SAINT CHRISTOPHER AND NEVIS

STATUTORY RULES AND ORDERS

No. 17 of 2022

Cannabis (Medicinal Cannabis Licensing) Regulations

Arrangement of Regulations

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Cannabis (Medicinal Cannabis Licensing) Regulations

In exercise of the power conferred by section 60 of the Cannabis Act, 2020, the Minister makes the following Regulations:

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Part I Preliminary

1. **Citation.**

These Regulations may be cited as the Cannabis (Medicinal Cannabis Licensing) Regulations, 2022.

2. **Interpretation.**

In these Regulations,

"applicant" means a person that has submitted an application pursuant to these rules that was accepted by the St. Kitts and Nevis medicinal cannabis authority for review and is waiting to be approved or denied by the Medicinal Cannabis Authority;

"Development Control and Planning Board" means the Development Control and Planning Board appointed under the Development Control and Planning Act, Cap. 20.07;

"medicinal cannabis card" means a medicinal cannabis patient identification card for Medicinal Cannabis issued by the Authority;

"medicinal cannabis cultivation licence" means a licence which shall be issued to allow for the growing, harvesting, drying, trimming, curing or packaging of medicinal cannabis;

"medicinal cannabis extract, isolate or concentrate" means the resin extracted from cannabis in its crude form, distilled to isolated form or recombined to concentrate form;

"medicinal cannabis dispensary" means an entity that is licensed pursuant to these Medicinal Regulations to operate a business that sells medicinal cannabis to authorized patients or authorized caregivers, but is not a caregiver;

"medicinal cannabis dispensary operations" means engaging in the storing and providing of medicinal cannabis to authorized patients and caregivers;

"medicinal cannabis goods" means all medicinal cannabis, medicinal cannabis extracts, resin, non-infused medicinal cannabis products and medicinal cannabis infused

products and may be used interchangeably with any of these within these Regulations;

“medicinal cannabis import or export licence” means a licence which shall be issued per transaction, to allow for the importation or exportation of medicinal cannabis and which will follow the international narcotics control board Regulations regarding controlled substances export and import procedures, with the addition of phytosanitary certification and other agriculture documents for medicinal cannabis plant material;

“medicinal cannabis export and import operations” means engaging in the importing and exporting of medicinal cannabis;

“medicinal cannabis infused products manufacturer licence” means a licence which shall be issued to allow for activities relating to the processing and manufacturing of medicinal cannabis products, including but not limited to, edibles and other derivative products, but does not include the extraction of medicinal cannabis;

“medicinal cannabis infused products manufacturer operations” means engaging in the manufacturing of medicinal cannabis products;

“medicinal cannabis lounge licence” means a licence which shall be used to establish an authorized place for patients to medicate;

“medicinal cannabis research licence” means a licence which shall be issued to allow for the conduct of scientific research relating to the development of medicinal cannabis;

“medicinal cannabis research and development operations” means engaging in the research and development of medicinal cannabis;

“medicinal cannabis special dispensing licence” means a licence which shall be issued to a person that is certified by the Authority to dispense medicinal cannabis at an authorized medicinal cannabis dispensary;

“medicinal cannabis testing facility” means an entity licensed and certified where the analytical information is determined and certification of the safety and potency of medicinal cannabis or medicinal cannabis infused products is carried out;

“medicinal cannabis testing facility operations” means engaging in the quantitative and qualitative analysis and testing of medicinal cannabis;

“medicinal cannabis transport licence” means a licence which shall be issued to allow for the transport of medicinal cannabis;

“medicinal cannabis transport operations” means engaging in the transporting of medicinal cannabis;

“minor’’ means a person who is under the age of eighteen years;

“monitoring” means the continuous and uninterrupted attention to potential alarm signals that could be transmitted from a security alarm system located at a medicinal cannabis business licenced premises, for the purpose of summoning law enforcement to the premises during alarm conditions;

“notice of denial" means a written statement from the authority, articulating the reasons or basis for denial of a licence application;

"owner" means the person or persons whose beneficial interest in the licence is such that they bear risk of loss other than as an insurer and have an opportunity to gain profit from the operation or sale of the establishment where each individual owner shall have a licence and includes any other entity that qualifies as an owner pursuant to regulation 23;

"point of sale system" means an electronic system working with the St. Kitts and Nevis tracking system that is able to track all inventory, transactions, employee details, hold multiple accounts; in this case for owner, licensee and authority;

"premises" means the designated structure or structures, or land specified in the application that is owned, leased, or otherwise held under the control of the applicant or licensee where the commercial cannabis activity will be or is conducted. the premises shall be a contiguous area and shall only be occupied by one licensee;

"Solid Waste Management Corporation" means the Solid Waste Management Corporation referred to under the Solid Waste Management Act, Cap. 11.05.

Part II
Medicinal Cannabis Business Applications, Fees And Licensing

3. **Medicinal cannabis business operations.**

The Authority shall authorize, regulate, track, monitor and licence the following Medicinal cannabis business operations to enable medicinal cannabis goods to be produced, tested, processed and obtained for use in accordance with the Cannabis Act 2020—

(a) medicinal Cannabis Cultivation Operations meaning licenced entities engaging in the cultivation of cannabis for medicinal purposes;

(b) medicinal Cannabis Infused Products Manufacturer Operations meaning licenced entities engaging in the processing and extraction of medicinal cannabis products;

(c) medicinal Cannabis Testing Facility Operations meaning licenced entities engaging in the quantitative and qualitative analysis and testing of Medicinal Cannabis;

(d) medicinal Cannabis Dispensary Operations meaning licenced entities engaging in the storing and providing of medicinal cannabis to authorized patients and caregivers;

(e) medicinal Cannabis Lounge Licence meaning licenced entities engaging in the operation of a medicinal lounge for approved patient use of medicinal cannabis;

(f) medicinal Cannabis Transport Operations meaning licenced entities engaging in the transporting of medicinal cannabis;

(g) medicinal Cannabis Research and Development Operations meaning licenced entities engaging in the research and development of medicinal cannabis; and

(h) medicinal Cannabis Export and Import Operations meaning licenced entities engaging in the importing and exporting of medicinal cannabis.

4. **General restrictions on business licensees and standards requirements.**

(1) A person shall not engage in the cultivation, processing, testing, dispensing, infused product manufacture, transport, export and import or use medicinal cannabis for any other purpose unless the person is the holder of the relevant licence specified under Regulation 5 of these Regulations.

(2) A person who contravenes subregulation (1) of this regulation commits an offence and is liable on summary conviction to the penalty specified under section 57 of the Cannabis Act, 2020.

(3) Any cannabis in St. Kitts and Nevis shall meet such standards for international trade including, but is not limited to, GMP, GPP, Fair trade, Global GAP, Euro GAP, GAP, HACCP and such other standards as may be specified by the Authority.

(4) Except as provided in sub-regulation (5) of this Regulation and Regulation 21, a person may apply for and be issued more than one licence under these Regulations.

(5) An applicant or licensee shall apply for, and if approved, shall obtain, a separate licence for each location where it engages in commercial cannabis activity.

(6) A licensee shall not sell, offer or provide alcoholic beverages or tobacco products on or at any premises licenced under these Regulations, however, a licensee may sell, offer, or provide a cannabis product that is an alcoholic beverage, including, but is not limited to, an infusion of medicinal cannabis or cannabinoids into an alcoholic beverage.

(7) It shall not be a violation of law for an agent of a licensing authority to possess, transport, or obtain cannabis or cannabis products as necessary to conduct activities reasonably related to the duties of the Authority.

5. **Types of Licenses.**

(1) Medicinal Cannabis shall be regulated in accordance with any of the following licences provided that all conditions attached thereto, and the requirements of the Cannabis Act 2020 and these Regulations are complied with—

(a) a Medicinal Cannabis Cultivation Licence, which shall be issued to allow for the growing, harvesting, drying, trimming, curing or packaging of medicinal cannabis;

(b) a Medicinal Cannabis Dispensary Licence, which shall be issued to allow for the dispensing of medicinal cannabis to authorized patients or caregivers;

(c) a Medicinal Cannabis Lounge Licence, which shall be used to establish an authorized place for patients to medicate;

(d) a Medicinal Cannabis Testing Facility Licence, which shall be issued to allow for the qualitative and quantitative analysis and testing of Medicinal Cannabis to ensure that Medicinal Cannabis entering the market is safe;

(e) a Medicinal Cannabis Processing and Extraction Licence, which shall be issued to allow for the processing and extraction of raw medicinal cannabis material into concentrated or isolated products;

(f) a Medicinal Cannabis Infused Products Manufacturer Licence, which shall be issued to allow for activities relating to the processing and manufacturing of

medicinal cannabis products, including but not limited to, edibles and other derivative products, but does not include the extraction of Medicinal Cannabis;

(g) a Medicinal Cannabis Transport Licence, which shall be issued to allow for the transport of medicinal cannabis;

(h) a Medicinal Cannabis Research Licence, which shall be issued to allow for the conduct of scientific research relating to the development of medicinal cannabis; and

(i) a Medicinal Cannabis Import or Export licence, which will follow the International Narcotics Control Board Regulations regarding controlled substances export and import procedures, with the addition of phytosanitary certification and other agriculture documents for medicinal cannabis plant material.

(2) A person who is granted a licence pursuant to the Cannabis Act 2020 and these Regulations, shall not transfer or assign his licence to another person or entity or cause or permit another person or entity to use the licence.

(3) Any purported transfer or assignment of a licence shall be null and void unless authorized by the Authority.

(4) Notwithstanding, section 4 of the Drugs (Prevention and Abatement of the Misuse of Drugs) Act, Cap. 9.08, a person who imports or brings into, or exports from the state of St. Kitts and Nevis any cannabis or cannabis-infused products except under and in accordance with a licence, and into or from port or place, authorized by the Authority, shall be guilty of an offence against the Cannabis Act 2020.

6. **Medicinal cannabis business application.**

(1) An application for a licence shall be complete and accompanied with the required fees which may be accepted and processed by the Authority.

(2) Where an application is complete, but further information is required before it can be fully processed, the applicant shall provide the additional requested information within the time frame given by the Authority in order for the application to be acted on in a timely manner and to be considered complete.

(3) An application shall include all attachments or supplemental information required by the forms supplied by the Authority.

(4) An application shall be accompanied by a full remittance for the whole amount of the application fees as specified in Regulation 30 of these Regulations.

(5) The applicant shall prove that all tax returns related to a medicinal cannabis business and proposed premises have been timely filed and are up to date.

(6) An applicant or an owner of a medicinal cannabis business shall be tax compliant and hold tax clearance.

(7) The Authority may refuse to accept an incomplete application.

(8) All applications for licences authorizing medicinal cannabis businesses shall be forms prescribed by the Authority.

(9) Applications submitted to the Authority may include, but may not be limited to, new business premises, renewals, transfers of ownership, change of locations, premises modifications, and changes in trade name.

(10) A medicinal cannabis applicant shall be over 21 years of age.

7. **Medicinal cannabis business - requirements for a licence application.**

(1) An application for a licence authorizing a medicinal cannabis business, shall be completed in the form set out is Schedule XIV and any required supplemental information shall be provided in the form set out in Schedule XV.

(2) An application for a new medicinal cannabis licence business shall include, but may not be limited to the following

(a) an application fee for each medicinal cannabis business, individual or premises as specified in Regulation 30 of these Regulations

(i) for an applicant who is an individual, the applicant shall provide both the first and last name of the individual;

(ii) for an applicant who is a business entity, the applicant shall provide the legal business name of the applicant;

(b) suitable evidence of proof of lawful presence or residence, where applicable; (c) proof of good moral character and reputation;

(d) where, the Authority has requested information concerning financial and management associations and financial interests of other persons in the business as defined in Regulation 23 of these Regulations,

(i) if the applicant for any licence pursuant to these Regulations is a corporation or limited liability company, it shall submit with the application the names, mailing addresses, and owner's background forms of all of its principal officers, directors, and owners, plus, a copy of its articles of incorporation or articles of organization and evidence of authorization to do business within this country and each applicant shall submit the names, mailing addresses, and background information of all persons owning any of the outstanding or issued capital stock, or of any persons holding a membership interest;

(ii) if the applicant for any licence pursuant to this Regulation is a partnership, it shall submit with the application the names, mailing addresses, and owner's background information of all of its partners and a copy of its partnership agreement;

(e) board of Inland Revenue tax payment information and Tax Clearance Certificate for all entities and locations or premises to be licenced;

(f) proof of funds documentation to adequately cover the total proposed project; (g) source of funds documentation for every investment or capital expenditure;

(h) a location diagram, where applicable, as defined in regulation 8 subregulation (3)(a) of these Regulations;

(i) a premises diagram, as defined in regulation 8 of these Regulations, detailing accurate floor plans, electrical plans, ventilation plans, monitoring system plan and security plan for the premises to be licenced;

(j) evidence that the applicant has the legal right to occupy and use the proposed location and that the proposed location complies with these Regulations;

(k) evidence that the proposed premises is in compliance with these Regulations;

(l) the deed, lease, contract, or other document governing the terms and conditions of occupancy of the premises licenced or proposed to be licenced;

(m) the type of licence as specified in Regulation 5 of these Regulations, for which the applicant is applying;

(n) whether the applicant has been denied a licence or has had a licence suspended or revoked by the Authority and the applicant shall provide the type of licence applied for, the reason for denial and the date of denial;

(o) the physical address of the premises;

(i) if the Authority is unable to confirm that the address provided is valid, then the applicant shall provide a document that confirms the physical address of the premises;

(ii) such a document may include a utility bill, deed, or title;

(p) the mailing address for the applicant, if different from the premises address; (q) the telephone number for the applicant and for the premises;

(r) the website address and email address of the applicant's business where applicable;

(s) contact information for the applicant's designated primary contact person including the name, title, phone number, and email address of the individual;

(t) a list of every business name the applicant is operating under including the address where such business is located;

(u) the applicant shall also supply the following financial information—

(i) a list of funds belonging to the applicant held in savings, checking, or other accounts maintained by a financial institution and the applicant shall provide, for each account, the financial institution's name, the financial institution's address, account type, account number, and the amount of money in the account;

(ii) a list of loans made to the applicant and for each loan, the applicant shall provide the amount of the loan, the date of the loan, terms of the loan, security provided for the loan, and the name, address, and phone number of the lender;

(iii) a list of investments made into the applicant's medicinal cannabis business and for each investment, the applicant shall provide the amount of the investment, the date of the investment, terms of the investment, and the name, address, and phone number of the investor;

(iv) a list of all gifts of any kind given to the applicant for its use in conducting medicinal cannabis business activity and for each gift,

the applicant shall provide the value of the gift or description of the gift, and the name, address, and phone number of the provider of the gift;

(v) a complete list of every individual who has a financial interest in the commercial medicinal cannabis business as defined in regulation 23 of these Regulations, who is not an owner as defined in regulation 22 of these Regulations.

(v) a complete list of every owner of the applicant as defined in Regulation 22 of these Regulations and each individual named on this list shall submit the following information—
(i) the full name of the owner;

(ii) the owner's title within the applicant entity;
(iii) the owner's date of birth and place of birth;
(iv) the owner's individual tax compliance certificate;
(v) the owner's mailing address;
(vi) the owner's telephone number, which may include a number for the owner's home, business, or mobile telephone;
(vii) the owner's email address;

(viii) the owner's current employer;

(ix) the percentage of the ownership interest held in the applicant entity by the owner;

(x) whether the owner has an ownership or a financial interest as defined in Regulations 22 and 23, respectively, of these Regulations in any other commercial medicinal cannabis business licenced under the Act;

(xi) a copy of the owner's government-issued identification, which may include a document issued by a federal, state, county, or municipal government that includes the name, date of birth, height, gender, and picture of the person, such as a driver licence, national identification or passport;

(w) a detailed description of the owner's convictions and a conviction within the meaning of this Regulation means a plea or verdict of guilty or a conviction following a plea of nolo contendere or such convictions dismissed under law of the state of St. Kitts and Nevis law shall be disclosed and for each conviction, the owner shall provide the following

(i) the date of conviction;

(ii) dates of incarceration, if applicable;

(iii) dates of probation, if applicable;

(iv) dates of parole, if applicable;

(v) a detailed description of the offence for which the owner was convicted;

(vi) a statement of rehabilitation for each conviction which is to be written by the owner and may contain evidence that the owner would like

the Authority to consider that demonstrates the owner's fitness for licensure;

(vii) supporting evidence may be attached to the statement of rehabilitation and may include, but is not limited to, dated letters of reference from employers, instructors, or professional counsellors that contain valid contact information for the individual providing the reference;

(x) where applicable, a detailed description of any administrative orders or civil judgements for violations of labour standards, any suspension of a medicinal cannabis business licence, revocation of a medicinal cannabis business licence, or sanctions for unlicenced medicinal cannabis activity by the Authority or law enforcement, against the applicant or a business entity in which the applicant was an owner, pursuant to the Cannabis Act 2020, but preceding the date of the application; and (y) attestation to the following statement

> "Under penalty of perjury, I hereby declare that the information contained within and submitted with the application is complete, true, and accurate. I understand that a misrepresentation of fact is cause for rejection of this application, denial of the licence, or revocation of a licence issued".

(3) Nothing in this regulation shall limit the Authority's ability to request additional information it considers necessary or relevant to determining an Applicant's suitability for licensure.

(4) Failure to provide such additional information by the requested deadline may result in denial of the application.

(5) All applications to reinstate a licence will be consider applications for new licences and this includes, but is not limited to—

(a) licences that have been expired for more than 90 days;

(b) licences that have been voluntarily surrendered; and (c) licences that

have been revoked.

(6) A person that holds a medicinal cannabis testing facility licence under the Cannabis Act 2020 and these Regulations is prohibited from licensure for any other activity, except testing, as authorized under these Regulations and a person that holds a medicinal cannabis testing facility licence shall not employ an individual who is also employed by any other medicinal cannabis business licensee that does not hold a medicinal cannabis testing facility licence.

(7) Except as provided in Regulation 21 of these Regulations, a person may apply for and be issued more than one medicinal cannabis business licence, except in the case of a Medicinal Cannabis Testing Facility Licence, under these Regulations, provided the licenced premises are separate and distinct.

(8) Each applicant or licensee shall apply for, and if approved, shall obtain, a separate licence for each location where it engages in commercial cannabis activity.

8. **Premises Diagram.**

(1) An applicant shall submit to the Authority, with the application, a complete and detailed diagram of the proposed premises which shall be used by the Authority to determine whether the premises meets the requirements under these Regulations and the Cannabis Act 2020.

(2) The Authority shall deny an application if the premises does not qualify for licensure pursuant to these Regulations.

(3) The premises diagram shall

(a) show the boundaries of the property and the proposed premises to be licenced, showing all boundaries, dimensions, entrances and exits, interior partitions, walls, rooms, washrooms, windows, and doorways, and shall include a brief statement or description of the principal activity to be conducted therein;

(b) show and identify areas of medicinal cannabis business activities applicable to the business operations, that will take place within the proposed location and premises, which shall include but may not be limited to, the following—

(i) storage;

(ii) batch sampling;

(iii) loading or unloading of shipments;

(iv) packaging and labelling;

(v) customer sales;

(vi) loading for deliveries;

(vii) extraction and processing;

(viii) cultivation, including information specified in subregulation (7) of this Regulation;

(ix) medicinal cannabis waste disposal;

(x) regular waste disposal or any special non-cannabis waste disposal required by the Ministry of Health;

(c) show reception areas;

(d) identify restricted access areas and limited access areas;

(e) identify waste disposal areas and show a cannabis waste disposal plan.

(4) Where the proposed premises referred to in subregulation (1) consists of only a portion of a property, the diagram shall be labelled indicating which part of the property is the proposed premises and what the remaining property is used for.

(5) Where the proposed premises consists of only a portion of a property that will contain two or more licenced premises, the diagram shall clearly show the designated entrances and walls under the exclusive control of the applicant for the premises, as well as the designated entrances and walls for each additional premises and shall also show all proposed common or shared areas of the property, which may include but may not be limited to, lobbies, bathrooms, hallways, and break-rooms.

(6) Where the proposed premises referred to in subregulation (1) is located on a portion of a property that also includes a residence, the diagram shall clearly show the designated buildings for the premises and the residence and shall have written consent of the owner of the residence regarding the medicinal cannabis business operating on the property.

(7) If the proposed premises will be a medicinal cannabis cultivation operation, in addition to the requirements of subregulations (1) to (6) of this Regulation, the applicant shall also provide a complete detailed diagram which shall include, but may not be limited to, the following

(a) the measurements of the planned canopy, including aggregate square footage and individual square footage of separate cultivation areas;

(b) clone or seedling areas;

(c) nutrient storage areas;

(d) immature plant areas;

(e) flowering plant areas;

(f) harvest and processing areas;

(g) drying and curing areas;

(h) roads;

(i) water crossings;

(j) points of diversion;

(k) water storage and delivery system;

(l) temperature control systems;

(m) humidity control systems;

(n) carbon dioxide systems;

(o) complete electrical plan;

(p) ventilation system;

(q) fire suppression plan; and

(r) all other facilities and infrastructure related to the cultivation.

9. **Operating procedures plan.**

A licensee application shall include a detailed description or plan of the applicant's operating procedures which shall include, but may not be limited to the following—

(a) transportation procedures;

(b) cultivation procedures;

(c) extraction and processing procedures;

(d) inventory procedures;

(e) monitoring and tracking procedures

(f) quality control procedures;

(g) security procedures;

(h) medicinal cannabis waste management procedures;

(i) delivery procedures; (j) safety procedures.

10. **Landowner approval.**

(1) Where the applicant is not the landowner of the real property upon which the premises is located, the applicant shall provide to the Authority

(a) a signed consent form, as set out in Schedule XVII, from the landowner or the landowner's agent that states that the applicant has the right to occupy the property and acknowledges that the applicant may use the property for the commercial medicinal cannabis activity for which the applicant is applying for licensure; or

(b) a copy of the rental or lease agreement.

(2) Where the occupier of the land referred to in subregulation (1) is a trustee, the landowner approval shall come from the person that holds equitable title in the real property.

(3) Where the applicant is the landowner of the real property upon which the premises is located, the applicant shall provide to the Authority a copy of the title or deed to the property.

11. **Information shall be provided truthfully.**

(1) An applicant shall submit information to the Authority in a full, faithful, truthful, and fair manner.

(2) The Authority may recommend denial of an application where the applicant has made intentional or purposeful misstatements, omissions, misrepresentations, or untruths in the application or in connection with the applicant's background investigation.

(3) The type of conduct refers to in subregulation (2), may be considered as the basis for additional administrative action against the applicant and it may also be the basis for criminal charges against the applicant.

12. **Accessibility of application forms.**

All application forms supplied by the Authority and filed by an applicant for a licence, including attachments, additional information and any other documents associated with the investigation, shall be accessible by the Authority, for a purpose authorized by these Regulations or for any other law enforcement purpose.

13. **Applicant bears burden of proof to meet licensing requirements.**

(1) An applicant shall at all times during the application process be capable of establishing that he is qualified to hold a licence.

(2) Where an applicant does not cooperate with the Authority during the application phase, such as, but is not limited to the circumstances where the Authority requests additional evidence of suitability and the applicant is unable to furnish such evidence by a date requested, the applicant's application may be rejected.

14. **Voluntary withdrawal of application.**

(1) The Authority and applicant may mutually agree to allow the voluntary withdrawal of an application for licensing in lieu of an application rejection proceeding.

(2) An applicant shall first submit a notice to the Authority requesting the voluntary withdrawal of the application and with the understanding that he was not obligated to

request the voluntary withdrawal and that any right to a hearing in the matter is waived once the voluntary withdrawal is approved.

(3) The Authority will consider the request along with any circumstances at issue with the application in making a decision to accept the voluntary withdrawal.

(4) The Authority may at its discretion grant the request without prejudice or deny the request.

(5) The Authority will notify the Applicant of its acceptance of the voluntary withdrawal and the terms thereof.

(6) If the Applicant agrees to a voluntary withdrawal granted without prejudice, then the Applicant is not eligible to apply again for licensing or approval until after expiration of one year from the date of such voluntary withdrawal.

15. **Rejection of an application.**

(1) The Authority shall have the right to reject an application for any reason.

(2) Where an application is rejected, the application fees minus a twenty-five percent processing fee shall be returned to the applicant within sixty days.

(3) The Authority shall reject the application for licensure or renewal of a licence if any of the following conditions apply

(a) where an applicant or business he is associated with, has the purpose or intent, in whole or in part, of transporting, cultivating, processing, extracting, testing, or distributing cannabis or cannabis infused products before receiving prior licences from all relevant authorities;

(b) where an applicant is statutorily disqualified from holding a licence;

(c) where there are already applications approved for the number of allowed operations within an area or within Saint Christopher and Nevis;

(d) where either the applicant, or the premises for which a licence is applied, does not qualify for licensure under these Regulations;

(e) failure or inability to comply with any of the provisions of these Regulations, or any requirement imposed to protect natural resources, including, but not limited to, protections for instream flow, water quality, fish and wildlife;

(f) failure to provide information required by the Authority;

(g) where the applicant, or any of its officers, directors, or owners has been convicted of an offence that is substantially related to the qualifications, functions, or duties of the business or profession for which the application is made, except that if the Authority determines that the applicant, owner, or licensee is otherwise suitable to be issued a licence, and granting the licence would not compromise public safety, the Authority shall conduct a thorough review of the nature of the crime, conviction, circumstances, and evidence of rehabilitation of the applicant or owner, and shall evaluate the suitability of the

applicant, owner, or licensee to be issued a licence based on the evidence found through the review;

(h) in determining which offences are substantially related to the qualifications, functions, or duties of the business or profession for which the application is made, the Authority shall include, but not be limited to, the following—

(i) violent felony conviction;

(ii) a serious felony conviction;

(iii) a felony conviction involving fraud, deceit, or embezzlement;

(iv) a felony conviction for hiring, employing, or using a minor in transporting, carrying, selling, giving away, preparing for sale, or peddling, any controlled substance to a minor; or selling, offering to sell, furnishing, offering to furnish, administering, or giving any controlled substance to a minor;

(v) except as provided for in subregulations (a) and (g)(iv) of this regulation, a prior conviction, where the sentence, including any term of probation, incarceration, or supervised release, is completed, for possession of, possession for sale, sale, manufacture, transportation, or cultivation of a controlled substance is not considered substantially related, and shall not be the sole ground for rejection of a licence;

(vi) a conviction for any controlled substance offence subsequent to licensure shall be grounds for revocation of a licence or rejection of the renewal of a licence;

(i) where an applicant, or any of its officers, directors, or owners, has been sanctioned by the Authority for unauthorized commercial cannabis activities or has had a cannabis licence suspended or revoked in the three years immediately preceding the date the application is filed with the Authority.

(4) An applicant may appeal a rejection pursuant to these Regulations as specified in Part VII of the Cannabis Act, 2020.

16. **Approval of an application.**

(1) Where the Authority approves an application, the application fees will be processed and the applicant will be informed by written post or via electronic mail and is expected to produce all licensing fees, as specified in Regulation 31, to the Board within thirty days of the applicant being informed of the approval.

(2) Where the applicant fails to pay all licensing fees to the Board within this time-frame specified in subregulation (1), the approval will become void and fifty percent of the application fees shall be refunded to the Applicant.

(3) Where the applicant cannot be contacted for any reason via post, electronic mail or phone, the approval will become void after 90 days and no application fees will be refunded.

(4) When the Applicant submits all licence fees, a provisional licence, as defined in Regulation 17 of these Regulations, will be granted, to give the approved applicant the

time to complete the proposed location and facility construct, which shall meet all guidelines and pass all inspections, as specified by these Regulations, before it is granted a medicinal cannabis business licence and allowed to begin operation.

17. **Provisional Licence.**

(1) Where the Authority approves an application for a medicinal cannabis business licence, a provisional licence shall be granted to the Applicant by the Authority.

(2) A provisional licence is granted to give the approved applicant the necessary time to complete the proposed project that is approved in the application and the approved applicant shall meet or exceed all requirements, guidelines, rules and obligations as specified within these Regulations, before receiving a medicinal cannabis business licence.

(3) Provisional licences shall be valid for one year starting from its issuance to the approved applicant

(a) if the approved applicant requires more than the validity period of the provisional licence to complete the proposed project, he may apply, in writing to the Authority, and no later than 30 days before the expiration of the provisional licence, for an extension to the provisional licence;

(b) if the Authority is satisfied that the approved applicant has been diligent in the attempt to complete the proposed project and does require more time to be ready for inspections, the Authority may grant an extension to the provisional licence; or

(c) if the Authority finds that the approved applicant has been neglectful in the attempt to complete the proposed project, upon the approved applicant's request for an extension to the provisional licence, the Authority may revoke the provisional licence and revoke the approval of the application as specified in Regulation 18.

(4) A provisional licence

(a) shall only be considered part of the process of approval and does not constitute nor guarantee an approved medicinal cannabis business licence;

(b) shall not be made public through any form of media, notice, advertising or publication; and

(c) shall not be used to gain any financial interest, investment, compensation, increase in private or publicly traded stock in any form, to the proposed medicinal cannabis business or to any other business, company, corporation, individual or entity owned by the applicant or any of the persons considered owners of the proposed medicinal cannabis business.

(5) An approved applicant or any owner of the proposed medicinal cannabis business found to be in contravention of this subregulation shall be guilty of an offence against these Regulations and shall have its provisional licence and approved application revoked.

18. **Licence revocability and eligibility.**

(1) A licence issued by the Authority to a medicinal cannabis business constitutes a revocable privilege.

(2) A licence issued by the Authority a provisional licence or approved application that is revoked shall not be refunded any fees and any owners, entity or applicant involved may not re-apply for a medicinal cannabis business licence for 3 years after such revocation.

(3) An applicant shall submit a complete application to the Authority before it will be accepted or considered.

(4) An applicant shall consult with the Authority to confirm whether the proposed medicinal cannabis business licence, location or premises is eligible for authorization.

19. **Medicinal cannabis business-process for renewing a licence.**

(1) The Authority will send a notice for licence renewal 90 days prior to the expiration of an existing licence by post or electronic mail to the licensee's mailing address or email address that is recorded on the Applicant's file.

(2) A licensee may apply for the renewal of an existing licence no less than 30 days prior to the licence's expiration date and such application shall be accompanied by the renewal fees specified in Regulation 32.

(3) Where the licensee, refer to subregulation (2), files a renewal application during the 30 day period prior to expiration, the licensee shall provide a written explanation detailing the circumstances surrounding the late filing accompanied by the late renewal fees specified in Regulation 32.

(4) Where the Authority accepts the application, then it may elect to administratively continuethe licence beyond the expiration date while it completes the renewal licensing process.

(5) An application for renewal will only be accepted if it is accompanied by the requisite renewal fees, as specified in Regulation 32.

(6) Failure to receive a notice for licence renewal does not relieve a licensee of the obligation to renew all licences as required.

(7) If a licence is not renewed before its expiration the following conditions shall apply—

(a) a licence is immediately invalid upon expiration if the licensee has not filed a late renewal application and remitted all of the required fees;

(b) the licensee shall not operate the medicinal cannabis business;

(8) Where a licensee files a late application with the Authority within the 30 day period after the expiration of the licence, the licensee shall provide a written explanation detailing the circumstances surrounding the late filing accompanied by the special late renewal fees specified in Regulation 32 and the Authority may administratively continue the licence from the date the late application was received until it can complete its renewal application process and investigate the extent to which the licensee operated with an expired licence to calculate penalty fines as specified in these Regulations.

(9) Where a Licensee files a renewal application after 30 days from date of expiration of the licence, the renewal application shall be treated as a new licence application.

20. **Excessive concentration.**

(1) In determining whether to grant or deny a licence for a medicinal cannabis business, the Authority shall consider if an excessive concentration exists in the area where the licensee will operate.

(2) For the purposes of this regulation, "excessive concentration" applies when one of the conditions as follows exist—

(a) the ratio of medicinal cannabis business licensees to a populated area within the country exceeds the ratio of similar establishments to the same population area in the county in which the applicant premises is to be located

(i) similar establishments shall include medical pharmacies within the country as an initial guide to the number of medicinal cannabis dispensary licences are granted;

(ii) the number of approved medicinal cannabis cultivation operations, extraction and processing operations and infused product manufacture operations licenced to supply the domestic market, shall be in direct consideration of and guided by, the number of medicinal cannabis dispensaries approved; or

(b) where approval of the application would unduly oversaturate the regulated market so as to perpetuate the illegal market for medicinal cannabis goods.

(3) The Authority shall calculate the ratios described in subregulation (2)(a) of this Regulation once every six months using the most current available data.

(4) The Authority's consideration of whether to grant or deny a licence shall be based upon the most recent ratio calculated by the Authority on the date of the Authority's decision.

(5) The existence of an excessive concentration shall not be considered in determining whether to grant, deny, or extend a provisional licence under Regulation 17 of these Regulations.

(6) The applicant may provide reliable evidence establishing, to the satisfaction of the Authority, that a denial of a licence would unduly limit the development of the regulated market so as to perpetuate the illegal market for medicinal cannabis goods.

21. **Monopolization.**

(1) A person or entity shall not monopolize, or attempt to monopolize, or to combine or conspire with any person or entity, to monopolize any part of the trade or commerce related to medicinal cannabis business or goods.

(2) The Prime Minister of St. Kitts and Nevis, with the approval of Cabinet, shall have the sole discretion whether to enforce this Regulation.

(3) A licensee or licenced entity or any of its owners found to be in contravention of subregulation (1) of this Regulation, has committed and offence against these Regulations and will be subject to licence revocation and complete asset seizure by the Authority.

(4) A licensee or licenced entity or any of its owners shall not

(a) make a sale or contract for the sale of medicinal cannabis or medicinal cannabis infused products, or to fix a price charged therefor, or discount from, or rebate upon, that price, on the condition, agreement, or understanding that the authorized consumer or licenced purchaser thereof shall not use or deal in the goods, merchandise, machinery, supplies, commodities, or services of a competitor or competitors of the seller, where the effect of that sale, contract, condition, agreement, or understanding may be to substantially lessen competition or tend to create a monopoly in any line of trade or commerce;

(b) sell any cannabis or cannabis products at less than cost for the purpose of injuring competitors, destroying competition, or misleading or deceiving purchasers or prospective purchasers;

(c) discriminate between different Regulations, communities, or cities or portions thereof, or between different locations in those Regulations, communities, or cities or portions thereof in St. Kitts and Nevis, by selling or furnishing the same medicinal cannabis or medicinal cannabis infused products at a lower price in one Regulation, community, or city or any portion thereof, or in one location in that Regulation, community, or city or any portion thereof, than in another, for the purpose of injuring competitors or destroying competition;

(d) sell any cannabis or cannabis products at less than the cost thereof to such vendor, or to give away any article or product for the purpose of injuring competitors or destroying competition; or

(e) have ownership or financial interest, as explained in Regulations 22 and 23, in more than twenty percent (20%), by number count, of the total number of medicinal cannabis business licences issued within St. Kitts and Nevis.

(5) A person who, as director, officer, or agent of any firm or corporation, or as agent of any person, violates the provisions of this chapter, or assists or aids, directly or indirectly, in that violation is responsible therefore equally with the person, firm, or corporation for which that person acts.

22. **Protection of local stakeholders.**

(1) A licenced medicinal cannabis cultivation, extraction or infused products manufacturer business licensee shall not sell its medicinal cannabis goods to another licenced medicinal cannabis business in St. Kitts and Nevis, of which it is an owner or has a financial interest in, as explained in Regulations 22 and 23 of these Regulations, for less than 10% net profit.

(2) A licenced medicinal cannabis cultivation, extraction or infused products manufacturer business licensee shall not sell or export its medicinal cannabis goods to another licenced medicinal cannabis business, of which it is an owner or has a financial

interest in, as explained in Regulations 22 and 23 of these Regulations, for less than 10% net profit.

(3) A licenced medicinal cannabis cultivation, extraction or infused products manufacturer business licensee shall not sell or export its medicinal cannabis goods to another licenced medicinal cannabis business for less than 10% net profit.

23. **Financial interest in a medicinal cannabis business.**

(1) A financial interest means an agreement to receive a portion of the profits of a Medicinal cannabis business, an investment into a Medicinal cannabis business, a loan provided to a Medicinal cannabis business, or any other equity interest in a Medicinal cannabis business except as provided in subregulation (6) of this Regulation.

(2) A person or entity that holds a financial interest in a medicinal cannabis business, except as provided for in subregulation (6), these individuals shall be required to submit the information required of owners under Regulations 7.

(3) For purposes of these Regulations, an agreement to receive a portion of the profits includes, but is not limited to, the following individuals—

(a) an employee who has entered into a profit share plan with the medicinal cannabis business;

(b) a landlord who has entered into a lease agreement with the medicinal cannabis business for a share of the profits;

(c) a consultant who is providing services to the medicinal cannabis business for a share of the profits;

(d) a person acting as an agent, such as an accountant or attorney, for the medicinal cannabis business for a share of the profits; (e) a salesperson who earns a commission.

(4) Where an entity has a financial interest in a medicinal cannabis business, then all individuals who are owners of that entity shall be considered financial interest holders and therefore owners of the medicinal cannabis business by the Authority for tracking and monitoring purposes and compliance with international guidelines and

(a) this shall include all entities in a multi-layer business structure that has ownership in the Medicinal cannabis business, the Chief Executive Officer or members of the board of directors of the entity, as well as the Chief Executive Officer, members of the board of directors, partners, trustees and all persons that have control of a trust, and managing directors or nonmember directors of the entity; and

(b) each entity disclosed as having a financial interest shall disclose the identities of all persons holding financial interests until only individuals remain.

(5) An entity, a partnership interest, limited or general, a joint venture interest, a licensing agreement, ownership of a share or shares in a corporation, or a limited liability company which is licenced, or having a secured interest in equipment, fixtures used directly in the manufacture or cultivation of medicinal cannabis or medicinal cannabis-infused product, equipment or inventory constitutes a direct financial interest.

(6) Notwithstanding subregulation (2) of this Regulation, the following persons or entities holding a financial interest that are not considered owners and are therefore not required to be listed on an application for licensure under regulation 7

(a) a bank or financial institution whose interest constitutes a loan;

(b) persons whose only financial interest in the medicinal cannabis businessis through an interest in a diversified mutual fund, blind trust, or similar instrument;

(c) persons whose only financial interest is a security interest, lien, or encumbrance on property that will be used by the medicinal cannabis business;

(d) persons who hold a share of common or publicly traded stock that is less than five (5) percent of the total shares in a publicly traded company or total public offering; or

(e) any person contracted to manage the overall operation of a licenced premises through a management company that is neither owned or partly owned by any applicant, person, entity or owner of the medicinal cannabis business nor is a shareholder in the Medicinal cannabis business and is therefore not considered an owner

(i) owners may hire managers, and managers may be compensated by salary;

(ii) a medicinal cannabis business licence may not be held in the name of the manager.

24. **Medicinal cannabis business - transfer of ownership and changes in a licenced entity.**

(1) An application for transfers of ownership or changes in corporate entity or ownership structure regarding the addition of a new owner by a licenced medicinal cannabis business authorized pursuant to these Regulations shall be made upon prescribed by the Authority.

(2) An application for transfers of ownership or any change in corporate entity or ownership structure regarding the addition of an owner by a licenced medicinal Cannabis Business shall include relevant application fees, as specified in these Regulations and application forms shall be complete in every required detail.

(3) Each Applicant for a transfer of ownership or changes in corporate entities or ownership structure regarding the addition of an owner by a licenced Medicinal cannabis business shall provide all the information required by regulation 7 regarding the proposed new owners.

(4) Nothing in this Regulation shall limit the Authority's ability to request additional information or evidence it considers necessary or relevant to determining a new owner's suitability for licensure and failure to provide such additional information or evidence by the requested deadline may result in denial of the application.

(5) The Authority will not approve a transfer of ownership application without first receiving written notification and approval from the relevant licensing authorities as specified in regulation 4 of these Regulations.

(6) If the proposed new owner for any licence pursuant these Regulations is a corporation or limited liability company, it shall submit with the application—

(a) the names, mailing addresses, and owner's background forms of all of its principal officers, directors, and owners;

(b) a copy of its articles of incorporation or articles of organization; and evidence of its authorization to do business within Saint Christopher and Nevis; and

(c) in addition, each Applicant shall submit the names, mailing addresses of all persons owning any of the outstanding or issued capital stock, or of any persons holding a membership interest.

(7) Where the applicant for a licence pursuant to these Regulations is a general partnership, limited partnership, limited liability partnership, or limited liability limited partnership, it shall submit with the application the names, mailing addresses, and Owner's background forms of all of its partners and a copy of its partnership agreement.

(8) A proposed transfer of partnership interest or any change in general or directing partners of any partnership holding a licence shall be reported and approved by the Authority.

(9) A proposed transfer of capital stock or any change in principal officers or directors of a corporation shall be reported to and approved by the Authority, prior to such transfer or change.

(10) A proposed transfer of ownership or any change in directors of any limited liability company holding a licence shall be reported to and approved by the Authority, prior to such transfer or change.

(11) It shall be considered a licence violation affecting public safety if a licensee engages in any transfer of ownership without prior approval from the Authority and any other relevant licensing authority.

(12) The Authority shall not accept an application for transfer of ownership if the licence to be transferred is expired for more than thirty (30) days, is voluntarily surrendered, or is revoked.

25. **Medicinal cannabis business - changing location of the licenced premises.**

(1) An owner or other authorized representative of a medicinal cannabis businessshall make application to the Authority for permission to change location of its licenced premises.

(2) The application referred to in subregulation (1), shall—

(a) be made upon forms prescribed by the Authority;

(b) be complete in every material detail and include remittance of all applicable fees;

(c) explain the reason for requesting such change;

(d) be supported by evidence that the application complies with any licensing authority requirements;

(e) contain a report of the relevant licensing authorities responsible for the location in which the medicinal cannabis business is to be situated, which shall demonstrate the approval of the licensing authorities with respect to the new location.

(3) No change of location shall be permitted until after the Authority considers the application, and such additional information as it may require, and issues to the applicant a permit for such change and—

(a) the permit shall be effective on the date of issuance, and the licensee shall, within one hundred and twenty (120) days, change the location of its business to the place specified therein and at the same time cease to operate a medicinal cannabis business at the former location;

(b) at no time may a medicinal cannabis business operate or exercise any of the privileges granted pursuant to the licence in both locations;

(c) for good cause shown, the one hundred and twenty (120) day deadline may be extended for an additional ninety (90) days; and

(d) the permit shall be conspicuously displayed at the new location, immediately adjacent to the licence to which it pertains.

(4) The new proposed location and premises shall meet all guidelines and rules relevant to it as specified within these Regulations.

(5) An Applicant who intends to change location shall file a change of location application with the Authority and pay the requisite change of location application fee as specified in regulation 30 of these Regulations.

26. **Death, incapacity, or insolvency of a licensee.**

(1) In the event of the death, incapacity, receivership, assignment for the benefit of creditors or other event rendering one or more owners incapable of performing the duties associated with the licence, the owner or owners' successor in interest such as, but is not limited to, an appointed guardian, executor, administrator, receiver, trustee, or assignee, who shall notify the Authority in writing, within ninety (90) calendar days, by submitting the Notification and Request Form, which is incorporated herein by reference.

(2) Where the successor in interest referred to in subregulation (1), intends to continue operations or cancel the existing licence, he shall submit to the Authority

(a) the name of the successor in interest;

(b) the name of any owner for which the successor in interest is succeeding and the licence number;

(c) the phone number, mailing address, and email address of the successor in interest;

(d) documentation demonstrating that the owner or owners are within the capacity of performing the duties associated with the licence such as, but is not limited to, a death certificate or a court order; and

(e) documentation demonstrating that the person making the request is the owner or owner's successor in interest such as, but is not limited to, a court order appointing guardianship, receivership, a will or trust agreement.

(3) The Authority may give the successor in interest written approval to continue operations on the licenced business premises for a period of time specified by the Authority

(a) if the successor in interest or another person has applied for a licence from the Authority for the licenced premises and that application is under review;

(b) if the successor in interest needs additional time to destroy or sell Medicinal cannabis goods; or

(c) at the succession of the cannabis enterprise.

(4) The successor in interest is held subject to all terms and conditions under which a state medicinal cannabis licence is held pursuant to the Cannabis Act 2020 and these Regulations.

27. **Non-citizen investment.**

(1) The provisions of the Non-Citizens Land Holding Regulations Act shall beapplicable to any non-citizen who is a director or shareholder of a company who invests in a medicinal cannabis business.

(2) A non-citizen holding a medicinal cannabis business licence pursuant to these Regulations

(a) with company ownership between 30 percent and 79 percent owned by the foreign entity, shall issue to the Government a 15 percent risk-free perpetual equity ownership of that company; and

(b) with company ownership between 80 percent and 100 percent owned by the foreign entity, shall issue to the Government a 25 percent risk-free perpetual equity ownership of that company.

28. **Factors considered when determining residency - medicinal cannabis business licence applicant.**

The Authority will review the totality of the evidence, and any single piece of evidence regarding the location of a person's primary home will not necessarily be determinative.

29. **Notification of criminal acts, civil judgments, administrative orders or health and safety issues after licensure.**

(1) A licensee shall ensure that the Authority is notified in writing of a criminalconviction of any owner, either by mail or electronic mail, within forty-eight (48) hours of the conviction and the written notification to the Authority shall include the date of conviction, the court summary proceedings, the name of the court in which the licensee was convicted, and the specific offence or offences for which the licensee was convicted.

(2) A licensee shall ensure that the Authority is notified in writing of a civil penaltyor judgment rendered against the licensee or any owner in their individual capacity, either by

mail or electronic mail, within forty eight (48) hours of delivery of the verdict or entry of judgment, whichever is sooner and the written notification shall include the date of verdict or entry of judgment, the court summary proceedings number, the name of the court in which the matter was adjudicated, and a description of the civil penalty or judgment rendered against the licensee.

(3) A licensee shall ensure that the Authority is notified in writing of an administrative order or civil judgement for violations of labour standards against the licensee or any owner in their individual capacity, either by mail or electronic mail, within forty eight (48) hours of delivery of the order and the written notification shall include the date of the order, the name of the agency issuing the order, and a description of the administrative penalty or judgement rendered against the licensee.

(4) A licensee shall ensure that the Authority is notified in writing of the revocation of a licence, permit, or other authorization, either by mail or electronic mail within forty-eight (48) hours of receiving notice of the revocation and the written notification shall include the name of the agency involved, a written explanation of the proceeding or enforcement action, and the specific violation or violations that led to revocation.

30. **Schedule of application fees - medicinal cannabis businesses.**

(1) The Application fees set out in Schedule I shall apply to medicinal cannabis business applicants.

(2) Application fees are due at the time an application is submitted.

(3) Any refund or refunds on application fees for any reason will be less by twenty-five percent (25%) as a processing fee.

(4) Where a medicinal cannabis business provisional licence is issued to an approved applicant, all application fees become non-refundable.

31. **Schedule of licence fees: medicinal cannabis businesses.**

(1) The licence fees for medicinal cannabis business approved applicants shall be as set out in Schedule II.

(2) Each licence fees is due within thirty (30) days of an application being approved.

(3) If a licence is denied, after the licence fee has been submitted but before the licence has been issued, or during the provisional licence period, an Applicant may request that the Authority refund the full licence fee after the denial appeal period has lapsed or after the completion of the denial appeal process, whichever is later.

(4) Where a medicinal cannabis business licence is issued to an approved applicant, all licence fees become non-refundable.

32. **Schedule of renewal fees: medicinal cannabis businesses.**

(1) The renewal fees for Medicinal cannabis business Licensees shall be as set out in Schedule III.

(2) Licence renewal fees are due at the time the renewal application is submitted –

(a) A renewal application submitted more than thirty (30) days prior to the expiration of the licence shall be accompanied by regular renewal fees;

(b) A renewal application submitted within thirty (30) days prior to the expiration of the licence shall be accompanied by a letter to the Authority explaining the reason for the late application and the specified late renewal fees;

(c) A renewal application submitted within thirty (30) days after to the expiration of the licence shall be accompanied by a letter to the Authority explaining

the reason for the late application and the specified special late renewal fees;

(d) A renewal application submitted after thirty (30) days from date of expiration of the licence shall be treated as a new licence application

(3) If an application for renewal is denied, an Applicant may request that the Authority refund the renewal fee after the denial appeal period has lapsed or after the completion of the denial appeal process, whichever is later.

(4) Where a medicinal cannabis business licence is renewed to a licensee, all renewal fees become non-refundable.

33. **Schedule of administrative service fees — all licensees.**

The administrative service fees set out in Schedule IV may apply to all licensees.

34. **Licensee required to keep mailing address current with the authority — all licensees.**

(1) A Licensee shall inform the Authority in writing of any change to its mailing address within thirty (30) days of the change.

(2) The Authority will not change a Licensee's information without explicit written notification provided by the Licensee or its authorized agent.

(3) Authority communications are sent to the last mailing address furnished by an applicant or a Licensee to the Authority.

(4) Failure to notify the Authority of a change of mailing address does not relieve a Licensee or Applicant of the obligation to respond to an Authority communication.

(5) The Authority will send any application, disciplinary or sanction communication, as well as any notice of hearing, to the last mailing address furnished to the Authority by the Licensee or Applicant.

35. **Length of licence - all licences.**

(1) All Medicinal cannabis business Licences are valid for three (3) years.

(2) A Licence may be valid for less than the applicable licence term if revoked, suspended, voluntarily surrendered, or otherwise disciplined.

Part III The Licenced Premises

36. **Premises.**

(1) Each licence shall have a designated licenced premise, with a distinct street address, property or building number where applicable, for the licensee's Medicinal cannabis business activity.

(2) Each licenced premises shall be subject to inspection by the Authority and shall meet all requirements and standards specified within these Regulations before being authorized.

(3) Licenced dispensaries authorized to engage in retail sales shall only serve authorized patients or caregivers who are within the licenced premises, or at a delivery address that meets the requirements of these Regulations.

(4) The sale and delivery of Medicinal cannabis goods shall not occur through a pass-out window or a slide-out tray to the exterior of the licenced premises.

(5) Licenced dispensaries authorized to engage in retail sales shall not operate as or with a drive-in or drive-through at which Medicinal cannabis goods are sold to persons within or about a motor vehicle.

(6) No Medicinal cannabis good shall be sold or delivered by any means or method to any person that is within a motor vehicle.

(7) Alcoholic beverages that do not contain medicinal cannabis shall not be stored or consumed on a licenced premises.

(8) Any licenced premises that is adjacent to another premises engaging inmanufacturing or cultivation shall be separated from those premises by walls, and any doors leading to the cultivation or manufacturing premises shall remain closed.

37. **Premises location.**

(1) Premises licenced under this division shall not be located within a 300-foot radius of a school providing instruction in kindergarten, primary, secondary or tertiary education, day care center, or youth center that is in existence at the time the licence is issued.

(2) If the proposed premises is located in a commercial property that shares space with residences, then all residents of the property shall agree in writing, to allow the proposed medicinal cannabis business to operate.

(3) A licenced premise shall not be in a location that requires persons to pass through a business or a private residence to access the licenced premise.

(4) A licenced premise shall not be in a location that requires persons to pass through the licenced premise to access a business or a private residence.

(5) A licenced premise shall not be located within a private residence.

(6) Licensees shall ensure that the Authority has immediate access to their licenced premises;

(a) If the Authority is denied access to a licensee's premises for any reason, the licensee shall be held responsible and be subject to disciplinary action.

(b) If the Authority is denied access to one licensee's premises because of another licensee's refusal to grant access when the only access to one licenced premises is through another licenced premises, all licensees shall be held responsible and subject to disciplinary action.

(7) Nothing in this Regulation shall be interpreted to prohibit two or more licenced premises from occupying separate portions of the same parcel of land or sharing common use areas, such as a bathroom, breakroom, hallway, or building entrance.

(8) All structures included as part of the licenced premises shall be permanently affixed to the land by a method that would cause the structure to ordinarily and reasonably remain affixed for an indefinite period of time.

(9) Structures that will not be considered to be permanent structures include but are not limited to

(a) shipping containers that are not affixed to the land;

(b) modular buildings that are not affixed to the land;

(c) structures that rest on wheels; or (d) any structure that can be readily moved.

38. **Limited access areas.**

(1) All areas where Medicinal cannabis goods are stored, cultivated, produced, manufactured, extracted, processed, tested, researched, and within any vehicle authorized for transport shall be identified as a Limited Access Area and shall be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state

"Do Not Enter — Limited Access Area –
Access Limited to Licenced Personnel and Escorted Visitors Only".

(2) All persons in a Limited Access Area in any Medicinal cannabis business shall be required to hold and properly display a current licence badge issued by the Authority at all times.

(3) Proper display of the licence badge shall consist of wearing the badge in a plainly visible manner, worn at or above the waist, and with the photo of the Licensee visible.

(4) The Licensee shall not alter, obscure, damage, or deface the badge in any manner.

(5) Prior to entering a Limited Access Area, all visitors and individuals without a valid owner or Manager Licence or Staff Licence, including outside vendors, and contractors, shall obtain a visitor identification badge from management personnel of the Licensee that shall remain plainly visible, worn at or above the waist, while in the Limited Access Area.

(6) Visitors shall be escorted by a licenced personnel at all times.

(7) No more than five visitors may be escorted by a single employee.

(8) The Licensee shall maintain a log of all visitor activity, for any purpose, within the Limited Access Area and shall make such logs available for inspection by the Inspectorate Division or relevant licensing authority or law enforcement.

(9) All visitors admitted into a Limited Access Area shall provide acceptable proof of age and shall be at least eighteen (18) years of age.

(10) The Licensee shall check an acceptable form of identification, as specified in Regulation 88 of these Regulations, for all visitors to verify that the name on the identification matches the name in the visitor log.

(11) A Licensee may not receive consideration or compensation for permitting a visitor to enter a Limited Access Area.

(12) All areas of ingress and egress to Limited Access Areas on the Licenced premises shall be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state—

"Do Not Enter — Limited Access Area –
Access Limited to Licenced Personnel and Escorted Visitors Only".

(13) All Limited Access Areas shall be clearly identified to the Authority or relevant licensing authority and described by the filing of a premises diagram as specified in Regulation 8 of these Regulations, reflecting the walls, partitions, counters and all areas of ingress and egress; the diagram shall also reflect all Propagation, processing, extraction, testing, research labs, cultivation, manufacturing, and Restricted Access Areas.

(14) A Licensee's proposed modification of designated Limited Access Area shall be approved by the Authority and licensing authorities as specified in Regulation 42 of these Regulations.

(15) Notwithstanding the requirements of subregulations (2) and (4) of this Regulation, nothing shall prohibit Authority or the Inspectorate Division, authorities from the licensing authority or any law enforcement agency, for a purpose authorized by these Regulations or for any other law enforcement purpose, from entering a Limited Access Area upon presentation of official credentials identifying them as such.

39. **Restricted access area.**

(1) All areas where Medicinal Cannabis or Medicinal Cannabis Infused Product are sold, displayed or dispensed shall be identified as a Restricted Access Area and shall be clearly identified by the posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of letters not less than a half inch in height, which shall state

"Restricted Access Area – Only Medicinal Cannabis Patients Allowed."

(2) An enclosed reception area shall be created and shall be supervised by a Licensee at all times to ensure that only persons with a valid authorized recommendation from an authorized medical professional and in possession of a valid Medicinal cannabis patient identification card are allowed in to the Restricted Access Area.

(3) When allowing a patient access to a Restricted Access Area, Licensees shall make reasonable efforts to limit the number of patients in relation to the number of Licensees in the Restricted Access Area at any time.

(4) The display for sale and the sale of Medicinal cannabis goods is allowed only in Restricted Access Areas.

(5) Any product displays that are readily accessible to the customer shall be supervised by a Licensee at all times when customers are present.

(6) Before a Patient leaves a Restricted Access area, licenced staff are obligated to seal the patient's purchase in a secure exit package, as specified in these Regulations, such as a heavy gauge, opaque container or opaque paper bag that is stapled.

(7) Exit packaging shall be distributed to prevent Medicinal Cannabis and its infused Products from being viewed by the public and to prevent any use or misuse of the product until the patient arrives at his or her private Lodging for consumption.

40. **Medicinal cannabis storage.**

(1) A medicinal cannabis store shall be within a Limited Access Area as specified in Regulation 38 of these Regulations.

(2) Applicants shall consider the following when designing a medicinal cannabis store
(a) a capacity and space where

(i) the storage area shall have the capacity for both storage and handling; (ii) ideally, space should be evenly divided between the two;

(iii) when designing a new facility, the storage space and capacity requirements should ot be underestimated;

(iv) the medical store shall include staging areas for preparing shipments which are being issuing and unloading deliveries that are being received;

(v) the receiving and shipping areas shall be separated to avoid confusion and to enhance efficiency and security;

(vi) if a facility will be repackaging products, a separate clean preparation area to conduct the repackaging shall be used and shall be located near to the issuing area. (b) a cold storage where

(i) in larger facilities it is more efficient to use cold rooms rather than numerous refrigerators or freezers due to excess heat generation;

(ii) ideally, larger facilities shall have one room with a negative temperature for frozen products between -5°C to -20°C and another room with a positive but cold temperature between 1° to 7°C for products requiring refrigeration;

(iii) smaller facilities shall have at least one unit with a negative temperature for frozen products between -5°C to -20°C and at least one other unit with a positive but cold temperature between 1° to 7°C for products requiring refrigeration. (c) a secure storage where

(i) medicinal cannabis stores shall be within a secure storage area;

(ii) A locked stainless steel or aluminium cabinet or cupboard may be sufficient for smaller facilities, while larger facilities shall require a vault or cage;

(iii) A cage shall illili a double locking method and shall be constructed using high tensile steel wire and a frame constructed using steel of no less than one quarter of an inch in thickness;

(iv) A cage used within an open warehouse facility shall be enclosed within a sealed concrete room with double locked doors and which shall be identified as a Limited Access Area;

(v) A medicinal cannabis store shall have an alarm system installed at all access points which shall be monitored by an approved off site monitoring company.

(d) ventilation where

(i) The location and design should ensure maximum air circulation to avoid concentrations of fumes or gases and to prevent condensation of moisture on products or walls;

(ii) Use an extractor fan and fume cabinet where necessary, to remove fumes, gases, and moisture;

(iii) Utilise an approved air filtration system. (e) a roof where

(i) tIhe design is a slanting roof to allow water run-off;

(ii) the roof is extended over the windows to give extra protection from rain and direct sunlight.

(f) a ceiling which is a double ceiling installed to provide insulation and ensure that supplies are kept cool. (g) walls and floor where

(i) the walls and floors of a medical store should be permanent and smooth for easy cleaning;

(ii) the walls shall be constructed of brick or concrete blocks;

(iii) perforated or bored bricks might be used for the upper portion of the wall to allow ventilation, but these should be screened to prevent the entry of rodents and other pests;

(iv) construct or treat floors of larger facilities are installed to ensure they can withstand the frequent movement of heavy products and equipment; (h) doors

(i) the Plan doors are wide enough to allow for the free and easy movement of supplies and handling equipment;

(ii) large facilities often use forklifts and other handling equipment and shall therefore ensure these larger doors are strong and reinforced to provide adequate security;

(iii) fit doors with two strong locks, and install metal grills for extra protection. (i) lighting

(i) Plan the storeroom with as much natural light (sunlight) in the day as possible to avoid the use of either florescent or incandescent bulb lighting during the day;

(ii) Florescent lighting emits ultraviolet rays, which have a negative effect on certain products and Incandescent bulbs emit heat;

(iii) take care to ensure that products are not in direct sunlight.

(j) windows

(i) plan windows that are high and wide to allow adequate ventilation;

(ii) windows shall be high enough to not be blocked by shelves and shall have wire mesh to keep out insects;

(iii) windows shall be burglar proofed using steel reinforcements.

(k) cupboards, and shall provide stainless steel or aluminum cupboards for the storage of specific products that shall be kept free from dust or light.

(l) first aid

(i) Keep a properly stocked first aid kit to treat employees or visitors who are injured in your facility;

(ii) Place the first aid kit in a central location that is easily accessible to all employees;

(iii) Ensure it is clearly marked and that all employees are aware of its location and contents. (m) shelves

(i) arrange shelves and racks in lines with a passageway not less than ninety centimetres (90cm) wide;

(ii) avoid placing shelves only around the edge of the room, which wastes a lot of space;

(iii) place the shelves ninety centimetres (90cm) from the walls of the storeroom to ensure they are accessible from both sides (n) cleaning

(i) write and post the schedule and instructions for cleaning the storeroom in multiple locations around the facility;

(ii) sweep and mop or scrub the floors of the storeroom regularly;

(iii) wipe down the shelves and products to remove dust and dirt;

(iv) dispose of garbage and other waste often, in a manner that avoids attracting pests;

(v) store garbage in covered receptacles; (o) water Access

(i) ensure the storeroom has easy access to a water outlet for cleaning;

(ii) if no running water is available, set up a system using, for example, several fifty-five (55) gallon drums on an elevated platform connected to pipes running into the store;

(iii) refill the drums regularly;

(iv) when rehabilitating an existing storage facility or constructing a new structure, install water outlets in several locations inside the structure so water is easily available from any location in the storeroom.

41. **Possession of licenced premises.**

(1) Persons licenced pursuant to these Regulations or those making application for such licences, shall demonstrate proof of lawful possession of the premises to be licenced or Licenced Premises.

(2) Evidence of lawful possession consists of properly executed deeds of trust, leases, or other written documents acceptable to the Authority and national licensing authorities.

(3) The Licenced premises shall only be those geographical areas that are specifically and accurately described in executed documents verifying lawful possession.

(4) Licensee shall not relocate to other areas or units within a building structure without first filing a change of location application and obtaining approval from the Authority and the national licensing Authority.

(5) A licensee shall not add additional contiguous units or areas, thereby altering the initially-approved premises, without filing an application to modify the Licenced Premises, as specified in Regulation 42 of these Regulations, to the Development Control and Planning Board on forms that will be approved by the Authority, including any applicable processing fee.

(6) A licensee shall not sublet any portion of a Licenced premises for any purpose, unless all necessary applications to modify the existing Licenced premises to accomplish any subletting have been approved by the Authority and national licensing authority.

42. **Changing, altering, or modifying licenced premises.**

(1) After issuance of a licence, the Licensee shall make no physical change, alteration, or modification of the Licenced premises that or substantially alters the Licenced premises or the usage of the Licenced Premises from the plans originally approved, without the prior written approval of both the Authority and the Development Control and Planning Board.

(2) The Licensee whose premises are to be or substantially changed is responsiblefor filing an application for approval on forms provided by the Development Control and Planning Board and approved by the Authority.

(3) Material or substantial changes, alterations, or modifications requiring approval include, but are not limited to, the following—

(a) any increase or decrease in the total physical size or capacity of the Licenced Premises;

(b) the sealing off, creation of, or relocation of a common entry way, doorway, passage or other such means of public ingress or egress, when such common entryway, doorway or passage alters or changes Limited Access Areas, such as the cultivation, harvesting, manufacturing, or sale of Medicinal Cannabis orMedicinal Cannabis-Infused Product within the Licenced Premises;

(c) within a Medicinal Cannabis Dispensary, the permanent addition of a separate sales counter that creates an additional point-of-sale location, and any permanent physical addition, all of which would require the installation of additional video surveillance cameras as specified in Regulation 48;

(d) The installation or replacement of electric fixtures or equipment, the lowering of a ceiling, or electrical modifications made for the purpose of increasing power usage to enhance cultivation activities; or

(e) The addition or deletion of Medicinal Cannabis Cultivation Operation licences that will be, or have been, combined with other commonly owned cultivation licences in a common area for the purpose of growing and cultivating Medicinal Cannabis.

(4) The Authority and Development Control and Planning Board may grant approval for the types of changes, alterations, or modifications described herein upon the filing of an application by the Licensee, and payment of any applicable fee.

(5) The Licensee shall submit all information requested by the Authority including but not limited to, documents that verify the following—

(a) The Licensee will continue to have possession of the premises, as changed, by ownership, lease, or rental agreement; and

(b) The proposed change conforms to any restrictions in Saint Christopher and Nevis related to the time, manner, and place of Medicinal Business Operations.

43. **Subletting of premises.**

A licensee shall not sublet any area designated as the licenced premises for the licensee's commercial Medicinal Cannabis activity.

44. **Licensee's responsibility for acts of employees and agents.**

When construing and enforcing the provisions of the Act and the Regulations in this Part, the act, omission, or failure of an agent, officer, representative, or other person acting for or employed by a licensee, within the scope of his or her employment or office, shall in every case be deemed the act, omission, or failure of the licensee.

45. **Age restriction.**

Employees or persons retained by a licensee to work within or on a licenced premises or to handle Medicinal cannabis goods shall be at least eighteen (18) years of age.

46. **Health and safety Regulations — medicinal cannabis business.**

(1) A Medicinal cannabis business shall be subject to inspection by the St. Kitts and Nevis Fire Department, building inspector or Health Inspector to confirm that no health or safety concerns are present.

(2) An inspection can result in additional specific standards to meet local requirements or restrictions related to Medicinal Cannabis Operations.

(3) A Medicinal cannabis business shall have a clearly visible emergency exit plan and clearly marked emergency exits.

(4) A fire safety inspection may result in the required installation of fire suppression systems, or other means necessary for adequate fire safety.

(5) The Licensee shall take all of the following reasonable measures and precautions to ensure the following Sanitary Conditions are met regarding Facility Health

(a) sufficient space for placement of equipment and storage of materials as is necessary for the maintenance of sanitary operations for production of Medicinal cannabis goods;

(b) any litter and waste is properly removed and the operating systems for waste disposal are maintained in an adequate manner so that they do not constitute a source of contamination in areas where Medicinal cannabis goods are prepared or exposed;

(c) floors, walls, and ceilings are constructed in such a manner that they may be adequately cleaned and each is kept clean and in good repair;

(d) there is adequate lighting in all areas where Medicinal cannabis goods are stored or sold, and where equipment or utensils are cleaned;

(e) there is adequate emergency lighting in all areas where Medicinal cannabis goods are processed or stored;

(f) the Licensee provides adequate screening or other protection against the entry of pests and maintains regular pest control procedures through a registered pest control company;

(g) rubbish shall be disposed of so as to minimize the development of odor and minimize the potential for the waste becoming an attractant, harborage, or breeding place for pests;

(h) any buildings, fixtures, and other facilities are maintained in a sanitary condition;

(i) toxic cleaning compounds, sanitizing agents, extraction solvents and other potentially harmful chemicals are identified, held, and stored in a manner that protects against contamination of Medicinal cannabis goods and in a manner that is in accordance with any applicable national or international guideline published as an Order by the Minister in the Official Gazette, or any law within St. Kitts and Nevis;

(j) all contact surfaces, including utensils and equipment used for the preparation of Medicinal cannabis goods, shall be cleaned and sanitized as frequently as necessary to protect against contamination and shall be used as follows

(i) equipment and utensils shall be so designed and of such material and workmanship as to be adequately cleanable, and shall be properly maintained;

(ii) only sanitizing agents approved by the Authority shall be used in Medicinal Cannabis Infused Products Manufacturing and shall be used in accordance with labelled instructions;

(k) each medicinal cannabis business provides its employees with adequate and readily accessible toilet facilities that are consistently maintained in a sanitary condition and good repair;

(l) medicinal cannabis goods that can support the rapid growth of undesirable microorganisms are held in a manner that prevents the growth of such microorganisms;

(m) the water supply shall be sufficient for the operations intended and shall be derived from a source that is a regulated water system and where private water supplies

shall be derived from a water source that is capable of providing a safe, potable, and adequate supply of water to meet the facility's needs;

(n) plumbing shall be of adequate size and design and adequately installed and maintained to carry sufficient quantities of water to required locations throughout the facility and which is able to properly convey sewage and liquid disposable waste from the facility;

(o) there shall be no cross connections between the potable and waste water lines;

(p) all operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of medicinal cannabis goods shall be conducted in accordance with adequate sanitation principles;

(q) storage and transport of finished Medicinal Cannabis or Medicinal Cannabis Infused Product shall be under conditions that will protect products against physical, chemical, and microbial contamination as well as against deterioration of any container; (r) hand-washing facilities shall

(i) be adequate and convenient and be furnished with running water at a suitable temperature;

(ii) be located in the authorized facility and in Medicinal Cannabis Infused Product preparation areas and where good sanitary practices require employees to wash or sanitize their hands, and provide effective hand-cleaning and sanitizing preparations and sanitary towel service or suitable drying devices.

(6) A Medicinal Cannabis Infused Products Manufacturer that manufacturers Edible Medicinal Cannabis Infused Product shall comply with all food and cooking related health and safety standards and rules of the Ministry of Health, and the Department of Environment to the extent applicable, with all the health and safety Regulations applicable to retail food establishments.

(7) The Licensee shall take all reasonable measures and precautions as follows to ensure the following Sanitary Conditions are met regarding employee Personal Health

(a) a person who, by Medicinal examination or supervisory observation, is shown to have, or appears to have, an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination for whom there is a reasonable possibility of contact with preparation surfaces for Medicinal Cannabis or Medicinal Cannabis Infused Product shall be excluded from any operations which may be expected to result in such contamination until the condition is corrected;

(b) a person working in direct contact with preparation of Medicinal cannabis goods shall conform to hygienic practices while on duty, including but not limited to

(i) maintaining adequate personal cleanliness;

(ii) washing hands thoroughly in an adequate hand-washing area before starting work and at any other time when the hands may have become soiled or contaminated; and

(iii) refraining from having direct contact with preparation of Medicinal cannabis goods if the person has or may have an illness, open lesion, including boils, sores, or infected wounds, or any other abnormal source of microbial contamination, until such condition is corrected.

47. **Security, alarm systems and lock standards.**

(1) Licenced Medicinal cannabis businesses shall implement security measures reasonably designed to prevent unauthorized entrance into areas containing medicinal cannabis and theft of medicinal cannabis goods from the licenced premises and these security measures shall include, but may not be limited to, the following

(a) adequate fencing or walls to prevent any medicinal cannabis goods from being viewed by the public;

(b) having employed at least one security personnel to guard the licenced premises and such security personnel shall—

(i) be employed at the licenced premises 24 hours daily, everyday;

(ii) carry a licenced firearm;

(iii) not be allowed into a limited access area unless in possession of an Individual Occupational Licence and authorized by the business licensee;

(c) prohibiting individuals from remaining on the licensee's premises if they are not engaging in activity expressly related to the operations of the licensee;

(d) establishing and maintaining limited access areas accessible only to authorized personnel;

(e) other than limited amounts of medicinal cannabis goods used for display purposes, samples, or immediate sale, storing all finished medicinal cannabis goods in a secured and locked room, safe, or vault, and in a manner reasonably designed to prevent diversion, theft, or loss.

(2) The following minimum Security Alarm Systems requirements shall apply to all Medicinal cannabis businesses

(a) each Licenced premises shall have a Security Alarm System, installed by an Alarm Installation Company, on all perimeter entry points and perimeter windows;

(b) each Licensee shall ensure that all of its Licenced premises are continuously monitored and licensees shall engage the services of a Monitoring Company to fulfill this requirement;

(c) the Licensees shall maintain up to date and current records and existing contracts on the Licenced premises that describe the location and operation of each Security Alarm System, a schematic of security zones, the name of the Alarm Installation Company, and the name of any Monitoring Company, as specified in these Regulations.

(d) upon request, Licensees shall make available to agents of the Authority or other relevant law enforcement agency, for a purpose authorized by these Regulations or any other law enforcement purpose, all information related to Security Alarm Systems, Monitoring, and alarm activity;

(e) any outdoor Medicinal Cannabis Cultivation Facility, or greenhouse cultivation, is a Limited Access Area and shall meet all of the requirements for Security Alarm Systems described in this rule;

(f) an Outdoor or Greenhouse Medicinal Cannabis Cultivation Facility shall provide sufficient security measures to demonstrate that outdoor areas are not readily accessible by unauthorized individuals;

(g) this shall, at a minimum include, security perimeter fencing designed to prevent the general public from entering the restricted or the Limited Access Areas;

(h) it shall be the responsibility of the Licensee to maintain physical security in a manner similar to a Medicinal Cannabis Cultivation Facility located in an indoor Licenced premises so it can be fully secured and alarmed;

(i) outdoor Medicinal Cannabis Facility products inclusive of Medicinal Cannabis shall not be able to be viewed from any direction by the general public.

(3) The following minimum Lock Standards requirements shall apply to all Medicinal cannabis businesses

(a) at all points of ingress and egress, the Licensee shall ensure the use of a commercial-grade, non-residential door locks;

(b) biometric locking mechanisms shall be used at all points of ingress into a Limited Access Area;

(c) at least 2 locks or locking mechanisms shall be utilized on all points of ingress and egress; and

(d) any Outdoor Medicinal Cannabis Cultivation Facility, or Greenhouse cultivation, shall meet all of the requirements for the lock standards described in this rule.

48. **Video surveillance.**

(1) The following minimum video surveillance requirements shall apply to all Medicinal cannabis businesses

(a) prior to exercising the privileges of a Medicinal cannabis business, an Applicant shall install fully operational video surveillance and camera recording system;

(b) the recording system shall record in high definition digital format and meet the requirements outlined in this rule;

(c) all video surveillance records and recordings shall be stored in a secure area that is only accessible to a Licensee's management staff and shall employ an Authority Approved Off Site Monitoring Company;

(d) video surveillance records and recordings shall be made available upon request to the Inspectorate Division, the Authority, or any local law enforcement agency for a purpose authorized by these Regulations or for any other local law enforcement purpose;

(e) video surveillance records and recordings of point-of-sale areas shall be held in confidence by all employees and representatives of the Authority, except that the Authority may provide such records and recordings to any relevant law

enforcement agency for a purpose authorized by these Regulations or for any local law enforcement purpose.

(2) The following minimum video surveillance equipment requirements shall apply to all Medicinal cannabis businesses

(a) video surveillance equipment shall, at a minimum, consist of digital or network video recorders, cameras capable of meeting the recording requirements described in this rule, video monitors, digital archiving devices, and a color printer capable of delivering still photos;

(b) all video surveillance systems shall be equipped with a failure notification system that provides prompt notification to the Licensee of any prolonged surveillance interruption or the complete failure of the surveillance system;

(c) licensees are responsible for ensuring that all surveillance equipment is properly functioning and maintained so that the playback quality is suitable for viewing and the surveillance equipment is capable of capturing the identity of all individuals and activities in the monitored areas;

(d) all video surveillance equipment shall have sufficient battery back-up to support a minimum of four hours of recording in the event of a power outage; (e) video recordings shall be backed up either off site or online.

(3) The following minimum Camera placement and Camera coverage requirements shall apply to all Medicinal cannabis businesses—

(a) camera coverage is required for all Limited Access Areas, point-of-sale areas, security rooms, all points of ingress and egress to Limited Access Areas, all areas where Medicinal cannabis goods is displayed for sale, and all points of ingress or egress to the exterior of the Licenced Premises;

(b) camera placement shall be capable of identifying activity occurring within 20 feet of all points of ingress and egress and shall allow for the clear and certain identification of any individual and activities on the Licenced Premises;

(c) at each point-of-sale location, camera coverage shall enable recording of the authorized patients, caregivers and employees facial features with sufficient clarity to determine identity;

(d) all entrances and exits to the facility shall be recorded from both indoor and outdoor vantage points;

(e) the system shall be capable of recording all pre-determined surveillance areas in any lighting condition and if the Licenced premises has a Medicinal Cannabis cultivation area, a rotating schedule of lighted conditions and zero- illumination can occur as long as ingress and egress points to Flowering areas remain constantly illuminated for recording purposes;

(f) areas where Medicinal Cannabis is grown, tested, cured, manufactured, or stored shall have camera placement in the room facing the primary entry door at a height which will provide a clear unobstructed view of activity without sight blockage from lighting hoods, fixtures, or other equipment;

(g) cameras shall also be placed at each location where weighing, packaging, transport, preparation, or Radio Frequency Identification Reader and other tagging activities occur;

(h) at least one camera shall be dedicated to record the access points to the secured surveillance recording area;

(i) all outdoor cultivation areas shall meet the same video surveillance requirements applicable to any other indoor Limited Access Areas.

(4) The following minimum video surveillance equipment Location and Maintenance requirements shall apply to all Medicinal cannabis businesses—

(a) the surveillance room or surveillance area shall be a Limited Access Area;

(b) surveillance recording equipment shall be housed in a designated, locked and secured room or other enclosure with access limited to authorized employees, agents of the Authority and other relevant law enforcement agencies for a purpose authorized by these Regulations or for any other law enforcement purpose, and service personnel or contractors;

(c) licensees shall keep a current list of all authorized employees and service Personnel who have access to the surveillance system or room on the Licenced Premises.

(d) licensees shall keep a surveillance equipment maintenance activity log on the Licenced premises to record all service activity including the identity of the individuals performing the service, the service date and time and the reason for service to the surveillance system;

(e) off-site Monitoring and video recording storage of the Licenced premises by the Licensee is not authorized;

(f) each Medicinal Cannabis Licenced premises located in a common or shared building shall have a separate surveillance room or area that is dedicated to that specific Licenced Premises.

(5) The following minimum video recording and retention requirements shall applyto all Medicinal cannabis businesses—

(a) all camera views of all Limited Access Areas shall be continuously recorded 24 hours a day;

(b) the use of motion detection is authorized when a Licensee can demonstrate that monitored activities are adequately recorded;

(c) all surveillance recordings shall be kept for a minimum of 40 days and be in a format that can be easily accessed for viewing.

(d) video recordings shall be archived in a format that ensures authentication of the recording as legitimately captured video and guarantees that no alteration of the recorded image has taken place;

(e) the Licensee’s surveillance system or equipment shall have the capabilities to produce a color still photograph from any camera image, live or recorded, of the Licenced Premises;

(f) the date and time shall be embedded on all surveillance recordings without significantly obscuring the recoded view;

(g) the date and time shall be synchronized with the mandated universal St. Kitts and Nevis tracking system;

(h) time is to be measured in accordance with the official St. Kitts and Nevis time established by the St. Kitts and Nevis Bureau of Standards or the U.S.A. Naval Observatory at website; http://www.time.gov/atlanticstandardtime;

(i) after the 40 day surveillance video retention schedule has lapsed, surveillance video recordings may be erased or destroyed prior to sale or transfer of the facility or business to another Licensee, or being discarded or disposed of for any other purpose;

(j) notwithstanding subregulation (5)(i) of this Regulation, surveillance video recordings may not be destroyed if the Licensee knows or should have known of a pending criminal, civil or administrative investigation or any other proceeding for which the recording may contain relevant information.

(6) All records applicable to the surveillance system shall be maintained on the Licenced premises and at a minimum, Licensees shall maintain a map of the camera locations, direction of coverage, camera numbers, surveillance equipment maintenance activity log, user authorization list and operating instructions for the surveillance equipment.

(7) All recorded video of all transactions shall be entered into the St. Kitts and Nevis Tracking System.

(8) Each administrative service specified in subregulation (1) of this Regulation shall be applied for directly to the Authority.

(9) Each administrative service fee is due at the time each applicable request is made.

Part IV
Medicinal Cannabis Waste Management

49. **Considering waste management.**

Medicinal cannabis businesses shall

(a) remain free of medicinal cannabis waste and other non-cannabis garbage;

(b) Maintain a clean environment where medicinal cannabis goods and any edible items are stored;

(c) maintain a pest control plan that will reduce the number of pests, whether insects or rodents;

(d) plan disposal techniques that are practical and simple; (e) monitor disposal practices on a regular, frequent basis.

50. **Non-medicinal cannabis waste disposal.**

(1) Different types of non-medicinal cannabis waste that shall be destroyed safely and effectively and their suggested methods of disposal include but may not be limited to (a) garden rubbish

(i) compost leaves, sticks, weeds, and trimmings from shrubs and trees, if feasible;

(ii) designate a separate area for composting; (b) cardboard cartons

(i) if possible, recycle cardboard;

(ii) if recycling is not possible, treat like ordinary rubbish; (c) ordinary rubbish

(i) recycle where possible;

(ii) where municipal solid waste facilities exist, dispose of ordinary rubbish in the municipal dump;

(iii) place in authorized garbage collection areas; (d) human waste

(i) use cesspit systems or other toileting facilities to dispose of all human waste;

(ii) follow all Regulations for sewage from commercial facilities under the Public Health Act, Cap. 9.21;

(e) hazardous Waste and a licensee shall manage all hazardous waste in compliance with all applicable hazardous waste laws in Saint Christopher and Nevis including the Solid Waste Management Act 11.05.

51. **Medicinal cannabis waste disposal.**

(1) Medicinal cannabis goods waste shall be stored, secured and managed in accordance with all applicable laws.

(2) Liquid waste from Medicinal cannabis businesses shall be disposed of in compliance the applicable water and sewage quality control law within St. Kitts and Nevis.

(3) Disposal of hazardous and chemical waste shall be conducted in a mannerconsistent with St. Kitts and Nevis laws.

(4) A licensee shall dispose of medicinal cannabis waste in a secured waste receptacle or in a secured limited access area on the licenced premises designated on the licensee's premises diagram or as identified in the licensee's cultivation plan;

(a) for the purposes of this Regulation, "secure waste receptacle" or "secured area" means physical access to the receptacle or area is restricted to only the licensee, employees of the licensee, agents of the Authority, or an authorized waste hauler contracted by the medicinal cannabis business and permitted by the Authority;

(b) public access to the designated receptacle or area shall be strictly prohibited.

(5) Medicinal cannabis goods waste shall be made unusable and unrecognizable prior to leaving the Licenced premises to prevent unlawful misuse.

(6) Medicinal cannabis goods waste shall be rendered unusable and Unrecognizable by grinding and incorporating the Cannabis waste with the following non-consumable, solid wastes, such that the resulting mixture is at least 50 percent non-cannabis waste

(a) paper waste;

(b) cardboard waste;

(c) food waste;

(d) grease or other compostable oil waste;

(e) compost activators;

(f) other wastes approved by the Authority that will render the Medicinal cannabis goods waste unusable and Unrecognizable as Cannabis; and (g) soil.

(7) After the Medicinal cannabis goods waste is made unusable and Unrecognizable, then the rendered waste shall be disposed of at a solid waste management facility managed by the Solid Waste Management Corporation.

(8) A licensee shall maintain accurate and comprehensive records regarding cannabis waste that account for, reconcile, and evidence all activity related to the generation or disposition of cannabis waste and all records required by this Regulation are records subject to inspection by the Authority and shall be kept pursuant to Regulation 135 of these Regulations.

(9) A Licensee shall not dispose of Medicinal cannabis goods waste in an unsecured waste receptacle not in possession and control of the Licensee.

(10) Medicinal Cannabis waste may be collected from a licensee in conjunction with a regular organic waste collection route used within St. Kitts and Nevis.

(11) All Medicinal Cannabis waste shall be identified, weighed on an authorized scale and tracked via the St. Kitts and Nevis Tracking System while on the Licenced premises until disposed of and a Licensee is required to maintain accurate and comprehensive records regarding waste material that accounts for, reconciles, and evidences all waste activity related to the disposal of Cannabis.

52. **Medicinal cannabis goods Destruction or Disposal.**

(1) Medicinal cannabis goods that either fail testing requirements, are expired or are placed under relevant disciplinary action shall be destroyed

(a) at the cost of the medicinal cannabis business licensee; and

(b) at an authorized medicinal cannabis goods disposal facility.

(2) An authorized medicinal cannabis goods disposal facility shall

(a) be registered in St. Kitts and Nevis;

(b) meet all standards of a waste disposal facility

(c) be tax compliant and possess a tax compliance certificate;

(d) be duly authorized by the Authority;

(e) possess a medicinal cannabis transport licence if it to be engaged in the transport of medicinal cannabis goods to be destroyed;

(f) ensure its designated drivers possess a medicinal cannabis individual occupational Licence;

(g) ensure its vehicles designated for transport of medicinal cannabis goods meet all required criteria specified in Regulation 67 of these Regulations; and

(h) maintain an account within the St Kitts and Nevis tracking system.

(3) If an authorized waste disposal agency, an authorized waste hauler is franchisedor contracted by the Authority, or a private waste hauler permitted by the Authority is being used to collect, process and dispose of medicinal cannabis goods for any authorized reason, before those medicinal cannabis goods are made unrecognizable or unusable, both the medicinal cannabis business licensee that owns the medicinal cannabis goods being destroyed and the Authority shall do all the following

(a) obtain and retain the following information from the authorized waste disposal agency, authorized waste hauler franchised or contracted by the Authority, or private waste hauler permitted by the Authority that will collect, process and dispose of the licensee's medicinal cannabis goods

(i) registered business name;

(ii) registered business address;

(iii) registered business contact information;

(iv) registered business Identification number;

(v) redicinal cannabis transport licence number where applicable;

(vi) redicinal cannabis individual occupational licence number;

(vii) authority Approval; and

(viii) name of the primary contact person of the registered business and contact person's phone number.

(b) obtain and retain a copy of a receipt from the authorized waste disposal agency, authorized waste hauler franchised or contracted by the Authority, or private waste hauler permitted by the Authority evidencing subscription to the medicinal cannabis waste collection and disposal service;

(c) ensure the medicinal cannabis goods to be destroyed are first individually and collectively reconciled within the St Kitts and Nevis Tracking System;

(d) obtain and retain, a copy of a certified weight ticket and receipt for each batch of medicinal cannabis goods to be destroyed;

(e) ensure that a Division Inspector is present at any medicinal cannabis disposal or destruction activity involving medicinal cannabis goods that have been ordered to be destroyed due to having failed testing requirements, due to becoming expired or due to disciplinary action or for any medicinal cannabis goods to be destroyed before having been made unusable or unrecognizable.

(4) If the medicinal cannabis business licensee is self-hauling cannabis waste to an authorized medicinal cannabis goods disposal facility, he shall

(a) meet all requirements of subregulation (3) of this Regulation;

(b) possess a medicinal cannabis transport licence;

(c) ensure the driver has a medicinal cannabis individual occupational licence where applicable;

(d) through use of the St Kitts and Nevis tracking system, ensure all medicinal cannabis goods scheduled for destruction is identified, weighed, reconciled and tracked while on the licenced premises until its destruction;

(e) transportation of self-hauled cannabis waste shall only be performed by the licensee or employees of the licensee.

(5) If cannabis waste is hauled to a recycling or composting center to be made unusable or unrecognizable as cannabis

(a) the recycling or composting center shall meet all criteria set forth in subregulation (2) of this Regulation;

(b) the Authority and the Licensee shall follow all criteria specified in subregulation (3) of this Regulation;

(c) if self-hauling to the authorized recycling or composting center the licensee shall meet all criteria specified in subregulation (4) of this Regulation;

(d) in addition to the tracking requirements specified in this Regulation, a licensee shall use the tracking system and documentation required pursuant to this Regulation to ensure the medicinal cannabis goods to be recycled or composted is identified, weighed, and tracked while on the licenced premises and until the cannabis waste becomes a new, reused, or reconstituted product, that shall not be a medicinal cannabis or cannabis end product.

Part V
St. Kitts and Nevis Tracking System

53. **Tracking all Inventory.**

(1) The Authority finds it essential to regulate, monitor, and track all Medicinal cannabis goods to eliminate diversion, inside and outside of the regulated Medicinal Cannabis system, and to ensure that all Cannabis cultivated, processed, extracted, tested, transported, used for infused products, researched, sold and disposed of in the regulated medicinal cannabis market is accounted for transparently.

(2) The St. Kitts and Nevis Cannabis Tracking System database shall be designed to flag irregularities for licensing authorities in this part and licensing authorities pursuant to these Regulations may access the database and inspect information related to licensees.

(3) The St. Kitts and Nevis Cannabis Tracking System shall allow for a properly documented chain of command on all medicinal cannabis goods.

(4) The Division shall immediately inform the Authority upon the finding of an irregularity or suspicious finding related to a licensee, applicant, or commercial medicinal cannabis activity for investigatory purposes.

(5) The Authority shall have 24-hour access to the electronic database of the St. Kitts and Nevis Cannabis Tracking System with real time tracking, read access data and view access to monitoring devices.

(6) The Board shall have an Executive Manager account with read access on each operational St. Kitts and Nevis Tracking System used, to be able to investigate, if necessary, the business records and transactions of the medicinal cannabis business.

(7) Any Licensee found to be tampering with the St. Kitts and Nevis Tracking System or the unique identifier tags hereinafter referred to as UID, in such a way as to deliberately contravene any of the rules set by the Authority commits an offence and shall be liable under section 57 of the Cannabis Act, 2020.

(8) The Authority will continuously update its tracking systems to promote the most effective means for the industry to account for and monitor its medicinal cannabis inventory and all financial transactions and money.

(9) Each licensee shall use the St. Kitts and Nevis tracking system for recording all applicable commercial medicinal cannabis activities.

(10) A licensee shall create and maintain an active and functional account within the St. Kitts and Nevis Tracking System prior to engaging in any commercial Medicinal Cannabis activity, including the purchase, sale, test, packaging, transfer, transport, return, destruction, or disposal, of any Medicinal cannabis goods.

(11) The licensee is responsible for the accuracy and completeness of all data and information entered into the tracking system as data entered into the tracking system is assumed to be accurate and can be used to take enforcement action against the licensee if not corrected.

(12) A licensee shall designate one licenced individual owner as the St. Kitts and Nevis Tracking System account manager and the account manager shall

(a) attend and successfully complete all required St. Kitts and Nevis Tracking System training, including any orientation and continuing education before undertaking medicinal cannabis business activity and where an account manager does not complete the required St. Kitts and Nevis Tracking System training update prior to renewing their annual licence, the account manager shall sign up for and complete state mandated training update, as prescribed by the Authority, within five business calendar days of licence renewal;

(b) the account manager and each user shall be assigned a unique log-on, consisting of a username and password where

(i) the account manager or each user accessing the St. Kitts and Nevis Tracking System shall only do so under his or her assigned log-on and shall not use or access a log-on of any other individual; and

(ii) no account manager or user shall share or transfer his or her log-on, username, or password, to be used by any other individual for any reason;

(c) maintain a complete, accurate, and up-to-date list of all St. Kitts and Nevis Tracking System users, consisting of their full names and usernames;

(d) within three (3) calendar days, cancel the access rights of any tracking system user from the licensee's tracking system account if that individual is no longer authorized to use the licensee's tracking system account;

(e) correct any data that is entered into the tracking system in error within three (3) calendar days of discovery of the error;

(f) monitor all notifications from the tracking system and resolve all issues included in the notification in the timeframe specified in the notification and shall not dismiss a notification from the tracking system until the issue(s) included in the notification has been resolved; and

(g) notify the Authority immediately for any loss of access that exceeds three (3) calendar days;

(h) a licensee shall monitor all compliance notifications from the St. Kitts and Nevis Tracking System and resolve the issues detailed in the compliance notification within five days unless extension of time is granted by the authority.

(13) A licensee shall keep a record, independent of the St. Kitts and Nevis Tracking System, of all compliance notifications received from the St. Kitts and Nevis Tracking System, and how and when compliance was achieved.

(14) If a licensee is unable to resolve a compliance notification within three business days of receiving the notification, the licensee shall notify the Authority immediately, by submitting the Notification and Request Form, which is incorporated herein by reference.

(15) A licensee is accountable for all actions its owners or employees take while logged into or using the St. Kitts and Nevis Tracking System, or otherwise while conducting St. Kitts and Nevis Tracking System activities.

54. **St. Kitts and Nevis Tracking System - Unique Identifiers (UID).**

(1) Within five (5) calendar days of the date the licensee's designated account manager or managers who was certified by the Authority to use the St. Kitts and Nevis tracking system, the designated account manager or managers shall request a Unique Identifier, hereafter referred to as a UID, using the St. Kitts and Nevis Tracking System as prescribed by the Authority.

(2) The licensee shall only use a UID provisioned and distributed by the Authority, or the Authority's designee.

(3) The licensee shall maintain a sufficient supply of UIDs in inventory to support the tagging of a cannabis plant in accordance with this Regulation.

(4) The licensee shall use the St. Kitts and Nevis Tracking System to document receipt of provisioned and distributed UIDs within three (3) calendar days of physical receipt of the UIDs by the licensee.

(5) Except as provided in these Regulations, all medicinal cannabis shall be entered into the St. Kitts and Nevis Tracking System by the licensee starting with germinated

seedling, clones or immature plants of medicinal cannabis which has been propagated onsite or purchased from a licenced nursery pursuant to these Regulations.

(6) The UID shall accompany the cannabis products through all phases of the growing cycle, as follows

(a) Licensees with germinated seedlings, clones or immature plants shall assign a UID to each established lot respectively;

(b) the lot UID shall be placed in a position so it is visible and within clear view of an individual standing next to the immature lot to which the UID was assigned; and

(c) all UIDs shall be kept free from dirt and debris.

(7) For the purposes of this subregulation, each lot of immature plants shall be uniform in strain or cultivar and shall not have more than one hundred (100) immature plants at any one time and

(a) any immature plant in a lot shall be labelled with its own UID and with the corresponding UID number assigned to the lot and shall be contiguous to one another to facilitate identification by the Authority; and

(b) each immature plant intended for retail sale shall have a UID affixed, and be labelled with the corresponding UID number of the lot, and be recorded in the St. Kitts and Nevis Tracking System prior to transfer from the licenced nursery or prior to further propagation.

(8) The licensee shall maintain the UID on each individual plant at the time any plant is moved to the designated canopy area or when an individual plant begins flowering.

(9) UIDs are required for each mature plant—

(a) uids shall be attached to the main stem, at the base of each plant;

(b) the UID shall be attached to the plant using a tamper evident strap or zip tie and placed in a position so it is visible and within clear view of an individual standing next to the mature plant to which the UID was assigned; and (c) UIDs shall be kept free from dirt and debris.

(10) Licensees are prohibited from removing the UID from the mature plant to which it was attached and assigned until the plant is harvested, destroyed, or disposed.

(11) Each harvest batch shall be assigned a unique harvest batch name and UID which will be associated with all UIDs for each individual plant, or portion thereof, contained in the harvest batch.

(12) UIDs are required for Medicinal cannabis goods and shall be associated with the corresponding harvest batch UID from which the medicinal cannabis, medicinal cannabis non-infused products and medicinal cannabis infused products were derived.

(13) Upon destruction or disposal of any medicinal cannabis goods, the applicable UIDs shall be retired in the St. Kitts and Nevis Tracking System by the licensee within three (3) calendar days of the destruction or disposal and be performed in accordance with the licensee's approved medicinal cannabis goods waste management plan.

(14) The Authority shall charge a fee to cover the reasonable costs of issuing the unique identifiers and for scheduled mandatory inspections.

55. **Tracking Funds and Money.**

(1) The Authority shall regulate, monitor, and track any funds surrounding a medicinal cannabis business to eliminate the diversion of funds, inside and outside of the regulated medicinal Cannabis system, and to maintain compliance with International obligations and guidelines related to anti-money laundering, combating the Financing of Terrorism and Combating financing of any illegal activities

(2) The Authority shall ensure that any monies regarding cultivation, processing, extraction, testing, transporting, infusing products, research, import, export, sale and disposal of medicinal cannabis goods under these Regulations are accounted for and are tracked and monitored in its entirety through the St. Kitts and Nevis Tracking System.

(3) The St. Kitts and Nevis Tracking System database shall be designed to flag irregularities to allow the Authority or any licensing authority to investigate a matter and a foreign law enforcement authority pursuant to these Regulations may access the database and inspect information related to licensees.

(4) An applicant, during the medicinal cannabis business Licence application process, shall submit source of funds documentation showing the sources of all the monies to be invested toward the proposed medicinal cannabis business.

(5) Every financial transaction conducted, beginning from the licence application process, covering each and every transaction related to the medicinal cannabis business operation, shall be recorded through the St. Kitts and Nevis Tracking System and all information shall be available in read access format to the Authority in real time.

(6) Recorded Transactions related to the Medicinal cannabis business Operation shall include but may not be limited to the following

(a) any investments made into the medicinal cannabis business;

(b) capital Expenditure;

(c) application and Licence Fees;

(d) loans;

(e) tangible Assets;

(f) purchases;

(g) rent;

(h) operational costs;

(i) utility costs;

(j) salaries;

(k) expenditures;

(l) sales;

(m) transfers;

(n) payment plans;

(o) taxes;

(p) banking;

(q) dividends.

(7) The St. Kitts and Nevis Tracking System shall allow for a properly documented chain of command of all finances and monies related to all medicinal cannabis goods and business transactions.

(8) The Division shall immediately inform the Authority upon the finding of an irregularity or suspicious finding related to a licensee, applicant, or commercial medicinal cannabis activity for investigatory purposes.

(9) The Authority shall have 24-hour access to The St. Kitts and Nevis Tracking electronic database with real time view access to monitoring devices.

(10) Members of the Authority shall have an Executive manager account with read access on each operational St. Kitts and Nevis Tracking System account used, to be able to investigate, where necessary, the business records and financial transactions of the medicinal cannabis business at any time.

(11) Any Licensee found to be tampering with the St. Kitts and Nevis Tracking System in such a way as to deliberately contravene any of the rules and standards set within these Regulations commits an offence and shall be liable under section 57 of the Cannabis Act, 2020.

(12) The Authority will continuously update its St. Kitts and Nevis Tracking System to promote the most effective means for the industry to account for and monitor its finance and monies related to medicinal cannabis business.

(13) An Anti-Money Laundering and Combating the Financing of Terrorism Course, provided by Authority, in collaboration with the office of National Drug and Money Laundering Control Policy shall be included in the training requirements management for the use of the St. Kitts and Nevis Tracking System at each licensed medicinal cannabis business.

(14) Each licensee shall use the St. Kitts and Nevis Tracking System for recording all applicable commercial medicinal cannabis activities and financial transactions.

(15) A licensee shall create and maintain an active and functional account within the St. Kitts and Nevis Tracking System prior to engaging in any commercial Medicinal Cannabis activity, including the purchase, sale, test, packaging, transfer, transport, return, destruction, or disposal, of any Medicinal cannabis goods.

(16) The licensee is responsible for the accuracy and completeness of all data and information entered into the St. Kitts and Nevis Tracking System and data entered into the tracking system is assumed to be accurate and can be used to take enforcement action against the licensee if not corrected.

(17) A licensee shall designate one licenced individual owner as the St. Kitts and Nevis Tracking System account manager and the account manager shall

(a) attend and successfully complete all required St. Kitts and Nevis Tracking System training, including any orientation and continuing education before undertaking medicinal cannabis business activity; and

(b) where an account manager did not complete the required St. Kitts and Nevis Tracking System training update prior to renewing their annual licence, the account manager shall sign up for and complete state mandated training update, as prescribed by the Authority, within five business calendar days of licence renewal;

(c) the account manager and each user shall be assigned a unique log-on, consisting of a username and password where

(i) the account manager or each user accessing the St. Kitts and Nevis Tracking System shall only do so under his or her assigned log-on and shall not use or access a log-on of any other individual;

(ii) no account manager or user shall share or transfer his or her log-on, username, or password, to be used by any other individual for any reason;

(d) maintain a complete, accurate, and up-to-date list of all St. Kitts and Nevis Tracking System users, consisting of their full names and usernames;

(e) within three (3) calendar days, cancel the access rights of any tracking system user from the licensee's tracking system account if that individual is no longer authorized to use the licensee's tracking system account;

(f) correct any data that is entered into the tracking system in error within three (3) calendar days of discovery of the error;

(g) monitor all notifications from the St. Kitts and Nevis Tracking System and resolve all issues included in the notification in the timeframe specified in the notification and shall not dismiss a notification from the St Kitts and Nevis Tracking System until the issue(s) included in the notification has been resolved; and

(h) notify the Authority immediately for any loss of access that exceeds three (3) calendar days and a licensee shall monitor all compliance notifications from the St. Kitts and Nevis Tracking System, and resolve the issues detailed in the compliance notification as soon as practicable.

(18) A licensee shall keep a record, independent of the St. Kitts and Nevis Tracking System, of all compliance notifications received from the St. Kitts and Nevis Tracking System, and how and when compliance was achieved.

(19) Where a licensee is unable to resolve a compliance notification within three business days of receiving the notification, the licensee shall notify the Authority immediately, by submitting the Notification and Request Form, which is incorporated herein by reference.

(20) A licensee shall be accountable for all actions its owners or employees take while logged into or using the St. Kitts and Nevis Tracking System, or otherwise while conducting St. Kitts and Nevis Tracking System activities.

56. **Requirements for weighing devices.**

(1) Weighing devices used by a medicinal cannabis business licensee shall be approved, registered and tested prior to being used.

(2) A weighing device shall work electronically, directly and in accordance with the St. Kitts and Nevis Tracking System.

(3) Weights shall be recorded and entered into the tracking system automatically and shall retain the ability to weigh medicinal cannabis in an emergency condition.

(4) Approved, registered and tested weighing devices shall be used whenever any one or more of the following apply

(a) medicinal cannabis goods are bought or sold by weight;

(b) medicinal cannabis goods are packaged for sale by weight;

(c) medicinal cannabis goods are weighed for entry into the tracking system; or

(d) the weighing device is used for any commercial purpose related to medicinal cannabis activity.

(5) For the purposes of this chapter a licensee shall use wet weight or net weight and shall be measured, recorded, and reported in the International System of Units, such as but is not limited to, kilograms, grams, or milligrams.

(6) A person using, weighing or measuring medicinal cannabis goods for sale within a licenced dispensary, shall possess a special dispensing licence.

57. **St. Kitts and Nevis tracking system reporting.**

(1) A licensee shall record in the St. Kitts and Nevis Tracking System, information regarding all commercial medicinal cannabis activity, including

(a) packaging of medicinal cannabis goods;

(b) weight or count of individual units of packaged medicinal cannabis or medicinal cannabis infused products sold, transferred, or received;

(i) for the purposes of this Regulation a licensee shall use wet weight or net weight;

(ii) wet weight and net weight shall be determined following weighing device requirements pursuant to these Regulations and measured, recorded, and reported in the International System of Units, such as but is not limited to, kilograms, grams, or milligrams; and

(iii) for the purposes of this Regulation count means the numerical count of the individual plants or individual packaged units;

(c) sale and transfer of medicinal cannabis goods;

(d) applicable tax on medicinal cannabis goods;

(e) transportation of medicinal cannabis goods to a licensee;

(f) receipt of medicinal cannabis goods;

(g) return of medicinal cannabis goods;

(h) destruction and disposal of medicinal cannabis goods;

(i) laboratory testing and results;

(j) any other activity as required pursuant to this division, or by any other relevant licensing authority;

(2) The following information shall be recorded for each activity entered in the St. Kitts and Nevis Tracking System

(a) name of the Medicinal cannabis goods;

(b) unique identifier (UID) of the Medicinal cannabis goods;

(c) type and description of the medicinal cannabis goods;

(d) amount of the Medicinal cannabis goods, by weight or count, and total sale price or wholesale cost of the Medicinal cannabis goods, as applicable;

(e) date and time of the activity or transaction;

(f) name and licence number of all licensees involved in the activity or transaction.

(3) Where the medicinal cannabis relates to a cultivation licensee, in addition to the applicable required information in subregulations (1) and (2) of this Regulation, the information from paragraphs (a) to (g) of this subregulation, shall be reported in the St. Kitts and Nevis Tracking System within twenty four (24) hours of the applicable event (a) creating an immature plant lot;

(b) move immature plants to a designated canopy area, or when an individual plant begins flowering, or when a UID is being applied to an immature plant;

(c) destroy or dispose of an immature or mature plant;

(d) the harvest of a mature plant, or portion thereof and the information as follows, shall be reported into the St. Kitts and Nevis Tracking System for each harvested plant, or portion thereof, or harvest batch

(i) the wet weight of each harvested plant, or portion thereof, which shall be obtained by the licensee, in the presence of a Division Inspector, immediately after harvest of the plant, or portion thereof;

(ii) the net weight of all harvested cannabis once the majority of drying, trimming, and curing activities have been completed and all processed medicinal cannabis reconciled with the wet weight and inspected and approved by a Division Inspector;

(iii) the weight of cannabis waste associated with each harvest batch;

(iv) the UID of each plant of the harvest and the harvest batch and the initiating date of the harvest which is the date the first mature cannabis plant or plants in the harvest batch were cut, picked, or removed from the soil or other growing media; (e) packaging information including

(i) number or count of individual packaged units;

(ii) net weight of each packaged unit;

(iii) sale price of each packaged unit;

(iv) UID of each packaged unit; (f) sample information regarding testing; and (g) testing results information.

(4) Where the medicinal cannabis relates to a Processor and Extraction licensee, in addition to the applicable required information in subregulations (1) and (2) of this Regulation, the information as follows, shall also be reported in the St. Kitts and Nevis Tracking System within twenty four (24) hours

(a) the Harvest batch UID of the medicinal cannabis from which the extracted or non-infused medicinal cannabis products are to be derived;

(b) net weight of the harvest batch before extraction;

(c) extraction method used;

(d) net weight of extracted batch;

(e) UID of extract batch;

(f) packaging information including

(i) number or count of individual packaged units;

(ii) net weight of each packaged unit;

(iii) sale price of each packaged unit; (iv) UID of each packaged unit. (g) sample information regarding testing; and (h) testing results information.

(5) Where the medicinal cannabis relates to an Infused Products Manufacturer licensee, in addition to the applicable required information in subregulations (1) and (2) of this Regulation, the information as follows, shall also be reported in the St. Kitts and Nevis
Tracking System within twenty-four (24) hours

(a) the batch UID of the harvested medicinal cannabis or the extracted or non- infused medicinal cannabis from which the medicinal cannabis infused products are to be derived;

(b) net weight of the harvest batch or extract batch before entering the infused product manufacture process;

(c) net weight of Cannabinoid content per manufacture batch;

(d) UID of product batch;

(e) packaging information including

(i) number or count of individual packaged units;

(ii) net weight of cannabinoid content of each packaged unit;

(iii) sale price of each packaged unit; (iv) UID of each packaged unit. (f) sample information regarding testing; and (g) testing results information.

(6) Where the medicinal cannabis relates to a Medicinal Cannabis Dispensary licensee, in addition to the applicable required information in subregulations (1) and (2) of this Regulation, the following information shall also be reported in the St. Kitts and Nevis
Tracking System within twenty four (24) hours

(a) the batch UID of the harvested medicinal cannabis or the extracted or non-infused medicinal cannabis from which any repackaged products are to be derived;

(b) net weight of the harvest batch or extract batch before entering the dispensary repackaging process;

(c) UID of product batch;

(d) repackaging information including

(i) number or count of individual packaged unit;

(ii) net weight of each packaged unit;

(iii) sale price of each packaged unit;

(iv) UID of each packaged unit;

(e) any relevant Testing results information; and

(f) authorized patient or caregiver UID on each transaction.

(7) Where the medicinal cannabis relates a Testing Facility licensee, in addition to the applicable required information in subregulations (1) and (2) of this Regulation, the following information shall also be reported in the St. Kitts and Nevis Tracking System within twenty-four (24) hours

(a) the batch UID of the harvested medicinal cannabis, the extracted or noninfused medicinal cannabis, or the medicinal cannabis infused product from which the collected samples are to be analyzed;

(b) net weight of the medicinal cannabis harvest batch, extract batch or count and type of the infused product batch from which the samples were collected;

(c) net weight of Cannabinoid content per infused product individual unit and batch;

(d) UID of individual samples collected;

(e) number or count of individual packaged units collected from each batch;

(f) any event resulting in damage, exposure, or compromise of the Medicinal Cannabis samples that would interfere with correct test results; and (g) testing results information.

(8) Where the Medicinal cannabis goods are being transported

(a) the licensee shall transport pursuant to a shipping manifest generated through the St. Kitts and Nevis Tracking System, that includes this subregulation paragraphs (a) to (c) of subregulation (2) of this Regulation, as well as

(i) the name, licence number, and licenced premises address of the originating licensee;

(ii) the name, licence number, and licenced premises address of the licensee transporting the Medicinal cannabis goods;

(iii) the name, licence number, and licenced premises address of the destination licensee receiving the Medicinal cannabis goods into inventory or storage;

(iv) the date and time of departure from the licenced premises and approximate date and time of departure from each subsequent licenced premises, if any;

(v) arrival date and estimated time of arrival at each licenced premises; and

(vi) driver licence number of the personnel transporting the Medicinal cannabis goods, and the make, model, and licence plate number of the vehicle used for transport;

(b) upon pick-up or receipt of Medicinal cannabis goods for transport, storage, or inventory, a licensee shall ensure that the Medicinal cannabis goods received are as described in the shipping manifest, and shall record acceptance or receipt, and acknowledgment of the Medicinal cannabis goods in the St. Kitts and Nevis Tracking System;

(c) if there are any discrepancies between the type or quantity of Medicinal cannabis goods specified in the shipping manifest and the type or quantity received by the licensee, the licensee shall record and document the discrepancy in the St. Kitts and Nevis Tracking System and in any relevant business record.

(9) Where Medicinal cannabis goods are being destroyed or disposed of, the licensee shall record in the St. Kitts and Nevis Tracking System the following additional information—

(a) the name of the employee performing the destruction or disposal;

(b) the reason for destruction or and disposal;

(c) the name of the entity being used to collect and process disposing of the Medicinal Cannabis waste, pursuant to Regulation 52 of these Regulations.

(10) The description for any adjustments made in the St. Kitts and Nevis Tracking System, shall include, but not limited to

(a) spoilage or fouling of the Medicinal cannabis goods;

(b) any event resulting in damage, exposure, or compromise of the Medicinal cannabis goods; or

(c) any other information as required pursuant to this part, or by any other applicable licensing authorities.

(11) Unless otherwise specified, all transactions shall be entered into the St. Kitts and Nevis Tracking System within 24 hours of occurrence.

(12) A Licensee shall only enter and record complete and accurate information into the St. Kitts and Nevis Tracking System, and shall correct any known errors entered into the St. Kitts and Nevis Tracking System immediately upon discovery.

58. **Loss of access.**

(1) Where at any point a licensee loses access connectivity to the St. Kitts and Nevis Tracking System for any reason, the licensee shall prepare and maintain comprehensive records detailing all commercial medicinal cannabis activities that were conducted during the loss of access connectivity.

(2) The licensee shall both document and notify the Authority immediately—

(a) when access to the system is lost;

(b) when access to the system is restored; and (c) the cause for the loss of access.

(3) The licensee shall immediately notify the Authority of any loss of connectivity, and shall not transport, transfer, receive, or deliver any Medicinal cannabis goods until such time as access connectivity is restored and all information recorded in the St. Kitts and Nevis Tracking System is accessible.

(4) Once access connectivity has been restored, the licensee shall

(a) within three calendar days, enter all commercial Medicinal Cannabis activity that occurred during the loss of access connectivity shall be entered into the St. Kitts and Nevis Tracking System within three business days of access being restored; and

(b) document the cause for loss of connectivity, and the date and time for when connectivity to the St. Kitts and Nevis Tracking System was lost and when it was restored.

59. **Reconciliation and Maintenance of Chain of Command.**

(1) In addition to other inventory reconciliation requirements under this part, a licensee shall reconcile the physical inventory of Medicinal cannabis goods at the licenced premises with the records in the St. Kitts and Nevis Tracking System database at least once every 30 calendar days.

(2) Where a licensee finds a discrepancy between its physical inventory and the St. Kitts and Nevis Tracking System database, the licensee shall conduct an audit, and notify the Authority of any reportable activity.

(3) Medicinal cannabis goods shall be tracked and monitored from each germinated seedling through to harvest, sale and disposal and licensees are required to maintain the chain of command for all medicinal cannabis goods through reconciliation within the St. Kitts and Nevis Tracking System.

(4) Any discrepancy or break in the chain of command shall be reported within 24 hours to the Authority and reconciliation sought as soon as possible.

(5) Maintaining the chain of command allows for the maintenance of the integrity of the medicinal cannabis regulated industry.

60. **Upon termination of licence.**

(1) A Licensee shall, upon the termination of a licence, close out the physical inventory of all medicinal cannabis, medicinal cannabis goods and UIDs, if applicable, prior to the effective date of any of the following changes to their licence

(a) voluntary surrender of a temporary licence or annual licence;

(b) expiration of an annual licence; or (c) revocation of a licence.

(2) Close-out of physical inventory includes, but is not limited to, all of the following items

(a) immature plants and their corresponding lot UIDs;

(b) mature plants and their corresponding plant UIDs;

(c) harvest batches and their corresponding UIDs;

(d) medicinal cannabis extracts and non-infused cannabis products and their corresponding UIDs;

(e) medicinal cannabis infused products and their corresponding UIDs;

(f) UIDs in the licensee's possession which have not been yet assigned in the St. Kitts and Nevis Tracking System.

(3) All transfers and sales shall be documented accordingly, pursuant to theseRegulations.

61. **Disaster relief.**

(1) Where a licensee is unable to comply with any licensing requirements due to a disaster, the licensee may notify the Authority of this inability to comply and request relief from the specific licensing requirement.

(2) The Authority may exercise its discretion to provide temporary relief from specific regulatory requirements under these Regulations and from other licensing requirements when allowed by law.

(3) Temporary relief from specific licensing requirements shall be issued for areasonable amount of time in order to allow the licensee to recover from the disaster.

(4) The Authority may require that certain conditions be followed in order for a licensee to receive temporary relief from specific licensing requirements.

(5) A licensee shall not be subject to an enforcement action for a violation of a licensing requirement in which the licensee has received temporary relief.

(6) For the purposes of this Regulation, "disaster" means condition of extreme peril to the safety of persons and property within St. Kitts and Nevis caused by such conditions as air pollution, fire, flood, hurricane, storm, tidal wave, epidemic, riot, drought, terrorism, sudden and severe energy shortage, plant or animal infestation or disease, the Government's warning of an earthquake or volcanic prediction, or an earthquake, or similar public calamity, other than conditions resulting from a labor controversy or any other local issue.

(7) A licenced premises that has been vacated by a licensee due to a disaster shall not be considered to have been, abandoned, or quit.

(8) Notwithstanding subregulation (1) of this Regulation, if a licensee needs to move Medicinal cannabis goods stored on the licenced premises to another location immediately to prevent loss, theft, or degradation of the Medicinal cannabis goods from the disaster, the licensee may move the Medicinal cannabis goods without obtaining prior approval from the Authority if the following conditions are met

(a) the Medicinal cannabis goods are moved to a secure location where access to the Medicinal cannabis goods can be restricted to the licensee, its employees, and contractors;

(b) the licensee notifies the Authority in writing that the medicinal cannabis goods have been moved and that the licensee is requesting relief from complying with specific licensing requirements pursuant to subregulation (a) of this Regulation within 24 hours of moving the Medicinal cannabis goods;

(c) the licensee agrees to grant the Authority access to the location where the Medicinal cannabis goods have been moved to for inspection; and

(d) the licensee submits in writing to the Authority within 14 calendar days of moving the Medicinal cannabis goods a request for temporary relief that clearly indicates what statutory and regulatory Regulations relief is requested from, the time period for which the relief is requested, and the reasons relief is needed for the specified amount of time.

62. **Applicant track-and-trace training requirement.**

A person who intends to use the St. Kitts and Nevis Tracking System shall first complete a training course set by the Authority before being authorized to use the system.

Part VI
Medicinal Cannabis Business Licences

63. **Applications.**

Medicinal cannabis business Applications shall follow all rules and guidelines set forth in Part II of these Regulations.

DIVISION 1- MEDICINAL CANNABIS TRANSPORT LICENCE

64. **Transport of medicinal cannabis and medicinal cannabis infused product.**

(1) A medicinal cannabis business shall obtain a medicinal cannabis transport licence from the Authority before engaging in the transport or delivery of medicinal cannabis or medicinal cannabis infused product.

(2) A person who is not authorized by the Authority pursuant to these Regulations who is in possession of a valid Individual Occupational Licence including an owner, manager or staff licence shall not transport Medicinal Cannabis or Medicinal Cannabis Infused Product.

(3) A medicinal cannabis business that does not possess a medicinal cannabis transport licence from the Authority shall not engage in the transport or delivery of medicinal cannabis goods.

(4) An individual who does not possess a current and valid Individual Occupational Licence from the Authority may not transport or deliver Medicinal cannabis goods.

(5) Medicinal cannabis goods shall only be transported between Licenced premises and between Licenced premises and an authorized patient or caregiver.

(6) A Licensee transporting Medicinal cannabis goods is responsible for ensuring that Medicinal cannabis goods are secured at all times during transport.

(7) The Transport of Medicinal cannabis goods shall be conducted by a motor vehicle that meets all requirements specified in Regulation 52 of these Regulations.

(8) The following requirements apply when a medicinal cannabis Transport Licensee transports Medicinal cannabis goods or samples

(a) while transporting Medicinal cannabis goods samples, a licenced employee shall ensure the Medicinal cannabis goods are not visible to the public and

(i) medicinal cannabis goods shall be locked in a fully enclosed box, container, or cage that is secured to the inside of the vehicle or trailer;

(ii) no portion of the enclosed box, container, or cage shall be comprised of any part of the body of the vehicle or trailer; and

(iii) for the purposes of this Regulation, the inside of the vehicle includes the trunk;

(b) while left unattended, vehicles, and trailers shall be locked and secured;

(c) a vehicle or trailer containing Medicinal cannabis goods samples shall not be left unattended in a residential area or parked overnight in a residential area;

(d) the licensee shall ensure that packages or containers holding Medicinal cannabis goods samples are neither tampered with, nor opened during transport;

(e) the medicinal cannabis transport licensee shall only travel between licensees, to an authorized patient or caregiver or to the authorized laboratory that is conducting regulatory compliance testing or quality assurance testing and a transport licensee shall not deviate from the travel requirements described in this Regulation, except for necessary fuel, or vehicle repair stops;

(f) licensees may transport multiple Medicinal cannabis goods or samples obtained from multiple licensees or delivered to multiple authorized patients at once;

(g) vehicles or trailers transporting Medicinal cannabis goods samples are subject to inspection by the Authority at any licenced premises or during transport at any time;

(h) no person under the age of eighteen years old shall be in a vehicle or trailer transporting Medicinal cannabis goods samples; and

(i) persons holding an individual occupational licence, including security, who meets the requirements of these Regulations shall be in a vehicle while transporting Medicinal cannabis goods or samples.

(9) Transport of Medicinal Cannabis or Medicinal Cannabis Infused Product shall be accompanied by the following

(a) a copy of the licence of the originating Medicinal cannabis business;

(b) the driver's valid Individual Occupational Licence;

(c) the driver's valid St. Kitts and Nevis Driver's Permit; and

(d) all required vehicle registration and insurance documentation.

(10) Transporting, or arranging for or facilitating the transport of, medicinal cannabis or medicinal cannabis infused products in violation of these Regulations is grounds for disciplinary action against the licensee.

(11) An authorized patient who transports medicinal cannabis goods shall carry such goods in a sealed exit package as specified by these Regulations.

65. **Preparation of medicinal cannabis and medicinal cannabis infused product for transport.**

(1) A Medicinal cannabis business shall comply with the specific rules associated with the final weighing and packaging of Medicinal cannabis goods as specified in the Cannabis Act, 2020 or Regulations made pursuant to the Act, before such items are prepared for transport pursuant to these Regulations.

(2) Medicinal cannabis goods shall be prepared for transport in a Limited Access Area, including the packing and labelling of transport containers.

(3) Sealed packages or containers may be placed in larger containers and such transport containers shall be labelled with the type and amount of Medicinal cannabis goods contained therein and the contents of transport containers shall be easily accessible and may be inspected by the Authority, any licensing authorities, and law enforcement agencies for a purpose authorized by these Regulations.

(4) A Medicinal cannabis business shall provide adequate refrigeration for perishable Medicinal Cannabis Infused Product during transport.

(5) Medicinal Cannabis and all associated products and plant wastes shall be recorded in the St. Kitts and Nevis Tracking System using unique identification tags prior to transport, to ensure accountability and to prevent diversion of product outside the Medicinal Cannabis System.

(6) Prior to transporting or delivering of medicinal cannabis or medicinal cannabis infused products, a medicinal cannabis business licensee shall perform as follows—

(a) complete an electronic shipping manifest as prescribed by the Authority;

(b) the shipping manifest shall include the unique identifiers of all the medicinal cannabis or medicinal cannabis infused products to be transported;

(c) the shipping manifest shall be input into the St. Kitts and Nevis Tracking System;

(d) the medicinal cannabis business licensee receiving the shipment shall maintain and submit each electronic shipping manifest through the St. Kitts and Nevis tracking system and shall make it available upon request to agents of the inspectorate division of the Authority or to any law enforcement officers.

(7) A medicinal cannabis business licensee, during transportation, shall maintain a physical copy of the shipping manifest and make it available upon request to agents of the Inspectorate Division of the Authority or to law enforcement officers where applicable.

66. **Medicinal cannabis transport licence - deliveries.**

(1) Deliveries, as defined in these Regulations, shall only be made by a licenced medicinal cannabis dispensary.

(2) Deliveries shall be made to Authorized Patients or caregivers that have registered, in person and prior to the first delivery to that authorized patient or caregiver, all required information with the medicinal cannabis dispensary that is delivering the Medicinal cannabis goods.

(3) Delivery of Medicinal cannabis goods shall be conducted by a motor vehicle that meets all requirements specified in Regulation 67.

(4) A licensee delivering medicinal cannabis goods shall comply with Regulation 68.

(5) An employee of a licenced medicinal cannabis dispensary, during delivery of medicinal cannabis or medicinal cannabis infused product to Authorized patients shall carry the following within the authorized vehicle

(a) a copy of the medicinal cannabis dispensary's current licence;

(b) a copy of the medicinal cannabis transport licence;

(c) the employee's medicinal cannabis individual occupational licence;

(d) a valid St. Kitts and Nevis Driver's permit;

(e) all required vehicle registration and insurance documentation.

(6) During delivery, the licensee shall maintain a physical copy of the delivery request and shall make it available upon request of an agent of the Authority or law enforcement officers where applicable.

(7) The delivery request documentation shall comply with state and federal law regarding the protection of confidential patient and medical information.

(8) A customer requesting delivery shall maintain a physical or electronic copy of the delivery request and shall make it available upon request by an agent of the Authority or law enforcement officers where applicable.

(9) Delivering, or arranging for or facilitating the delivery of medicinal cannabis or medicinal cannabis infused products in violation of these Regulations is grounds for disciplinary action against the licensee.

67. **Medicinal cannabis transport licence – vehicle requirement.**

(1) Where a person is in possession of a medicinal cannabis licence and he intends for his vehicle to be used for the transport of Medicinal cannabis goods, such vehicle shall meet the following criteria

(a) possess all relevant documents

(i) the vehicle shall be properly registered in St. Kitts and Nevis pursuant to motor vehicle laws;

(ii) the vehicle shall be registered either in the name of the medicinal cannabis business licensee or in the name of the individual occupational licensee but need not be registered in the name of the authorized driver;

(iii) vehicle registration shall be kept in the vehicle at all times;

(iv) the vehicle shall be roadworthy and shall have passed all official St. Kitts and Nevis vehicle inspection processes;

(v) the Vehicle shall be covered by an Insurance plan in accordance with the St. Kitts and Nevis Law;

(vi) the year, make, model, licence plate number, and numerical Vehicle Identification Number (VIN) for each vehicle or trailer used to transport Medicinal cannabis goods samples shall be submitted to the Authority;

(vii) the vehicle shall meet all standard requirements under the Vehicle and Traffic Act Cap. 460

(b) secure medicinal cannabis storage during Transport

(i) the vehicle shall have a secure transport container installed within the vehicle;

(ii) the secure transport container shall be constructed of stainless steel or aluminum;

(iii) the secure transport container shall be locked during transport with two locks;

(iv) the secure transport container shall be affixed to the vehicle in such a way so that it shall not be easily removed;

(v) the vehicle shall have a refrigerated secure transport container for transport of medicinal cannabis goods requiring refrigeration;

(c) the authorized transport vehicle shall not advertise in any way or have any signage related to medicinal cannabis;

(d) the authorized transport vehicle shall be a client of a roadside assistance program, whether through its insurer or otherwise;

(e) the vehicle shall be outfitted with a camera that shall record in real time, the transport activity;

(f) the vehicle shall be outfitted with a GPS tracking system to monitor, in real time, and record, the movements of the Authorized vehicle during transport activity; and

(g) the vehicle shall be outfitted with an alarm system.

(2) The medicinal cannabis business Licensee shall provide the Authority with the information required by this Regulation in writing for any new vehicle or trailer that will be used to transport Medicinal cannabis goods samples prior to using the vehicle or trailer.

(3) The medicinal cannabis business licensee shall provide the Authority with the information required under this Regulation and with any changes to the information required by this Regulation in writing within 10 calendar days.

68. **Medicinal cannabis transport licence – driver requirements.**

(1) An authorized driver shall neither consume nor permit the consumption of medicinal cannabis or medicinal cannabis infused products within the Authorized vehicle at any time.

(2) In order to be authorized to transport medicinal cannabis or medicinal cannabis infused products, a driver shall meet the following criteria— (a) possess a valid St. Kitts and Nevis Driver's permit;

(b) be at least twenty one years of age

(c) possess a valid medicinal cannabis Individual Occupational Licence.

DIVISION 2 – MEDICINAL CANNABIS BUSINESS CULTIVATION LICENCE

69. **Medicinal cannabis cultivation operation – licence privileges.**

(1) A Medicinal Cannabis Cultivation Operation may exercise the privileges granted to it by the Authority.

(2) Licenced premises used for Medicinal Cannabis Cultivation facility shall be on privately owned land with authorization from the owner of the land if the owner is not the Licensee.

(3) A Cultivation operation shall not be approved on public land without the consent of the Authority.

(4) A Medicinal Cannabis Cultivation Operation may propagate, cultivate, harvest, prepare, dry, cure, package, store, and label Medicinal Cannabis Flower.

(5) The areas where medicinal cannabis cultivation activities take place shall be considered to be limited access areas and shall follow all guidelines regarding these.

(6) Storage of medicinal cannabis within a cultivation operation shall be done in a separate limited access area within the licenced premises and shall follow all rules regarding medicinal cannabis storage.

(7) A Medicinal Cannabis Cultivation Operation may only transfer Medicinal Cannabis to a Medicinal Cannabis Dispensary, Medicinal Cannabis Processor or Medicinal Cannabis Infused Products Manufacturer pursuant to these Medicinal cannabis Regulations.

(8) Medicinal Cannabis plants shall be

(a) packaged in units of one kilogram or less and following packaging rules specified in these Regulations; (b) labelled pursuant to these Regulations;

(c) securely sealed in a tamper-evident manner.

(9) The packages shall be transported to the medicinal cannabis business in an authorized vehicle and recorded as inventory at the receiving Medicinal cannabis business.

(10) Licensees shall follow proper guidelines on growing, chemical use, flushing of excess chemicals, drying and curing the Medicinal Cannabis in such a way that there are no harmful residues left in the final product.

(11) Medicinal Cannabis provided by a Licenced Cultivation Facility shall meet or pass all Testing standards specified in these Regulations in order to move on to the Licenced Dispensary, Licenced Extractor or Licenced Infused Products Manufacturer.

(12) Medicinal Cannabis provided by a Licenced Cultivation Facility that fails the Testing standards specified in these Regulations shall be destroyed at the cost of the licensee within an authorized disposal facility.

70. **Medicinal Cannabis Cultivation Operation - General Limitations or Prohibited Acts.**

(1) An authorized Medicinal Cannabis Cultivation Operation may transfer Medicinal Cannabis to another licenced Medicinal cannabis business.

(2) A Medicinal Cannabis Cultivation Operation is prohibited from selling Medicinal Cannabis that is not packaged and labelled in accordance with these Regulations.

(3) A Medicinal Cannabis Cultivation Operation shall not sell Medicinal Cannabis to a patient or caregiver.

(4) A Medicinal Cannabis Cultivation Operation shall not permit the consumption Medicinal cannabis goods on its Licenced Premises.

(5) Any medicinal cannabis that is not sold to a downstream licenced medicinal cannabis business within ten (10) months of the harvest date of the particular batch, shall be destroyed at the cost of the licensee at an authorized disposal facility.

71. **Medicinal cannabis cultivation operation specific guidelines.**

(1) The Authority shall set the total number of plants allowed for each proposed harvest cycle, separately to each Licensee.

(2) Each plant shall be tagged from germination with a unique identifier and input into the St. Kitts and Nevis Tracking System to be tracked and monitored from its germination stage to harvest and sale.

(3) The Licensee shall be responsible for ensuring all medicinal cannabis plants are tagged and the information regarding any cannabis plant is continuously maintained and updated in the tracking system.

(4) A Licensee shall ensure that every grow light and other electrical connections are properly connected by an electrical professional and is inspected and approved by the St. Kitts and Nevis Fire Department.

(5) A licensee shall engage in an indoor or greenhouse type of cultivation operation, unless otherwise authorized by the Authority, and he shall—

(a) take all measures to prevent public observation; and

(b) ensure that no pest residue remains on the final cannabis plant or product.

(6) The licensee shall give two (2) weeks' notice to the Authority through the St. Kitts and Nevis Tracking System before harvest of any medicinal cannabis and pay the inspection fees specified in Regulation 33 of these Regulations.

(7) The Licensee shall correspond with the Authority to ensure an inspector is present during harvest and processing of medicinal cannabis.

(8) The Licensee shall not engage in Harvest or processing activity without an inspector present.

(9) The Licensee shall also record, through the St. Kitts and Nevis Tracking System, any medicinal cannabis waste and shall reconcile such waste with the tagged plant or plants.

72. **Medicinal cannabis cultivation facility specifications.**

(1) A medicinal cannabis cultivation facility shall meet all requirements, including but is not limited to, requirements regarding premises, storage, transport, security, health and safety as specified by these Regulations.

(2) The licensee shall meet all premises security requirements as specified within these Regulations.

(3) The licensee shall maintain within the licenced premises, separated areas as follows

(a) designated office area;

(b) designated pesticide area;

(c) designated fertilizer area;

(d) designated soil storage area;

(e) designated canopy areas;

(f) designated drying area;

(g) designated curing area;

(h) designated processing area;

(i) designated packaging area;

(j) esignated composting area or areas if the licensee will compost cannabis waste or soil amendments on site;

(k) designated secured area or areas for cannabis waste; and

(l) designated secured area or areas for harvested cannabis storage.

(4) The minimum standards concerning cultivation methods and procedures shall include, but may not be limited to, the following

(a) sufficient fresh air ventilation;

(b) sufficient air extraction ventilation that may include a ventilation clearance above the roof of the licenced premises;

(c) sufficient air filtration for particulate, gases and scents;

(d) smoke detectors;

(e) pest control;

(f) a sufficient fire suppression system; and

(g) the minimum standards listed in this subregulation shall be approved by the Authority, Ministry of Health and the St. Kitts and Nevis Fire Department.

73. **Medicinal cannabis cultivation operation – testing.**

(1) The licenced cultivator shall store medicinal cannabis in harvest batches within a limited access area, on the licenced cultivation premises before testing until

(a) the cannabis batch passes the testing requirements pursuant to these Regulations and is transported to a licenced cannabis extractor, Infused Products Manufacturer or Dispensary; or

(b) the cannabis batch fails the testing requirements pursuant to these Regulations and is destroyed;

(2) A Medicinal Cannabis Cultivation Operation shall provide samples of its Medicinal Cannabis to a licenced Testing Facility for Medicinal Cannabis testing and research to ensure the health and safety of each of its product batches.

(3) The Testing Facility will notify the licensee of the results in writing and the Medicinal Cannabis Cultivation Operation shall include such writing as part of labelling to the Medicinal Cannabis Dispensary.

(4) The licenced Cultivator shall arrange for a testing laboratory to obtain a representative sample of each cannabis batch at the Cultivator's licenced premises and

(a) after obtaining the sample, the testing laboratory representative shall maintain custody of the sample; and (b) transport it to the testing laboratory.

(5) Upon issuance of a certificate of analysis by the testing laboratory that the cannabis batch has passed the testing requirements pursuant to these Regulations, the licenced Cultivator shall conduct a quality assurance review before distribution to ensure the labelling and packaging of the cannabis and cannabis products conform to the requirements of these Regulations.

(6) The Medicinal Cannabis Cultivation Operation shall maintain the testing results as part of its business books and records as specified in these Regulations.

(7) Cannabis batches are subject to quality assurance and testing prior to sale to a medicinal cannabis dispensary, an Infused Products Manufacturer or a medicinal cannabis extractor and Processor, except for immature cannabis plants and seeds.

74. **Prohibited chemicals.**

(1) The chemicals listed in subregulation (3) of this Regulation shall not be used in any medicinal cannabis cultivation.

(2) Where a licensee possess one or more of the chemicals or a container of such chemicals, listed in subregulation (3), under any trade name, he contravenes this Regulation. (3) The Prohibited chemicals are set out in Schedule V.

(4) The use of Dimethyl sulfoxide (DMSO) in the production of Medicinal Cannabis shall be prohibited and possession of DMSO upon the Licenced premises shall be prohibited.

(5) Notwithstanding the Pesticides and Toxic Chemicals Act 2008, the chemicals listed in subregulation (3) shall not be used in any medicinal cannabis cultivation.

DIVISION 3 – MEDICINAL CANNABIS BUSINESS PROCESSOR AND EXTRACTION LICENCE

75. **Medicinal cannabis processing and extraction operation - licence privileges.**

(1) A Medicinal Cannabis Processing and Extraction Operation may exercise privileges granted to it by the Authority.

(2) Licenced premises used for Medicinal Cannabis Processing and Extraction facility shall be on the Licensee's privately owned land or on land where the owner of the land has authorized the Licensee in writing to use the land in such a manner.

(3) A medicinal cannabis Processing and Extraction operation shall not be approved on public land without the consent of the Authority.

(4) A Medicinal Cannabis Processing and Extraction Operation may process, extract, isolate, concentrate, package, store, label and sell their Medicinal Cannabis product.

(5) An area where medicinal cannabis processing and extraction activities take place shall be considered to be a limited access area and shall follow guidelines issued by the Authority.

(6) Storage of medicinal cannabis within a processing and extraction operation shall be done in a separate limited access area within the licenced premises and shall follow all directions issued by the Authority regarding medicinal cannabis storage.

76. **Medicinal cannabis processing and extraction operation – general limitations or prohibited acts.**

(1) A Medicinal Cannabis Processing and Extraction Operation may transfer solely medicinal cannabis extract, isolate or concentrate to a licenced Medicinal Cannabis Infused Products Manufacturer or to a licenced medicinal cannabis Dispensary.

(2) A Medicinal Cannabis Processing and Extraction Operation shall not sell medicinal cannabis extract, isolate or concentrate that is not packaged and labelled in accordance with these Regulations.

(3) A Medicinal Cannabis Processing and Extraction Operation shall not sell medicinal cannabis goods to a patient or caregiver.

(4) A Medicinal Cannabis Processing and Extraction Operation shall not permit the consumption of medicinal cannabis, Medicinal Cannabis extract, isolate or concentrate or Medicinal Cannabis infused products on its Licenced Premises.

(5) Medicinal Cannabis extracts, isolates and concentrates shall be

(a) packaged in units of one kilogram or less and following packaging rules specified in these Regulations;

(b) labelled pursuant to these Regulations; and (c) securely sealed in a tamper-evident manner.

(6) A licensee shall transport medicinal cannabis goods to and from the medicinal cannabis business in a vehicle authorized by the Authority in accordance with a Transport Licence and recorded as inventory at the receiving Medicinal cannabis business.

(7) Licensees shall follow proper guidelines on chemical use and extraction process guidelines of the Medicinal Cannabis in a manner that results in no harmful residue remaining in the final cannabis product.

(8) Medicinal cannabis goods provided by a Licenced processing and extraction Facility shall meet or pass all Testing standards specified in these Regulations, in order to move on to the Licenced Dispensary or Licenced Infused Products Manufacturer.

(9) Medicinal cannabis goods provided by a Licenced Extraction and Processing Facility that fails the Testing standards specified in these Regulations, shall be destroyed at the cost of the licensee within an authorized disposal facility as specified in Regulation 52.

77. **Medicinal cannabis processing and extraction operation – specific guidelines.**

(1) A Licensee of a Medicinal Cannabis Processing and Extraction Operation shallobtain medicinal cannabis plant material from an authorized medicinal cannabis cultivation licensee.

(2) Each plant in a Medicinal Cannabis Processing and Extraction Operation shall be tagged from germination with a unique identifier and input into the St. Kitts and Nevis Tracking System and shall be tracked and monitored from its germination stage to harvest and sale.

(3) A Licensee shall be responsible for ensuring all medicinal cannabis plant material batches from the medicinal cannabis cultivation licensee are tagged and the information regarding plants has been input into the tracking system, and the licensee shall continuously maintain and update in the tracking system all extracted products.

(4) The Licensee shall, in addition to all the tracking and reporting requirements in these Regulations, record and report the total net weight of the plant material and the total net weight of all the end product produced and ensure reconciliation within the St. Kitts and Nevis Tracking System.

(5) The licensee shall ensure that all extraction and processing equipment are properly set up and maintained by a qualified professional and is inspected and approved by a public health officer and an official from the St. Kitts and Nevis Fire Department.

(6) A licensee shall meet all premises security requirements as specified within these Regulations.

(7) A licensee shall that ensure all extracted and processed medicinal cannabis goods are each affixed with a Unique Identifier and entered into the St. Kitts and Nevis Tracking System prior to its sale.

(8) A licensee shall record and reconcile through the tracking system, all medicinal cannabis waste.

78. **Medicinal cannabis processing and extraction facility specifications.**

(1) A medicinal cannabis processing and extraction facility shall meet all requirements, including but is not limited to, requirements regarding premises, storage, transport, security, health and safety as specified by these Regulations.

(2) The licensee shall maintain within the licenced premises, separated areas as follows

(a) designated office area;

(b) designated chemicals area;

(c) designated secured medicinal cannabis plant material storage area;

(d) designated extraction area;

(e) designated processing area;

(f) designated volatile solvents area;

(g) designated packaging area;

(h) designated secured area for cannabis waste; and

(i) designated secured area for medicinal cannabis extracted and processed goods storage.

(3) A Licensee shall take any action necessary to capture or otherwise limit risk of explosion, combustion, or any other unreasonably dangerous risk to public safety created by volatile solvents and

(a) the minimum standards concerning extraction methods and procedures shall include, but may not be limited to, the following

(i) sufficient fresh air ventilation in extraction area;

(ii) sufficient air extraction ventilation that may include a fume cabinet and ventilation clearance above the roof of the licenced premises;

(iii) sufficient air filtration for particulate, gases and scents;

(iv) a sufficient fire suppression system; and

(b) the minimum standards listed in subregulation (3)(a) of this Regulation shall be approved by the Authority, a public health officer and an St. Kitts and Nevis Fire Department Official.

79. **Medicinal cannabis processing and extraction operation - testing.**

(1) The licenced extraction and processing operation shall store extracted and processed medicinal cannabis goods in batches within a Limited Access Area, on the Licenced premises before testing and continuously until either of the following occurs

(a) a batch passes the testing requirements pursuant to these Regulations and is transported to a licenced medicinal cannabis Infused Products Manufacturer or medicinal cannabis dispensary; or

(b) a batch fails the testing requirements pursuant to these Regulations and isdestroyed.

(2) A Medicinal Cannabis Processing and Extraction Operation shall provide samples of its Medicinal cannabis goods to a Testing Facility with a Licence for Medicinal Cannabis testing and qualification to ensure the health and safety of each of its product batches.

(3) The Testing Facility will notify the licensee of the results by print, which the Medicinal Cannabis Processing and Extraction Operation shall include as part of labelling to the medicinal cannabis infused products manufacturer or Medicinal Cannabis Dispensary.

(4) The processor and extractor licensee shall arrange for a medicinal cannabis testing laboratory to obtain a representative sample of each product batch at the Processing and Extraction operation's licenced premises; after obtaining the sample, the testing laboratory representative shall maintain custody of the sample and transport it to the testing laboratory.

(5) Upon issuance of a certificate of analysis by the testing laboratory that the cannabis batch has passed the testing requirements pursuant to these Regulations, the licenced Processing and Extraction operation shall conduct a quality assurance review before distribution to ensure the labelling and packaging of the medicinal cannabis products conform to the requirements of these Regulations.

(6) The Medicinal Cannabis Processing and Extraction Operation shall maintain the testing results as part of its business books and records according to these Regulations.

(7) Medicinal Cannabis product batches are subject to quality assurance and testing prior to sale at a medicinal cannabis dispensary or at a medicinal cannabis Infused Products Manufacturer.

DIVISION 4 - MEDICINAL CANNABIS BUSINESS INFUSED PRODUCTS MANUFACTURER LICENCE

80. **Medicinal cannabis infused products manufacturer - licence privileges.**

(1) A Medicinal Cannabis Infused Products Manufacturer shall only exercise those privileges granted to it by the Authority.

(2) Medicinal Cannabis or medicinal cannabis infused products within a Licenced Medicinal Cannabis Infused Products Manufacturer premises shall not be observable to the public.

(3) Facility shall meet all Health and building Regulations for its purposes as well as be inspected and approved by Health and Fire Official and by the Development Control and Planning Board.

(4) A Medicinal Cannabis Infused Products Manufacturer may only sell its ownMedicinal Cannabis Infused Products to Medicinal Cannabis Dispensaries.

(5) A Medicinal Cannabis Infused Products Manufacturer may manufacture, prepare, package, label and store Medicinal Cannabis Infused Product, that are comprised of Medicinal Cannabis, in raw, processed or extracted forms and other ingredients intended for use or consumption, such as edible products, ointments, or tinctures.

(6) A Medicinal Cannabis Infused Products Manufacturer shall not manufacture, prepare, package, store, or label Medicinal Cannabis Infused Product in a location that is operating as a retail food establishment or a wholesale food registrant.

(7) A Medicinal Cannabis Infused Products Manufacturer shall provide samples of its Medicinal Cannabis Infused Product to a Testing Facility that has obtained a Licence to test Medicinal Cannabis for standards testing purposes.

(8) The Medicinal Cannabis Infused Products Manufacturer shall maintain the testing results as part of its business books and records.

81. **Medicinal cannabis infused products manufacturer - general limitations or prohibited acts.**

(1) A Medicinal Cannabis Infused Products Manufacturer is prohibited from selling Medicinal Cannabis Infused Product that are not properly packaged and labelled according to these Regulations.

(2) A Medicinal Cannabis Infused Products Manufacturer is prohibited from selling Medicinal Cannabis or Medicinal Cannabis Infused Product to an authorized patient or caregiver.

(3) A Medicinal Cannabis Infused Products Manufacturer shall not permit the consumption of medicinal Cannabis or medicinal Cannabis infused products on its Licenced Premises.

(4) A Medicinal Cannabis Infused Products Manufacturer shall provide adequate refrigeration for perishable Medicinal Cannabis Infused Product intended for consumption and shall utilize adequate storage facilities and transport methods.

(5) All medicinal cannabis that is not sold to a downstream licenced medicinal cannabis business within ten (10) months of the manufacture date of the particular batch, shall be destroyed at the cost of the licensee at an authorized disposal facility.

(6) Medicinal Cannabis Infused Product Manufacturer shall ensure that its manufacturing processes are designed so that its Edible Medicinal Cannabis Infused Product shall be–

(a) not designed to be appealing to children or easily confused with commercially sold candy or foods that do not contain cannabis;

(b) produced and sold with a standardized concentration of cannabinoids not to exceed ten (10) milligrams tetrahydrocannabinol (THC) per serving;

(c) delineated or scored into standardized serving sizes if the edible medicinal cannabis infused product contains more than one serving;

(d) homogenized to ensure uniform disbursement of cannabinoids throughout the product;

(e) manufactured and sold under sanitation standards established by the Ministry of Health, in consultation with the Authority, that are similar to the standards for preparation, storage, handling, and sale of food products;

(f) provided to customers with sufficient information to enable the informed consumption of the product, including the potential effects of the cannabis product and directions as to how to consume the cannabis product, as necessary.

82. **Medicinal cannabis infused products manufacturer - specific guidelines.**

(1) The Licensee shall obtain its medicinal cannabis raw material from an authorized medicinal cannabis cultivation licensee or a medicinal cannabis processing and extraction licensee.

(2) Each plant shall have been tagged from germination with a unique identifier and input into the St. Kitts and Nevis tracking system and shall have been tracked and monitored from its germination stage to harvest and sale.

(3) The Licensee shall be responsible for ensuring all medicinal cannabis raw material batches from the medicinal cannabis cultivation or extraction licensees are tagged and the information regarding all raw material has been input into the tracking system, and the licensee shall continuously maintain and update in the tracking system all infused products maintaining chain of command.

(4) In addition to all the tracking and reporting requirements in these Regulations, the Licensee shall record and report the total net weight of the raw material and the total net weight of all the cannabinoids in the end product produced and ensure reconciliation within the tracking system.

(5) The licensee shall ensure all preparation and infusion equipment are properly set up and maintained by a qualified professional and is inspected and approved by the health and St. Kitts and Nevis Fire Departments.

(6) The licensee shall meet all premises security requirements as specified within these Regulations.

(7) The licensee shall ensure all infused medicinal cannabis goods are each affixed with a Unique Identifier and entered into the St. Kitts and Nevis Tracking System prior to downstream sale.

(8) The licensee shall also record and reconcile through the tracking system, all medicinal cannabis waste.

83. **Medicinal cannabis infused products manufacturer facility specifications.**

(1) A medicinal cannabis infused products manufacturer facility shall meet all requirements including those regarding premises, storage, transport, security, health and safety as specified by these Regulations.

(2) The licensee shall maintain within the licenced premises the following separated areas

(a) designated office area;

(b) designated chemicals area;

(c) designated Gas area where applicable;

(d) designated secured medicinal cannabis raw material storage area;

(e) designated kitchen area;

(f) designated cold storage area;

(g) designated wash area;

(h) designated dry goods storage area;

(i) designated packaging area;

(j) designated secured area for cannabis waste; and

(k) designated secured area for medicinal cannabis infused products storage.

(3) Licensees shall enact sufficient methods or procedures to capture or otherwise limit risk of explosion, combustion, or any other unreasonably dangerous risk to public safety created by volatile solvents or gas;

(a) the minimum standards concerning cooking and infusion methods and procedures shall include but may not be limited to the following

(i) sufficient fresh air ventilation in kitchen area;

(ii) sufficient air extraction ventilation that shall include ventilation clearance above the roof of the licenced premises;

(iii) sufficient air filtration for particulate, gases and scents;

(iv) a sufficient fire suppression system; and

(b) the minimum standards listed in this subregulation shall be approved by the Authority, Ministry of Health and the St. Kitts and Nevis Fire Department.

84. **Medicinal cannabis infused products manufacturer operation - testing.**

(1) The licenced medicinal cannabis infused products manufacturer operation shall store infused medicinal cannabis goods in batches within a limited access area, on the Licenced premises before testing and continuously until

(a) a batch passes the testing requirements pursuant to these Regulations and is transported to a licenced medicinal cannabis Dispensary; or

(b) a batch fails the testing requirements pursuant to these Regulations and is destroyed.

(2) A Medicinal Cannabis Infused Products Manufacturer Operation shall provide samples of its Medicinal cannabis goods to a Testing Facility with a Licence for Medicinal Cannabis testing and qualification to ensure the health and safety of each of its product batches.

(3) The Testing Facility will notify the licensee of the results in writing, which the Medicinal Cannabis Infused Products Manufacturer Operation shall include as part of labelling to the Medicinal Cannabis Dispensary.

(4) The Infused Products Manufacturer licensee shall arrange for a medicinal cannabis testing laboratory to obtain a representative sample of each product batch at the Infused Products Manufacturer operation's licenced premises and

(a) after obtaining the sample, the testing laboratory representative shall maintain custody of the sample and transport it to the testing laboratory; and

(b) notwithstanding any other rule of Law, Edible medicinal cannabis Infused Products shall require testing at an authorized medicinal cannabis testing Facility and shall not be required to be tested by the Bureau of Standards of St. Kitts and Nevis.

(5) Upon issuance of a certificate of analysis by the testing laboratory that the cannabis batch has passed the testing requirements pursuant to these Regulations, the licenced Infused Products Manufacturer operation shall conduct a quality assurance review before distribution to ensure the labelling and packaging of the medicinal cannabis products conform to the requirements of these Regulations.

(6) The Medicinal Cannabis Infused Products Manufacturer Operation shall maintain the testing results as part of its business books and records according to these Regulations.

(7) Medicinal Cannabis product batches are subject to quality assurance and testing prior to sale at a medicinal cannabis dispensary.

DIVISION 5 – MEDICINAL CANNABIS BUSINESS DISPENSARY LICENCE

85. **Medicinal cannabis dispensary - licence privileges.**

(1) A Medicinal Cannabis Dispensary shall exercise the privileges granted by the Authority.

(2) A Medicinal Cannabis Dispensary may only sell Medicinal Cannabis Flower that it has purchased from a Licenced Medicinal Cannabis Cultivation Operation.

(3) A Medicinal Cannabis Dispensary may sell Medicinal Cannabis Infused Product that it has purchased from a Licenced Medicinal Cannabis Infused Products Manufacturer, where each product is pre-packaged and labelled upon purchase from the manufacturer.

(4) A Medicinal Cannabis Dispensary may sell processed Medicinal Cannabis and Medicinal Cannabis Extract Product that it has purchased from a Licenced Medicinal Cannabis Processor and Extractor, where every product are pre-packaged and labelled upon purchase from the Processor.

(5) A Medicinal Cannabis Dispensary may provide Samples of its products for testing and research purposes to a Medicinal Cannabis Testing Facility or to a Medicinal Cannabis Research and Development facility that has obtained a Licence to test or research Medicinal Cannabis.

(6) A Medicinal Cannabis Dispensary may store inventory on licenced premises and any inventory stored on the Licenced premises shall be secured in a limited access area compliant with Regulations 38 and 40 of these Regulations, and tracked consistently with the inventory tracking rules as specified in these Regulations.

(7) A Medicinal Cannabis Dispensary shall not sell medicinal cannabis to any person, except to Authorized Patients and Caregivers or to Authorized Research Facilities.

(8) A medicinal cannabis dispensary may sell medicinal cannabis, non-infused medicinal cannabis products and medicinal cannabis infused products.

(9) A person who is an authorized special dispensing licencee may dispense Medicinal Cannabis to Authorized Patients and Caregivers at Licenced Medicinal Cannabis Dispensaries.

86. **Medicinal cannabis sales - general limitations or prohibited acts.**

(1) A person shall not distribute Medicinal cannabis goods shall not to any person except to authorized patients or caregivers during authorized business hours.

(2) Authorized hours for Medicinal Cannabis Dispensaries shall be between 8:00am and 1:00am and may be during any day of the week or year.

(3) Licensees shall not permit the consumption of medicinal cannabis goods on the Licenced premises except when such dispensary is also licenced as a Medicinal Cannabis Lounge.

(4) A Medicinal Cannabis Dispensary and its employees are prohibited from selling more than two (2) ounces or fifty-six grams (56g) of Medicinal Cannabis flower or fourteen grams (14g) of medicinal cannabis extract during a single sales transaction or during a single day to an Authorized Patient or Caregiver unless otherwise authorized by the Authority.

(5) Nothing in these rules prohibits a Licensee from refusing to sell Medicinal cannabis goods to an authorized patient or caregiver.

(6) A Medicinal Cannabis Dispensary shall not display Medicinal cannabis goods outside of a designated Restricted Access Area or in a manner in which Medicinal cannabis goods can be seen from outside the Licenced Premises.

(7) Medicinal cannabis goods that is not on display, shall be stored in a Limited Access Area in a medicinal cannabis storage compliant with regulations 38 and 40.

(8) A Medicinal Cannabis Dispensary shall not sell any expired Medicinal cannabis Infused Product.

(9) All point-of-sale systems and scales used for weighing medicinal cannabis shall be compliant with the universal St. Kitts and Nevis tracking system and authorized by the Authority as specified in Regulation 56.

87. **Medicinal cannabis dispensary – facility specifications.**

(1) A medicinal cannabis dispensary shall meet all requirements including those regarding premises, storage, transport, security, health and safety as specified by these Regulations.

(2) A person who intends to obtain a licence to operate a medicinal cannabis dispensary, in addition to subregulation (1) of this Regulation, the medicinal cannabis dispensary shall fulfil the requirements as follows

(a) utilize opaque windows and doors to prevent a person outside the premises from viewing activity inside the premises;

(b) create a reception area that is separated from the Dispensary by a controlled access door where

(i) the reception area shall not allow any view of the dispensary area while the controlled access door is closed;

(ii) the receptionist shall possess a valid individual occupational licence;

(iii) the receptionist shall issue first issue medicinal cannabis Patient Identification Cards to a Patient or caregiver in possession of an authorized medicinal cannabis recommendation but who is not yet in possession of a Patient Identification Card, and shall enter the relevant information into the St. Kitts and Nevis tracking system;

(iv) the receptionist shall validate the authenticity of the documents of the patient or caregiver before allowing the patient or caregiver to enter the dispensary area; and

(v) the receptionist shall record the information regarding the Patient's or caregiver's visit to the dispensary, including but not limited to, the patient or caregiver unique identifier information, visit date, entry time and exit time;

(c) the dispensary area shall clearly be labelled, by use of adequate signage, as a restricted access area where authorized staff, patients or caregivers are allowed;

(d) each cannabis product sale shall be entered into the St. Kitts and Nevis Tracking System and each entry shall include as follows

(i) the individual product information inclusive of the product unique identifier code;

(ii) the patient or caregiver information or unique identifier code;

(iii) the individual product cost and total transaction value; and (iv) the tax gained by the sale of the medicinal cannabis goods.

88. **Acceptable forms of identification for medicinal cannabis sales.**

(1) Medicinal Cannabis Dispensaries shall only sell Medicinal cannabis goods to a patient as permitted by these Regulations if that patient can produce

(a) a valid recommendation from an authorized medical practitioner or a medicinal cannabis card; and

(b) an adequate, current and valid proof of identification.

(2) Where a Patient is in possession of an authorized recommendation, but is a first time applicant for an Identification Card, he may apply for the card from an from an Authorized medicinal cannabis dispensary and pay any required fee.

(3) An applicant for a medicinal cannabis dispensary licence shall provide proof of identification to the Authority which shall be a government-issued identification as follows

(a) a driver's permit, issued by relevant authorities in St. Kitts and Nevis;

(b) an St. Kitts and Nevis voters identification card; or (c) an St. Kitts and Nevis Passport.

(4) Non-residents without a valid recommendation from another regulated medicinal cannabis jurisdiction shall apply for a recommendation from an authorized medical practitioner and obtain a visiting patient identification card or where a non-resident is in possession of a valid recommendation from his home jurisdiction, he shall apply to the Authority, solely, for a visiting patient identification card.

(5) The sole accepted form of proof of identification for non-residents is a valid passport.

(6) A Licensee shall physically view and inspect the patient's recommendation and proof of identification to confirm the authenticity of the documents presented and to enter the Authorized patient's or caregiver's information into the St Kitts and Nevis Tracking System.

DIVISION 6 – MEDICINAL CANNABIS BUSINESS LOUNGE LICENCE

89. **Medicinal cannabis lounge - licence privileges.**

(1) A Medicinal Cannabis Lounge shall exercise privileges granted solely by the Authority.

(2) A Medicinal Cannabis Lounge shall allow an authorized patient who is allowed entry at its licenced premises to consume medicinal cannabis goods.

(3) Subject to subregulation (2), a medicinal cannabis lounge shall allow for thesmoking, vaporizing, and ingesting of medicinal cannabis goods on the licenced premises.

(4) Tobacco use may be allowed.

90. **Medicinal cannabis lounge – general limitations or prohibited acts.**

(1) Medicinal cannabis goods shall solely be used by an authorized patient on the licenced premises during authorized business hours.

(2) Authorized business hours, referred to in subregulation (1), for a MedicinalCannabis Lounge shall be between 8:00a.m and 1:00a.m and may be during any day of the year.

(3) Access to the area where cannabis consumption is allowed is restricted to persons eighteen (18) years of age or older.

(4) Cannabis consumption shall not be visible from any public place or any nonage restricted area.

(5) Sale or consumption of alcohol or tobacco is not allowed on the premises.

(6) A medicinal cannabis lounge shall not have a kitchen for cooking on the licenced premises, but

(a) hot or refrigerated non-alcoholic beverages may be sold; or

(b) snacks that do not require any preparation in excess of heating in a microwave may be sold on the licenced premises.

(7) A medicinal cannabis lounge licensee may also be licenced as a medicinal cannabis dispensary within the same licenced premises, providing all requirements for both licences are adhered to.

(8) A medicinal cannabis lounge licensee shall not permit the sale of medicinal cannabis goods on the licenced premises except where such medicinal cannabis lounge is also licenced as a Medicinal Cannabis Dispensary.

91. **Medicinal cannabis lounge – facility specifications.**

(1) A medicinal cannabis lounge shall meet all requirements including those regarding premises, storage where applicable, security, health and safety as specified by these Regulations.

(2) A person who intends to obtain a licence to operate a medicinal cannabis lounge, in addition to subregulation (1) of this Regulation, the medicinal cannabis lounge shall fulfil the requirements as follows

(a) use opaque windows and doors, such that no activity may be viewed from outside the premises;

(b) create a reception area that is separated from the Lounge by a controlled access door where

(i) the reception area shall not allow any view of the Lounge area while the controlled access door is closed;

(ii) the receptionist shall possess a valid individual occupational licence;

(iii) the receptionist shall validate the authenticity of the documents of the Patient or caregiver before allowing the patient or caregiver to enter the lounge area; and

(iv) the receptionist shall record the information regarding the Patient's or caregiver's visit to the lounge, including but not limited to, the patient or caregiver unique identifier information, visit date, entry time and exit time.

(c) the lounge area shall clearly be labelled, by use of adequate signage, as a restricted access area, wherein only authorized staff and Patients or caregivers are allowed.

(3) The minimum standards regarding a medicinal cannabis lounge facility shall include but may not be limited to

(a) sufficient fresh air ventilation in extraction area;

(b) sufficient air extraction ventilation that shall include ventilation clearance above the roof of the licenced premises;

(c) sufficient air filtration for particulate, smoke, gases and scents;

(d) heat detectors;

(e) a sufficient fire suppression system; and

(f) the minimum standards listed in subregulation (3) of this Regulation shall be approved by the Authority, the Ministry of Health and the St. Kitts and Nevis Fire Department.

92. **Acceptable forms of identification for medicinal cannabis lounge.**

(1) A Medicinal Cannabis Lounge shall allow sole entry to authorized patients and caregivers as permitted by these Regulations if that patient or caregiver can produce–

(a) a valid recommendation from an authorized health practitioner;

(b) a Medicinal cannabis Patient Identification Card for Medicinal Cannabis; and

(c) an adequate, currently valid proof of identification.

(2) An applicant for a medicinal cannabis lounge licence shall provide proof of identificationto the Authority which shall be a government-issued identification as follows

(a) a driver's permit, issued by relevant authorities in St. Kitts and Nevis;

(b) an St. Kitts and Nevis voters identification card; or (c) an St. Kitts and Nevis Passport.

(3) Acceptable forms of Identification from non-resident authorized patients shall be restricted to a valid passport.

(4) A Licensee shall physically view and inspect the patient's recommendation and proof of identification to confirm the authenticity of the documents before allowing them access to the lounge area.

DIVISION 7 – MEDICINAL CANNABIS BUSINESS EXPORT OR IMPORT LICENCE

93. **Medicinal cannabis schedule internationally.**

(1) For the purpose of considering international standards, medicinal cannabis is a schedule 1 controlled product within the international drug conventions to which St. Kitts and Nevis is a signatory party.

(2) The Import or Export of Medicinal Cannabis, Medicinal cannabis Extract or resin or Medicinal Cannabis Infused Product, shall follow existing established procedures with the St. Kitts and Nevis Customs and Excise Division, for the import or export of scheduled and controlled drugs.

94. **Special provisions relating to international trade.**

(1) The Authority shall not knowingly permit the import of medicinal cannabis goods into St. Kitts and Nevis or the export of medicinal cannabis goods out of St. Kitts and Nevis to any country or territory except

(a) in accordance with the laws and Regulations of that country or territory; and

(b) within the limits of the total of the estimates for that country or territory, as defined in paragraph 2 of article 19 of the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol, with the addition of the amounts intended to be re-exported.

(2) The Authority shall

(a) control under licence the import and export of medicinal cannabis goods; and

(b) control and monitor all persons and enterprises carrying on or engaged in such import or export.

(3) A Division Inspector shall inspect any consignment of medicinal cannabis goods prior to the medicinal cannabis goods being released for export or prior to being released to the consignee after authorized import.

95. **Medicinal cannabis import or export – raw cannabis plant material or seeds.**

In the case of import or export of any Medicinal cannabis in raw form, actual plant material for any medical, scientific or other government regulated purpose or Medicinal cannabis seeds

(a) each document for import or export of a scheduled drug or controlled substance shall be made available by both the importer and exporter; and

(b) every document shall be accompanied by phytosanitary certification, to be issued by the Plant Protection Division, of the Ministry of Agriculture of St. Kitts and Nevis.

96. **Medicinal cannabis export and import authorizations – general rules.**

(1) A person authorized to engage in the import or export of medicinal cannabis goods shall require a separate import or export authorization to be obtained for each such import or export whether it consists of one or more types of medicinal cannabis goods.

(2) The authorization referred to in subregulation (1) shall include but may not be limited to

(a) the name of the drug;

(b) the international non-proprietary name if any;

(c) the quantity to be imported or exported;

(d) the name and address of the importer and exporter;

(e) the government issued Authorization or Licence number of the importer and exporter; and

(f) the period within which the importation or exportation shall be effected.

(3) The export authorization shall also state the number and date of the importcertificate and the name and contact information of the Authority by whom it has been issued.

(4) The import authorization may allow an importation in more than one consignment.

(5) Before issuing an export authorization the Authority shall require an importcertificate, issued by the competent authorities of the importing country or territory and certifying that the importation of the medicinal cannabis goods referred to therein, is approved and such certificate shall be produced by the person or establishment applying for the export authorization.

(6) A copy of the export authorization shall accompany each consignment, and the Government Authority issuing the export authorization shall send a copy directly to the Government Authority of the importing country or territory.

(7) The Government Authority of the importing country or territory, when the importation has been effected or when the period fixed for the importation has expired, shall return the export authorization, with an endorsement to that effect, to the Government
Authority of the exporting country or territory and

(a) the endorsement shall specify the amount actually imported; or

(b) if a lesser quantity than that specified in the export authorization is actually exported, the quantity actually exported shall be stated by the competent authorities on the export authorization and on an official copy thereof.

(8) An export of a consignment to a post office box shall be prohibited.

(9) Transfer of any payment, monies or funds relating to the medicinal cannabis goods stated on the Authorizations, to a bank or to an account of a consignee other than the consignee named in the export authorization, shall be prohibited.

(10) Exports of consignments to a bonded warehouse shall be prohibited except where the government of the importing country certifies on the import certificate, produced by the person or establishment applying for the export authorization, that it has approved the importation for the purpose of being placed in a bonded warehouse and

(a) in such case, the export authorization shall specify that the consignment is exported for such purpose; and

(b) each withdrawal from the bonded warehouse shall require a permit from the authorities having jurisdiction over the warehouse.

(11) Consignments of medicinal cannabis goods entering or leaving St. Kitts and Nevis not accompanied by an export authorization shall be detained by the competent authorities.

(12) A licensee shall not permit any medicinal cannabis goods consigned to another country to pass through its territory, unless a copy of the export authorization for such consignment is produced to the competent authorities of that Country.

(13) The competent authorities of any country or territory through which a consignment of medicinal cannabis goods is permitted to pass shall take all due measures to prevent the diversion of the consignment to a destination other than that named in the accompanying copy of the export authorization unless the Government of that country or territory through which the consignment is passing authorizes the diversion and

(a) the Government of the country or territory of transit shall treat any requested diversion as if the diversion were an export from the country or territory of transit to the country or territory of new destination; and

(b) if the diversion is authorized, the provisions of subregulation (7) of this Regulation shall also apply between the country or territory of transit and the country or territory which originally exported the consignment.

(14) No consignment of medicinal cannabis goods while in transit, or whilst being stored in a bonded warehouse, may be subjected to any process which would change the nature of the medicinal cannabis goods in question and the packing may not be altered without the permission of the competent authorities.

(15) Any medicinal cannabis goods to be imported or exported shall meet all Testing and Standards Requirements of these Regulations prior to being approved to be imported or exported.

(16) All medicinal cannabis goods to be imported or exported shall be entered and tracked in the St. Kitts and Nevis Tracking System.

(17) The provisions of subregulations (11), (12) and (13) of this Regulation relating to the passage of medicinal cannabis goods through the territory of a Party do not apply where the consignment in question is transported by aircraft which does not land in a country or territory of transit or

(a) if the aircraft lands in any such country or territory, those provisions shall be applied so far as circumstances require; and

(b) the provisions of this Regulation are without prejudice to the provisions of any international agreements which limit the control which may be exercised by any of the Parties to the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol, over drugs in transit.

97. **Medicinal cannabis import licence – specific rules.**

(1) A person who holds an import licence is authorized to import, for medical or scientific purposes, the specified goods on the licence, which may include as follows

(a) medicinal cannabis goods;

(b) medicinal cannabis genetics, with the approval from the relevant departments of the Ministry of Agriculture and which maybe in the form as follows

(i) seeds;

(ii) clones; or

(iii) tissue culture;

(c) equipment related to medicinal cannabis businesses; and (d) paraphernalia related to medicinal cannabis use.

(2) Each Import Licence, if approved by the Authority, shall be signed by the Minister.

(3) A person who holds an import licence is also required to be authorized to possess, transfer, transport, send or deliver the specific shipment authorized on the licence to the extent necessary to import the medicinal cannabis goods specified on the Licence.

(4) The import licence shall set out the information as follows

(a) the name and mailing address of the holder;

(b) the destination address of the shipment;

(c) the unique licence number;

(d) regarding the shipment of medicinal cannabis goods to be imported

(i) the description of the medicinal cannabis goods;

(ii) the intended use of the medicinal cannabis goods;

(iii) if applicable, the brand name of the medicinal cannabis goods;

(iv) quantity of the medicinal cannabis goods; and

(v) the percentage of THC and CBD of the medicinal cannabis goods, except in the case of medicinal cannabis plants and medicinal cannabis seeds;

(e) the name and address of the exporter in the country of export;

(f) the port of entry into St. Kitts and Nevis;

(g) the address of the customs office to which the shipment is to be delivered;

(h) each mode of transportation used, the country and port of export and, if applicable, any country of transit or transshipment;

(i) any conditions that the Minister considers appropriate;

(j) the effective date of the licence; and (k) the date of expiry of the licence.

(5) The Authority may refuse to issue an import licence for any reason, which may include, but shall not be limited to

(a) the applicant does not hold a medicinal cannabis business licence;

(b) the case where the Minister has reasonable grounds to believe that the shipment to which the licence application pertains would contravene these Regulations or the laws of the country of export or any country of transit or transshipment, or

(c) the importation of the medicinal cannabis goods is for the purpose of exporting it.

(6) An import licence is valid until the earliest of the following dates

(a) the date on which the shipment is imported;

(b) the date of expiry of the licence;

(c) the date of expiry of the licence;

(d) the date of its revocation; or

(e) the date of revocation of the licence for exportation issued by the competent authority of the country of export that pertains to the shipment.

(7) A holder of an import licence shall provide a copy of the import licence to the customs office at the time of importation.

(8) The holder of an import licence shall ensure that, after the imported medicinal cannabis goods is released, it is transported directly to the destination address set out in the licence.

(9) Circumstances for the revocation of an import licence may include but shall not be limited to where

(a) the licence holder has requested, in writing, the revocation;

(b) the export authorization has been revoked;

(c) the importation of the medicinal cannabis goods is for the purpose of exporting it; or

(d) a licence that has been suspended is not reinstated because the reasons for the suspension still exist or the licence holder has not demonstrated to the Authority that the suspension is unfounded.

(10) The Authority may, for the purpose of verifying whether an importation of medicinal cannabis goods complies with these Regulations, provide to a customs officer any information provided in the import licence and inform that customs officer whether the import licence has been suspended or revoked.

98. **Medicinal cannabis export licence – specific rules.**

(1) It shall be unlawful to export from St. Kitts and Nevis any medicinal cannabis goods unless

(a) It is exported to a country which is a party to

(i) the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol;

(ii) the Convention on Psychotropic Substances of 1971; or

(iii) the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988;

(b) the country referred to in paragraph (a), shall institute and maintain, conformity with any convention to which it is a party, a system for the control of imports of narcotic drugs which the Authority considers adequate;

(c) the narcotic drug is consigned to a holder of such permits or licences as may be required under the laws of the country of import, and a permit or licence to import such drug has been issued by the country of import;

(d) substantial evidence is furnished to the Authority by the exporter that

(i) the narcotic drug is to be applied exclusively to medical or scientific uses or Government regulated use within the country of import; and

(ii) there is an actual need for the narcotic drug for medical or scientific uses or other Government regulated use within such country; and

(e) a permit to export the narcotic drug in each instance has been issued by the Authority and signed by the Minister.

(2) Notwithstanding subregulation (1) of this Regulation, the Authority may authorize medicinal cannabis to be exported from St. Kitts and Nevis to a country which is a party to any of the international instruments mentioned in subregulation (1) of this Regulation if the particular drug is to be applied to a special scientific or research purpose in the country of destination and the authorities of such country will permit the importation of the particular drug for such purpose.

(3) A person who holds a medicinal cannabis export licence is authorized to export medicinal cannabis goods for medical, scientific or other Government regulated purposes.

(4) Each Export Licence, if approved by the Authority, shall be signed by the Minister.

(5) A holder of an export licence is also required to be authorized to possess, transfer, transport, send, deliver or sell the shipment of medicinal cannabis goods to the extent necessary to export the medicinal cannabis goods.

(6) The export licence shall set out the information as follows

(a) the name and mailing address of the holder;

(b) the destination of the consignment;

(c) the unique licence number;

(d) regarding the shipment of medicinal cannabis goods to be exported, the information to be included are as follows

(i) the description of the medicinal cannabis goods;

(ii) the intended use of the medicinal cannabis goods;

(iii) if applicable, the brand name of the medicinal cannabis goods;

(iv) the quantity of the medicinal cannabis goods;

(v) the percentage of THC and CBD of the medicinal cannabis goods, except in the case of medicinal cannabis plants and medicinal cannabis seeds;

(e) the name and address of the importer;

(f) the port of exit from St. Kitts and Nevis, the country and port of import and, if applicable, any country of transit or transshipment;

(g) the address of the customs office, sufferance warehouse or bonded warehouse to which the shipment is to be delivered, if applicable;

(a) each mode of transportation used;

(b) any conditions that the Minister considers appropriate; (c) the effective date of the licence; and

(d) the date of expiry of the licence.

(7) The Authority may refuse to issue an export licence for any reason, which may include, but shall not be limited to

(a) the applicant does not hold a medicinal cannabis business licence;

(b) the case where the Minister has reasonable grounds to believe that the shipment to which the Licence application pertains, would contravene these Regulations or the laws of the country of import or any country of transit or transhipment, or

(c) the shipment would not comply with the licence for importation issued by a competent authority of the country of import.

(8) An export licence is valid until the earliest of the following dates

(a) the date on which the shipment is exported;

(b) the date of expiry of the licence or the date of its revocation;

(c) the date of its revocation, or

(d) the date of expiry of the licence for importation issued by the competent authority of the country of import that pertains to the shipment or the date of its revocation.

(9) A person who holds an export licence shall provide a copy of the export licence to the customs office at the time of exportation.

(10) Circumstances for the revocation of an export licence may include but shall not be limited to

(a) the licence holder has requested, in writing, the revocation;

(b) the import licence has been revoked; or

(c) a licence that has been suspended is not reinstated because the reasons for the suspension still exist or the licence holder has not demonstrated to the Authority that the suspension is unfounded.

(11) The Authority may, for the purpose of verifying whether an exportation ofmedicinal cannabis goods complies with these Regulations, provide to a customs officer any information provided in the export licence application and inform that customs officer whether the export licence has been suspended or revoked.

99. **Exception for exportation for subsequent export.**

The Authority may authorize any medicinal cannabis goods to be exported from St. Kitts and Nevis to a country for subsequent export from that country to another country, if each of the requirements as follows are adhered to

(a) the country to which the medicinal cannabis goods is exported from St. Kitts and Nevis , referred to in this Regulation as the “first country”, and the country to which the medicinal cannabis goods is exported from the first country, referred to in this Regulation as the “second country”, are parties to the Single Convention on Narcotic Drugs, 1961, and the
Convention on Psychotropic Substances, 1971;

(b) the first country and the second country have instituted and maintains conformity with such Conventions, a system of controls of imports of controlled substances which the Authority considers adequate;

(c) with respect to the first country, the medicinal cannabis goods is consigned to a holder of such permits or licences as may be required under the laws of such country, and a permit or licence to import the medicinal cannabis goods has been issued by the country;

(d) with respect to the second country, substantial evidence is furnished to the Authority by the person who will export the medicinal cannabis goods from St. Kitts and Nevis that

(i) the medicinal cannabis goods is to be consigned to a holder of such permits or licences as may be required under the laws of such country, and a permit or licence to import the medicinal cannabis goods is to be issued by the country; and

(ii) the medicinal cannabis goods is to be applied exclusively to medical, scientific, or other legitimate uses within the country.

(e) the medicinal cannabis goods will not be exported from the second country, except that the medicinal cannabis goods may be exported from a second country if that second country issues an export certificate or authorization for the medicinal cannabis goods;

(f) within thirty (30) days after the medicinal cannabis goods is exported from the first country to the second country, the person who exported the medicinal cannabis goods from St. Kitts and Nevis delivers to the Authority

(i) documentation certifying that such export from the first country has occurred; and

(ii) information concerning the consignee, country, and product;

(g) a licence to export the medicinal cannabis goods from St. Kitts and Nevis has been issued by the Authority and signed by the Minister.

DIVISION 8 – MEDICINAL CANNABIS RESEARCH AND DEVELOPMENT LICENCE

100. **Government obligation to promote research.**

The Authority shall promote and commission objective scientific research to be completed within St. Kitts and Nevis, regarding the efficacy and safety of administering cannabis as part of medical treatment.

101. **Medicinal cannabis research and development licensee general obligations.**

(1) Every Licensee shall develop a program and conduct studies intended to ascertain the general medical safety and efficacy of cannabis and if found valuable, shall develop medical guidelines for the appropriate administration and use of cannabis.

(2) The studies may include studies to ascertain the effect of cannabis on motor skills.

(3) The program may immediately solicit proposals for research projects to be included in the cannabis studies.

(4) Program requirements to be used when evaluating responses to its solicitation for proposals, shall include, but may not be limited to, the requirements as follows

(a) proposals shall demonstrate the use of key personnel, including clinicians or scientists and support personnel, who are prepared to develop a program of research regarding cannabis' general medical efficacy and safety;

(b) proposals shall contain procedures for outreach to patients with various medical conditions who may be suitable participants in research on cannabis; (c) proposals shall contain provisions for a patient registry;

(d) proposals shall contain provisions for an information system that is designed to record information about possible study participants, investigators, and clinicians, and deposit and analyze data that accrues as part of clinical trials;

(e) proposals shall contain protocols suitable for research on cannabis, addressing patients diagnosed with acquired immunodeficiency syndrome (AIDS) or human immunodeficiency virus (HIV), cancer, glaucoma, or seizures or muscle spasms associated with a chronic, debilitating condition;

(f) proposals may also include research on other serious illnesses, provided that resources are available and medical information justifies the research;

(g) proposals shall demonstrate the use of a specimen laboratory capable of housing plasma, urine, and other specimens necessary to study the concentration of cannabinoids in various tissues, as well as housing specimens for studies of toxic effects of cannabis;

(h) proposals shall demonstrate the use of a laboratory capable of analyzing cannabis, provided to the program under this Regulation, for purity and cannabinoid content and the capacity to detect contaminants.

(5) To ensure objectivity in evaluating proposals, the program shall use a peer review process that is modelled on the process used by International Institutes of Health and of Research, and that guards against funding research that is biased in favour of or against particular outcomes and

(a) peer reviewers shall be selected for their expertise in the scientific substance and methods of the proposed research, and their lack of bias or conflict of interest regarding the applicants or the topic of an approach taken in the proposed research.

(b) peer reviewers shall judge research proposals on several criteria, foremost among which shall be both of the following

(i) the scientific merit of the research plan, including whether the research design and experimental procedures are potentially biased for or against a particular outcome; and

(ii) researchers' expertise in the scientific substance and methods of the proposed research, and their lack of bias or conflict of interest regarding the topic of, and the approach taken in, the proposed research.

(6) The program shall be established as follows

(a) the program shall be located at an authorized research facility that shall include faculty experienced in organizing multidisciplinary scientific endeavours and, in

particular, strong experience in clinical trials involving psychopharmacologic agents; or

(b) the facilities at which research under the auspices of the program is to take place shall accommodate the administrative offices, including a director of the program, as well as a data management unit, and facilities for storage of specimens.

(7) The Authority shall, when awarding grants under this Part, implement principles and parameters of the other well-tested International or Regional research programs administered by various universities or hospitals, modelled after programs that follow international guidelines, including peer review evaluation of the scientific merit of applications.

(8) The scientific and clinical operations of the program may occur, partly at university campuses, and partly at hospitals or other public or private health institutions, that have clinicians or scientists with expertise to conduct the required studies.

(9) Criteria for selection of research programs to award grants, shall give particular weight to the organizational plan, leadership qualities of the program director, and plans to involve investigators and patient populations from multiple sites.

(10) The funds received by the Licensee shall be allocated to various specific research studies in accordance with a scientific plan.

(11) The size, scope, and number of studies funded shall be commensurate with the amount of appropriated and available program funding.

(12) Any personnel involved in approved research programs shall possess anIndividual Occupational Licence.

(13) Studies conducted pursuant to this Regulation shall include the greatest amount of new scientific research possible on the medical uses of, and medical hazards associated with, cannabis.

(14) The program shall consult with Research agencies in other States, and other appropriate agencies in an attempt to avoid duplicative research and the wasting of research dollars.

(15) The program shall make every effort to recruit qualified patients and qualified physicians from throughout St. Kitts and Nevis.

(16) The cannabis studies shall employ state-of-the-art research methodologies.

(17) The program shall ensure that all cannabis used in the studies is of the appropriate medical quality and shall be obtained from licenced medicinal cannabis businesses designated to supply cannabis for authorized research.

(18) The program may review, approve, or incorporate studies and research by independent groups presenting scientifically valid protocols for medical research, regardless of whether the areas of study are being researched by the committee.

102. **Medicinal cannabis research and development licensee specific obligations.**

(1) To enhance understanding of the efficacy and adverse effects of cannabis as a pharmacological agent, the program shall conduct focused controlled clinical trials on the

usefulness of cannabis in patients diagnosed with AIDS or HIV, cancer, glaucoma, or seizures or muscle spasms associated with a chronic, debilitating condition.

(2) The program may add research on other serious illnesses, provided that resources are available and medical information justifies the research.

(3) The studies shall focus on comparisons of both the efficacy and safety of methods of administering the drug to patients, including inhalational, tinctural, topical, rectal and oral, evaluate possible uses of cannabis as a primary or adjunctive treatment, and develop further information on optimal dosage, timing, mode of administration, and variations in the effects of different cannabinoids and varieties of cannabis.

(4) The program shall examine the safety of cannabis in patients with various medical disorders, including cannabis's interaction with other drugs, relative safety of inhalation versus oral forms, and the effects on mental function in medically ill persons.

(5) The program shall be limited to providing for objective scientific research to ascertain the efficacy and safety of cannabis as part of medical treatment, and shall not be construed as encouraging or sanctioning the social or recreational use of cannabis.

(6) The program shall, prior to any approving proposals, seek to obtain and implement research protocol guidelines from other reputable research organizations following international guidelines and best practices.

(7) Licensees may solicit, apply for, and accept funds from foundations, private individuals, and all other funding sources that can be used to expand the scope or timeframe of the cannabis studies that are authorized under the Research and Development Licence.

(8) The program shall not expend more than five (5) percent of its General Fund allocation in efforts to obtain money from outside sources.

(9) In no case shall the program accept any funds that are offered with any conditions other than that the funds be used to study the efficacy and safety of cannabis as part of medical treatment.

(10) Any donor shall be advised that funds given for purposes of this Regulation will be used to study both the possible benefits and detriments of cannabis and that he or she will have no control over the use of these funds.

(11) Within six months of the effective date of this Regulation, the program shall report to the Authority on the progress of the cannabis studies

(a) thereafter, the program shall issue a report to the Authority every six months detailing the progress of the studies;

(b) the interim reports required under this paragraph shall include, but may not be limited to, data on all of the following

(i) The names and number of diseases or conditions under study;

(ii) The number of patients enrolled in each study by disease; (iii) Any scientifically valid preliminary findings.

(12) No more than 10 percent of the total funds appropriated may be used for all aspects of the administration of this Regulation.

(13) This Regulation shall be implemented only to the extent that funding for itspurposes is appropriated in the annual Budget.

(14) Any products developed from research conducted under a medicinal cannabis research and development licence in St. Kitts and Nevis, that has received Government Funding from St. Kitts and Nevis towards that specific project, shall submit twenty percent (20%) risk free perpetual ownership of that product to the Government of St. Kitts and Nevis.

Part VII
Medicinal Cannabis Testing Facility Licence: Licencee and Laboratory Rules

DIVISION 1 – LINCENSEE AND LABORATORY RULES

103. **Licence for medicinal cannabis testing facility.**

(1) If a Testing Facility wishes to test and analyze medicinal cannabis, it shall first complete an Authority application, pay all applicable fees and obtain a licence for at least one Owner to engage in testing and analysis.

(2) The licence referenced in this rule may only be granted to or held by a Medicinal Cannabis Testing Facility whose certifications and equipment are up to date, valid and in good standing.

(3) A person holding a Licence to test and analyze medicinal cannabis shall comply with all requirements in this part of these Regulations.

(4) Any violation of such requirements in connection with testing and analyzing of medicinal cannabis shall constitute a violation of these rules and a violation in connection with the person's Medicinal Cannabis Testing Facility licence.

104. **Medicinal cannabis testing facility licence - general laboratory licence requirements.**

(1) A licenced laboratory shall maintain ISO/IEC 17025 accreditation for the testing of the following

(a) cannabinoids;

(b) heavy metals;

(c) microbial impurities;

(d) mycotoxins;

(e) residual pesticides;

(f) residual solvents and processing chemicals; and (g) if tested, terpenoids.

(2) Each testing laboratory licenced premises shall have ISO/IEC 17025 accreditation.

(3) A licenced laboratory shall retain, and make available to the Authority upon request, all records associated with the licensee's ISO/IEC 17025 certificate of accreditation.

105. **Laboratory licence application.**

In addition to the information required in Regulation 7, an application for a testing laboratory licence shall include the following valid certificate of accreditation, issued by an accreditation body that attests to the laboratory's competence to perform testing including all the required analytes and the standard operating procedures and the method validation reports for the testing of the following

(a) cannabinoids;

(b) heavy metals;

(c) microbial impurities;

(d) mycotoxins;

(e) residual pesticides;

(f) residual solvents and processing chemicals; and (g) if tested, terpenoids.

106. **Interim testing laboratory licence.**

(1) An applicant may apply for an interim licence prior to receiving ISO/IEC 17025 accreditation provided that the applicant meets all other licensure requirements for a testing laboratory and submits to the Authority an application in compliance with regulation 7 and an attestation that the applicant has or intends to seek ISO/IEC 17025 accreditation for all testing methods required by the Authority.

(2) An interim testing laboratory licence shall be valid for 12 months and shall function under the same Regulations for an accredited laboratory.

(3) To timely renew an interim licence, a completed licence renewal form and the annual renewal licence fee pursuant to Regulation 32 shall be received by the Authority from the licensee no earlier than 60 calendar days before the expiration of the licence and no later than 3:00 p.m. Atlantic Standard Time on the last business day before the expiration of the licence submitted to the Authority at its office.

(4) Failure to receive a notice for licence renewal does not relieve a licensee of the obligation to renew an interim licence as required.

(5) In the event the licence is not renewed prior to the expiration date, the licensee shall not test any commercial cannabis goods until the licence is renewed.

(6) A licensee may submit a licence renewal form up to 30 calendar days after the licence expires. Any late renewal form will be subject to a late fee required by subregulation (3) of this Regulation.

(7) The licence renewal application shall contain the information as follows— (a) the name of the licensee;

(i) for licensees who are individuals, the applicant shall provide both the first and last name of the individual;

(ii) for licensees who are business entities, the licensee shall provide the legal business name of the applicant;

(b) the licence number and expiration date;

(c) the licensee's address of record and licenced premises address; and

(d) an attestation that all information provided to the Authority in the original application under regulation 7 or subsequent notification under regulation 36 of these Regulations is accurate and current.

(8) The Authority may renew an interim licence for an initial renewal period of 12 months.

(9) After one renewal, the Authority may renew the interim licence for additional 12 month periods if the licensee has submitted an application for the ISO/IEC 17025 accreditation.

(10) In addition to the information required for a renewal form pursuant to subregulation (f) of this Regulation, any renewal request pursuant to this Regulation shall also include an attestation that the licensee's application for each ISO/IEC 17025 is pending with the accrediting body, the name of the accrediting body, and the date the application was submitted to the accrediting body.

(11) The licensee shall notify the Authority if the application for each ISO/IEC 17025accreditation is granted or denied within 1 business day of receiving the decision from the accrediting body.

(12) If the accrediting body grants or denies the licensee's application for any ISO/IEC17025 accreditation before the expiration of the interim licence, the Authority may terminate the interim licence at that time.

(13) The Authority may revoke an interim licence at any time.

DIVISION 2 – SAMPLING MEDICINAL CANNABIS GOODS

107. **Sampling standard operating procedures.**

(1) The laboratory shall develop and implement a sampling standard operating procedure (SOP) that describes the laboratory's method for obtaining representative samples of medicinal cannabis goods.

(2) The laboratory shall use and submit to the Authority, its Standard Operating Procedures for sampling medicinal cannabis or medicinal cannabis infused products.

(3) The laboratory shall retain a copy of the sampling SOP on the licenced laboratory premises and ensure that the sampling SOP is accessible to the authorized sampler during sampling.

108. **General sampling requirements.**

(1) The laboratory that obtains a representative sample from a licenced Medicinal cannabis business shall perform all the required testing at one licenced laboratory premises.

(2) The laboratory may obtain and analyze samples only from batches in final form.

(3) The laboratory sampler shall collect a representative sample from each batchfollowing the procedures specified in the laboratory's sampling standard operating procedures.

(4) The laboratory shall ensure that the sample is transported and subsequently stored at the licenced laboratory premises in a manner that prevents degradation, contamination, co-mingling, and tampering

(a) if the medicinal cannabis specifies on the label how the medicinal cannabis shall be stored, the laboratory shall store the sample as indicated on the label;

(b) the testing laboratory shall store medicinal cannabis samples and medicinal cannabis infused product in a limited access medicinal cannabis store as specified in regulation 40.

(5) The laboratory shall complete and maintain a chain of custody (COC) form for each sample that the laboratory collects and analyses.

(6) Once a representative sample has been obtained for regulatory compliance testing, the licenced testing laboratory that obtained the sample shall complete the regulatory compliance testing.

(7) If a licenced laboratory is unable to competently complete the regulatory compliance testing after sampling and before a COA is issued, the licenced medicinal cannabis business who arranged for the testing of the batch(s) may request approval from the Authority to have the impacted batch(s) re-sampled and tested by another licenced laboratory

(a) the request shall be made in writing to the Authority and shall include all of the following

(i) the name and licence number of the distributor;

(ii) the batch numbers;

(iii) the type and quantity of cannabis goods;

(iv) the name and licence number of the laboratory that took the initial sample and is not able to competently complete the regulatory compliance testing;

(v) the name and licence number of the laboratory proposed to re- sample and complete the regulatory compliance testing for the batch(s); and

(vi) the reason why the laboratory which initially took the sample cannot competently complete the regulatory compliance testing;

(b) the Authority will review the request and determine if the laboratory which initially took the sample is unable to competently complete the regulatory compliance testing and if the Authority determines that the laboratory is unable to competently complete the regulatory compliance testing, the Authority, in its discretion, may approve the request in whole or part and set conditions for the re-sampling and testing;

(c) no re-sampling of any batch shall occur prior to the licenced medicinal cannabis business receiving written approval from the Authority.

109. **Chain of custody (COC).**

(1) The laboratory shall develop and implement a COC protocol to ensure accurate documentation is recorded for the sampling, transport, handling, storage, and destruction of samples.

(2) The COC protocol shall require the use of a physical COC form as well as input into the St. Kitts and Nevis Tracking System.

(3) The sampler shall use a COC to record the following information for each sampled batch

(a) laboratory's name, licenced premises address, and licence number;

(b) date and time sampling started and ended;

(c) lcenced medicinal cannabis business' name, licenced premises address, and licence number;

(d) batch number of the batch from which the representative sample was obtained and assigned unique sample identifier;

(e) sample matrix;

(f) total batch size, by weight, or unit count;

(g) total weight, or unit count of the representative sample;

(h) sampling conditions or problems encountered during the sampling process, if any;

(i) printed name and signature of the licenced Medicinal cannabis business employee; and

(j) printed name and signature of the sampler.

(4) Each time the sample changes custody between licensees, is transported, or is destroyed, the date, time, and the names and signatures of persons involved in these activities shall be recorded on the COC physical and electronic formats.

(5) Once the custody of the sample changes between licensees, the COC form for that change of custody may not be altered.

110. **Harvest batch sampling.**

(1) The sampler shall obtain a representative sample from each prepacked or unpacked harvest batch.

(2) The representative sample shall weigh 0.35% of the total harvest batch weight.

(3) A sampler may collect a representative sample greater than 0.35% of the totalharvest batch weight of a prepacked or unpacked harvest batch if necessary to perform the required testing or to ensure that the samples obtained are representative.

(4) The prepacked or unpacked harvest batch from which a sample is obtained shallweigh no more than 50.0 pounds; laboratory analyses of a sample collected from a harvest batch weighing more than 50.0 pounds shall be deemed invalid and the harvest batch from which the sample was obtained shall not be released for retail sale.

(5) When the sampler obtains a representative sample from an unpacked harvestbatch, the sampler shall do all the following

(a) collect the number of sample increments relative to the unpacked harvest batch size is as listed in the table set out in Schedule VI;

(b) obtain sample increments from random and varying locations of the unpacked harvest batch, both vertically and horizontally

(i) To the extent practicable, the sample increments obtained from an unpacked harvest batch shall be of equal weight; and

(ii) To the extent practicable, collect an equal number of sample increments from each container if the unpacked harvest batch is stored in multiple containers.

111. **Medicinal cannabis infused product batch.**

(1) The sampler shall obtain a representative sample from each medicinal cannabis infused product batch.

(2) The sampler may collect a greater number of sample increments if necessary to perform the required testing or to ensure that the samples obtained are representative.

(3) The medicinal cannabis infused product batch from which a representative sample is obtained shall contain no more than 150,000 units and laboratory analyses of a sample collected from a medicinal cannabis product batch containing more than 150,000 units shall be deemed invalid and the medicinal cannabis product batch from which the representative sample was obtained shall not be released for retail sale.

(4) The sampler shall obtain a representative sample of a medicinal cannabis product by collecting, at minimum, the number of sample increments relative to the batch size as listed in the table, set out in Schedule VII, where each sample increment consists of 1 packaged unit.

112. **Laboratory transportation of medicinal cannabis goods samples.**

Laboratory transport of medicinal cannabis or medicinal cannabis infused products samples shall follow all transport procedures and other requirements specified in Regulations 64, 65, 67 and 68 of these Regulations.

113. **Laboratory receipt of samples obtained from a medicinal cannabis business.**

(1) The laboratory may accept and analyze a sample from a licenced medicinal cannabis business for the required testing under these Regulations only if there is an accompanying COC form for the sample.

(2) The laboratory employee who receives the sample shall date, print, sign their name on the accompanying sample COC and input their unique occupational licence number where applicable.

(3) The laboratory shall not analyze a sample obtained from a licenced medicinal cannabis business and the batch from which the sample was obtained may not be released for retail sale, if any of the following occur

(a) the sample is received at the laboratory without the requisite COC form;

(b) the tamper-evident material is broken prior to the sample being received at the laboratory; or

(c) there is evidence of sample commingling, contamination, degradation, or a related occurrence rendering the sample unusable for analytical testing when the sample is received at the laboratory.

DIVISION 3 – STANDARD OPERATING PROCEDURES

114. **Laboratory analyses standard operating procedures.**

(1) The laboratory shall develop, implement, and maintain written standard operating procedures (SOP) for sample preparation and each required test method.

(2) The laboratory shall use and submit to the Authority the following (a) the Sample Preparation Standard Operating Procedures Form; and (b) the Test Methods Standard Operating Procedures Form.

(3) The laboratory shall keep each SOP at the licenced laboratory premises and ensure that each SOP is accessible to laboratory employees during operating hours.

(4) The laboratory shall make each SOP available for inspection by the Authority upon request, as well as any other SOPs associated with the licensee's ISO/IEC 17025 certificate of accreditation.

115. **Validation of test methods.**

(1) The laboratory may use a nonstandard, amplified, or modified test method or a method that is designed or developed by the laboratory to validate the methods for analyses of samples.

(2) The laboratory shall follow the guidelines set forth in the US Food and Drug Administration's Guidelines for the Validation of Analytical Methods for the Detection of Microbial Pathogens in Foods and Feeds, 2nd Edition, April 2015, incorporated herein by reference, to validate test methods for the microbial analysis of samples.

(3) The laboratory shall include and address the criteria listed in the table, set out in Schedule VIII, when validating test methods for microbial analyses of samples and the laboratory shall follow the guidelines set forth in the US Food and Drug Administration's Guidelines for the Validation of Chemical Methods for the FDA FVM Program, 2nd Edition, April 2015, incorporated herein by reference, to validate test methods for chemical analysis of samples.

(4) The laboratory shall include and address the following criteria to validate test methods for chemical analyses of samples

(a) accuracy;

(b) precision;

(c) linearity and range;

(i) the Coefficient of Determination (r2) for all calibration curves shall be greater than or equal to 0.99;

(ii) linear regression or quadratic regression shall only be used for calibration curves and curves shall not be weighted at all or only weighted at $^{1}/_{x}$.

(c) LoQ for analytes tested shall be within the range of the calibration curve.

(d) calibration standard—

(i) for calibration curves, there shall be a minimum of five calibration standards, not including zero; and

(ii) each calibration curve shall include an Initial CalibrationVerification (ICV);

(e) sensitivity and selectivity;

(f) limit of detection and limit of quantitation;

(g) recovery;

(h) reproducibility; and (i) robustness.

(5) The laboratory shall use certified reference materials, to validate the following chemical analyses and the test method used for analysis is valid if the percent recovery of the certified reference material is between 80% to 120% for all required analytes.

DIVISION 4 – LABORATORY TESTING AND REPORTING

116. **Required testing.**

(1) Any sample increments of medicinal cannabis Infused Products collected shall be homogenized prior to sample analyses, notwithstanding foreign material testing.

(2) The laboratory shall test each representative sample for the following

(a) cannabinoids;

(b) foreign material;

(c) heavy metals;

(d) microbial impurities;

(e) mycotoxins;

(f) moisture content and water activity;

(g) residual pesticides;

(h) residual solvents and processing chemicals; and (i) if applicable, terpenoids.

(3) The laboratory shall report the results of each analysis performed by the laboratory on the certificate of analysis.

(4) The laboratory that obtained the representative sample shall complete all required testing for each representative sample for regulatory compliance testing.

117. **Moisture content and water activity testing.**

(1) The laboratory shall analyze at minimum 0.5 grams of the representative sample of dried flower to determine the level of water activity and the percentage of moisture content

(a) the dried flower sample, including pre-rolled medicinal cannabis, shall be deemed to have passed water activity testing if the water activity does not exceed 0.65 (Aw) and the laboratory shall report the result of the water activity test on the certificate of analysis (COA) and indicate "pass" or "fail" on the COA;

(b) the laboratory shall report the result of the moisture content test on the COA as a percentage.

(2) The laboratory shall analyze at least 0.5 grams of the representative sample of solid edible medicinal cannabis products to determine the level of water activity.

(a) a solid edible medicinal cannabis product shall be deemed to have passed water activity testing if the water activity does not exceed 0.85 Aw.

(b) the laboratory shall report the result of the water activity test on the COA and indicate "pass" or "fail" on the COA.

(3) If the sample fails water activity testing, the batch from which the sample was collected fails water activity testing and shall not be released for retail sale.

118. **Residual solvents and processing chemicals testing.**

(1) The laboratory shall analyze at minimum 0.25 grams of the representative sample of medicinal cannabis to determine whether residual solvents or processing chemicals are present.

(2) The laboratory shall report the result of the residual solvents and processing chemicals testing in unit micrograms per gram (µg/g) on the COA and indicate "pass" or "fail" on the COA.

(3) The sample shall be deemed to have passed the residual solvents and processing chemicals testing if the presence of any residual solvent or processing chemical listed in the following tables in Category I and Category II does not exceed the indicated action levels;

(a) notwithstanding subregulation (3) of this Regulation, the limit for ethanol does not apply to cannabis goods that are intended to be orally-consumed products containing alcohol;

(b) notwithstanding subregulation (3) of this Regulation, the limit for ethanol or isopropyl alcohol does not apply to cannabis goods that are intended to be topical cannabis goods.

(4) If the sample fails residual solvents and processing chemicals testing, the batch from which the sample was collected fails residual solvents and processing chemicals testing and shall not be released for retail sale.

119. **Residual pesticides testing.**

(1) The laboratory shall analyze at minimum 0.5 grams of the representative sample of cannabis goods to determine whether residual pesticides are present.

(2) The laboratory shall report whether any Category I Residual Pesticides are detected above the limit of detection (LOD) and shall report the result of the Category II Residual Pesticides testing in unit micrograms per gram (µg/g) on the COA.

(3) The laboratory shall indicate "pass" or "fail" on the COA.

(4) The laboratory shall establish a limit of quantitation (LOQ) of 0.10 µg/g or lower for all Category I Residual Pesticides.

(5) The sample shall be deemed to have passed the residual pesticides testing if both of the conditions set out in Schedule X are met

(a) the presence of any residual pesticide listed in the following tables in Category I are not detected; and

(b) the presence of any residual pesticide listed in the following tables in Category II does not exceed the indicated action levels.

(6) If the sample fails residual pesticides testing, the batch from which the sample was collected fails residual pesticides testing and shall not be released for retail sale.

120. **Microbial impurities testing.**

(1) The laboratory shall analyze at minimum 1.0 grams of the representative sample of medicinal cannabis goods to determine whether microbial impurities are present.

(2) The laboratory shall report the result of the microbial impurities testing by indicating "pass" or "fail" on the COA.

(3) The sample of medicinal cannabis goods shall be deemed to have passed the microbial impurities testing if all of the following conditions are met

(a) shiga toxin–producing Escherichia coli is not detected in 1 gram;

(b) salmonella spp. Is not detected in 1 gram; and

(c) pathogenic Aspergillus species A. fumigatus, A. flavus, A. niger, and A. terreus are not detected in 1 gram.

(4) If the sample fails microbial impurities testing, the batch from which the sample was collected fails microbial impurities testing and shall not be released for retail sale.

121. **Mycotoxin testing.**

(1) The laboratory shall analyze at minimum 0.5 grams of the representative sample of medicinal cannabis goods to determine whether mycotoxins are present.

(2) The laboratory shall report the result of the mycotoxins testing in unit micrograms per kilograms (µg/kg) on the COA and indicate "pass" or "fail" on the COA.

(3) The sample shall be deemed to have passed mycotoxin testing if both the following conditions are met

(a) total of aflatoxin B1, B2, G1, and G2 does not exceed 20 µg/kg of substance, and

(b) ochratoxin A does not exceed 20 µg/kg of substance.

(4) If the sample fails mycotoxin testing, the batch from which the sample was collected fails mycotoxin testing and shall not be released for retail sale.

122. **Foreign material testing.**

(1) The laboratory shall analyze the representative sample of medicinal cannabis goods to determine whether foreign material is present.

(2) The laboratory shall report the result of the foreign material test by indicating "pass" or "fail" on the COA.

(3) The laboratory shall perform foreign material testing on the total representative sample prior to sample homogenization.

(4) When the laboratory performs foreign material testing, at minimum, the laboratory shall do all of the following:

(a) examine both the exterior and interior of the dried flower sample; and (b) examine the exterior of the cannabis product sample.

(5) The sample shall be deemed to have passed the foreign material testing if the presence of foreign material does not exceed

(a) 5% of the total sample area covered by sand, soil, cinders, or dirt;

(b) 0.5% of the total sample area covered by mold;

(c) 1 insect fragment, 1 hair, or 1 count mammalian excreta per 3.0 grams; or (d) 0.5% of the total sample area covered by an imbedded foreign material.

(6) If the sample fails foreign material testing, the batch from which the sample was collected fails foreign material testing and shall not be released for retail sale.

123. **Heavy metals testing.**

(1) The laboratory shall analyze at minimum 0.5 grams of the representative sample of medicinal cannabis goods to determine whether heavy metals are present.

(2) The laboratory shall report the result of the heavy metals test in unit micrograms per gram (μg/g) on the COA and indicate "pass" or "fail" on the COA.

(3) The sample shall be deemed to have passed the heavy metals testing if the presence of heavy metals does not exceed the action levels listed in the table Set out in Schedule XI.

(4) If the sample fails heavy metals testing, the batch from which the sample was collected fails heavy metals testing and shall not be released for retail sale.

124. **Cannabinoid testing.**

(1) The laboratory shall analyze at minimum 0.5 grams of the representative sample of cannabis goods to determine the cannabinoid profile such as THC; THCA; CBD; CBDA; CBG; and CBN.

(2) The laboratory shall establish a limit of quantification (LOQ) of 1.0 mg/g or lower for all cannabinoids analyzed and reported.

(3) The laboratory shall report the result of the cannabinoid testing on the COA, at minimum—

(a) a percentage for THC, THCA, CBD, and CBDA;

(i) when the laboratory reports the result of the cannabinoid testing for harvest batch representative samples on the COA in dry-weight percent, they shall use the following equation—

Dry-weight percent cannabinoid = wet-weight percent cannabinoid / (1 — percent moisture / 100);

(b) a percentage for Total THC and Total CBD, if applicable;

(c) milligrams per gram (mg/g) if by dry-weight or milligrams per illiliter (mg/ mL) if by volume for THC, THCA, CBD, and CBDA;

(d) milligrams per gram (mg/g) if by dry-weight or milligrams per illiliter (mg/ mL) if by volume for Total THC and Total CBD, if applicable;

(e) milligrams per package for THC and CBD;

(f) milligrams per package for Total THC and Total CBD, if applicable;

(g) milligrams per serving for THC and CBD, if any;

(h) milligrams per serving for Total THC and Total CBD, if any and if applicable; and

(i) the laboratory shall report the results of all other cannabinoids analyzed on the COA both as a percentage and in either milligrams per gram (mg/g) if by weight or milligrams per illiliter (mg/mL) if by volume.

(4) The laboratory shall calculate the total cannabinoid concentration as follows— (a) for concentration expressed in weight—

Total cannabinoid concentration (mg/g) = (cannabinoid acid form concentration (mg/g) x 0.877) + cannabinoid concentration (mg/g);

(b) for concentration expressed in volume—

Total cannabinoid concentration (mg/mL) = (cannabinoid acid form concentration (mg/mL) x 0.877) + cannabinoid concentration (mg/mL).

(5) Any cannabinoids found to be less than the LOQ shall be reported on the COA as "<1 mg/g" if by dry-weight or "<1 mg/mL" if by volume.

125. **Terpenoid testing.**

(1) If requested, the laboratory shall analyze at minimum 0.5 grams of the representative sample of cannabis goods to determine the terpenoid profile of the sample.

(2) The laboratory shall report the result of the terpenoid testing on the COA both as a percentage and in either milligrams per gram (mg/g) if by weight or milligrams per milliliter (mg/mL) if by volume.

126. **Certificate of analysis (COA).**

(1) The laboratory shall generate a COA for each representative sample that the laboratory analyzes.

(2) The laboratory shall ensure that the COA contains the results of all required analyses performed for the representative sample.

(3) The laboratory shall, within 1 business day of completing all analyses of a sample, upload the COA into the St Kitts and Nevis Tracking System.

(4) The laboratory shall not release to any person any cumulative or individual test results prior to completing all analyses and providing the COA to the Authority.

(5) The COA shall contain, at minimum, the following information—

(a) the term "Regulatory Compliance Testing" in font no smaller than 14-point which shall appear in the upper-right corner of each page of the COA. No text or images shall appear above the term "Regulatory Compliance Testing" on any page of the COA;

(b) laboratory's name, licenced premises address, and licence number;

(c) licenced medicinal cannabis business name, licenced premises address, and licence number;

(d) batch number of the batch from which the sample was obtained and for medicinal cannabis goods that are already packaged at the time of sampling, the labeled batch number on the packaged medicinal cannabis goods shall match the batch number on the COA;

(e) sample identifying information, including matrix type and unique sample identifiers;

(f) sample history, harvest or production date, including the date collected, the date received by the laboratory, and the date of sample analyses and corresponding testing results;

(g) for dried flower samples, the total weight of the batch, in grams or pounds, and the total weight of the representative sample in grams;

(h) for medicinal cannabis product, the total unit count of both the representative sample and the total batch size;

(i) the analytical methods, analytical instrumentation used, and corresponding Limits of Detection (LOD) and Limits of Quantitation (LOQ);

(j) an attestation on the COA from the laboratory supervisory or management employee that all LQC samples were performed and met the acceptance criteria; and

(k) analytes detected during the analyses of the sample that are unknown, unidentified, or injurious to human health if consumed, if any.

(6) The laboratory shall report test results for each representative sample on the COA as follows

(a) indicate an overall "pass" or "fail" for the entire batch;

(b) when reporting qualitative results for each analyte, the laboratory shall indicate "pass" or "fail";

(c) when reporting quantitative results for each analyte, the laboratory shall use the appropriate units of measurement as required under this chapter;

(d) when reporting results for each test method, the laboratory shall indicate "pass" or "fail";

(e) when reporting results for any analytes that were detected below the analytical method LOQ, indicate "<LOQ", notwithstanding cannabinoid results;

(f) when reporting results for any analytes that were not detected or detected below the LOD, indicate "ND"; and

(g) indicate "NT" for any test that the laboratory did not perform.

(7) The laboratory supervisory or management employee shall validate the accuracy of the information contained on the COA and sign and date the COA.

DIVISION 5 – POST TESTING PROCEDURES

127. **Remediation and retesting.**

(1) A medicinal cannabis goods batch that has been additionally processed after failed testing shall be retested and successfully pass all the analyses required under this chapter.

(2) The licenced medicinal cannabis business shall arrange for remediation of a failed medicinal cannabis goods batch and if the batch cannot be remediated, the batch shall be destroyed at the cost of the licenced medicinal cannabis business at an authorized disposal facility.

(3) If a failed batch is not remediated or reprocessed in any way it cannot be retested and any subsequent COAs produced without remediation or reprocessing of the failed batch will not supersede the initial regulatory compliance testing COA.

(4) A medicinal cannabis goods batch may only be remediated twice and if the batch fails after the second remediation attempt and the second retesting, the entire batch shall be destroyed.

(5) Within one business day of completing the required analyses of a representative sample obtained from a remediated cannabis goods batch, the laboratory shall upload the COA information into the St Kitts and Nevis Tracking System.

(6) Nothing in this Regulation shall be interpreted to prevent a cannabis goods batch from being retested when the COA is 10 or more months old.

128. **Post testing sample retention.**

(1) The laboratory shall retain the reserve sample, consisting of any portion of a sample that was not used in the testing process.

(2) The reserve sample shall be kept, at minimum, for 45 business days after the analyses, after which time it may be destroyed and denatured to the point the material is rendered unrecognizable and unusable.

(3) The laboratory shall securely store the reserve sample in a manner that prohibits sample degradation, contamination, and tampering.

(4) The laboratory shall provide the reserve sample to the Authority upon request.

DIVISION 6 – LABORATORY QUALITY ASSURANCE AND QUALITY CONTROL

129. **Laboratory quality assurance (LQA) program.**

(1) The laboratory shall develop and implement a LQA program to assure the reliability and validity of the analytical data produced by the laboratory and the LQA program shall, at minimum, include a written LQA manual that addresses the following

(a) quality control procedures;

(b) laboratory organization and employee training and responsibilities, including good laboratory practice (GLP);

(c) LQA objectives for measurement data;

(d) traceability of data and analytical results;

(e) instrument maintenance, calibration procedures, and frequency;

(f) performance and system audits;

(g) corrective action procedures;

(h) steps to change processes when necessary;

(i) record retention and document control;

(j) test procedure standardization; and (k) method validation.

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

130. **Laboratory quality control (LQC) samples.**

(1) The laboratory shall use LQC samples and adhere to good laboratory practice (GLP) in the performance of each analysis according to the following specifications

(a) the laboratory shall analyze LQC samples in the same manner as the laboratory analyzes medicinal cannabis goods samples;

(b) the laboratory shall use at least one negative control, one positive control, and one laboratory replicate sample in each analytical batch for each target organism during microbial testing

(i) if one of the controls produces unexpected results, the samples shall be re-prepped and re-analyzed with a new set of controls;

(ii) if the result of the microbial analyses is outside the specified acceptance criteria in the table set out in Schedule XII, the laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.

(2) The laboratory shall prepare and analyze at least one of each of the following LQC samples for each analytical batch

(a) method blank;

(b) laboratory control sample (LCS); and

(c) laboratory replicate sample or matrix spike sample.

(3) The laboratory shall analyze, at minimum, a continuing calibration verification (CCV) sample at the beginning of each analytical sequence and every 10 samples thereafter.

(4) If the result of the chemical analyses is outside the specified acceptance criteria in the table set out in Schedule XIII, the laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.

(5) If any analyte is detected above any action level, as described in this chapter, the sample shall be re-prepped and reanalyzed in replicate within another analytical batch

(a) for quantitative analyses, the re-prepped sample and its associated replicate shall meet the acceptance criteria of RPD =30%;

(b) for qualitative analyses, the re-prepped sample and its associated replicate results shall concur.

(6) If any LQC sample produces a result outside of the acceptance criteria, the laboratory cannot report the result and the entire batch cannot be released for retail sale and then the laboratory shall determine the cause and take steps to remedy the problem until the result is within the specified acceptance criteria.

(7) If the laboratory determines that the result is a false-positive or a false-negative, The Authority may request the laboratory to re-sample or re-test.

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

131. **Limits of detection (LoD) and limits of quantitation (LoQ) for quantitative analyses.**

(1) The laboratory shall eithor calculate the LOQ according to subsection (2) or calculate the LOD for chemical method analyses according to any of the following methods— (a) signal-to-noise ratio of between 3:1 and 2:1;

(b) standard deviation of the response and the slope of calibration curve using a minimum of 7 spiked blank samples calculated as follows

LOD = (3.3 x standard deviation of the response) / slope of the calibration curve.

(2) The laboratory shall calculate the LOQ for chemical method analyses according to any of the following methods

(a) signal-to-noise ratio of 10:1, at minimum;

(b) standard deviation of the response and the slope using a minimum of 7 spiked blank samples calculated as follows

LOQ = (10 × standard deviation of the response) / slope of the calibration curve.

132. **Required proficiency testing.**

(1) The laboratory shall annually, successfully participate in a proficiency testing program for each of the following test methods

(a) cannabinoids;

(b) heavy metals;

(c) microbial impurities;

(d) mycotoxins;

(e) residual pesticides;

(f) residual solvents and processing chemicals; and (g) if tested, terpenoids.

(2) The laboratory shall report all analytes available by the proficiency testing program provider and for which the licensee is required to test as required under this chapter.

(3) The laboratory shall participate in the proficiency testing program by following the laboratory's existing SOPs for testing cannabis goods.

(4) The laboratory shall rotate the proficiency testing program among the laboratory employees who perform the test methods.

(5) Laboratory employees who participate in a proficiency testing program shall sign the corresponding analytical reports or attestation statements to certify that the proficiency testing program was conducted in the same manner as the laboratory tests of cannabis goods.

(6) A supervisory or management laboratory employee shall review and verify the accuracy of results reported for all proficiency testing program samples analyzed.

(7) The laboratory shall request the proficiency testing program provider to send results concurrently to the Authority, if available, or the laboratory shall provide the proficiency testing program results to the Authority within 3 business days after the laboratory receives notification of their test results from the proficiency testing program provider.

133. **Satisfactory and unsatisfactory proficiency test performance.**

(1) The laboratory shall be deemed to have successfully participated in a proficiency testing program for an analyte tested in a specific method if the test results demonstrate a "satisfactory" or otherwise proficient performance determination by the proficiency testing program provider.

(2) The laboratory may not report test results for analytes that are considered by the proficiency testing program provider as "unacceptable," "questionable," "unsatisfactory", or otherwise deficient.

(3) The laboratory may resume reporting test results for analytes that were deemed "unacceptable," "questionable," "unsatisfactory", or otherwise deficient, only if both of the following conditions are met

(a) the laboratory satisfactorily remedies the cause of the failure for each analyte; and

(b) the laboratory submits, to the Authority, a written corrective action report demonstrating how the laboratory has fixed the cause of the failure.

134. **Laboratory audits.**

(1) The laboratory shall conduct an internal audit at least once per year or in accordance with the ISO/IEC 17025 accrediting body's requirement, whichever is more frequent.

(2) The internal audit shall include all of the components required by the ISO/IEC 17025 internal-audit standards.

(3) Within 3 business days of completing the internal audit, the laboratory shall submit the results of the internal audit to the Authority.

(4) Within 3 business days of receiving the Accrediting Body on-site audit findings the laboratory shall submit the results to the Authority.

Part VIII Business Records

135. **Business records required.**

(1) A medicinal cannabis business shall maintain the information required in this Part in a physical format that is readily understood by a reasonably prudent business person as well as maintaining an electronic format through the St. Kitts and Nevis Tracking System.

(2) Each medicinal cannabis business shall retain all books and records necessary to fully account for the business transactions conducted under its licence for the current year and seven preceding calendar years; the medicinal cannabis business' books and records for the preceding six months or complete copies of such records shall be maintained on its licenced premises at all times and shall include, but may not be limited to the following

(a) medicinal cannabis business licence;

(b) all applicable Individual Occupational Licences;

(c) cultivation plan;

(d) all records evidencing compliance with the environmental protection and public health and safety measures;

(e) all supporting documentation for data or information entered into the St. Kitts and Nevis Tracking System;

(f) all UIDs assigned to product in inventory and all unassigned UIDs;

(g) UIDs associated with product that has been retired from the St. Kitts and Nevis Tracking System shall be retained for six (6) months after the date the tags were retired;

(h) financial records related to the licenced commercial cannabis activity,including but not limited to, bank statements, tax records, contracts, purchase orders, sales invoices, and sales receipts;

(i) personnel records, including each employee's full name, individual occupational licence number or individual tax payer identification number,

date of employment, and, where applicable, date of termination of employment;

(j) records related to employee training for the St. Kitts and Nevis Tracking System or other requirements of this chapter and shall include, but may not be limited to, the date(s) training occurred, description of the training provided, and the names of the employees that received the training;

(k) contracts with other state licenced cannabis businesses;

(l) all permits, licences, and other authorizations to conduct the licensee's commercial cannabis activity;

(m) records associated with composting or disposal of cannabis waste;

(n) documentation associated with loss of access to the St. Kitts and Nevis Tracking System.

(3) The books and records shall fully account for all the transactions of the business and shall include, but shall not be limited to—

(a) a current employee list which shall provide the full name and licence number of each employee and all non-employee owners, who work at a medicinal cannabis business;

(b) secure facility information regarding its licenced premises, includingmaintaining the business contact information for vendors that maintain video surveillance systems and security alarm systems;

(c) licenced premises diagram inclusive of a diagram of all approved limitedaccess areas and restricted access areas;

(d) emergency exit plan;

(e) a visitor log which shall list all visitors entering limited access areas or restricted access areas;

(f) all records normally retained for tax purposes; (g) loss of records and data—

(i) any non-purposeful loss of electronically-maintained records shall not be considered a mitigating factor for violations of this rule;

(ii) licensees are required to exercise due diligence in preserving and maintaining all required records.

(4) A medicinal cannabis business shall maintain accurate and comprehensive inventory tracking records through the St. Kitts and Nevis Tracking System and physically where applicable, that account for, reconcile, and evidence all inventory activity for medicinal cannabis from either seed or immature plant stage until the medicinal cannabis or medicinal cannabis infused product is destroyed or sold to another medicinal cannabis business or to an authorized patient or caregiver where applicable.

(5) A medicinal cannabis business shall maintain adequate records for all activities of transport related to medicinal cannabis and medicinal cannabis infused product.

(6) A licensee shall provide on-demand access to on-premises records following a request from the Authority during normal business hours or hours of apparent operation, and shall provide access to off-premises records within three business days following a request from the Authority.

136. **Record retention.**

(1) Each licensee shall keep and maintain the following records related to commercial medicinal cannabis activity for at least seven years—

(a) financial records including, but not limited to, bank statements, sales invoices, receipts and tax records;

(b) personnel records, including each employee's full name, social security or individual tax payer identification number, date employment begins, and date of termination of employment where applicable;

(c) training records including, but not limited to, the content of the training provided and the names of the employees that received the training;

(d) contracts with other licensees regarding commercial medicinal cannabis activity;

(e) permits, licences, and other local authorizations to conduct the licensee's commercial medicinal cannabis activity;

(f) security records, except for surveillance recordings required pursuant toRegulation 48 of these Regulations;

(g) records relating to the composting or destruction of medicinal cannabis goods;

(h) documentation for data or information entered into the St. Kitts and Nevis Tracking System;

(i) all other documents prepared or executed by an owner or their employees or assignees in connection with the licenced commercial medicinal cannabis business.

(2) All required records shall be prepared and retained in accordance with the following conditions timely accurate electronic records shall be input into the St. Kitts and

Nevis

(a) Tracking System;

(b) physical records shall be legible; and

(c) records shall be stored in a secured area where the records are protected from debris, moisture, contamination, hazardous waste, fire and theft.

(3) The Authority may make any examination of the electronic records or of the books and physical records of any licensee as it considers necessary to perform its duties under the Cannabis Act 2020 and these Regulations.

(4) All records are subject to review by the Authority anytime the licensee isexercising the privileges of the licence or at any other time as mutually agreed to by the

Authority and the licensee—

(a) prior notice by the Authority to review records is not necessary;

(b) the Authority may review records outside of the licensee's standard daily business hours.

(5) Records shall be kept in a manner that allows records to be produced for the Authority immediately upon request at the licenced premises in either hard copy or electronic form, whichever the Authority requests.

137. **Sales invoice or receipt requirements.**

(1) The medicinal cannabis business licensee shall prepare a sales invoice or receipt for every sale, or transfer of medicinal cannabis goods to another medicinal cannabis business licensee or to an authorized patient or caregiver.

(2) Sales invoices and receipts shall be retained electronically and may also be maintained physically but shall be readily accessible for examination by the Authority or any law enforcement authority and any other competent authority.

(3) Each sales invoice or receipt shall include all of the following—

(a) name, business address, and Authority issued licence number of the seller;

(b) name, business address, and Authority issued licence number of the purchaser;

(c) UID of the authorized patient or caregiver;

(d) the date of any sale or transfer of medicinal cannabis goods shall be the date of sale or transfer to the medicinal cannabis business licensee or authorized patient or caregiver receiving it;

(e) invoice or receipt number;

(f) net weight, count or quantity of medicinal cannabis goods sold or transferred;

(i) for the purposes of these Regulations a licensee shall use wet weight or net weight;

(ii) wet weight and net weight shall be determined following weighing device requirements pursuant to these Regulations and shall be measured, recorded, and reported in either U.S. customary units (e.g., ounce or pound); or International System of Units (e.g., kilograms, grams, or milligrams);

(iii) for the purposes of this Regulation, "count" means the numerical count of the individual plants or individual packaged units of medicinal cannabis goods;

(g) cost to the purchaser, including any discount applied to the total price, shall be recorded on the invoice;

(h) description for each item, including strain or cultivar, and name of product;

(i) signature or Business Seal or Stamp of the seller, or designated representative of the seller, acknowledging accuracy of the medicinal cannabis goods being sold or transferred;

(j) signature or Business Seal or Stamp of the purchaser, or designated representative of the purchaser, acknowledging receipt or rejection of the medicinal cannabis goods.

138. **Independent audit may be required.**

(1) When the Authority considers it necessary, it may require a medicinal cannabis business to undergo an audit by an independent accountant and the scope of the audit may include, but need not be limited to, financial transactions and inventory control measures.

(2) In such instances, the Authority may attempt to mutually agree upon the selectionof the independent accountant with a medicinal cannabis business, however, the Authority always retains the right to select the independent accountant regardless of whether a mutual agreement can be reached.

(3) The medicinal cannabis business will be responsible for all direct costs associated with the independent audit.

(4) The Authority has discretion to determine when an audit by an independent accountant is necessary.

(5) The following is a non-exhaustive list of examples that may justify an independent audit—

(a) a medicinal cannabis business does not provide requested records to the Authority;

(b) the Authority has reason to believe that the medicinal cannabis business does not properly maintain its business records;

(c) the Authority has reason to believe that the medicinal cannabis has committed a violation related to record keeping or inventory control;

(d) the Authority has reason to believe that the medicinal cannabis has committed a violation related to diversion.

(6) As determined by the Authority, the scope of an audit conducted by the Authority would not be so extensive as to jeopardize the regular duties and responsibilities of the Authority audit or enforcement staff.

(7) A medicinal cannabis business shall pay the cost of the audit and timely cooperate with the Authority's requirement that it undergo an audit in accordance with these Regulations.

(8) Failure to comply with this rule may constitute a licence violation affecting public safety.

139. **Inventory audits.**

(1) The Authority may perform an audit of the physical inventory and inventory as reported in the St. Kitts and Nevis Tracking System of any licensee at the Authority's discretion.

(2) Inventory audits of the licensee shall be conducted during standard business hours or at other reasonable times as mutually agreed to by the Division and the licensee.

(3) Prior notice of an inventory audit is not required.

140. **Notification of diversion, theft, loss, or criminal activity.**

A licensee shall notify the Division and law enforcement authorities within twenty four (24) hours of discovery of any diversion, theft, loss of, or criminal activity related to licensee's medicinal cannabis goods or upon discovering any of the following—

(a) any discrepancy or any significant discrepancy identified during inventoryand the level of significance shall be determined by the Authority;

(b) diversion, theft, loss, or any criminal activity pertaining to the operation ofthe medicinal cannabis business licensee;

(c) diversion, theft, loss, or any criminal activity by any agent or employee of the retailer pertaining to the operation of the medicinal cannabis business licensee;

(d) the loss or unauthorized alteration of records related to medicinal cannabis goods, authorized patients, authorized caregivers, or medicinal cannabis business employees or agents; or (e) any other breach of security.

141. **Inspections, investigations, and audits applicability.**

(1) A licensee or applicant shall be subject to inspection, investigation, or audit of their licenced premises and records by the department to determine compliance with applicable laws and Regulations.

(2) An inspection, investigation or audit may be conducted by the Division in collaboration with an officer from the Royal Police Force of St. Kitts and Nevis, a Public Health Officer, Development Control and Planning Board Officials, St. Kitts and Nevis Fire Department Officials or an official from St. Kitts and Nevis Public utilities authority.

(3) The Authority shall conduct inspections, investigations, examinations, and audits of licensees including, but not limited to, a review of any books, records, accounts, inventory, or onsite operations specific to the licence.

(4) The Authority may conduct an inspection, investigation, examination, or audit for any of the following purposes—

(a) to determine accuracy and completeness of the application prior to issuing a licence;

(b) to determine compliance with licence requirements including, but not limited to, the cultivation plan;

(c) to audit or inspect any records outlined in this Part of these Regulations;

(d) to respond to a complaint received by the Authority regarding the licensee;

(e) to inspect incoming or outgoing shipments of medicinal cannabis goods; and

(f) as considered necessary by the Authority.

(5) Inspections, investigations, examinations, and audits of a licenced premises shall be conducted at any time, or as otherwise agreed to by the Division and the licensee or its agents, employees, or representatives.

(6) Prior notice of inspection, investigation, or examination is not required.

(7) No applicant, licensee, or any agent or employee shall interfere with, obstruct, or impede the Authority's inspection, investigation, or audit and this includes, but is not limited to, the following actions—

(a) denying the Authority access to the licenced premises;

(b) providing false or misleading statements;

(c) providing false, falsified, fraudulent, or misleading documents and records; and

(d) failing to provide records, reports, and other supporting documents.

(8) Where an inspection, investigation, examination, or audit, has is completed, the Authority shall notify the licensee of any violation or action the Authority may be taking, where applicable.

142. **Manager or staff change to be reported.**

(1) A medicinal cannabis business shall provide the Authority with a written report within seven days after any change in manager or staff occurs.

(2) A medicinal cannabis business shall also maintain a copy of this written report with its business records.

(3) Failure to report a change in a timely manner may result in disciplinary action.

143. **Schedule of taxes on medicinal cannabis business operations.**

(1) The St. Kitts and Nevis Sales Tax of 15% is levied on a taxable supply of all medicinal cannabis goods, medicinal derivatives and medicinal cannabis infused products sold within the State.

(2) An export tax duty of 25% is levied on the export of medicinal cannabis, medicinal derivatives and medicinal cannabis infused products meeting all other export requirements and intended for export.

144. **Intellectual property rights.**

(l) Individuals shall be allowed to apply for intellectual property rights regarding their medicinal cannabis goods.

(2) Application for intellectual property rights shall be made at the Intellectual Property office of St. Kitts and Nevis and shall follow all guidelines issued by such.

Part IX Miscellaneous

145. **Forms.**

(1) The application from is set out in Schedule XIV.

(2) The form for supplemental information for licence applications is set out in Schedule XV.

(3) The application form for occupational licence for a group is set out in Schedule XVI.

(4) The consent form to be signed by a property owner to allow their property to be utilized for cannabis related purposes set out in Schedule XVII.d to forfeiture of any goods or money in respect of which the offence has been committed.

SCHEDULE I

(regulation 30)

Application Fees Medicinal Cannabis Business

TYPE OF LICENCE	St. Kitts-Nevis Fees
Cultivator License	$3,000
Research & Development License	$8,000
Laboratory License	$15,000
Manufacturer License	$8,000
Retail Distributor (Therapeutic (Facility)	$8,000
Import License	$3,000
Export License	$3,000
Transport License	$3,000
Lounge	$5,000

Residents for St. Kitts-Nevis are expected to pay half or special waiver can be granted of the fees that are proposed.

SCHEDULE II

(regulation 30) Licence Fees Medicinal Cannabis Business Approved Applicant

1.	**Medicinal Cannabis Cultivation Licence Fee**	Foreigners and not local citizen	Local citizen
(a)	Tier 1 – up to 11000 square feet	$30,000	$1.000
(b)	Tier 2 – 11001 square feet to 22,000 square feet	$40,000	$1,500
(c)	Tier 3 – 22,001 square feet to 33,001 square feet	$50,000	$2,000
(d)	Tier 4 – 33,001 acre to 1 acre	$60,000	$3,000
(e)	Tier 5 – 1 to 5 acres or more	$170,000	$5,000
(f)	Tier 6 – 5 acres or more	$4,200,000	$200,000
2.	**Medicinal Cannabis Research and Development Licence Fee**	$120,000	$60,000
3.	**Medicinal Cannabis Testing Facility Licence Fee**	$120,000	$60,000
4.	**Medicinal Cannabis – Manufacturer Licence Fee**	$200,000	$100,000
5.	**Medicinal Cannabis Dispensary Licence Fee**	$225,000	$10,000

6.	**Medicinal Cannabis Transport Licence Fee**	$50,000	$25,000
7.	**Medicinal Cannabis Lounge Licence Fee**	$60,000	$30,000
8.	**Medicinal Cannabis Export Licence Fee**	$9,000	$4,500
9.	**Medicinal Cannabis Export Licence Fee**	$9,000	$4,500

Traditional Cultivator licence Fee

Country	**Licence Class**	**Size of Land (Acres)**	**Renewal period (Years)**	**NON-REFUNDABLE APPLICATION FEES (EC$)**	**Licence Fee (EC$)**
St Kitts	Traditional Cultivator	Up to 1	3	100	No cost for first 3 years

1. **All fees are in EC currency.**
2. **Licences are valid for three years, but persons can pay annually.**

SCHEDULE III

(regulation 32) Renewal Fees Medicinal Cannabis Businesses

1.	**Medicinal Cannabis Cultivation Licence Fee**	Foreigners and not local citizen	Local citizen
(a)	Tier 1 – up to 11000 square feet	$30,000	$1.000
(b)	Tier 2 – 11001 square feet to 22,000 square feet	$40,000	$1,500
(c)	Tier 3 – 22,001 square feet to 33,001 square feet	$50,000	$2,000
(d)	Tier 4 – 33,001 acre to 1 acre	$60,000	$3,000
(e)	Tier 5 – 1 to 5 acres or more	$170,000	$5,000
(f)	Tier 6 – 5 acres or more	$4,200,000	$200,000
2.	**Medicinal Cannabis Research and Development Licence Fee**	$120,000	$60,000
3.	**Medicinal Cannabis Testing Facility Licence Fee**	$120,000	$60,000
4.	**Medicinal Cannabis – Manufacturer Licence Fee**	$200,000	$100,000
5.	**Medicinal Cannabis Dispensary Licence Fee**	$225,000	$10,000
6.	**Medicinal Cannabis Transport Licence Fee**	$50,000	$25,000
7.	**Medicinal Cannabis Lounge Licence Fee**	$60,000	$30,000
8.	**Medicinal Cannabis Export Licence Fee**	$9,000	$4,500
9.	**Medicinal Cannabis Export Licence Fee**	$9,000	$4,500

Traditional Cultivator licence Fee					
Country	**Licence Class**	**Size of Land (Acres)**	**Renewal period (Years)**	**NON-REFUNDABLE APPLICATION FEES (EC$)**	**Licence Fee (EC$)**
St Kitts	Traditional Cultivator	Up to 1	3	100	No cost for first 3 years

1. **All fees are in EC currency.**
2. **Licences are valid for three years, but persons can pay annually.**

SCHEDULE IV

(regulation 33)

Administrative Service Fees

(A) ADMINISTRATIVE TYPE	St. Kitts-Nevis Fees
World Check due diligence fee for international applicants	$7,000 (per director)
Seed to Sale software sign on fee (onetime fee)	$300 (tier one cultivation and processors) $700 all other licenses
(B) MISCELLANEOUS TYPE	St. Kitts-Nevis Fees
Certified copy of license	$800
Certified replacement of license	$800
Reinspection	$500

SCHEDULE V

(regulation 74)

Prohibited Chemicals

CHEMICAL NAME ------- CAS Registry Number (or EDF Substance ID)

	ALDRIN	309-00-2
	ARSENIC OXIDE (3)	1327-53-3
	ASBESTOS (FRIABLE)	1332-21-4
	AZODRIN	6923-22-4
	1,4-BENZOQUINONE 2,3,5,6-TETRACLORO	118-75-2

	BINAPACRYL	485-31-4

	2,3,4,5-BIS (2-BUTENYLENE) TETRAHYDROFURFURAL	126-15-8
	BROMOXYNIL BUTYRATE	EDF-186
	CADMIUM COMPOUNDS	CAE750
	CALCIUM ARSENATE [2ASH3O4.2CA]	7778-44-1
	CAMPHECHLOR	8001-35-2
	CAPTAFOL	2425-06-1
	CARBOFURAN	1563-66-2
	CARBON TETRACHLORIDE	56-23-5
	CHLORDANE	57-74-9
	CHLORDECONE (KEPONE)	143-50-0
	CHLORDIMEFORM	6164-98-3
	CHLOROBENZILATE	510-15-6
	CHLOROMETHOXYPROPYLMERCURIC ACETATE	EDF-183
	COPPER ARSENATE	10103-61-4
	2,4-D, ISOOCTYL ESTER	25168-26-7
	DAMINOZIDE	1596-84-5
	DDD	72-54-8
	DDT	50-29-3
	DI(PHENYLMERCURY)DODECENYLSUCCINATE [PMDS]	EDF-187
	1,2-DIBROMO-3-CHLOROPROPANE (DBCP)	96-12-8
	1,2-DIBROMOETHANE	106-93-4
	1,2-DICHLOROETHANE	107-06-2

	DIELDRIN	60-57-1
	4,6-DINITRO-O-CRESOL	534-52-1
	DINITROBUTYL PHENOL	88-85-7
	ENDRIN	72-20-8
	EPN	2104-64-5
	ETHYLENE OXIDE	75-21-8
	FLUOROACETAMIDE	640-19-7
	GAMMA-LIND ANE	58-89-9
	HEPTACLOR	76-44-8
	HEXACHLORBENZENE	118-74-1
	1,2,3,4,5,6-HEXACHLOROCYCLOHEXANE (ISOMER MIX)	608-73-1
	1,3-HEXANEDIOL, 2-ETHYL	94-96-2
	LEAD ARSENATE	7784-40-9
	LEPTOPHOS	21605-90-5
	MERCURY	7439-97-6
	METHAMIDOPHOS	10265-92-6
	METHYLPARATHION	298-00-0
	MEVINPHOS	7786-34-7
	MIREX	2385-85-5
	NITROFEN	1836-75-5
	OCTAMETHYLDIPHOSPHORAMIDE	152-16-9
	PARATHION	56-38-2
	PENTACHLOROPHENOL	87-86-5
	PHENYLMERCURIC OLEATE [PMO]	EDF-185

	PHOSPHAMIDON	13171-21-6
	PYRIMINIL	53558-25-1
	SAFROLE	94-59-7
	SODIUM ARSENATE	13464-38-5
	SODIUM ARSENITE	7784-46-5
	TERPENE POLYCHLORINATES (STROBANE6)	8001-50-1
	THALLIUM (I) SULFATE	7446-18-6
	2,4,5- TP ACID (SILVEX)	93-72-1
	TRIBUTYLTIN COMPOUNDS	EDF-184
	2,4,5 – TRICHLOROPHENOL	95-95-4
	VINYL CHLORIDE	75-01-4

SCHEDULE VI

(regulation 110) Number of Sample Increments relative to the Unpacked Harvest Batch Size

Unpacked Harvest Batch Size (pounds)	Number of Increments (per sample)
[redacted] 10.0	8
10.1 – 20.0	16
20.1 – 30.0	23
30.1 – 40.0	29
40.1 – 50.0	34

SCHEDULE VII

(regulation 111)

Number of Sample Increments relative to Medicinal Cannabis Infused Product Batch Size

Medicinal Cannabis Infused Product (units)	Number of Sample Increments (per sample)
[redacted] 50	2
51 – 150	3
151 – 500	5

501 – 1,200	8
1,201 – 3,200	13
3,201 – 10,000	20
10,001 – 35,000	32
35,001 – 150,000	50

SCHEDULE VIII

(regulation 115) Criteria to be listed when Validating Test Methods for Microbial Analyses of Samples

Criteria	Requirement
Number of target organisms; inclusivity	5
Number of non-target organisms; exclusivity	5
Number of analyte levels per matrix: qualitative methods	3 levels: high and low inoculum levels and 1 uninoculated level
Number of analyte levels per matrix: quantitative methods	4 levels: low, medium and high inoculum levels and 1 uninoculated level
Replicates per food at each level tested	2 or more replicates per level

SCHEDULE IX

(regulation 118) Residual Solvents and Processing Chemicals Testing List

Category I Residual Solvent or Processing Chemical	CAS No.	Cannabis Product Action Level (µg/g)
1,2-Dichloroethane	107-06-2	1.0
Benzene	71-43-2	1.0
Chloroform	67-66-3	1.0
Ethylene oxide	75-21-8	1.0
Methylene chloride	75-09-2	1.0
Trichloroethylene	79-01-6	1.0
Category II Residual Solvent or Processing Chemical	CAS No.	Cannabis Product or Pre-roll Action Level (µg/g)
Acetone	67-64-1	3000
Acetonitrile	75-05-8	300

Butane	106-97-8	5000
Ethanol	64-17-5	5000
Ethyl acetate	141-78-6	5000
Ethyl ether	60-29-7	5000
Heptane	142-82-5	3000
Hexane	110-54-3	200
Isopropyl alcohol	67-63-0	5000
Methanol	67-56-1	3000
Pentane	109-66-0	3000
Propane	74-98-6	5000
Toluene	108-88-3	600
Total xylenes (ortho-, meta-, para-)	1330-20-7	2000

SCHEDULE X

(regulation 119) Residual Pesticides Testing List

Category I Residual Pesticide	CAS No.
Aldicarb	116-06-3
Carbofuran	1563-66-2
Chlordane	57-74-9
Chlorfenapyr	122453-73-0
Chlorpyrifos	2921-88-2
Coumaphos	56-72-4
Daminozide	1596-84-5
DDVP (Dichlorvos)	62-73-7
Dimethoate	60-51-5
Ethoprop(hos)	13194-48-4
Etofenprox	80844-07-1
Fenoxycarb	72490-01-8
Fipronil	120068-37-3
Imazalil	35554-44-0
Methiocarb	2032-65-7
Methyl parathion	298-00-0
Mevinphos	7786-34-7
Paclobutrazol	76738-62-0
Propoxur	114-26-1

Spiroxamine		118134-30-8	
Thiacloprid		111988-49-9	
Category II Residual Pesticide	CAS No.	Action Level (μg/g)	
		Inhalable Cannabis Goods	Other Cannabis Goods
Abamectin	71751-41-2	0.1	0.3
Acephate	30560-19-1	0.1	5
Acequinocyl	57960-19-7	0.1	4
Acetamiprid	135410-20-7	0.1	5
Azoxystrobin	131860-33-8	0.1	40
Bifenazate	149877-41-8	0.1	5
Bifenthrin	82657-04-3	0.3	0.5
Boscalid	188425-85-6	0.1	10
Captan	133-06-2	0.7	5
Carbaryl	63-25-2	0.5	0.5
Chlorantraniliprole	500008-45-7	10	40
Clofentezine	74115-24-5	0.1	0.5
Cyfluthrin	68359-37-5	2	1
Cypermethrin	52315-07-8	1	1
Diazinon	333-41-5	0.1	0.2
Dimethomorph	110488-70-5	2	20
Etoxazole	153233-91-1	0.1	1.5
Fenhexamid	126833-17-8	0.1	10
Fenpyroximate	111812-58-9	0.1	2
Flonicamid	158062-67-0	0.1	2
Fludioxonil	131341-86-1	0.1	30
Hexythiazox	78587-05-0	0.1	2
Imidacloprid	138261-41-3	3	3
Kresoxim-methyl	143390-89-0	0.1	1
Malathion	121-75-5	0.5	5
Metalaxyl	57837-19-1	2	15
Methomyl	16752-77-5	1	0.1
Myclobutanil	88671-89-0	0.1	9

Naled	300-76-5	0.1	0.5
Oxamyl	23135-22-0	0.5	0.2
Pentachloronitrobenzene	82-68-8	0.1	0.2
Permethrin	52645-53-1	0.5	20
Phosmet	732-11-6	0.1	0.2
Piperonylbutoxide	51-03-6	3	8
Prallethrin	23031-36-9	0.1	0.4
Propiconazole	60207-90-1	0.1	20
Pyrethrins	8003-34-7	0.5	1
Pyridaben	96489-71-3	0.1	3
Spinetoram	187166-15-0, 187166-40-1	0.1	3
Spinosad	131929-60-7, 131929-63-0	0.1	3
Spiromesifen	283594-90-1	0.1	12
Spirotetramat	203313-25-1	0.1	13
Tebuconazole	107534-96-3	0.1	2
Thiamethoxam	153719-23-4	5	4.5
Trifloxystrobin	141517-21-7	0.1	30

SCHEDULE XI

(regulation 123)

Heavy Metals Testing

	Action Level (µg/g)	
Metal	Inhalable Cannabis Goods	Other Cannabis Goods
m	0.2	0.5
	0.5	0.5
	0.2	1.5
y	0.1	1.0

SCHEDULE XII

(regulation 130) Acceptable Results for Microbial Analyses

tory Sample	Acceptance Criteria	Corrective Action
e control	Produces expected Result, positive	Re-prep and reanalyze the entire analytical batch, once. If problem

	result	persists, locate and remedy the source of unexpected result, then re-prep samples and reanalyze with a new set of controls.
ve	Produces expected result, negative result	Re-prep and reanalyze the entire analytical batch, once. If problem persists, locate and remedy the source of
e or	Produces result	unexpected unexpected result, then re-prep samples and reanalyze with a new set of controls.
tory	Sample results shall concur	reanalyze sample and associated replicate sample once. If problem persists re-prep samples and reanalyze.

SCHEDULE XIII

(regulation 130)

Acceptable Results for Chemical Analyses

Laboratory Control Sample	Acceptance Criteria	Corrective Action
Method blank Sample	Not to exceed LOQ	reanalyze entire analytical batch once. If method blank is still greater than the LOQ for any analyte, locate the source of contamination then re-prep samples and reanalyze.
LCS	Percent recovery 70% to 130%	reanalyze the entire analytical batch, once. If problem persists, re-prep samples and reanalyze or re-run the initial calibration curve.
Laboratory Sample	RPD [illegible]30%	reanalyze sample and associated replicate sample once. If problem persists re-prep samples and reanalyze.
Matrix spike sample	Percent recovery Between 70% to 130%	reanalyze sample and associated matrix spike sample once. If problem persists reprep samples and reanalyze.
CCV	Percent recovery	reanalyze all samples that followed

	Between 70% to 130%	the last CCV that met the acceptance criteria. If CCV still fails, re-run the initial calibration curve and all samples in the analytical sequence.

SCHEDULE XIV

(regulation 145)

Application Form

Form 1

1. THE MEDICINAL CANNABIS INDUSTRY ACT 2020

The Medicinal Cannabis (Licensing) Regulations, 2021

MEDICINAL CANNABIS AUTHORITY

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2. LICENCE APPLICATION FORM

Instructions to Applicant *(Please also consult the Instructions for Completing the Forms and Application Procedure Checklist set out in the Appendix hereto)*

1. Please read the form carefully and complete in **BLOCK CAPITALS**.
2. A separate application is required for each licence being applied for.
3. Each licence will be only applicable to the particular premises for which it is issued.
4. Individuals may apply for cultivation licences only. However, a registered sole trader may apply for any of the licences.
5. In completing this form, please note that:

a. Sections A, D, E and F should be completed by all applicants;

b. Section B should be completed by individuals and sole traders only;

c. Section C should be completed by companies and other businesses; and

d. Section F which consists of the Authorisation for Background Checks and the Final Declaration must both be signed.

6. Kindly initial the bottom of each page.

SECTION A: TYPE OF LICENCE

1. ALL applicants should complete this section

TYPE OF LICENCE

Please indicate the type of license for which you are applying:

Cultivation (Class A) (Less than 1 acre)	Traditional Cultivator	
Cultivation (Class B) (1-5 acres)	Retail (Dispensing/ Pharmacy)	Research
Cultivation (Class C) (Over 5 acres)	Transportation	Import
Laboratory	Processor	Export
Lounge		

Please indicate whether this is your first application or if you are applying for a renewal:

First-time Applicant (*If you have ticked this box, please move to the next section*)

Application for Renewal

Current Licence Holder, type:

Applied previously, and awaiting approval, please indicate:

The date of application (MM-YYYY)

Licence type:

Applied previously, and application not approved, please indicate: The date of application (MM-YYYY)

Licence Type:

SECTION B: INDIVIDUAL INFORMATION

2. ***Complete this section only if you are an Individual or Sole Trader***
(If sole trader please attach copy of Registration of Business Name Certificate)

SURNAME	FIRST NAME	MIDDLE NAME
OTHER NAMES (IF APPLICABLE)	MAIDEN NAME (IF APPLICABLE)	MOTHER'S MAIDEN NAME
GENDER Male Female	MARITAL STATUS Single Married Widowed	DATE OF BIRTH (DD-MM-YYYY)
PLACE OF BIRTH (TOWN, COUNTRY)	NATIONALITY	LENGTH OF TIME LIVING IN SAINT KITTS AND NEVIS (IN YEARS):

IDENTIFICATION 1 #: Type: [ ] Driver's Licence [ ] Passport [ ] Identification Card	IDENTIFICATION 2 #: Type: [ ] Driver's Licence [ ] Passport [ ] Identification Card
PERMANENT ADDRESS	

MAILING ADDRESS (IF DIFFERENT FROM ABOVE)		
ADDRESS OF PREMISES BEING LICENCED (IF APPLICABLE)		
CONTACT NUMBER(S) (HOME)	(WORK)	(MOBILE)
EMAIL ADDRESS(ES)		

SECTION C: COMPANY/BUSINESS INFORMATION

3. ***Complete this section only if you are a Business or Company, including Cooperative (Please attach copy of Articles of Incorporation and Registration Certificate of Company)***

NAME OF COMPANY/BUSINESS		
REGISTERED ADDRESS		
MAILING ADDRESS (IF DIFFERENT FROM ABOVE)		
ADDRESS OF PREMISES BEING LICENCED (IF APPLICABLE)		
TYPE OF COMPANY/BUSINESS: [ ] Partnership [ ] Limited Liability [ ] Cooperative [ ] Friendly Society	REGISTRATION NUMBER:	
CONTACT NUMBER(S)	EMAIL ADDRESS(ES)	
AUTHORISED AGENT:		
SURNAME	FIRST NAME	MIDDLE NAME
POSITION	GENDER MALE FEMALE	DATE OF BIRTH (DD-MM-YYYY)
CONTACT NUMBER(S)	EMAIL ADDRESS(ES)	

SECTION D: GENERAL DECLARATIONS

4. ***All applicants should complete all the questions in this section.***

If necessary, please use a supplementary sheet to provide all of the required information

1. Are you, any of your Directors or any of your employees under the age of eighteen (18)?	[ ] Yes [ ] No
2. Are you the titled owner of the premises being licenced (land, buildings or vehicle)?	[ ] Yes [ ] No If no, state the name of the legal (titled) owner of the property. _____ If no, please also provide copy of title and complete Form 3 (Consent of Property Owner Form)

3. Have you, any of your Directors, your parent company or any related entity ever applied for a licence to handle medicinal cannabis or medicinal cannabis products in any other jurisdiction (whether or not the licence was issued)?	[ ] Yes [ ] No If yes, state jurisdictions and type of licence: _____ _____ _____ Status: [ ] Current [ ] Denied [ ] Being processed [ ] Issued, but then Revoked/Suspended
4. Have you, any of your Directors, your parent company or any related entity ever applied for a casino or racing licence in any other jurisdiction (whether or not	[ ] Yes [ ] No If yes, state jurisdictions and type of licence: _____ _____

the licence was issued)?	_____ Status: [ ] Current [ ] Denied [ ] Being processed [ ] Issued, but then Revoked/Suspended
5. Have you or any of your Directors ever been convicted of any serious offence?	[ ] Yes [ ] No If yes, state jurisdiction, type of crime and sentence dates or penalties paid, if any: _____ _____
6. Is the location of your property/facility within 600 metres of any of the following? (Tick all that apply)	[ ] Schools/Colleges [ ] Childcare centres [ ] Playground [ ] Community Centre [ ] Library [ ] Place of Worship
7. Please state the name(s) of the beneficial owner(s) of the company.	
8. Please name parent company(ies) and any related entity(ies) (if applicable).	

SECTION E: STATEMENT OF FINANCIAL HISTORY

5. ***All applicants should complete all the questions in this section.***

Please attach supporting documents for all questions to which you have answered 'Yes'.

1. Are you, any of your Directors, your parent company or any related entity delinquent in the payment of any judgments or tax liabilities due to any governmental agency anywhere?	[ ] Yes [ ] No
2. Have you, any of your Directors, your parent company or any related entity filed a bankruptcy petition in the past 5 years, or had such a petition filed against it?	[ ] Yes [ ] No
3. Are you, any of your Directors, your parent company or any related entity ever been a party to any business trust instrument?	[ ] Yes [ ] No

4. Has a complaint, judgment, consent decree, settlement or other disposition related to a violation of any financial or trade regulation ever been filed or entered against you, any of your Directors, your parent company or any related entity?	[ ] Yes [ ] No
5. Have you, any of your Directors, your parent company or any related entity been a party to a lawsuit in the past 5 years, either as a plaintiff or defendant, complainant or respondent, or in any other fashion, in this or any other country?	[ ] Yes [ ] No
6. Have you, any of your Directors, your parent company or any related entity completed financial statements, either audited or unaudited, in thepast two years?	[ ] Yes [ ] No

7.Attach a list detailing the operating and investment accounts for this business, including financial institution name, address, telephone number, and account number for each account.

8.Attach a list detailing each outstanding loan and financial obligation obtained for use in this business, including creditor name, address, phone number, loan number, loan amount, loan terms, date acquired, and date due.

SECTION F: AUTHORISATION FOR BACKGROUND CHECKS

6. ***All applicants must sign this section for their application to be processed.***

Please READ CAREFULLY and sign to give consent.

I, _____, hereby authorise the Medicinal Cannabis Authority, or its duly authorised representative, to validate the accuracy of the information provided in connection with this application for a licence. I understand that the Medicinal Cannabis Authority may utilise independent agencies to assist in checking such information, and I specifically authorise such an investigation by information services and outside entities of the Medicinal Cannabis Authority's choice. I also understand that by not signing, I am withholding my permission and that in such a case, no investigation will be done, and my application for a licence will not be processed.

_____

Signature

FINAL DECLARATION

1. All applicants must sign this section for their application to be processed.

I, _____, declare that this form and all the attachments, statements, disclosures and supporting documents are true and correct to the best of my knowledge and belief. I further declare that this statement is executed with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for the refusal to issue a licence by the Medicinal Cannabis Authority, and that where, after the issue of a licence, a statement made in connection with the applicant is found to be false, the licence may be revoked.

_____ _____

Position Signature

_____

Date

SCHEDULE XV

(regulation 145)

Supplemental Information for Licence Application Form

Please respond <u>ONLY</u> to the specific sub-form related to the licence for which you are applying.

Sub-Form A: Cultivation Licence/ Traditional Cultivators Licence (as applicable)	
1. What is the size of the property (in acreage)?	
2. What is the anticipated crop yield (kg/square metre per harvest)?	
3. How long is each crop expected to take to harvest?	
4. What type of cannabis will you be growing?	[ ] Cannabis Sativa [ ] Cannabis Indica [ ] Cannabis Ruderalis [ ] Hybrid Composition
5. How will the crop be grown? [Tick all that apply]	[ ] Indoor [ ] Outdoor [ ] Greenhouse [ ] Hydroponics [ ] Other, please specify:_____

6. For what type of use are you cultivating? [Tick all that apply	[ ] Export [ ] Manufacturing [ ] Dispensing [ ] Research
7. Do you have a buyer(s), or have you started discussions or entered intoany preliminary agreement with an entity(ies) to purchase your crop? If you are also applying for a licence toprocess your own product, please tick YES.	[ ] Yes [ ] No If yes, please indicate name of person or company and the status of the agreement (confirmed, in-process, etc.): _____ Estimated Quantity to be purchased_____ **(Attach agreement if finalised)**
8. Please provide a detailed description of the transportation process you intend to use in accordance with *Subpart III G.*	

SUB-FORM B: RETAILER	
1. What Cannabis items do you intend to sell? (Please attach list if necessary)	
2. Have you started discussions with anentity/entities to purchase products? (Please attach list if necessary)	[ ] Yes [ ] No If yes, please indicate name of person(s) orcompany(ies): ....
3. Do you intend to sell other non-cannabis items on the same premises?	[ ] Yes [ ] No If yes, please attach list of items.
SUB-FORM C: LOUNGE	
1. What Cannabis items do you intend to sell? (Please attach list if necessary)	
2. Have you started discussions with anentity/entities to purchase products?	[ ] Yes [ ] No If yes, please indicate name of person(s) orcompany(ies):

(Please attach list if necessary)	....
3. Do you intend to sell other non-cannabis items on the same premises?	[ ] Yes [ ] No If yes, please attach list of items.
SUB-FORM D: MANUFACTURING LICENCE	
1.(a) What is the size of the property (in square metres)? (b) Please include diagram of the premises in accordance with *Regulation 26(a) (vi).*	Indoor: _____ Outdoor: _____ [ ] Tick if diagram or plan is attached

2. What medicinal cannabis products are you intending to manufacture? (Please attach list of products)	
3. Have you started discussions with an entity(ies) to sell your products? (Please attach list or agreement, if necessary)	[ ] Yes [ ] No If yes, please indicate name of person(s) or company(ies): _____ _____ _____
4. Do you propose to use a registered trade mark or patent? Is it owned or being used under a licence? (Please attach a copy of the trade mark or patent as registered).	[ ] Yes [ ] No [ ] Owned [ ] Used under Licence
5. Provide description of the procedures specified in *Regulation 26(a) (vii), (viii), (ix), (x) and (xi)* where necessary. (Please attach documents, as applicable).	

6. Provide detailed description of the transportation process you intend to use in accordance with *Subpart III G.*	

SUB-FORM E: DISPENSING LICENCE	
1. What Cannabis items do you intend to sell? (Please attach list if necessary)	
2. Have you started discussions with anentity/entities to purchase products? (Please attach list if necessary)	[ ] Yes [ ] No If yes, please indicate name of person(s) orcompany(ies): ....
3. Do you intend to sell other non-cannabis items on the same premises?	[ ] Yes [ ] No If yes, please attach list of items.

Sub-Form F: Import/Export Licence		
1. Reason for import/export (for example, sale, manufacture, research):		
2. Please attach copies of relevant licences and (if required) evidence that the licence has been renewed or renewal is in process.		
Details of licence	**Licence No.**	**Expiry Date**

3. Shipping agents or Broker agents in Saint Kitts- Nevis		
Name	**Address**	**Service provided**

Storage and security

All sections must be completed (include additional pages if required)

Storage address:	
(If you do not take possession of any – or certain - drugs at your premises, please specify)	
Date of last security report	Provided by:
Date of last inspection by Medicinal Cannabis Authority	Provided by:
4. Description of security measures	
Secure storage (for example, vault or safe):	
Access method to secure storage:	
Building security and access control:	
Transport process in accordance with Sub-part III G:	
Details of any losses and/or thefts of medicinal cannabis/medicinal cannabis products (include where applicable, medicinal product name, amount, storage address, date, outcome and any security modifications). Attach extra pages if more space is required:	

5. Please provide the relevant information and documents required as per regulation 34 or 41, where applicable, in relation to the country of exporter/ importer (as applicable) all required documents must be certified by a Notary Public in the country of export/import and attached.

6. Proposed Authorised Contacts **Applications for import licence or export licence are only accepted from, or discussed with, the licence holder or additional persons who are confirmed as authorised contacts for a specified licence.**
Use this page to specify authorised contacts associated with the licence(s) sought in this application.

Employee's full name	Position held	Office use only

7. Declaration and consent
I hereby apply to the Medicinal Cannabis Authority, for an import licence/export licence in accordance with the Medicinal Cannabis Industry Act. I declare that, to the best of my knowledge, all the information in this application is true, correct and complete. I am aware that giving false or misleading information constitutes an offence.
Signature of applicant:
Name: Date:
Total number of pages in this application:

. **Proposed export activity**

NB: Complete this table ONLY if you are applying for a licence to export)

Prohibited Export (No trade names)	Strength/Concentration of drug	Unit description	Number of Units required	Office use only			
				(Conversion factor	Base drug quantity	S/T Licence	NDS Drug Code

Proposed Import activity

NB: Complete this table ONLY if you are applying for a licence to export)

Prohibited Export (No trade names)	Strength/Concentration of drug	Unit description	Number of Units required	Office use only			
				(Conversion factor	Base drug quantity	S/T Licence	NDS Drug Code

Sub-Form G: Research Licence	
1. What is the square footage of the premises?	Indoor: _____ Outdoor:_____
2. What activities do you plan on undertaking? (Tick all that apply)	[ ] Research Only [ ] Research and Cultivation for Research [ ] Research and Sample Manufacturing [ ] Analytical Services
3. Do you intend to research other items on the same premises?	[ ] Yes [ ] No If yes, attach list of items.
Sub-Form H: Transportation Licence	
1. How many vehicles do you wish to be licensed? _____ (Attach list with make, model, year of each vehicle along with licence, engine and chassis number)	
2. Where will the vehicle(s) be routinely parked when not in use?	
3. For what type of use are you transporting? [Tick all that apply]	[ ] Research & Development [ ] Manufacturing [ ] Dispensing [ ] Export [ ] Import
4. What type of product do you intend to transport? [Tick all that apply]	[ ] Raw Material [ ] Manufactured Products
5. Have you started discussions with an entity to transport their crops? (Attach list if necessary)	[ ] Yes [ ] No If yes, please indicate name of person or company: _____ (Attach list if necessary)
6. Do you intend to transport other	[ ] Yes [ ] No

non-cannabis items using the same vehicle?	If yes, please attach list of items.

DECLARATION

All applicants must sign this section for their application to be processed.

I, _____, declare that this form and all the attachments, statements, disclosures and supporting documents are true and correct to the best of my knowledge and belief. I further declare that this statement is executed with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for the refusal to issue a licence by the Medicinal Cannabis Authority, and that where, after the issue of a licence, a statement made in connection with the applicant is found to be false, the licence may be revoked.

_____ _____

Position Signature

_____ Date

SCHEDULE XVI

(regulation 145) Application Form for Occupational Licence (Group)

Please attach Official Police Record for each Employee as well as certified copy of their ID and a photo signed by a JP.
You may use multiple copies of this form if necessary.

EMPLOYEE INFORMATION

EMPLOYEE #1

Surname First Name Middle Name

Position Management? [ ] Yes [ ] No
Director? [ ] Yes [ ] No

ID #: Date of Birth (DD-MM-YYYY)

Social Security Number Type: [ ] Driver's Licence [ ] Passport
[ ] NationalIdentificationCard

EMPLOYEE #2

Surname First Name Middle Name

Position Management? [ ] Yes [ ] No
Director? [ ] Yes [ ] No

ID #: Date of Birth (DD-MM-YYYY)

Social Security Number Type: [ ] Driver's Licence [ ] Passport
[ ] NationalIdentificationCard

EMPLOYEE #3

Surname First Name Middle Name

Position Management? [ ] Yes [ ] No
Director? [ ] Yes [ ] No

ID #: Date of Birth (DD-MM-YYYY)

Social Security Number Type: [ ] Driver's Licence [ ] Passport
[ ] NationalIdentificationCard

Name of Individual/Business/Company:

.....

....

Authorised Agent Date

SCHEDULE XVII

(regulation 145) Consent Form from Property Owner

If the property (land, buildings, or motor vehicle) to be licensed is not owned by the applicant, this form must be completed by the applicant and the declaration signed by the titled owner(s).

Please attach the relevant lease or rental agreement (if applicable).

1. Name of Applicant.....

2. Type of Property: [ ] Land [ ] Land with Building(s) [ ] Motor Vehicle [ ] Retail Space

3. Description of Property (include Volume/Folio and Address or Engine/Chassis No. as appropriate):
.....
.....
.....
.....
.....
.....

4. Description of intended use of property in relation to Cannabis:

.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....

FOR SOLE OWNERS
[Please include copy of official identification of the owner certified by a Justice of the Peace]

I, ..., declare that
I am the owner of this property and I am fully aware of the intended use of the property as outlined in Section 2 above and freely give myconsent for such activities to be conducted on the site.

Signed .....

Date .....

Address .....

Phone: .....

FOR MULTIPLE OWNERS
(Please include copy of official identification of the owners certified by a Justice of the Peace.Where the propertyis owned by a Company, this section is to be signed by all Owners/ Directors, and the Certificate of Registrationattached)

We, ...
.....
.....
.....
..... declare that we are the owners of this property and are fully aware of the intended use of the property as outlined in Section 2 (Page 1) above and freely give our consent for such activities to be conducted on the site.

Signed ..... Date .....

Address .....

Phone: .....

Signed ..... Date .....

Address .....

Phone: .....

Signed ..... Date .....

Address .....

Phone: .....

Signed ..... Date .....

Address .....

Phone: .....

Signed ..... Date .....

Address .....

Phone: .....

Signed ..... Date .....

Address .....

Phone: .....

Made this 28th day of July, 2022.

TIMOTHY HARRIS
Prime Minister

GOVERNMENT PRINTERY
ST KITTS W I