registered laboratory as prescribed in the Cannabis Testing And Laboratory Regulations.

(d) to sell cannabis exclusively to a Central Trading Entity.

(e) notwithstanding subsection (d), in the case where a person holds a Cultivation and Manufacturing License, the holder of the licenses may make a written request to the Regulated Substance Authority (RSA) to bypass the Central Trading Entity. To bypass the Central Trading Entity pursuant to the Cannabis and Industrial Hemp fee regulations.

(f) conduct ancillary activities such as drying, trimming and milling cannabis;

(2) A holder of a valid Cultivation License must not conduct the following activities outdoors in relation to cannabis –

(a) test, except for internal purposes;

(b) store;

(c) package, or;

(d) label.

Application for a Cultivation License

11. –(1) An application to be granted a Cultivation License may submitted to the RSA, in electronic, typed or printed format.

(2) Applications shall be –

(a) completed as prescribed in Schedule 1, Form 1 ID Schedule 1;

(b) accompanied by –

(i) all requisite documentation and information;

(ii) the non-refundable application fees as prescribed in The Cannabis Fees Regulations;

(iii) documentation evidencing ownership or authority to use the property on which the holder of the Cultivation License intends to cultivate cannabis or engage in any activities commensurate therewith or required thereby towit –

(1) title deed;

(2) authorization for occupation;

(3) permission or consent to conduct activities stated under the license for which the applicant is applying for.

(iv) grant for security clearance as prescribed in section 14;

(v) site plan as specified in section 16;

(vi) pest management plan as specified in section 19

(vii) waste management plan as specified in section 20;

(viii) the details and evidence as requested by the RSA.

(c) signed and dated by the applicant or person authorized by applicant to sign, indicating that all the information provided in support of the application is correct and complete to the best of their knowledge.

(2) The RSA shall have the right to require additional documentation to establish whether an applicant satisfies the mandatory qualifications and criteria, including information pertinent to ensuring public health and safety;

Waiver of non-refundable application fee

12. A non-refundable application fee for a traditional cultivators license may be waived for an applicant for up to five years, if the Minister so determines.

Security clearances

13. –(1) The RSA shall assess and where applicable grant security clearances for all directors.

(2) A holder of a Cultivation License shall notify the RSA of all employees or perspective employees of the Licensed Cultivator. Security clearance shall be required for all employees as part of the hiring process.

(2) The RSA upon receipt of the notice shall conduct due diligence checks on the persons referenced in the notice and if satisfied may issue a security clearance authorizing that person to engage or be employed with the a holder of a Cultivation License.

(3) An individual shall not be granted a security clearance or shall have the security clearance revoked if–

(i) he/she has been convicted of a criminal offence, except where the offence is a minor traffic offence or has been spent in accordance with the Criminal Records (Rehabilitation of Offenders) Act, Cap 3.13;

(ii) he/she has been convicted of an offence under the Act;

(iii) the RSA has reasonable grounds to believe that the individual poses a risk to public health or safety, including the risk of cannabis being diverted to an illicit market or activity; or

(iv) he/she is terminated or ceases to be employed with the Licensed Cultivator.

Refusal to grant security clearance

14. –(1) If the RSA intends to refuse to grant a security clearance, the RSA must provide the applicant, holder of the Cultivation License or applicant of the Cultivation License, with a written notice of the refusal.

(2) In the event a security clearance is not granted –

(a) the RSA has the right to deny the application for Cultivation License;

(b) the holder of the Cultivation License shall not hire or continue to employ the individual.

(c) the applicant may resubmit a request, if the conditions of refusal no longer exist or apply.

Site Plan

15. –(1) Pursuant to section 12(2)(b)(v) the applicant shall submit to the RSA, a site plan that includes the following –

(a) boundaries;

(b) entrances;

(c) exits;

(d) interior partitioning;

(e) walls;

(f) rooms;

(g) windows;

(h) doorways.

(i) a brief statement or description of the principal activities to be conducted therein, along with the interior and exterior dimensions and boundaries of the premises, where applicable;

(j) all roads and water crossing on the property;

(k) all water sources identified and labeled for use, including but not limited to irrigation and domestic use, and;

(l) all designated harvested cannabis storage areas.

(2) The site plan must demonstrate that it can meet the physical security measures outlined in section 18.

Site inspection

16. –(1) Pursuant to the Act, the RSA may conduct an inspection of the premises, in order to verify the site plan and –

(a) to ensure that the site is designed, constructed and can be maintained in a manner that ensures good production practice measures. Such measures shall –

(i) permit any building or part of the building be kept clean and orderly;

(ii) ensure the effective cleaning of all surfaces in the building or part of the building;

(iii) prevent the contamination of cannabis, ingredients or tools that will be used in the cultivation process, and;

(iv) prevents the introduction of peripheral substances to the cannabis, ingredients or tools that will be used in the cultivation process.

(a) that it is designed or constructed in a manner that ensures that any part of the building where cannabis is stored or used, is equipped with natural or artificial lighting that is appropriate for the activity being conducted. Any light fixtures in the building or part of the building shall –

(i) be capable of withstanding repeated cleaning and, if necessary be repeatedly sanitized if necessary to prevent contamination of the cannabis, ingredients or tools that are used in the production process, and

(ii) in the event of a breakage, not present a risk of contamination of the cannabis, ingredients or tools that are used in the production process.

Physical security measures

17. –(1) The proposed site must demonstrate that physical security measures are present to deter and prevent unauthorized access. Such security measures shall include –

(a) visual monitoring of the perimeter, operations area and storage area of the site which must be monitored at all times by visual recording devices to detect any attempt or actual unauthorized access;

(b) visual recording devices which must be capable of making and storing visual recordings of any attempt or actual unauthorized access;

(c) a means of restricting access that prevents unauthorized access;

(d) a physical barrier that prevents unauthorized access of the site, the said barrier shall cover the entire perimeter of the site and be at least eight (8) feet with barbed wire of at least six (6) inches to the top.

(e) physical barriers surrounding storage areas that are capable of preventing unauthorized access, and that access to each storage area is restricted to individuals whose presence is required by their duties.

(2) The holder of a cultivation license shall establish and implement an identification and sign-in/sign-out procedure for all persons accessing the premises, including authorized individuals, suppliers, and visitors. An individual who enters the site and is not employed by the recognized laboratory shall be escorted by an employee of the laboratory at all times while within the site.

(3) The holder of a cultivation license shall maintain a record of all authorized individuals who are not laboratory employees who enter the site of the recognized laboratory. The record shall include the individuals name, the company the individual works for, the reason for the visit, the date and the times the individual entered and exited the site. These records shall be made available to the RSA immediately upon request.

(4) Notwithstanding the requirements in this section, the RSA may, for Traditional Cultivation licensees or applicants, suspend the requirements of some or all of the above Physical Security Measures for up to two years and may suspend for a period of an additional two years, if so authorized by the Minister.

Pest Management Plan

18. A holder of a Cultivation License shall develop a pest management plan that includes –

(a) the product name and active ingredient(s) of all pesticide products to be applied to cannabis, and;

(b) any integrated pest control procedures, including chemical, biological, and cultural methods, that will be used to deter and control pests on the cultivation site.

Waste Management Plan

19. –(1) The holder of a Cultivation License shall ensure that waste disposal is done in accordance with Waste Management Act Cap. 6.05. It is the responsibility of the licensee to properly evaluate waste and to determine if it should be designated and handled as a hazardous waste as defined in the Waste Management Cap. 6.05.

(2) A holder of a Cultivation License shall establish and implement standard operating procedures that describes the method or methods by which the licensee will dispose waste, including cannabis waste.

(3) A licensee shall dispose of cannabis waste using only the following methods –

(i) onsite composting of cannabis waste;

(ii) reintroduction of cannabis waste back into agricultural operation through onsite organic waste recycling methods, including but not limited to tilling directly into agricultural land and no-till farming.

(4) The licensee shall ensure that any hazardous cannabis waste is stored in a secure waste receptacle or secured area on the site listed in the license until the time of

Commented [1]: Collection by a local waste disposal agency approved by the RSA

disposal. Physical access to the receptacle or area shall be confined to the licensee and employees of the licensee.

(5) Notwithstanding this subsection, the RSA may permit the use of non-hazardous cannabis waste for industrial purposes by the Licensed Cultivator or a duly authorized or licensed third party.

(6) In the case of a batch of cannabis or cannabis product that is being disposed of because it has failed internal quality testing, regulatory compliance requirements or quality assurance review by a distributor, including the Central Trading Entity, the licensee shall comply with the following additional requirements –

(i) All cannabis or cannabis products in the batch shall be rendered unusable prior to disposal and entered into the seed-to-sale system established by the RSA, as well as documented in the system of auditing.

(ii) Rendering of the cannabis or cannabis product shall be done under video surveillance, unless the rendering is performed by the RSA.

Approval of Cultivation License

20. A licence may be approved for up to 3 years in the first instance and for up to 5 years upon renewal. Upon approval of a Cultivation License –

(a) the applicant shall pay the licence fee prescribed in the Cannabis Fee Regulations;

(b) the Minister may, by written notice waive the annual license fee for a maximum of five (5) years.

(c) In the case of a traditional cultivator the license may only be renewable for up to ten (10) years from the issuance of the first lience. Any subsequent renewal

shall be classified consistent with the tier classification relevant to the cultivation license.

(d) the applicant shall sign a Record Keeping Attestation form referenced in Schedule 1 attesting that they will retain documents and information as prescribed in these regulations;

(e) the applicant shall submit a request to grant security clearance for any additional individuals who require access to the site as part of their employment duties;

(f) the RSA shall –

(i) grant security clearances for all approved individuals;

(ii) present the approved person with the Cultivation License as prescribed in Schedule 1. The Cultivation License shall set out the following information:

(1) the name of the approved person;

(2) the license number;

(3) the address of the site where the activity is authorized and, if applicable, of each building within the site;

(4) any conditions that the RSA considers appropriate;

(5) signed seal of the RSA;

(6) the effective date of license, and;

(7) the expiration date of the license.

(2) The Cultivation License shall be kept at the address of the site where the activity is authorized.

Changes to the information in a license

21. –(1) The holder of the Cultivation License must submit an application in electronic, typed or printed format to the RSA for an amendment to the certificate if they propose to make any of the following changes:

(a) a change to the name of the person on the license;

(b) a change to the address of the site or building within the site where the activity is authorized, or;

(c) a change to the authorized activity at the site or the authorized activity that may be conducted at each building within the site.

(2) The application for changes to the license shall include –

(a) a description of the change;

(b) the proposed new site plan;

(c) a signed and dated declaration by the applicant or person authorized by applicant to sign, indicating that all the information provided in support of the application is correct and complete to the best of their knowledge.

Approval of a change

22. The RSA –

(a) shall have the right to require additional documentation to establish whether the requested changes satisfy the mandatory qualifications and criteria, including information pertinent to ensuring public health and safety;

(b) may inspect the site, if the proposed changes require revisions to the site plan to ensure that the proposed changes are sufficient to meet the required measures under section 17;

(c) shall, upon approval of the changes, reissue a new license if required.

Renewal of a Cultivation License

23. A holder of a license shall within 3 months of the date of expiration on the Cultivation License submit to the RSA –

(a) a completed request for renewal form as prescribed in Schedule 1;

(b) all requisite documentation and information;

(c) the details and evidence as requested by the RSA.

Pesticide Products Use Requirements

24. A holder of a Cultivation License shall comply with all applicable statutes and regulations under the Pesticides and Toxic Chemicals Control Act - Cap.11.15 and Limits of Resides and Contaminants for Cannabis Regulations.

Weighing Devices

25. A holder of a Cultivation License shall use weighing devices that are tested, approved and labeled in accordance to the Metrology Act, No. 17, 2000, and calibrated Saint Lucia Bureau of Standards, whenever the licensee is determining the weight of cannabis that is to be sold or entered into the seed-to-sale tracking system established by the RSA.

Operational terms and requirements for a Cannabis Cultivator

26. A holder of a Cultivation License must –

(a) retain a copy of any site plan that is submitted to the RSA referenced in section 12(2)(b)(v), including any updated designs as referenced in section 22(2)(b) and;

(i) retain a copy for a retention period as prescribed in section 40.

(b) obtain a security clearance from the RSA for every member of staff as part of the hiring process as referenced in section 14. Failure to comply shall be a Class B offence under the Act.

(c) within the first 6 weeks of obtaining the license and prior to commencing operations establish the following :

(i) register for the seed-to-sale system established by the RSA. Failure to comply shall be a Class C offence under the Act.

(ii) designate and retain a person as the master grower as specified in section [].

(iii) shall ensure that any sanitizer, agronomic input, pesticide products or non-food chemical agent that is present on the site are –

(1) properly and clearly labeled and identified;

(2) suitable for its intended use and does not present a risk of contamination of cannabis;

(3) handed and used in a manner that does not pose a risk of contamination of the cannabis or is used in accordance with the manufacturer's instructions.

(iv) establish mechanisms to ensure that the cannabis be stored under conditions that maintain their quality;

(v) set up a system of auditing that allows for the rapid and complete recall of every lot or batch of cannabis that has been sold or distributed.

(d) ensure that any system that supplies water to the site is appropriate for any activity that is conducted in respect to cannabis;

(e) ensure that security measures listed in section 18 are complied with and if there is any occurrence or detection of any attempt or actual unauthorized access at the site –

(i) record the date and time of the occurrence;

(ii) retain visual recordings and records of the occurrence;

(iii) determine the appropriate measures to be taken in response and;

(1) the date and time when the response was taken.

(iv) provide a notice to the RSA, with a detailed report, including information under this subsection, and –

(1) retain the detail report for the period of time specified in section

Master grower

27. –(1) A holder of a Cultivation License must retain the services of one individual as the master grower.

(2) The master grower is responsible for the cultivation, propagation and harvesting of cannabis and must have sufficient knowledge of the provisions of the Act and the Cannabis Regulations in relation to those activities.

(3) A holder of a Cultivation License may designate one individual as the alternate master grower who is qualified to replace the master grower.

Testing

28. –(1) A holder of a Cultivation License shall not sell or distribute cannabis unless it has met the applicable mandatory testing requirements as prescribed in the Cannabis Testing and Laboratory Regulations and the Limits for Residues and Contaminants for Cannabis Regulations.

(2) Notwithstanding subsection (1), the cultivator may deliver to the Central Trading Entity, prior to testing, cannabis airmarked for sale and the Central Trading Entity may facilitate testing of the cannabis on behalf of the cultivator. In such circumstances the sale is deemed to take place after the testing and upon satisfactory results.

(3) Testing must be conducted –

(a) by a recognized laboratory as prescribed under the Act, and;

(b) on a representative sample of each lot or batch of cannabis in its final form prior to sale, as prescribed in the Cannabis Testing and Laboratory Regulations.

(c) on sufficient quantity to enable the determination of the quality of the cannabis.

(3) In the event that cannabis is found to exceed the residual pesticide tolerance limits specified in the Limits for Residues and Contaminants for Cannabis Regulations, the licensee shall –

(a) not sell, distribute, package, or label the said cannabis for sale or use for manufacturing;

(b) quarantine the cannabis;

(c) notify the RSA to facilitate the destruction of the cannabis, as prescribed in section 30.

(4) The holder of a cannabis license who receives an analytical testing result that indicates that their cannabis exceeds the residual pesticide limits prescribed in Limits for Residues and Contaminants for Cannabis Regulations may request a retest of the cannabis, within seven (7) days of receipt of the initial results.

Destruction of cannabis

29. –(1) A holder of a Cultivation License is authorized to destroy cannabis only –

(a) using a method that does not result in any person being exposed to cannabis smoke or cannabis vapor, and

(b) in the presence of at least two individuals, one of which must be an employee of the holder of the license for which the cannabis is being destroyed and the other must be a represented of the RSA;

(c) the RSA may request a representative of the Saint Lucia Bureau of Standards to be present at the time of destruction.

(2) A holder of a Cultivation License, if they destroy cannabis or cause it to be destroyed document the following information –

(a) a description of the cannabis;

(b) the date on which the cannabis is destroyed;

(c) the net weight of the cannabis on the date of pre-destruction.

(d) the address of the location at which the cannabis is destroyed;

(e) a brief description of the method of destruction, and;

(f) the names of the individuals who witness the destruction referred to in subsection (2)(b) and;

(g) a statement by the witnesses for each instance in which cannabis is destroyed, that is signed and dated by the persons referred to in subsection (2)(b).

(3) The licensee must document and retain records of the destruction, for a retention period, as prescribed in section 40.

Sale of cannabis to a Central Trading Entity

30. –(1) A holder of a Cultivation License shall be permitted to sell their cannabis to a Central Trading Entity subsequent to –

(a) receiving passing test results as prescribed in the Cannabis Testing and Laboratory Regulations;

(b) labeling as prescribed in the Packing and Labeling Regulations relevant to premanufactured cannabis; –

(c) retain the documentation and information as prescribed in section [];

(d) Documentation evidencing the manifest

(e) entering all relevant information into the seed-to-sale tracking system established by the RSA.

(f) In the first instance presenting a valid original or certified true copy of the applicable licence in the first instance, along with –

(i) proof of identity, to ensure that the transporter is licensed,

(ii) documentation to verify the cultivator

(iii) Authorization for transportation

(2) A holder of a Cultivation Processing License is allowed keep cannabis if –

(a) the licensee also has a cannabis Processing License, or Export License and;

(b) upon receipt of written authorization from the RSA.

Failed regulatory compliance requirements

31. –(1) A batch or lot has failed regulatory compliance requirements if it has failed to –

(a) meet the applicable mandatory testing requirements set out in the Cannabis Testing and Laboratory Regulations, and the Limits for Residues and Contaminants for Cannabis Regulations;

(b) Label the cannabis as prescribed in these regulations and the Packaging and Labeling Regulations, or

(c) any other regulatory compliance requirements as set out in these requirements.

(2) A cannabis batch or lot that fails any regulatory compliance requirements established by these regulations and otherwise shall be destroyed unless –

(a) The cannabis batch may be remediated through the corrective action of relabeling; or

(b) A corrective action plan for the remediation of the failed cannabis batch or lot is approved by the RSA. The corrective action plan must be submitted by the holder of the cultivation license who intends to remediate the said batch or lot and must not sell or distribute the batch or lot to another licensee unless the RSA has approved the corrective action plan.

Recall action plan

32. The holder of a Cultivation License shall ensure that the following are established –

(a) factors within the daily routine of the cultivation process that would necessitate a recall;

(b) employee responsible for implementing the recall procedures;

(c) a mechanism to notify all persons within their supply chain that have, or could have, obtained the cannabis or cannabis products, including communication and outreach via media, as necessary and appropriate;

(d) a mechanism to notify any licensees that supplied or received the recalled cannabis; and

(e) instructions to the general public and other licensees for the return or destruction of the recalled cannabis or cannabis products.

(f) establish procedures for the collection and facilitation of destruction by the RSA, of any recalled cannabis or cannabis products. The recalled cannabis or cannabis products shall be subject to auditing by the RSA.

Recall

33. –(1) The recall of cannabis and levels of severity shall be dictated by these Regulations as specified in Schedule 2 and pursuant to Standards Act (Act No. 14 of 1990).

(2) A holder of a Cannabis Cultivation License shall conduct a recall if any of the risks levels, as prescribed in Schedule 2 are encountered.

(3) A holder of a Cannabis Cultivation License shall conduct the recall within the timeframe specified in Schedule 2.

(4) A holder of a Cannabis Cultivation License shall notify the RSA of any recall within 24 hours of initiating the recall.

(5) If the RSA believes on reasonable grounds that cannabis or a cannabis product poses a risk to human health or safety, the RSA may, by written notice, order that the cannabis and cannabis product be recalled or sent to a place designated by the RSA.

(6) The holder of a Cultivation License shall conduct a recall simulation based on the system of auditing referred to in section 27.(1)(c)(v) –

(a) the simulation shall occur once every 12 months;

(b) after completing the simulation, a detailed report must be prepared that sets out how it was conducted and the results, and;

(c) the report shall be retained for a period as prescribed in section 40.

(2) The report specified in subsection (b) shall contain the following information –

(a) a description of the cannabis sold;

(b) each lot or batch number of the cannabis to be recalled, together with, if known, the lot or batch number of any cannabis products that used the cannabis;

(c) the rational for commencing the recall;

(d) the quantity of cannabis product that is sold or distributed;

(e) the period during which the licensee sold or distributed the cannabis;

(f) contact information for the individual who is responsible for the recall as specified in section 33(b).

(g) the timeline and manner in which the recall is expected to be carried out, including –

(i) the expected date for the commencement of the recall;

(ii) how and when the RSA will be informed of the progress of the recall, and;

(iii) the expected completion date of the recall.

(h) a description of any other measure the licensee intends to take in respect to the recall.

Exportation

34. A holder of a Cultivation License may not export unless they also possess a valid Export License, and in such case, is subject to the requirements under the Cannabis Importation and Exportation Regulations.

Transportation

35. A holder of a Cultivation License is subject to the requirements under the Cannabis Transportation Regulations.

Lost or theft

36. A holder of a Cultivation License must, if a theft or loss of cannabis is encountered that cannot be explained based on normally accepted operational activities –

(a) notify the police force within 24 hours after becoming aware of its theft of loss, and

(b) provide the RSA with a written notice within 72 hours after becoming aware of the loss or theft.

Notices

37. –(1) A holder of a Cultivation License must notify the RSA of any of the following changes within 7 days of the occurrence –

(a) a change to the mailing address, telephone number, email address or facsimile number;

(b) the replacement or addition of an individual who must hold a security clearance as referred to in section 14.

(2) A holder of a Cultivation License must notify the RSA, if they wish to cancel the Cultivation License.

(3) A holder of a Cultivation License shall retain a copy of all notices sent to the RSA for a retention period as prescribed in section 40 or otherwise in this Act.

Financial reporting

38. A holder of Cannabis License shall be required to make financial reports as mandated by the Income Tax Act, Cap.15.02, the Act and the Cannabis Levy Regulations.

Requirements for retention of documentation and information

39. –(1) A holder of a Cultivation License is required to retain a document that contains the following information for each lot or batch of cannabis –

(a) the date on which it is harvested and the net weight on that date;

(b) the date on which drying processes are completed and the net weight on that date;

(c) the date on which dried or fresh cannabis is packaged and the net weight;

(d) the date on which the cannabis was sold or transferred, in the case of a licensee who possess a Cultivation and Manufacturing License;

(e) a description of the cannabis;

(f) the internal lot or batch number assigned to the cannabis;

(g) any information that is obtained through the required testing and any other results that relates to the phytocannabinoid and terpene content of the cannabis.

(2) A holder of a Cultivation License is required to retain documents or information in a manner that ensures –

(a) that an audit, either internal or external can be made in a timely manner;

(b) that the document is available at the site specified in the license, and

(c) that the document and information is retained until the end of the retention period of –

(i) at least two years after

1. the date of the events listed in section (a) to (g);
2. submitting the site plan specified in section 27(a) to the RSA;
3. completion of a recall report specified in section 34;
4. the date that the cannabis was destroyed, as specified in section 30;
5. the notice is sent or provided to the RSA as specified in section 38.
6. any occurrence listed in section 27(e)(i) and 27(e)(iii)

(ii) at least one years after the date of any occurrence listed in section 27(e)(ii).

(3) A holder of a Cultivation License shall enter all required information specified by the RSA, into the seed-to-sale tracking system established by the RSA, as specified in the Attestation form submitted as part of the application process.

(4) In the event that the Cultivation License is canceled, suspended, revoked or expired, the holder of a Cultivation License shall continue to retain documentation and information as specified under this section.

Exceptions – urgent notices

40. Individuals are obligated to notify the RSA immediately if –

(a) a person who is required to obtain a security clearance is convicted of –

(i) a criminal offence, except where the offence is a minor traffic offence or for possession of up to 30grams of cannabis or has been spent in accordance with the Criminal Records (Rehabilitation of Offenders) Act, Cap 3.13, or

(ii) an offence under the Act.

(b) they are aware of any information that poses a risk to public health or public safety, including the risk of cannabis being diverted to an illicit market or activity.

Forms

41. For the purpose of facilitating a person applying for a Cultivation License, the requisite forms are set out in Schedule 1.

MEDICINAL CULTIVATION regulations35

Schedule 1

[Form serial #]

FC XX

APPLICATION FOR A CULTIVATION LICENSE

(*Please complete and submit this application in electronic or printed form).*

Please read the following explanatory notes carefully:

a) Missing information or documents may result in a delay in the processing of the application. Please ensure that all documents listed in the applicable checklist is attached upon submission of the application.

b) Must provide original copies of the following document EXCEPT where stated otherwise:

Please check the class of cultivation license requested (see attached appendix for criteria of each class):

☐ Traditional Cultivation License
☐ Medical Tier One (Micro Medical Cultivation) License
☐ Medical Tier Two (Small Medical Cultivation) License
☐ Medical Tier Three (Medium Scale Medical Cultivation) License
☐ Medical Tier Four (Large Scale Medical Cultivation) License

If applying for a Traditional Cultivation License, please answer the following. Are you currently recognized as a Religious Organization pursuant to the Public Consumption Space and Religious Cannabis Regulations?

☐ Yes ☐ No

Application checklist for applicants applying as a company:

☐ Certificate of Incorporation
☐ Notice of Directors (notice of change of directors must be submitted if applicable)
☐ Notice of Beneficial Owners
☐ Corporate organizational chart

Application checklist continued - all applicants

☐ Application fee of $1500
☐ Two of the IDs detailed in Section 1 (Certified Copies)
☐ Site plan (as specified in section of the Cultivation License)
☐ Completed Form 1 # RSAXXX
☐ Completed Form 2 # RSAXXX for each Director, Beneficial Owner and each employee

[Insert RSA Logo here]

[Form serial #]

1. APPLICANT INFORMATION

1.1 Full Name

Last Name

First name

Other name(s)

1.2 Address

Permanent address

City

1.3 Contact Details

Home phone

Cell phone

Work phone

Facsimile

Email address

1.4 Identification

National Insurance Number (NIC)

Please provide 2 forms of ID and include a copy of each ID for which you have provided the details:

National ID Card Number

Exp. Date (DD-MM-YY)

Passport Number

Exp. Date (DD-MM-YY)

Driver's License Number

Exp. Date (DD-MM-YY)

2. COMPANY or RELIGIOUS ORGANIZATION INFORMATION (if applicable)

2.1 Name of entity

2.2 Type of company or religious organization (business activity or purpose)

2.3 Current position

[Insert RSA Logo here]

[Form serial #]

2.4. Business address

Address

City

2.5 Business mailing address (if different from 1.4 above)

Address

City

2.6 Business contact information

Telephone

Facsimile

E-mail address

Website

3. PROPOSED SITE

3.1 Address

Permanent address

City

The undersigned hereby affirms that the information contained in this application is true and accurate as of the date shown below and the undersigned is authorised to execute this application

This ..... day of ..... , ...

APPLICANT

Name

Signature

MEDICINAL CULTIVATION regulations38

OUTDOOR GROW				
Licence Class	**Nationality**	**Acreage / Size**	**Employee Limit**	**Employee Criteria**
Traditional Cultivation Licence	Natural person or religious organisation	≦ 3 acres	10	60% National
Medical Tier One (Micro Medical Cultivation) Licence	Natural or Legal Persons	≦ 1 acre	10	40% National
Medical Tier Two (Small Medical Cultivation) Licence	Natural or Legal Persons	1-5 acres	10	40% National
Medical Tier Three (Medium Medical Cultivation) Licence	Natural or Legal Persons	5-15 acres	15	40% National
Medical Tier Four (Large Medical Cultivation) Licence	Natural or Legal Persons	15 or more acres	more than 15	40% National
INDOOR GROW				
Licence Class	**Nationality**	**Size (SqFt)**	**Employee Limit**	**Employee Criteria**
Traditional Cultivation Licence	Natural person or religious organisation	≦ 500 SqFt	10	60% National
Medical Tier One (Micro Medical Cultivation) Licence	Natural or Legal Persons	≦ 500 SqFt	15	40% National
Medical Tier Two (Small Medical Cultivation) Licence	Natural or Legal Persons	500-1500 SqFt	15	40% National
Medical Tier Three (Medium Medical Cultivation) Licence	Natural or Legal Persons	1500-3000 SqFt	15	40% National
Medical Tier Four (Large Medical Cultivation) Licence	Natural or Legal Persons	3000 or more SqFt	15	40% National

MEDICINAL CULTIVATION regulations39

[Form serial #]

APPLICATION FOR A GRANT FOR SECURITY CLEARANCE

(*Please complete and submit this application in electronic or printed form).*

Please read the following explanatory notes carefully:

a) Missing information or documents may result in a delay in the processing of the application. Please ensure that all documents listed in the applicable checklist is attached upon submission of the application.
b) Must provide original copies of the following document EXCEPT where stated otherwise:

Application checklist:

☐ Bio-page of passport (Certified copy)
☐ Certificate character
☐ Application fee of $100
☐ Two of the IDs detailed in Section 1 (Certified Copies)

1. APPLICANT INFORMATION

1.1 Full Name

Last Name

First name

Other name(s)

1.2 Address

Permanent address

City

1.3 Contact Details

Home phone

Cell phone

Work phone

Facsimile

Email address

[Insert RSA Logo here]

[Form serial #]

1.4 Identification

National Insurance Number (NIC)

Please provide forms of ID and include a copy of each ID for which you have provided the details:

National ID Card Number | Exp. Date (DD-MM-YY)

Passport Number | Exp. Date (DD-MM-YY)

Driver's License Number | Exp. Date (DD-MM-YY)

2. COMPANY or COORPERATIVE INFORMATION

2.1 Name of entity

2.2 Type of company or corporative (business activity or purpose)

2.3 Current position

2.4. Business address

Address

City

2.5 Business mailing address (if different from 2.4 above)

Address

City

2.6 Business contact information

Telephone | Facsimile

E-mail address

Website

[Insert RSA Logo here]

[Form serial #]

3. DETAILS

Detail the purpose of requesting a grant for security clearance

The undersigned hereby affirms that the information contained in this application is true and accurate as of the date shown below and the undersigned is authorised to execute this application

This ..... day of ..... , ...

APPLICANT/PERSON AUTHORIZED BY APPLICANT

Name

Signature

[Insert RSA Logo here]

[Form serial #]

RECORD KEEPING ATTESTATION

(*Please complete and submit this form in electronic or printed form).*

Please complete the required information. If a section is not applicable, indicate it as such.
All fields indicated by an asterisk (*) are mandatory.

1. GENERAL INFORMATION

1.1 Full Name

Last Name*

First name*

Other name(s)

1.2 Name of entity

1.3 Type of company or religious organization (business activity or purpose)

2. RECORD KEEPING METHOD

2.1. What is your recording keeping method?*

☐ Paper-based

☐ Electronic based

☐ Other (please specify below)

[Insert RSA Logo here]

[Form serial #]

3. ATTESTATION

The undersigned hereby attests that:

- All applicable documents and information required under the Cannabis Regulations that must be retained by a holder of a Cultivation License will be retained accordingly for the noted retention periods as outlined by the respective regulations.
- All applicable documents and information will be entered into the seed-to-sale tracking system as specified by the RSA.

This ..... day of ..... , ...

APPLICANT/PERSON AUTHORIZED BY APPLICANT

Name

Signature

[Insert RSA Logo here]

[Form serial #]

STATUTORY DECLARATION

I, the undersigned, ……., as part of my application for and intended issuance of a Medicinal Cultivation License, hereby consent to and authorize the Regulatory Substances Authority to inspect my property and facility to ensure that I meet the terms and conditions set out in the Cannabis & Industrial Hemp Act and all applicable Cannabis Regulations and the recognition to be issued.

This ……. day of …… , …….

APPLICANT/PERSON AUTHORIZED BY APPLICANT

Name

Signature

Schedule 2

(Section 34)

Risk Level	Description	Timeline for Action
Level I	There is a reasonable probability that the use of or exposure to the affected cannabis or cannabis product will cause serious adverse health effects or loss of life. Level I risks included but are not limited to, a label that contains incorrect information that could potentially affect public health and safety, such as incorrect labeling of allergens, or a license holder has been made aware that the mandatory testing shows that the cannabis or cannabis product exceeds the tolerance limits for residues or contaminants as prescribed in the Limits of Residues and Contaminants Regulations.	Initial contact should be made as soon as possible, and at most within ONE BUSINESS DAY of commencing the recall.
Level II	The use of or exposure to the affected cannabis or cannabis product may cause temporary adverse health consequences or the probability of serious adverse health effects is remote. Level II risks include, but are not limited to mislabelling of a cannabis product wherein the	Initial contact should be made as soon as possible, and at most within FOUR BUSINESS DAYS of commencing the recall

	label shows a lower concentration of the total THC than what was listed on the label.	
Level III	The use of, or exposure to, the affected cannabis or cannabis product is not likely to cause any adverse health effects. Level III risks include but not limited to a product label that was printed without the mandatory health warning messages, or the mandatory Standardized Cannabis Symbol as prescribed in the Cannabis Packaging and Labeling Regulations	Initial contact should be made as soon as possible, and at most within SEVEN BUSINESS DAYS of commencing the recall
Level IV	Instances where the cannabis or cannabis product has not reached the end consumer. A Stop Sale may be utilized instead of a recall. Level IV risks include if the product was distributed to other cannabis license holders, or the product is at the distribution level but not at the retail level, or the product has been put on the shelves for retail but not sold. Level IV Stop Sale may be the option.	Initial contact should be made immediately to ensure that the cannabis and cannabis products do not make it further down the supply chain. In the event it does, the risk level shall be increased appropriately.

Schedule 3

Cannabis Cultivation License

[Insert Logo Here]

Regulated Substance Authority
Saint Lucia

Licence No.

CANNABIS CULTIVATION LICENCE

LICENCE HOLDER:
[Insert name here]

DATE OF ISSUE: [YYYY-MM-DD]
DATE OF EXPIRY: [YYYY-MM-DD]

LICENCE SITE:
[Insert location here]

LICENCE TYPE:
[Insert Licence Type]

This licence authorizes the above mentioned holder to engage in cultivation of cannabis at the site specified in this licence, until the expiration date of this licence. This licence issued in accordance with the *Cannabis Act* and *Cannabis Regulations* and is not transferable to any other person or site location. This licence shall be displayed in a prominent place at all times at the licenced site. The licence shall be subject to suspension or revocation if the licence is determined to be in violation of the *Cannabis Act* and *Cannabis Regulations* adopted thereunder.

[Insert Seal Here]

Name
Chief Executive Officer
Regulated Substance Authority

Name
Chief Licencing Officer
Regulated Substance Authority