MEDICINAL MANUFACTURING REGULATIONS1

CANNABIS MEDICINAL

PROCESSING

REGULATIONS

ARRANGEMENT OF REGULATIONS

- 1. Citation
- 2. Interpretation
- 3. Application
- 4. Non-application
- 5. Criteria for a Processor's License
- 6. Authorized activities
- 7. Application for a Processor's License
- 8. Security clearances
- 9. Refusal to grant security clearance
- 10. Site design
- 11. Site inspection
- 12. Physical security measures
- 13. Pest Management Plan
- 14. Waste management plan
- 15. Approval of the Processor's License
- 16. Processor's License fees

- 17. Changes to the information in a License
- 18. Approval of a change
- 19. Renewal of a Processor's License
- 20. Weighing devices
- 21. Operations Manager
- 22. Operational terms and requirements of Cannabis Processor
- 23. Quality Assurance
- 24. Pesticide product
- 25. Purchasing cannabis
- 26. Shared-use facility
- 27. General manufacturing requirements and registration of new products
- 28. Testing
- 29. Limits of variability
- 30. Maximum quantity of THC
- 31. Prohibited cannabis products
- 32. Dried and fresh cannabis
- 33. Edible cannabis

- 34. Use of tinctures
- 35. Failed regulatory compliance requirements
- 36. Selling of cannabis products
- 37. Recall action plan
- 38. Recall
- 39. Importation
- 40. Exportation
- 41. Transportation
- 42. Destruction of cannabis
- 43. Lost or theft
- 44. Notices
- 45. Financial reporting
- 46. Requirements for retention of documentation and information
- 47. Reports to inland revenue
- 48. Exceptions urgent notices
- 49. Forms
- 50. Schedule 1

51. Schedule 2

52. Schedule 3

53. Schedule 4

CANNABIS MEDICINAL PROCESSING REGULATIONS

Citation

1. This Regulation may be cited as the Cannabis Medicinal Processor's Regulations.

Interpretation

2. In this Regulation –

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

"allergen" means any protein from any of the following foods, or any modified protein, including any protein fraction, that is derived from peanuts, eggs, milk, soybeans, wheat or triticale, sesame seeds, mustard seeds, crustaceans, molluscs, fish or nuts including almonds, Brazil nuts, cashews, hazelnuts, macadamia nuts, pecans, pine nuts, pistachios or walnuts;

"authorized individuals" means employees of the Central Trading Entity 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" has the same meaning as in the Cannabis & Industrial Hemp Act, No. [] of 2024;

"cannabis product" means cannabis of only one of the classes set out in Schedule 1, or a cannabis accessory that contains one of the

classes set out in Schedule 1 after it has been packaged and labelled for sale or distribution to a consumer at the retail level;

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

"**cannabis topicals**" means a substance or mixture of substance that contains cannabis and that is intended for use directly or indirectly, exclusively on external body surfaces, including hair and nails.

- "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.
- "**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.
- "cannabis waste" means any material intended for disposal that contains cannabis and may be hazardous cannabis waste and nonhazardous 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.
 - "**certificate of analysis**" means a document issued by a recognized laboratory that communicates the results of the scientific tests done on a class of cannabis set out in Schedule 1;
- "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;
- "class two dispensary" has the same meaning as in the Cannabis & Industrial Hemp Act, No. [] of 2024; "employee" means any person directly employed by a holder of a Processor's 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 Processor's License;

"hermetically sealed container" means a container that, due to its design, is secure against the entry of micro-organisms, including spores;

"licensed dispensary" means a Class One Dispensary License or a Class Two Dispensary License as prescribed in the Act;

"processing " or "processed" means all aspects of the extraction, infusion, post-processing, remediation, and packing and labelling processes, including processing, preparing, holding, and storing of cannabis products and its components and ingredients;

"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;

"**new product**" means a product that is manufactured by a holder of a Processor's License that has not yet been approved for retail by the RSA. It includes products where the label has been modified or rebranded.

"person" has the same meaning as the 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 nonconformance 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;

"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 procedure**" (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;

"**tincture**" means a solution of cannabis extract, derived either directly from the cannabis plant or from a manufactured cannabis extract, dissolved in alcohol, glycerin, or vegetable oils. For purposes of this definition, "vegetable" includes botanically classified fruits and vegetables and their seeds;

"water activity" means the ratio of the water vapor pressure of the component to the vapor pressure of pure water, at the same temperature and pressure;

Application

3. These Regulations apply to all applicants and holders of a Medicinal Processor's License.

Non-application

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

Criteria for a Processor's License

- 5. -(1) A holder of a Processor's License must
 - i. be a natural or legal person;
 - ii. ensure that at least 40 % of the employees are Saint Lucian citizens;

Authorized activities

- 6. -(1) A holder of a valid Processor's License is authorized to conduct the following activities
 - i. to possess cannabis;

- ii. to produce cannabis products, by means other than cultivating, propagating or harvesting;
- iii. to alter the chemical or physical properties of cannabis by the use of organic solvents;
- iv. to sell cannabis to a licensed dispensary;
- v. to submit samples to a registered laboratory as prescribed in the Cannabis Testing And Laboratory Regulations;
- vi. may offer to conduct activities listed in subsection (b) and (c) with written authorization from the Regulated Substance Authority (RSA).

Application for a Processor's License

- 7. -(1) An application to be granted a Processor's License may be submitted to the RSA, in electronic, typed or printed format.
 - (2) Applications shall be
 - (a) completed as prescribed in Schedule 2 Form ID []
 - (b) accompanied by -
 - (i) all requisite documentation and information;
 - (ii) the non-refundable application fees as prescribed in the Cannabis & Industrial Hemp Fee Regulations.
 - (iii) business plan;
 - (iv) proof of financial ability to maintain the terms and requirements of the Processor's License as dictated by the
 Act, the Cannabis Regulations, other applicable regulations and guidelines, standard operating procedures and
 industry standards;

documentation evidencing ownership or authority to use the property on which the holder of the Processor's License intends to process cannabis or engage in any activities commensurate therewith or required thereby to wit –

(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.
- (vi) grant for security clearance as prescribed in section 9;
- (vii) site plan as specified in section 11;
- (viii) pest management plan as specified in section 13;
- (ix) waste management plan as specified in section 15;
- (x) the details and evidence as requested by the RSA.
- (c) signed and dated by the applicant or person authorized by the applicant to sign, indicating that all the information provided in support of the application is correct and complete to the best of their knowledge.
- (3) 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.

Security clearances

- 8. -(1) The RSA shall assess and where applicable grant security clearances for all directors.
 - (2) A holder of a Processor's License shall notify the RSA of all employees or prospective 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 Processor's 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, except when the offense is for possession of less than 30g of cannabis, 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

9. –(1) If the RSA intends to refuse to grant a security clearance, the RSA must provide the applicant, holder of the Processor's License or applicant of the Processor's 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 Processor's License;
 - (b) the holder of the Processor's 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

- 10. -(1) Pursuant to section (2)(b)(viii) 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.
 - (2) The site plan shall include 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;
 - (1) The site plan must also demonstrate the following –

- (a) that it can meet the physical security measures outlined in section 13.
- (b) that it is designed and constructed with a system that allows for filtration and ventilation;
- (c) that the site is designed or constructed with hand cleaning and hand sanitization stations and washrooms;
- (d) that the site is designed or constructed in a manner that ensures that it meets the fire safety code.

Site inspection

- 11. –(1) Pursuant to the Act, the RSA may conduct an inspection of the premises as part of the application process and throughout
 the lifespan of the license, 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 the 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 production process, and;
 - (iv) prevents the introduction of peripheral substances to the cannabis, ingredients or tools that will be used in processing.
 - (v) include power generation or power backup.

- (b) 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.
- (c) that the system that allows for filtration and ventilation specified in section 11(2)(ii) ensures that
 - (i) the air can be filtered to prevent the escape of odors associated with cannabis plant materials to the outdoors;
 - (ii) it provides natural or mechanical means of ventilation with sufficient air exchange to supply clean air and remove unclean air as a means to prevent the contamination of cannabis or ingredients that will be used in the production process;
 - (iii) the system is accessible and, if necessary for its cleaning, maintenance or inspection is capable of being disassembled;
- (d) that the site is designed or constructed with hand cleaning and hand sanitization stations and washrooms as specified in section 11(2)(iii) that
 - (i) are equipped and adequate in number and size for the number of individuals using them;

- (ii) are capable of withstanding repeated cleaning and, as necessary, repeated sanitization, and
- (iii) are located so that –
- (2) they can be readily accessible to individuals;
- (3) they do not present any risk of contamination of cannabis.
 - (e) the site is designed or constructed in a manner that ensures that the temperature and humidity
 - (i) of the building or part of the building where cannabis is stored or used is maintained at levels that are appropriate for the activity being conducted with the cannabis;
 - (ii) system is accessible and, if necessary, is capable of being disassembled for cleaning, maintenance or inspection;
 - (iii) system is disposed to repeated cleaning, and
 - (iv) system permits it to function in accordance with its intended use.
 - (f) to ensure that any equipment, including conveyances are designed, constructed and can be maintained in a manner that –
 - (i) permits the effective cleaning of its surfaces;
 - (ii) prevents the contamination of cannabis, ingredients or tools that will be used in the production process;
 - (iii) permits it to function in accordance with its intended use
 - (1) is accessible, and
 - (2) is capable of withstanding repeated cleaning and, as necessary, repeated sanitization

- (iv) prevents the introduction of peripheral substances to the cannabis, ingredients or tools that will be used in processing, and
- (v) protects the ingredients, including cannabis from cross-contamination against with allergens.
- (i) exterior facility and grounds must meet the following minimum standards in order to minimize the risk of potential contamination –
 - (i) be equipped with draining areas in order to prevent pool or stagnant water;
 - (ii) grass, weeds, vegetation shall be cut within the immediate vicinity of the cannabis processing premises;
 - (iii) litter and waste should not be present and should be removed;
 - (iv) roads, yards, and parking lots shall be maintained in a manner so that these areas do not constitute a source of contamination in areas where cannabis products are handled or transported;
 - (v) access points to the building, such as windows, exhaust fans, ventilation ducts or plumbing vents shall be screened, sealed or otherwise protected to minimize the risks of pests entering the building;
 - (vi) waste treatment and disposal systems shall be present and maintained in order to prevent contamination in areas where cannabis and cannabis products may be exposed.
- (3) The site must meet requirements of and approved by the development control authority.

Physical security measures

- **12.** The proposed site must demonstrate that physical security measures are present to deter and prevent unauthorized access. Such security measures shall include
 - (i) 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;
 - (ii) visual recording devices which must be capable of making and storing visual recordings of any attempt or actual unauthorized access;
 - (iii) an intrusion detection system which operates at all times and is capable of detecting any attempt or actual unauthorized
 access to the site and any attempted or actual tampering with the system;
 - (i) The intrusion detection system in subsection (c) must be capable of being monitored at all times;
 - (iv) a means of restricting access to each operation and storage area to individuals whose presence in the area is required by their duties;
 - (v) a means of recording the identity of every individual entering or exiting the site and accessing operations and storage areas;
 - (vi) physical barriers surrounding operations and storage areas that are capable of preventing unauthorized access.
 - (2) The holder of a Processor's 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 holder of a Processor's License shall be escorted by an employee of the licensee at all times while within the site.

(3) The holder of a Processor's License shall maintain a record of all authorized individuals who are not employees who enter the processing site. 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.

Pest Management Plan

- 13. A holder of a Processor's 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 processing site.

Waste management plan

- 14. -(1) Pursuant to section 22(d)(i)(3), the holder of a Processor's 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 Act Cap. 6.05.
 - (2) A holder of a Processor's License shall establish and implement standard operating procedures that describes the methodor 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.
 - (iii) Collection by a local waste disposal agency approved by RSA.
- (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 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 Processor 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, 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 the Processor's License

- **15.** –(1) Upon approval of the Processor's License
 - (a) the applicant shall pay the annual license fee pursuant to the cannabis & industrial hemp fee regulations.
 - (b) the applicant shall sign a Record Keeping Attestation form referenced in Schedule 2, attesting that they will retain documents and information as prescribed in section ;
 - (c) 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;
 - (d) the RSA shall
 - (i) grant security clearances for all approved individuals as prescribed in section 9;
 - (ii) present the approved person with the Processor's License as prescribed in . The Processor's License shall set out the following information:
 - (1) the name of the approved company or corporative;
 - (2) the certificate 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 certificate, and;
- (7) the expiration date of the certificate.

(2) The Processor's License shall be displayed at the address of the site where the activity is authorized and, if applicable, at each building within the site.

Processor's License fees

- 16. -(1) Pursuant to section 16(1)(a), a holder of a Processor's License shall pay the applicable annual licencing fee pursuant to the Cannabis Fee Regulations
 - (2) A holder of a Processor's License, who also has a Cultivation License may be permitted to pay a lowered application fee as pursuant to the Cannabis & Industrial Hemp Fee regulations.
- **17.** –(1) The holder of the Processor's 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.

(d) Any other change to the license.

- (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

18. 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 11;
- (c) shall, upon approval of the changes, reissue a new license if required.

Renewal of a Processor's License

19. –(1) A holder of a license shall within 3 months of the date of expiration on the Processor's License submit to the RSA

(a) a completed request for renewal form as prescribed in Schedule 2;

- (b) all requisite documentation and information;
- (c) the details and evidence as requested by the RSA.
- (2) A license shall be renewed by the RSA subsequent to the satisfaction of all relevant criteria and upon payment of the prescribed fee.

Weighing devices

20. A holder of a Processor's 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.

Operations Manager

-(1) The holder of a Processor's License must retain the services of a person to be designated as the operations manager.

Operational terms and requirements of Cannabis Processor

- **21.** A holder of a Processor's License shall –
- 22. designate and retain a person as the operations manager

The operations manager -

i. is responsible for the ensuring that all operations within Processing facility is performed in compliance with the Act and the Cannabis Regulations;

- ii. must have sufficient knowledge of the provisions of the Act and the Cannabis Regulations in relation to activities conducted by Processor;
- (2) The holder of a Processor's License may designate one individual as the alternate operations manager who is qualified to replace the operations manager.
 - a) retain a copy of any site plan that is submitted to the RSA referenced in section 7(b)(viii), including any updated designs as referenced in section 18(2)(b) and;
 - (i) retain a copy for a retention period as prescribed in section .
 - b) obtain a security clearance from the RSA for every member of staff as part of the hiring process as referenced in section 9. Failure to comply shall be a Class B offence under the Act.
 - c) within the first 6 weeks of obtaining the Processor's License 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) standard operating procedures for all applicable parts of the processing and packaging processes to ensure that activities are conducted in compliance with all applicable Cannabis Regulations under the Act. Such standard operation procedures should be developed for
 - (1) security plan in keeping with the physical security measures;

- (2) purchasing cannabis from a Central Trading Entity with a certificate of recognition as prescribed in the Central Trading Entity Regulations.
- (3) cannabis waste management procedures which shall ensure that waste disposal is done in accordance with Waste Management Act, Cap. 6.05;
- (ii) sampling procedures of cannabis products to be tested as prescribed in the Cannabis Testing and Laboratory Regulations.
- (iii) packaging and labeling of cannabis products in keeping with the Packaging and Labeling Regulations SI.
- (iv) transportation of cannabis products.
- (v) all other applicable operations.
- (b) establish mechanisms to ensure that the cannabis be stored under conditions that maintain their quality;
- (c) establish mechanisms to ensure that the cannabis be distributed under conditions that maintain their quality;
- (d) set up a system of auditing that allows for the rapid and complete recall of every lot or batch of cannabis products that has been sold or distributed.
- (e) establish and ensure good production practices, including -
 - (i) that individuals who enter or is in any building or part of a building where operation or storage areas exist,
 wears clothing, footwear and protective coverings, including gloves, a hairnet, or beard net and a smock, that
 are in good condition and clean and that are appropriate for the activity being conducted;

- (ii) that any equipment used at the site are designed, constructed, maintained, operated and arranged in a manner that –
 - (1) permits the effective cleaning of its surfaces;
 - (2) is accessible and, if necessary for its cleaning, maintenance or inspection, is capable of being easily disassembled;
 - (3) permits it to function in accordance with its intended use;
 - (4) prevents the contamination of cannabis or tools that will be used in the operation and distribution processes, and
 - (5) prevents the introduction of peripheral substances to the cannabis or tools that will be used in operations and distribution process.
- (f) ensure that any individual who conducts activities in relation to his or her duties has the competencies and qualifications that are necessary to conduct those activities at the site;
- (g) as part of their staff compliment, retain the services of an individual who is responsible for quality assurance as specified in section 24;
- (h) ensure that security measures listed in section 13 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
- (iv) the date and time when the response was taken.
- (v) provide a notice to the RSA, with a detailed report, including information under this subsection.
- (i) ensure that no animal is present in any building or part of a building where cannabis or any part of the operations process will be.
- (j) ensure that any biological, chemical or physical hazard that presents a risk of contamination of the cannabis or anything that will be used as an ingredient in the cannabis production process is identified and analyzed.

Quality Assurance

- **23.** Pursuant to section 21(j), the holder of a Processor's License must designate and retain the services of a quality assurance personnel. The responsibilities of the quality assurance person are to
 - (a) assure the quality and approval of the cannabis before it is made available for sale and distribution;
 - (b) ensure that all standard operating procedures are created and maintain a revision history;
 - (c) investigate every complaint received in respect to the quality of the cannabis, if necessary, immediately taking measures to mitigate any risk, and

(d) immediately investigate and, if necessary, immediately take measures to mitigate any risk if there is any grounds for reasonable suspicion that the cannabis or any part of the operations, distribution and sale process presents a risk of injury to human health or is non-compliant with the applicable measures listed in section 11(2);

Pesticide product

- 24. –(1) Cannabis must not be treated with a pesticide product unless as prescribed under the Cannabis Residues, Contaminants and Limits Regulations.
 - (2) Notwithstanding subsection (1), edible cannabis may be treated during the course of production with pesticide products subject to meeting testing requirements as specified in the Cannabis Residues, Contaminants and Limits Regulations.

Purchasing cannabis

- **25.** –(1)A holder of a Processor's License shall be permitted to purchase cannabis from a Central Trading Entity as prescribed in the Central Trading Entity Regulations.
 - (2) A holder of a Processor's License may purchase cannabis from a License Cultivator if authorized by the RSA subject to the provision of the Medicinal Cultivation Regulations and the Central Trading Entity Regulations.

Shared-use facility

26. –(1) A holder of a Processor's License must not manufacture edible cannabis or store cannabis at a shared-use facility without prior approval from the RSA.

- (2) The RSA may permit a holder of a Processor's License to manufacture cannabis products at a shared use facility, provided that all activities related to cannabis production are done in a physically separate space.
- (3) In the event that the RSA permits a shared-use facility, the holder of the Processor's License must ensure that physical or other effective means are used to separate cannabis or anything that will be used as an ingredient from anything that presents a risk of contamination of the cannabis or the ingredient that will be used in the cannabis product production.

General processing requirements and registration of new products

- 27. –(1) A holder of Processor's License must ensure that any water, steam or ice that is used or might come in contact with cannabis extract, cannabis topicals, edible cannabis or anything that will be used as an ingredient is potable, or at minimum does not pose a risk of contamination of the cannabis extract, cannabis topicals, edible cannabis extract, cannabis topicals, edible used as an ingredient.
 - (2) The cannabinoids and terpenes must be uniformly distributed throughout the cannabis extract or cannabis topical.
 - (3) For every new product that is processed by a holder of a Processor's License, the licensee shall submit the following information to the RSA, prior to the cannabis product being sold or distributed
 - (a) the name of the cannabis product;
 - (b) the label of the cannabis product; and
 - (c) the certificate of analysis obtained by a recognized laboratory.
 - (4) The RSA shall –

- (a) register the new cannabis product;
- (b) keep a register, in a physical or electronic form, of all approved cannabis product;
- (c) shall issue a notice to the registrant of the new cannabis product, or any License Processor that so requests, with a notice of registration of product.

[Note: Please ensure similar requirements are listed in the Import /Export Regulations] **Testing**

- 28. –(1) A holder of a Processor's 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) Testing must be conducted
 - i. by a recognized laboratory as prescribed under the Act, and;
 - ii. on a representative sample of each lot or batch of cannabis or cannabis product, as prescribed in the Cannabis Testing and Laboratory Regulations.
 - iii. on sufficient quantity to enable the determination of the quality of the cannabis.
 - (3) In the event that cannabis or cannabis product 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 processing ;

- (b) quarantine the cannabis;
- (c) notify the RSA to facilitate the destruction of the cannabis, as prescribed in section 43.
- (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.

Limits of variability

- 29. –(1) The concentration of THC or CBD or any other cannabinoid displayed on the label for a cannabis extract, cannabis topical or an cannabis accessory that contains such, must not contain less than 85% or more than 115% of THC or CBD or any other cannabinoid of that quantity concentration.
 - (2) The concentration of THC or CBD or any other cannabinoid displayed on the label of edible cannabis must not contain
 - (a) less than 85% or more than 115% of that quantity concentration if the THC or CBD or any other cannabinoid exceeds more than 5 mg;
 - (b) less than 80% or more than 120% of that quantity concentration if the exceeds more than 2 mg;
 THC or CBD or any other cannabinoid
 - (c) less than 75% or more than 125% of that quantity concentration if the does not exceed 2 mg;
 THC or CBD or any other cannabinoid

- (3) In the case of cannabis products that are not discrete units but is represented as being able to be divided into discrete units, each represented unit must not contain –
 - (a) a quantity of not of THC less than 75% or more than 125% of that quantity concentration, taking into consideration of THCA to be converted to THC;
 - (b) a quantity of CBD less than 75% or more than 125% of that quantity concentration, taking into consideration of CBDA to be converted to CBD.

Maximum quantity of THC

- **30.** –(1) Notwithstanding section 29
 - i. a cannabis extract, a cannabis topical or a cannabis accessory that contains cannabis extract or cannabis topicals, which are intended for retail or distribution must not contain a quantity of THC that exceeds the amount prescribed by the Minister, taking into account the potential to convert THCA into THC.
 - Edible cannabis or a cannabis accessory that contains edible cannabis, which is intended for retail use must not contain a quantity of THC that exceeds the amount prescribed by the Minister, taking into account the potential to convert THCA into THC.
 - (2) Notwithstanding subsection (1)(b), the Medicinal Cannabis Advisory Council may prescribe in the case of an edible cannabis product that is an orally dissolving product, such as sublingual lozenges or mouth strips, the percentage of the amount prescribed by the Minister of THC per package.

(3) Cannabis products which is categorized as Class Two Medicinal Cannabis, as prescribed by the Minister shall only available be for sale at a Class Two Dispensary.

Prohibited cannabis products

- 31. The following cannabis products are prohibited from being sold or distributed
 - i. a cannabis product which is intended to be applied in the area of the human eye bounded by the infraorbital and supraorbital including the eyebrows, the skin underlying the eyebrows, the eyelids, the eyelashes, the conjunctival sac of the eye, the eyeball and the soft tissue that lies below the eye and within the infraorbital ridge;
 - ii. a cannabis product that is intended to be applied on damaged or broken skin or to penetrate the skin barrier other than by absorption;
 - iii. alcoholic beverages;
 - iv. a cannabis product must not contain or have on it anything that may cause injury to the health of the user when the cannabis product is used as intended or in a reasonably foreseeable way;
 - v. any cannabis product that contains any non-cannabinoid additive that can increase the potency, toxicity, or addictive potential, or that would create an unsafe combination with other psychoactive substances including, but not limited to nicotine;
 - vi. any cannabis product that, if unopened, must be stored at or below 4° C to prevent the cannabis product from becoming contaminated before its durable life date;

- vii. any edible cannabis, or cannabis accessory that contains edible cannabis, that is intended for retail that is in a hermetically sealed container if any component of the edible cannabis has a pH that exceeds 4.6 and a water activity that exceeds 0.85 at a temperature of $22 \pm 2^{\circ}$ C;
- viii. meat, poultry or seafood products of any kind;
 - ix. any product that is manufactured by the addition of cannabinoid extract or concentrate to commercially available candy or snack food items without further processing of the product. Notwithstanding, a commercially available food items may be used as ingredients in a cannabis product, provided that it is used in a way that renders the product unrecognizable from the commercially available items and the label including ingredients lists does not reference the commercially available food items.
 - x. any product that the RSA ascertains is easily confused with commercially available food items that do not contain cannabis;
- xi. any cannabis product that is attractive to children as set out in the Act;
- xii. any product that the RSA ascertains, on a case-by-case basis, is attractive to children;
- xiii. any inhalable cannabis product that is delivered into the lungs through a metered-dose inhaler or dry-powder inhaler.
 Nothing in this section shall be interpreted to prohibit other dry-powder cannabis products or metered-dose vaporizers containing cannabis or cannabis oil.

xiv. THC or THCA must not be added to dried or fresh cannabis that will become a cannabis product or will be contained in a cannabis accessory that will become a cannabis product.

Dried and fresh cannabis

- **32.** –(1) Dried and fresh cannabis that is a cannabis product or is contained in a cannabis accessory that is a cannabis product, must not contain or have on it anything other than the cannabis plant, including the phytocannabinoid produced by, or found in, such a plant, regardless of whether that part has been processed or not.
 - (2) Notwithstanding subsection (1), dried and fresh cannabis may contain or have on it residues of a pest control product within the threshold limits set out in the Limits of Residues and Contamination for Cannabis Regulations.
 - (3) The net weight of a discrete unit of dried cannabis that is intended to be consumed by means of inhalation must not exceed the amount prescribed by the Minister.

Edible cannabis

- **33.** Edible cannabis that is a cannabis product, or that is contained in a cannabis accessory that is a cannabis product must not contain
 - i. caffeine unless it is introduced through the use of ingredients that naturally contain caffeine and the total amount of caffeine in each immediate container of the cannabis product does not exceed the amount prescribed by the Minister.
 - ethyl alcohol or have on it ethyl alcohol unless the concentration of ethyl alcohol does not exceed 0.5% w/w of the edible cannabis.

Use of tinctures

34. A tincture shall be no more than 2 fluid ounces and shall include a calibrated dropper or similar device that is capable of measuring a single serving.

Failed regulatory compliance requirements

- 35. -(1) A batch or lot has failed regulatory compliance requirements if it has failed to
 - i. 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;
 - ii. label the cannabis product as prescribed in these regulations and the Packaging and Labeling Regulations, or
 - iii. any other regulatory compliance requirements as set out in these requirements.
 - (2) A finished cannabis product batch or lot that fails any regulatory compliance requirements established by these regulations and otherwise shall be destroyed unless –
 - (a) The cannabis product batch or harvest batch may be remediated through the corrective action of relabeling pursuant to subsection (b) or
 - (b) A corrective action plan for the remediation of the failed cannabis product batch or lot is approved by the RSA, pursuant to section (3). The corrective action plan must be submitted by the holder of the Processor's License who intends to remediate the said batch or lot and must not receive the batch or lot from another licensee unless the RSA has approved the corrective action plan.

- (3) A cannabis product batch or lot that fails regulatory compliance testing for cannabinoid or terpenoid content may be remediated by relabeling the product with the correct information that is obtained from the certificate of analysis provided that the THC limits set out in section 30 are met.
 - (a) Excluding the provisions of subsection (2)(b), a cannabis product batch, lot or a harvest batch that fails regulatory compliance requirements or quality assurance review shall not be remediated unless the RSA has approved a corrective action plan submitted by the holder of the Processor's License who will be performing the remediation. In the case of edible cannabis, corrective action plans shall only be approved if the conditions under subsection (2)(b) and (a) are applicable.
 - (b) Edible cannabis products that fail regulatory compliance requirements because the per package limit of THC has exceeds the THC limit as set out in section 30 may be remediated by repacking under the following conditions –
 - (i) the RSA has approved a corrective action plan for repacking the product;
 - (ii) the product batch or lot is returned to the processor who packaged the product;
 - (iii) the product is not altered in any way, and
 - (iv) the product is labeled to accurately state the contents and is in compliance with the Packing and Labeling Regulations.
 - (v) corrective action plans shall be submitted to the RSA and reviewed on a case-by-case basis. A corrective action plan shall contain the following information –

- 1. the legal business name and the license number of the licensed processor;
- 2. the brand name and each lot or batch number of the cannabis product for which the remediation is to done;
- 3. the size of the lot or batch for which the remediation is to be done;
- 4. the contact information for the individual who is responsible for the corrective action, including their name, email address and phone number;
- 5. a description of how the cannabis product or harvest batch will be remediated so that the cannabis product or harvest batch or lot, or any product produced therefrom, will meet the regulatory compliance requirements, and
- 6. any additional information requested by the RSA.
- 7. all corrective action plans and remediation activities shall be documented and recorded

as part of the system of auditing referred to in section 21.

Destruction of cannabis

- **36.** –(1) A holder of a Processor's 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 Processor's License must, 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 36(1)(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 36(1)(b).
- (3) The licensee must document and retain records of the destruction, for a retention period, as prescribed in section 46(2)(c)(i)(3).

Selling of cannabis products

37. –(1) All cannabis products that are manufactured by a holder of a Processor's License shall be sold to a Licensed Dispensary, a holder of a Processor's License or a holder of a Cannabis License that is authorized to export cannabis.

- (2) Sale of cannabis by a holder of a Processor's License to any person or entity not listed in subsection (1) shall be a Class D offence.
- (3) A holder of a Processors License shall not sell a cannabis product which is not registered as prescribed in section 27.
- (4) Sale of cannabis product that is not registered, as prescribed in section 27 by a holder of a Processor's License shall be a Class C offence.

Recall action plan

- 38. The holder of a Processor's License shall ensure that the following are established
 - (a) factors within the daily operations of the entity that would necessitate a recall;
 - (b) employee responsible for implementing the recall procedures;
 - (c) a mechanism to notify all customers 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 goods; 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

- **39.** –(1) The recall of cannabis and levels of severity shall be dictated by the Cannabis Regulations and pursuant to Standards Act (Act No. 14 of 1990)
 - (2) The holder of a Processor's License shall conduct a recall if any of the risks levels, as prescribed in the Limits of Residues and contaminants of Cannabis Regulations, Medical Processing Regulations and Cannabis Testing Regulations.
 - (3) The holder of a Processor's License shall conduct the recall within the timeframe specified in Schedule 4.
 - (4) The holder of a Processor's License 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 Processor's License shall conduct a recall simulation based on the system of auditing referred to in section 21(f) –
 - (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 45(1)(h) and 45(2).
 - (7) The report specified in subsection 39(2) 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 identified to be recalled;
- (c) the name and address of each licensee from which the cannabis was obtained;
- (d) the rational for commencing the recall;
- (e) the quantity of cannabis product that is sold or distributed;
- (f) the quantity of cannabis that is affected by the problem or potential problem underlying the recall;
- (g) the period during which the licensee sold or distributed the cannabis;
- (h) contact information for the individual who is responsible for the recall as specified in section (b);
- (i) in the case of exported cannabis, the permit number of the exported cannabis, and all relevant information that is included in the permit –
 - (1) including the destination country, and
 - (2) contact information of the receiver;
- (j) the timeline and manner in which the recall is expected to be carried out, including -
 - (1) the expected date for the commencement of the recall;
 - (2) how and when the RSA will be informed of the progress of the recall, and;
 - (3) the expected completion date of the recall.

(k) a description of any other measure the holder of the certificate of recognition intends to take in respect to the recall.

Importation

40. –(1) A holder of a Processor's License may not import unless they also possess a valid import License, and in such case, is subject to the requirements under the Cannabis Importation and Exportation Regulations.

Exportation

41. A holder of a Processor's License may not export unless they also posses a valid Export License, and in such a case is subject to the requirements under the Cannabis Importation and Exportation Regulations.

Transportation

42. A holder of a Processor's License may not transport cannabis and cannabis products unless they also posses a valid Transport License, in such case is subject to the requirements under the Cannabis Transportation Regulations.

Lost or theft

- **43.** A holder of a Processor's License must, if a theft or loss of cannabis is encountered that cannot be explained on the basis of 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

44. –(1) A holder of a Processor's License must notify the RSA of any of the following changes within 7 days a change occurs;

- (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 9.
- (2) A holder of a Processor's License shall retain a copy of all notices sent to the RSA for a retention period as prescribed in section 46 or otherwise in this Act.

Financial reporting

45. 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

- 46. –(1) When purchasing or selling cannabis or cannabis products, A holder of a Processor's License is required to retain a document that contains the following information for each lot or batch of cannabis
 - (a) the name of the person to which it is purchased or sold;
 - (b) the address of the location from which it is purchased or sold and the place to which it is sent of delivered;
 - (c) the date on which it is purchased or sold, packaged;
 - (d) a description of the cannabis;
 - (e) the internal lot or batch number assigned to the product;
 - (f) the external lot or batch number assigned by the licensee;
 - (g) the weight of the cannabis that is purchased, and

- (h) 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 Processor's 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 the date on which
 - (1) the cannabis is purchased from a licensed cultivator;
 - (2) the cannabis is sold to licensed processors and researchers;
 - (3) the cannabis was destroyed as specified in section 43;
 - (4) the notice is sent or provided to the RSA specified in section 45.
 - (5) any occurrence listed in section 22(k)(i) and 22(k)(iii);
 - (ii) at least one year after the date of any occurrence listed in section 22(k)(ii);
 - (iii) at least one year after the date of the video recording specified in section or 15(4)(ii);
 - (iv) in the case of imported cannabis, as prescribed in the Cannabis Importation and Exportation Regulations;
 - (v) in the case of exported cannabis, as prescribed in the Cannabis Importation and Exportation Regulations;

- (vi) in the case of pre-packaged products sold to Class 1 Dispensaries, as prescribed in the these Regulations, and the Packing and Labeling Regulations;
- (3) A holder of a Processor's 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 a Processor's License is canceled, suspended, revoked or expired, A holder of the Processor's License shall continue to retain documentation and information as specified under this section.

Exceptions – urgent notices

- 47. Individuals are obligated to notify the RSA immediately if
 - (a) a person who is required to obtain a security clearance is convicted of -
 - (a) 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, or
 - (b) 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

48. For the purpose of facilitating a Processor's License, the requisite forms are set out in Schedule 2.

Schedule 1

(Sections 5)

Table 1: Classes of Cannabis

Item	Class of Cannabis	
1	dried cannabis	
2	fresh cannabis	
3	cannabis plants	
4	cannabis plant seeds	
5	edible cannabis	
6	cannabis extracts	
7	cannabis topicals	

Schedule 2

[Form serial #]

FC XX

APPLICATION FOR A PROCESSOR'S 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 answer the following question: Do you possess or are also applying for a Traditional Processor's License

Yes

No

If, yes please provide the name on the Processor's License application or the name registered to the Cultivation License and the license number if applicable

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

(Section 7)

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 Processor's 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

|--|

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 (I	<u>N</u> IC)	
Please provide 2 forms of ID a	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 INFORMATIC	ON CONTRACTOR OF CONT	
2.1 Name of entity		
2.2 Type of company (business activity or purpose)		
2.3 Current position	1	
	[Insert RSA Logo here]	
[Form serial #]		
2.4. Business address		
Address		
City		

2.5 Business mailing addres	ss (if different from 1.4 abo	ve)
Address		
City		
2.6 Business contact inform	nation	
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

[Insert RSA Logo here]

[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)

 \Box Certificate character

 \Box 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)

- **COMPANY or COORPERATIVE INFORMATION** 2.
- 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

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

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 Processor's 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.

APPLICANT/PERSON AUTHORIZED BY APPLICANT

Name

Signature

[Insert RSA Logo here]

[Form serial #]

STATUTORY DECLARATION



I, the undersigned,, hereby consent to, as part of the Processor's License, permit the Regulatory 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.

APPLICANT/PERSON AUTHORIZED BY APPLICANT Name

Signature

Schedule 3

Cannabis Processor's License

[Insert Regulated Substance Authority Logo Saint Lucia Here]

Licence No.	
-------------	--

CANNABIS PROCESSOR'S 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 processing 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]

Chief Executive Officer Regulated Substance Authority Name Chief Licencing Officer Regulated Substance Authority

MEDICINAL MANUFACTURING REGULATIONS65

Schedule 4

		(Section 39)
Risk Level	Description	Timeline for Action
Level I	There is a reasonable probability that the use of	Initial contact should be made
	or exposure to the affected cannabis or	as soon as possible, and at
	cannabis product will cause serious adverse	most within ONE BUSINESS
	health effects or loss of life. Level I risks	DAY of commencing the
	included but are not limited to, a label that	recall.
	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.	
Level II	The use of or exposure to the affected cannabis	Initial contact should be made
	or cannabis product may cause temporary	as soon as possible, and at
	adverse health consequences or the probability	most within FOUR
	of serious adverse health effects is remote.	BUSINESS DAYS of
	Level II risks include, but are not limited to	commencing the recall
	mislabelling of a cannabis product wherein the	

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