Subdivision 4

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Subdivision 6

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(2) A manufacturing licensee shall provide samples of its edible medicinal cannabis infused products in a manner specified by these Regulations, to an analytical service provider facility approved by the Authority.

(3) The analytical service provider facility will notify the manufacturing licensee of the results in writing in the form of a Certificate of Analysis, and the manufacturing licensee shall include any of the required results as part of its product labelling.

(4) The edible medicinal cannabis infused products manufacturer licensee shall provide a representative sample of each product batch stored at the manufacturer's licensed premises for final testing prior to being sold to the analytical service provider in accordance with these Regulations.

(5) Upon issuance of a Certificate of Analysis by the analytical service provider facility indicating that a product batch has passed the testing requirements, the manufacturing licensee shall conduct a Quality Assurance review before distribution of the batch, to ensure the labelling and packaging of the edible medicinal cannabis infused products conform to the requirements of the Act and its Regulations, the Standards Act, and all other relevant enactment.

(6) The manufacturing licensee shall maintain the testing results for all batches of edible medicinal cannabis infused products as part of its business records and these shall be retained for a period of not less than three (3) years after the date on which the testing results were issued by the Analytical Service Provider facility.

Subpart XII

Medicinal Cannabis Research Laboratories

Division 1

Analytical Service Provider

Definitions

113. (1) For the purposes of this Part -

"acceptance criteria" means the specified limits placed on the characteristics of an item or method that are used to determine data quality;

"accreditation body" means an impartial non-profit organisation that operates in conformance with the international organisation for standardisation (ISO)/ international electrotechnical commission (IEC) standard 17011 and is a signatory to the international

laboratory accreditation cooperation (ILAC) mutual recognition arrangement (MRA) for testing;

"action level" means the threshold value that provides the criterion for determining whether a sample passes or fails an analytical test;

"analyte" means a substance which chemical constituents are being identified and measured;

"analytical batch" means a set of more than twenty (20) samples that is prepared together for the same analysis with laboratory quality control (LQC) samples;

"analytical method" means a technique used qualitatively or quantitatively to determine the composition of a sample or a microbial contamination of a sample;

"analytical sequence" means a group of samples that are analysed sequentially using the same instrument calibration curve;

"Analytical Service Provider" means the operator of an Analytical Service Provider Facility and may include a research licensee;

"Analytical Service Provider Facility" means a laboratory that is authorised or licensed under the Medicinal Cannabis Industry Act or its Regulations to provide analytical services and conduct research in relation to medicinal cannabis;

"cannabis concentrate" means cannabis that has undergone a process to concentrate one or more active cannabinoids, thereby increasing the product's potency and includes, the separated resinous trichomes of cannabis, tinctures, capsules, suppositories, extracts, vape cartridges, inhaled products such as dab, shatter, wax and tablets;

"CAS number" means the following unique numerical identifier assigned to every chemical substance by Chemical Abstracts Service, a division of the American Chemical Society –

(a) CBD (cannabidiol) - CAS number 13956-29-1;

(b) CBDA (cannabidiolic acid) - CAS number 1244-58-2;

(c) CBG (cannabigerol) - CAS number 25654-31-3;

(d) CBN (cannabinol) - CAS number 521-35-7;

"certificate of accreditation" means a document issued by an accreditation body that attests to the laboratory's competence to carry out specific testing analysis;

"Certificate of Analysis" (COA) means the report prepared by the laboratory about the analytical testing performed and results obtained by the laboratory;

"certified reference material" means a reference material prepared by a certifying body or a party independent of the laboratory with ISO/IEC 17034 accreditation;

"chain of custody" (COC) means the chronological documentation that records the sequence of custody, control, transfer, analysis, and disposal of a sample;

"coefficient of determination" (commonly denoted as "r2") means a statistical measure that determines how well the regression approximates the actual data points in the calibration cure, with a regression of 1 being a perfect fit;

"continuing calibration verification" (CCV) means a type of quality control sample that includes each of the target method analytes that is a mid-range calibration standard which checks the continued validity of the initial calibration of the instrument;

"corrective action" means an action taken by the laboratory to resolve, and prevent from recurrence, a problem with the technical operations of the laboratory;

"exclusivity" means the specificity of the test method for validating microbial testing methods and it evaluates the ability of the method to distinguish the target organisms from similar but genetically distinct non-target organisms;

"foreign material" means any filthy, putrid, or decomposed substance including hair, insects, excreta, or related adulterant that may be hazardous or cause illness or injury to the consumer;

"frequency" means the number of items occurring in each category which may be determined by analytical method or laboratory specific requirements for accuracy, precision of the analysis, or statistical calculation;

"inclusivity" means, related to microbiological method validation, the sensitivity of the test method and it evaluates the ability of the test method to detect a wide range of target organisms by a defined relatedness;

"inhalable" means consumable in gaseous or vapour form through the lungs;

"initial calibration verification" (ICV) means a solution of each of the target method analytes of known concentration that is obtained from a source external to the laboratory and different from the source of calibration standards;

"ISO/IEC" means the Joint Technical Committee of the International Organization For Standardisation (ISO) and the International Electrotechnical Commission (IEC);

"ISO/IEC 17025" means the general requirements specified by the ISO/IEC for the competence of testing and calibration laboratories;

"ISO/IEC 17034" means the general requirements established by the ISO/IEC for the competence of reference material producers;

"ISO/IEC 17043" means the general requirements established by the ISO/IEC for proficiency testing;

"laboratory" means an Analytical Service Provider Facility;

"laboratory control sample" (LCS) means a blank matrix to which known concentrations of each target method analytes are added and the spiked concentration shall be a midrange concentration of the calibration curve for the target analytes and the LCS is analysed in the same manner as the representative sample;

"laboratory replicate sample" means a sub-sample taken of the representative sample used for laboratory quality control purposes to demonstrate reproducibility and it is prepared and analysed in the identical manner as the

representative sample while the results from replicate analyses are used to evaluate analytical precision;

"laboratory employee" means any person directly employed by the laboratory but does not include an independent contractor, third party entity, or any other entity acting on behalf of the laboratory;

"laboratory quality assurance" (LQA) means the set of operating principles that enable laboratories to produce defensible data of know accuracy and precision and includes employee training, equipment preventative maintenance procedures, calibration procedures, quality control testing, among other things.

"limit of detection" (LOD) means the lowest quantity of a substance or analyte that can be distinguished from the absence of that substance within a stated confidence limit;

"limit of quantitation" (LOQ) means the minimum concentration of an analyte in a specific matrix that can be reliably quantified while also meeting predefined goals for bias and imprecision;

"linear regression" means the determination, in analytical chemistry, of the best linear equation for calibration data to generate a calibration curve, then, concentration of an analyte in a sample can then be determined by comparing a measurement of the unknown to the calibration curve, and a linear regression uses the following equation-

$Y=mx + b$; where m= slope, b = intercept;

"matrix" means the substances that are present in a sample but does not include the analytes of interest;

"matrix spike sample" means a sample prepared by adding a known quantity of each of the target analyte to a sample matrix or to a matrix that is as closely representative of the matrix being analysed as possible and the spiked concentration shall be at a mid-range concentration of the calibration curve for the target analytes;

"method blank" means an analyte free matrix to which all reagents are added in the same volumes or proportions as used in the sample preparation and is processed in exactly the same manner as the samples;

"moisture content" means the percentage of water in a sample, by weight;

"non-target organism" means an organism that the test method or analytical procedure is not testing for and which can be used in evaluating the specificity of a test method;

"percent recovery" means the percentage of a measured concentration relative to the added (spiked) concentration in a reference material or matrix spike sample and a laboratory shall calculate the percent recovery by dividing the sample result by the expected result then multiplying the quotient by 100;

"practical experience" means experience performing scientific analytical tests in a laboratory setting using equipment, instruments, kits, and materials routinely found in a laboratory and includes experience in any type of laboratory setting and is not limited to cannabis-specific laboratories;

"proficiency test" means an evaluation of a laboratory's performance against pre-established criteria by means of inter-laboratory comparisons of test measurements;

"quadratic regression" means the determination, in analytical chemistry, of the best parabola equation for calibration data to generate a calibration curve, where the concentrate of an analyte in a sample can then be determined by comparing a measurement of the unknown to the calibration curve, and a quadratic regression uses the following equation- $y = ax2 + bx + c$; where a, b and c are numerical coefficients;

"quality control" means the set of measures implemented within an analytical procedure to ensure that the measurement system is operating in a state of statistical control for which errors have been reduced to acceptable levels;

"quality control sample" means a sample that is produced and used by a laboratory for the purpose of assuring

the quality of the data and results and can include blank samples, matrix spike samples, laboratory control samples, replicate samples, and reference material samples;

"reagent" means a compound or mixture added to a system to cause a chemical reaction or test if a reaction occurs and a reagent may be used to tell whether a specific chemical substance is present by causing a reaction to occur with the chemical substance;

"reference material" means material containing a known concentration of an analyte of interest that is in solution or in a homogeneous matrix;

"reference method" means the method by which the performance of an alternate method is measured or evaluated;

"relative percent difference" (RPD) means the comparative statistic that is used to calculate precision or random error which is calculated using the following equation-

RPD = I(representative sample measurement – replicate sample measurement) I/ [representative sample measurement + replicate sample measurement] / 2) x 100%;

"representative" means a small quantity of the batch whose characteristics represent, as accurately as possible, the entire batch, thus allowing the results to be generalised;

"representative sample" means a sample that is comprised of several sample increments of medicinal cannabis product that are collected from a batch for testing;

"reserve sample" means any portion of a batch that, together with other increments, make up the sample;

"sampler" means trained and authorised personnel responsible for obtaining samples of medicinal cannabis product from licensee;

"sanitise" means to sterilise, disinfect, or make hygienic;

"standard operating procedure" (SOP) means a written document that provides detailed instructions for the performance of all aspects of an analysis, operation, or action;

"tamper-evident" means a one-time use security tape or seal that is affixed to the opening of a package, allowing a person to recognise whether the package has been opened;

"target organism" means an organism that is being tested for, in an analytical procedure or test method;

"THC" and "delta-9 THC" means tetrahydrocannabinol, CAS number 1972-08-3;

"THCA" means tetrahydrocannabinolic acid, CAS number 23978-85-0;

"topical medicinal cannabis products" means medicinal cannabis products intended to be applied to the skin and not intended to be ingested or inhaled and liquid solutions that contain more than o.5% alcohol by volume as an ingredient and are not otherwise an alcoholic beverage, shall only be considered medicinal cannabis products if they are packaged in a container no larger than two (2) fluid ounces;

"Total CBD" means the sum of CBD and CBDA and total CBD is calculated using the following equation as applicable -

Total CBD concentration (mg/g)= CBDA concentration (mg/g) x 0.877) + CBD concentration (mg/g);

"Total THC" means the sum of THC and THCA and total THC is calculated using the following equation-

Total THC concentration (mg/g)= THCA concentration (mg/g) x 0.877) + THC concentration (mg/g);

"validation" means the confirmation by examination and objective evidence that the requirements for a specific intended use or analytical method are fulfilled; and

"water activity" means the measure of the quantity of water in a product that is available and is therefore capable of supporting bacteria, yeasts, and fungi and which is reported in units Aw.

Subdivision 1

Requirements For Analytical Service Provider Facility

Analytical Service Provider Facility – general requirements

114. (1) The Authority may enter into contract with an Analytical Service Provider to secure such services that an Analytical Service Provider Facility is situated in Saint Vincent and the Grenadines.

(2) An Analytical Service Provider which entered into a contract with the Authority to provide analytical services requires only an authorisation from the Authority to conduct its daily activities.

(3) Whereas, any other Analytical Service Provider which provides analytical services shall apply for a research licence and all other relevant licences to conduct its daily activities.

(4) No person who has a direct or an indirect economic interest in an Analytical Service Provider shall have an interest, direct or otherwise in any commercial medicinal cannabis operation or any activity relating to the commercial cultivation, transportation, sale, manufacturing, dispensing, importing or exporting of medicinal cannabis.

Maintenance of accreditation

115. An Analytical Service Provider shall ensure that the Analytical Service Provider Facility, which the Analytical Service Provider operates –

(a) maintains ISO/IEC 17025 accreditation for the testing of the following –

(i) cannabinoids;

(ii) foreign matter inspection;

(iii) heavy metals;

(iv) microbial impurities;

(v) moisture content and water activity

(vi) mycotoxins;

(vii) residual pesticides;

(viii) residual solvents and processing chemicals;

(ix) terpenoids;

(x) homogeneity testing of edible medicinal cannabis; and

(xi) any other analysis that may become necessary

(b) retains and makes available to the Authority, upon request, all records associated with the ISO/IEC 17025 certificate of accreditation pursuant to these Regulations.

Accreditation requirements for testing facilities

116. (1) An Analytical Service Provider shall, in relation to the Analytical Service Provider Facility, operate in accordance with the requirements of the ISO/IEC 17025 standard and shall obtain accreditation within two years from the date of receipt of approval from the Authority to operate the Analytical Service Provider Facility.

(2) Pursuant to subregulation (1) an Analytical Service Provider shall provide the Authority with copies of routine surveillance visit reports and any other type of assessment conducted by the organisation from which accreditation was obtained, including, without limitation, any deficiencies identified in and any corrections made in response to said reports.

(3) For the avoidance of doubt, inspection by an accrediting organisation is not a substitute for inspection by the Authority in accordance with the provisions of the Act.

(4) Nothing in this regulation prevents an Analytical Service Provider Facility from seeking additional accreditation from other approved certification bodies.

Employment of scientific director: responsibilities and qualifications

117. (1) An Analytical Service Provider shall employ at the Analytical Service Provider Facility operated by the Analytical Service Provider, a scientific director who shall be responsible for –

(a) ensuring that the Analytical Service Provider Facility achieves and maintains quality standards of practice;

(b) supervising all staff of the Analytical Service Provider Facility; and

(c) providing or ensuring provision of ongoing and appropriate training of all employees.

(2) Pursuant to subregulation (1) a person shall not be employed as a scientific director unless the person holds -

(a) a master's degree in chemical or biological sciences from an accredited college or university, and has at least two years of post-degree experience in an analytical or research laboratory;

(b) a bachelor's degree in biological, chemical, agriculture, environmental, or any related sciences from an accredited college or university, plus at least four years

full-time practical experience working in an analytical or research laboratory; or

(c) a bachelor's degree in any field from an accredited college or university, plus at least eight years of full-time practical experience working in an analytical or research laboratory, four years of which shall have been in a supervisory or management position.

Qualification requirements of other employees

118. (1) An employee at an Analytical Service Provider Facility must be at least eighteen years.

(2) An Analytical Service Provider shall develop and implement an employee training program to ensure that the employees at the Analytical Service Provider Facility that is operated by the Analytical Service Provider, possess the necessary skills and experience to carry out their duties effectively and efficiently.

Subdivision 2

Approved Testing Methods

Testing methodologies; Practices, procedures and programs relating thereto; Inspections

119. (1) An Analytical Service Provider shall ensure that the Analytical Service Provider Facility follows published standard methods such as the Guidelines for Laboratories performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals produced by Association of Official Analytical Chemists (AOAC) International.

(2) An Analytical Service Provider shall provide to the Authority evidence that testing methods including: published standards, modified standards, and in-house protocols meet the required performance capabilities.

(3) The Authority may require an Analytical Service Provider Facility be monitored and validated by an independent third party in order to assess the correct execution of the analytical testing methodologies used in the Analytical Service Provider Facility.

(4) An Analytical Service Provider shall ensure that the Analytical Service Provider Facility operated by the Analytical Service Provider –

(a) maintains internal standard operating procedures; and

(b) maintains a quality control and quality assurance program.

Subdivision 3

Laboratory Quality Assurance And Quality Control

Laboratory Quality Assurance Programme

120. (1) An Analytical Service Provider shall ensure that the Analytical Service Provider Facility develops and implements a Laboratory Quality Assurance programme to assume the reliability and validity of the analytical data produced by the laboratory and the LQA programme shall, at minimum, include a written LQA Manual that addresses the following –

(a) quality control procedures;

(b) laboratory organisation and employee training and responsibilities;

(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 standardisation; and

(k) method validation.

(2) The Analytical Service Provider shall ensure that each year the LQA programme and manual are reviewed and amended, whenever there is a change in methods, laboratory equipment, or the supervisory or management of the Analytical Service Provider Facility.

Laboratory Quality Control samples

121. (1) An Analytical Service Provider shall ensure that the Analytical Service Provider Facility uses Laboratory Quality Control (LQC) samples in adherence with the following specifications -

(a) the Analytical Service Provider Facility shall analyse LQC samples in the same manner as it analyses the medicinal cannabis samples;

(b) the Analytical Service Provider Facility 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 and, if one of the controls produces unexpected results, the samples shall be re-prepped and re-analysed with a new set of controls;

(c) if the results of the microbial analyses are outside the specified acceptance criteria provided in Table 1 of Schedule 3, the Analytical Service Provider shall determine the cause and take such steps to remedy the problem until the result is within specified acceptance criteria.

(2) The Analytical Service Provider shall ensure that the Analytical Service Provider Facility prepares and analyses 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) Pursuant to subregulation (2), the Analytical Service Provider Facility shall analyse, at a minimum, a continuing calibration verification (CCV) sample at the beginning of each analytical sequence and every ten (10) samples thereafter.

(4) If the result of the chemical analyses is outside the specified acceptance criteria, as provided in Table II of Schedule 3, the Analytical Service Provider Facility shall determine the cause and take such 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 Part, the sample shall be re-prepped and reanalyse in replicate within another analytical batch and -

(a) for quantitative analyses, the re-prepped sample and its associated replicate shall meet the acceptance criteria of RPD d"30%; and

(b) for qualitative analyses, the re-prepped sample and its associated replicate results shall concur.

(6) If any LQC sample produces a result that falls outside the acceptance criteria, the medicinal cannabis shall not report the result and the entire batch shall not be released for sale and thereafter, the medicinal

cannabis laboratory shall determine the causes of the result and take such steps to remedy the problem until the result is within the specified acceptance criteria.

(7) If the analytical service provider facility determines that the result is a false-positive or a false-negative, the Authority may request it to conduct a re-sample or a re-test of the chemical analyses.

(8) The analytical service provider facility shall compile and generate one LQC sample report for each analytical batch that includes LQC acceptance criteria, measurements, analysis date, and matrix.

Limits of Detection (LOD) and Limits of Quantitation (LOQ) for quantitative analyses

122. (1) The Analytical Service Provider Facility shall 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; or

(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 Analytical Service Provider Facility shall calculate the LOQ for chemical method analyses according to any of the following methods -

(a) signal-to-noise ratio 10:1, at minimum; or

(b) standard to deviation of the response and the slope using minimum of 7 spiked blank samples calculated as follows -

LOQ = (10 x standard deviation of the response) / slope of the calibration curve.

Proficiency testing programme

123. (1) An Analytical Service Provider Facility shall participate in a proficiency testing programme provided by an entity accredited to ISO/ IEC 17043 as approved by the Authority, and shall bear the cost of subscription to such a programme.

(2) This proficiency testing programme shall be conducted on an ongoing basis for each analysis performed at the facility.

(3) An Analytical Service Provider Facility shall participate in the proficiency testing programme by following its existing SOPs and test methods for testing medicinal cannabis products with the same number of replicate analyses, standards testing analysts and equipment as used for product testing.

(4) All employees of an Analytical Service Provider Facility who participate in any proficiency testing programme shall sign the corresponding analytical reports or attestation statements to certify that the proficiency testing programme was conducted in the same manner as the laboratory tests of medicinal cannabis products.

(5) An Analytical Service Provider Facility shall rotate the proficiency testing programme among the laboratory employees who perform test methods.

(6) The scientific director of an Analytical Service Provider Facility shall review and verify the accuracy of results reported and evaluate all proficiency test results and take any required corrective actions.

Results of proficiency testing to be sent to Authority

124. The Analytical Service Provider Facility may request the proficiency testing programme provider to send results concurrently to the Authority, if available, or the Analytical Service Provider shall cause same to be provided to the Authority, within three (3) days after the Analytical Service Provider Facility receives notification of their test results from the proficiency testing programme provider.

Satisfactory and unsatisfactory proficiency test performance

125. (1) An Analytical Service Provider Facility shall be considered by the Authority to have successfully participated in a proficiency testing programme for an analyte tested in a specific method, if the test results demonstrate a "satisfactory" proficiency performance determination by the proficiency testing program provider.

(2) An Analytical Service Provider Facility shall not report test results for analytes that are considered by the proficiency testing program provider as "unacceptable," "questionable," "unsatisfactory", or "deficient".

(3) An Analytical Service Provider Facility may resume reporting test results for analytes that were considered "unacceptable," "questionable," "unsatisfactory", or otherwise "deficient", only if both of the following conditions are met –

(a) the Analytical Service Provider Facility satisfactorily remedies the cause of the failure for each analyte; and

(b) submits to the Authority, a written corrective action report demonstrating it has remedied the cause of the failure.

(4) The report of false positive results in any analytical test which forms part of the proficiency programme conducted at the Analytical Service Provider Facility will be considered an unsatisfactory score for the proficiency test.

(5) Where an Analytical Service Provider fails to have the Analytical Service Provider Facility participate in a proficiency test, the Authority may suspend or revoke the licence or authorisation in accordance with the Act.

Audit and certification of Analytical Service Provider Facility

126. (1) An Analytical Service Provider Facility may be audited and certified by the Saint Vincent and the Grenadines Bureau of Standards or by a body approved by the Bureau of Standards.

(2) Pursuant to subregulation (1) the audit may be conducted of the quality and standards of the Analytical Service Provider Facility and of each test performed.

(3) The requirements for quality standards for both general testing laboratory requirements, as well as for each category of methods for each test, may also be audited.

(4) Pursuant to subregulation (1), an audit shall also include -

(a) a review of the records of the Analytical Service Provider Facility;

(b) a compliance audit;

(c) an on-site verification of the laboratory's ability to operate in accordance with the provisions of this Part;

(d) an on-site verification of sampling procedure.

(5) An Analytical Service Provider Facility shall be subject to unannounced audits by the Authority and such audits may include –

(a) a review of method validation of the Analytical Service Provider Facility; and

(b) emergency visits to address a serious safety or compliance issue.

Analytical Service Provider Facility – internal audits

127. (1) An Analytical Service Provider Facility shall conduct an internal audit at least once per year or in accordance with the ISO/IEC 17025 accrediting body's requirement.

(2) The internal audit shall include all of the components required by the ISO/IEC 17025 internal-audit standards.

(3) Within three (3) days of completing the internal audit, the Analytical Service Provider Facility shall submit the results of the internal audit to the Authority.

Validation of test methods

128. (1) An Analytical Service Provider may, in accordance with ISO/IEC 17025,_use a nonstandard method; a laboratory-designed or -developed method; a standard method used outside its intended scope; or an amplification or a modified standard method for the analysis of samples. The Analytical Service Provider shall validate any proposed analytical method for each matrix.

(2) The methods of validation used by the Analytical Service Provider in relation to subregulation (1) shall be subject to review by the Authority.

(3) The Analytical Service Provider shall include at minimum the criteria as provided in Table III of Schedule 3 when validating test methods for microbiological analysis of samples.

(4) An Analytical Service Provider Facility shall include at minimum the following criteria to validate test methods for chemical analyses of samples -

(a) accuracy;

(b) precision;

(c) linearity and range whereby –

(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 $^{1}/_{x}$; and

(iii) LOQ for analytes tested shall be within the range of the calibration curve;

(d) calibration standards whereby -

(i) for calibration curves, there shall be a minimum of five calibration standards, not including zero; and

(ii) each calibration shall include an Initial Calibration Verification (ICV);

(e) sensitivity and selectivity;

(f) limit of detection and limit of quantitation;

(g) recovery;

(h) reproducibility; and

(i) robustness

(5) The Analytical Service Provider Facility shall use certified reference materials, to validate all chemical analyses used to assess the quality and safety of medicinal cannabis and the test method used for analysis shall be valid, only if the percent recovery of the certified reference materials is between 80% to 120% for all required analytes.

Subdivision 4

Sampling

Sampling Standard Operating Procedures

129. (1) An Analytical Service Provider Facility shall develop and implement sampling standard operating procedures (SOPs) that prescribe its method for obtaining representative samples of medicinal cannabis and medicinal cannabis products.

(2) The Analytical Service Provider Facility shall use and submit to the Authority, its standard operating procedures for sampling medicinal cannabis or medicinal cannabis products.

(3) An Analytical Service Provider shall ensure that a copy of any sampling SOP is kept at the Analytical Service Provider Facility and that it is accessible to the authorised sampler during sampling.

Analytical Service Provider Facility analyses Standard Operating Procedures

130. (1) An Analytical Service Provider Facility shall develop, implement, and maintain written SOPs for sample preparation and each required test method and shall use them and submit to the Authority.

(2) An Analytical Service Provider shall ensure that copies of the SOPs are kept at the Analytical Service Provider Facility in which the Analytical Service Provider operates, and that the SOPs are accessible to all employees during the operating hours of Analytical Service Provider Facility.

(3) An Analytical Service Provider shall make each SOP available for inspection by the Authority, upon request, as well as any other SOPs associated with the Analytical Service Provider's ISO/IEC 17025 certificate of accreditation.

General sampling requirements

131. (1) An Analytical Service Provider Facility which obtains a representative sample from a commercial medicinal cannabis operation shall perform all the required testing of the sample at the facility.

(2) An Analytical Service Provider shall provide training to the staff of a commercial medicinal cannabis operation on the proper collection

and transportation of the sample from the premises of the commercial medicinal cannabis operation to the Analytical Service Provider Facility.

(3) An Analytical Service Provider Facility shall inform the Authority, in writing, of all sampling arrangements with the medicinal cannabis operation.

(4) An Analytical Service Provider Facility may obtain and analyse samples from batches in final form or from batches during the production process.

(5) An Analytical Service Provider Facility shall collect a representative sample from each batch following the procedures specified in the facility's sampling SOPs.

(6) An Analytical Service Provider shall ensure that a sample to be tested is transported and subsequently stored at the Analytical Service Provider Facility in a manner which prevents degradation, contamination, and co-mingling.

Surveillance and confirmation testing

132. (1) The Authority may collect and test random and equitable surveillance samples to prevent sample tampering by producers and prevent inadvertently or fraudulently inaccurate test results from Analytical Service Provider Facilities.

(2) The Authority shall -

(a) use data to help revise test requirements and limits in addition to aiding in defining a statistically significant sample size;

(b) randomly collect surveillance samples of lots of product recently sampled by Analytical Service Provider Facilities;

(c) have these samples tested and compare results to those obtained from the Analytical Service Provider Facility; and

(d) investigate discrepancies to determine cause and submit the resulting reports to appropriate entities.

Chain of Custody (COC)

133. (1) Each time a sample of medicinal cannabis changes custody between licensees or between a licensee and an analytical service provider, is transported, or is destroyed, the date, time, and the names and signatures of persons involved in these activities shall be recorded on a physical COC Form and in electronic formats.

(2) A commercial medicinal cannabis operation who requests the testing of a sample shall initiate a chain of custody form for each sample delivered to an Analytical Service Provider Facility and retain a copy of the form and deliver the original with the specimen to the Analytical Service Provider Facility.

(3) An Analytical Service Provider Facility may accept and analyse a sample from a licensee for the required testing under these Regulations only if there is an accompanying chain of custody form for the sample.

(4) An Analytical Service Provider Facility shall establish policies for an adequate chain of custody and requirements for samples of products provided for testing or research purposes, including, without limitation, policies and requirements for –

(a) issuing instructions for the minimum sample and storage requirements;

(b) documenting the condition of the external package and integrity seals utilised to prevent contamination of, or tampering with, the sample;

(c) documenting the condition and amount of the sample provided at the time of receipt;

(d) documenting all persons handling the original samples, aliquots and extracts;

(e) documenting all transfers of samples, aliquots and extracts referred to another research laboratory for additional testing or whenever requested by a client;

(f) maintaining a current list of authorised employees and restricting entry to the laboratory to only those authorised employees;

(g) securing the laboratory during nonworking hours;

(h) securing short- and long-term storage areas when not in use;

(i) utilizing a secured area to log-in and aliquot samples;

(j) ensuring samples are stored appropriately; and

(k) documenting the disposal of samples, aliquots and extracts.

(5) An Analytical Service Provider Facility shall complete and maintain a chain of custody form for each sample that the facility collects and analyses.

(6) An employee of the Analytical Service Provider Facility who receives the sample shall date, print and sign his name on the accompanying sample on the chain of custody form and print his identification number where applicable on the form.

(7) An Analytical Service Provider Facility shall record the following information in relation to each sampled batch that is delivered for testing at the facility -

(a) the name, address, and licence number of the commercial medicinal cannabis operation who requests the testing;

(b) the date and time sampling started;

(c) the batch number from which the representative sample was obtained and the UID;

(d) the sample matrix;

(e) the total batch size, by weight, by volume, or unit count;

(f) the total weight, volume, or unit count of the representative sample; and

(g) the sampling conditions, including name and signature of sampler, or problems encountered during the sampling process, if any, and any other pertinent information.

(8) An Analytical Service Provider Facility shall not analyse a sample obtained from a licensee and the batch from which the sample was obtained may not be released for sale, if any of the following occurs –

(a) the sample is received at the facility without the requisite chain of custody form;

(b) the tamper-evident material is broken prior to the sample being received at the Analytical Service Provider Facility; or

(c) there is evidence of sample co-mingling, contamination, degradation, or a related occurrence rendering the sample unusable for analytical testing at the time the

sample is received at the Analytical Service Provider Facility.

(9) Once the custody of the sample changes between licensees or between a licensee and an Analytical Service Provider, the COC form for that change of custody may not be altered.

134. If an Analytical Service Provider Facility is unable to competently complete the regulatory compliance testing after sampling and before a COA is issued, the commercial medicinal cannabis operation who arranged for testing of the batch may request approval from the Authority to have the impacted batch resampled and tested by another Analytical Service Provider facility, if one is available in the following manner -

(a) the request shall be made in writing to the Authority and shall include all of the following:

Authorised resubmission for testing

(i) The name and licence number of the medicinal cannabis operation;

(ii) The relevant batch numbers of medicinal cannabis

(iii) The type and quantity of medicinal cannabis goods;

(iv) The name and address of the Analytical Service Provider Facility that took the initial sample and is not able to competently complete the regulatory compliance testing;

(v) The name and address of the Analytical Service Provider Facility proposed to re-sample and complete the regulatory compliance testing for the batch (es); and

(vi) The reason why the Analytical Service Provider facility which initially took the sample cannot competently complete the regulatory compliance testing.

(b) the Authority will review the request and determine if the Analytical Service Provider Facility which initially took the samples is unable to competently complete the regulatory compliance testing and if the Authority determines that the Analytical Service Provider Facility 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 commercial medicinal cannabis operation receiving written approval from the Authority.

Harvest batch sampling

135. (1) An Analytical Service Provider Facility 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.

(3) The Analytical Service Provider Facility may collect a representative sample greater than 0.35% of the total harvest batch of a prepacked or unpacked harvest batch if necessary, to perform the required testing or to ensure that the samples obtained are representative and in such case the sampler shall provide a written explanation to the licensee.

(4) The prepacked or unpacked harvest batch from which a sample is obtained shall comprise of no more than 22.5 kilograms and facility analyses of a sample collected from a harvest batch comprising of more than 22.5 kilograms shall be considered invalid and the harvest batch from which the sample was obtained shall not be released for sale.

(5) Where the Analytical Service Provider Facility obtains a representative sample from an unpacked harvest batch, the laboratory shall -

(a) collect the number of sample increments relative to the unpacked harvest batch size as listed in guildlines povided by the Authority;

(b) obtain sample increments from random and varying locations of the unpacked harvest batch, in both vertical and horizontal orientations, and to the extent practicable -

(i) the sample increments obtained from an unpacked harvest batch shall be of equal weight; and

(ii) an equal number of sample increments shall be collected from each container if the unpacked harvest batch is stored in multiple containers.

Medicinal cannabis manufactured product batch

136. (1) An Analytical Service Provider Facility shall obtain a representative sample from each medicinal cannabis manufactured product batch.

(2) The Analytical Service Provider Facility may collect a greater number of sample increments where necessary, to perform the required testing or to ensure that the samples obtained are representative.

(3) The medicinal cannabis manufactured product batch from which a representative sample is obtained shall contain no more than

150,000 units laboratory analyses of any sample collected from a medicinal cannabis product batch containing more than 150,000 units shall be considered invalid and the medicinal cannabis product batch from which the representative sample was obtained shall not be released for sale.

(4) The Analytical Service Provider Facility 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 stipulated in guidelines prescribed by the Authority.

137. (1) An Analytical Service Provider may, on a case-by-case basis, be authorised or licensed to transport, import or export medicinal cannabis for testing or scientific purposes.

(2) The application for an import or export licence or authorisation will follow the protocols established by the Authority, the Act, and these regulations, as applicable.

(3) The Authority may authorise a contracted Analytical Service Provider to transport medicinal cannabis samples and related material to or from the Analytical Service Provider Facility for analytical testing.

(4) In regard to subregulation (3), the medicinal cannabis being transported by the Analytical Service Provider must be:

a) obtained from a licensee for the purpose of analytical testing;

b) be imported for the purpose of analytical testing; or

c) be approved for export for analytical testing.

(5) The Analytical Service Provider shall transport the samples in accordance with regulations 69 to 71 and all other relevant enactments specifically that-

a) an employee, who will be driving a motor vehicle on behalf of the Analytical Service Provider, to transport cannabis items must have a valid driver's licence; and

b) the Analytical Service Provider shall ensure that any motor vehicle used to transport medicinal cannabis samples is licensed or authorised to do so by the Authority.

(6) The transport of medicinal cannabis samples and related material shall be under conditions that will protect products against physical, chemical and microbial contamination including:

a) containers for transport shall be designed to prevent spillage or comingling during transport; and

b) containers shall be regularly cleaned and sanitised.

(7) The Analytical Service Provider shall transport medicinal cannabis samples within a locked, secured area, shielded from view from the exterior of the vehicle.

Subdivision 5

Laboratory Analyses and Reporting

Required Testing

138. (1) Any sample increments of medicinal cannabis products collected by an Analytical Service Provider Facility shall be homogenised prior to sample analyses, notwithstanding foreign material testing.

(2) The Analytical Service Provider Facility shall test a representative sample of a product type in accordance with the general body of required tests prescribed in Table I of Schedule 4 and the testing parameters include, at minimum, the following:–

(a) cannabinoids;

(b) foreign matter inspection;

(c) heavy metals;

(d) microbial impurities;

(e) mycotoxins;

(f) moisture content and water activity;

(g) residual pesticides;

(h) residual solvents and processing chemicals;

(i) homogeneity testing of edible medicinal cannabis; and

(j) if applicable, terpenoids.

(3) Pursuant to subregulation (2), any raw cannabis material used to produce extracts, oils, or any type of cannabis-infused product, must undergo quality control testing in accordance with these regulations.

(4) The Analytical Service Provider Facility shall report the results of each analysis performed on the Certificate of Analysis, and shall forward all completed Certificates of Analysis to the Authority.

Import, export and transportation of sample medicinal cannabis products.

139. (1) An Analytical Service Provider Facility shall analyse at minimum, 0.5 grams of the representative sample of dried medicinal cannabis flower including pre-rolled medicinal cannabis, to determine the level of water activity and the percentage of moisture content.

(2) Pursuant to subregulation (1), the dried medicinal cannabis flower sample shall be considered to have passed water activity testing, if the water activity does not exceed 0.65 Aw and moisture content does not exceed 15%.

(3) An Analytical Service Provider Facility shall report the result of the moisture content test on the COA as a percentage.

(4) An Analytical Service Provider Facility shall analyse at least 0.5 grams of the representative sample of solid edible medicinal cannabis infused products to determine the level of water activity.

(5) Pursuant to subregulation (4), a solid edible medicinal cannabis infused product shall be considered to have passed water activity testing if the water activity does not exceed 0.85 Aw.

(6) The Analytical Service Provider Facility shall report the result of the water activity test on the COA and indicate whether or not the moisture content of the sample was within tolerance limits.

(7) If the sample fails water activity testing, the batch from which the sample was collected fails activity testing and shall not be released for sale.

Moisture content and water activity testing

140. (1) An Analytical Service Provider Facility shall analyse at minimum, 0.5 grams of the representative sample of medicinal cannabis products to determine whether residual pesticides are present.

(2) The Analytical Service Provider facility shall report whether any category I Residual Pesticides as specified in Table V of Schedule 3 are detected above the limit of detection (LOD) and shall report the result in relation to same.

(3) The Analytical Service Provider Facility shall indicate "pass" or "fail" on the COA.

(4) The Analytical Service Provider Facility shall establish a limit of quantitation (LOQ) of 0.10 ug/g or lower for all Category I Residual Pesticides as specified in Table V of Schedule 3.

(5) The sample shall be considered to have passed the residual pesticides testing if both of the following conditions are met -

(a) the presence of any residual pesticide listed in the tables in Category 1 in are not detected; and

(b) the presence of any residual pesticide listed in the tables in Category II in Table VI of Schedule 3 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 sale.

(7) The lists of residual pesticides in the Schedule 3 shall coincide with international standards, but may be adjusted as best practices change.

Residual Pesticides Testing

141. (1) An Analytical Service Provider Facility shall analyse, at minimum, 0.25 grams of the representative sample of medicinal cannabis extracts to determine whether residual solvents or processing chemicals are present.

(2) The Analytical Service Provider Facility shall report to the result of the residual solvents and processing chemicals testing in units of micrograms per gram (ug/g) on the COA and indicate whether or not the solvent level in the sample was within tolerance limits.

Residual solvents and processing chemicals testing

(3) The sample shall be considered to have passed the residual solvents and processing chemical testing if the presence of any residual solvent or processing chemical listed in the tables in Category I and Category II **o**f Tables VII and VIII respectively, of Schedule 3 does not exceed the indicated action levels.

(4) Notwithstanding subregulation (3) –

(a) the limit for ethanol shall not apply to medicinal cannabis products that are intended to be orally-consumed products and contain alcohol; and

(b) the limit for ethanol or isopropyl alcohol shall not apply to medicinal cannabis products that are intended to be topical medicinal cannabis products.

(5) If the sample fails the residual solvents and processing chemicals testing, the batch from which the sample was collected is deemed to have failed the residual solvents and processing chemicals testing and shall not be released for sale.

Microbial impurities testing

142. (1) An Analytical Service Provider Facility shall analyse, at minimum 1.0 grams of the representative sample of medicinal cannabis to determine whether microbial impurities are present.

(2) The Analytical Service Provider Facility shall report the result of the microbial impurities testing by indicating on the COA whether or not the microbial content in the sample is within tolerance limits.

(3) The sample of medicinal cannabis products shall be considered to have passed the microbial impurities testing if all of the following conditions are met –

(a) pathogenic *Escherichia coli* is not detected in 1 gram;

(b) *Salmonella spp.* is not detected in 1 gram;

(c) pathogenic Aspergillus species *A. fumigatus*, *A. flavus*, *A. niger*, and *A. terreus* are not detected in 1 gram;

(d) total Enterobacteriaceae is less than 10 CFU/g;

(e) yeast and mold are less than 1000 CFU/g; and

(f) *Clostridium botulinum* is not detected in 1 gram.

(4) If the sample fails microbial impurities testing, the batch from which the sample was collected is deemed to have failed microbial impurities testing and shall not be released for sale.

Mycotoxin testing

143. (1) An Analytical Service Provider Facility shall analyse, at minimum, 0.5 grams of the representative sample of medicinal cannabis to determine whether mycotoxins are present.

(2) The Analytical Service Provider Facility shall report the result of the mycotoxins testing in units of micrograms per kilograms (ug/kg) on the COA and indicate whether or not the content of mycotoxins in the sample is within tolerance limits.

(3) The sample shall be considered to have passed mycotoxin testing if both the following conditions are met –

(a) the total of aflatoxin B1, B2, G1 and G2 does not exceed 20 ug/kg of substance; and

(b) the amount of ochratoxin A does not exceed 20 ug/kg of substance.

(4) If the sample fails mycotoxin testing, the batch from which the sample was collected is deemed to have failed mycotoxin testing and shall not be released for sale

Foreign material testing

144. (1) An Analytical Service Provider Facility shall analyse the representative sample of medicinal cannabis to determine whether foreign material is present.

(2) The Analytical Service Provider Facility shall report the result of the foreign material test by indicating on the COA whether or not the content of foreign matter in the sample is within tolerance limits.

(3) The Analytical Service Provider Facility shall perform foreign material testing on the total representative sample prior to sample homogenisation.

(4) When the Analytical Service Provider Facility performs foreign material testing, at minimum, it 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 medicinal cannabis product sample.

(5) The sample shall be considered 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 mould;

(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 embedded foreign material.

(6) If the sample fails foreign material testing, the batch from which the sample was collected is deemed to have failed foreign material testing and shall not be released for sale.

Heavy metals testing

145. (1) An Analytical Service Provider Facility shall analyse, at minimum, 0.5 grams of the representative sample of medicinal cannabis to determine whether heavy metals are present.

(2) The Analytical Service Provider Facility shall report the result of the heavy metals test in units of micrograms per gram (ug/g) on the COA and indicate whether or not the content of heavy metals in the sample is within tolerance limits.

(3) The sample shall be considered to have passed the heavy metals testing if the presence of heavy metals does not exceed the action levels listed in Table IV of Schedule 3.

(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 sale.

Cannabinoid testing

146. (1) An Analytical Service Provider Facility shall analyse, at minimum, 0.5 grams of the representative sample of medicinal cannabis products, to determine the cannabinoid profile such as THC; THCA; CBD; CBDA; CBG; and CBN.

(2) The Analytical Service Provider Facility shall establish a limit of quantification (LOQ) of 1.0 mg/g or lower for all cannabinoids analysed and reported.

(3) The Analytical Service Provider Facility shall report the result of the cannabinoid testing on the COA in the following manner, or as otherwise approved in writing by the Authority:

(a) a percentage for THC, THCA, CBD, and CBDA and 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 milliliter (mg/mL) if by volume for THC, THCA, CBD and CBDA;

(d) milligrams per gram (mg/g) if by dry-weight or milligrams per milliliter (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.

(4) The Analytical Service Provider Facility shall report the results of all other cannabinoids analysed 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.

(5) The Analytical Service Provider Facility 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).

(6) 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.

Terpenoid testing

147. (1) If requested, an Analytical Service Provider Facility shall analyse, at minimum, 0.5 grams of the representative sample of medicinal cannabis products, to determine the profile of terpenoids such as, alpha-bisabolol, beta-caryophyllene, beta-myrcene, and limolene.

(2) The Analytical Service Provider Facility shall establish a limit of qualification (LOQ) of 1.0 mg/ml or lower for all terpenoids reported.

(3) The Analytical Service Provider Facility shall report the result of the terpenoid testing on the COA both as a percentage and in either milligrams or per gram (mg/g) if by weight or milligram or milliliter (mg/ml) if by volume.

(4) Any terpenoids found to be less than the LOQ shall be reported on the COA as "<1 mg/g if by weight, and "<1 mg/mL" if by volume.

Homogeneity Testing

148. (1) The Analytical Service Provider shall analyse a sample of edible medicinal cannabis infused product to determine whether the product is of homogeneous cannabinoid content.

(2) A sample of edible medicinal cannabis infused product shall be deemed to have passed homogeneity testing if the potency variance (difference between the Analytical Service Provider Facility measured cannabinoid concentration and the producer's) does not exceed +/-15%,

with 10% of the product containing no more than 20% of the total cannabinoid content of the product.

(3) If a sample fails homogeneity testing, the batch from which the sample was collected fails homogeneity testing and shall not be released for sale.

Pesticide use and testing

149. (1) A licensee shall only use a pesticide that is approved by the National Pesticide Control Board and such use is subject to review by the Authority.

(2) Pursuant to subregulation (1) the Authority may require an Analytical Service Provider Facility to test medicinal cannabis for substances such as fungicides, herbicides, or growth regulators.

(3) Any measurable and positively verified detection of a pesticide or analyte that is found on medicinal cannabis, which is not a pesticide or analyte that is pursuant to subregulation (1), shall be reported to the Authority by the Analytical Service Provider Facility that conducted the testing.

(4) If a harvest batch is found to contain pesticide residues, it shall not be manufactured, packaged, labelled for sale or otherwise processed, but shall be destroyed.

(5) Upon notification of the failed testing results, the licensee who provided the harvest batch shall quarantine the harvest batch and make the necessary arrangements with the Authority for the destruction of the harvest batch.

(6) An inspector shall witness the destruction of the harvest batch and where non-compliance this procedure shall result in the revocation of the licence issued to the Analytical Service Provider.

(7) Where a licensee believes that the results of the pesticides testing which relates to a harvest batch from the commercial medicinal cannabis operation of the licensee are not accurate the licensee may request a retest of the harvest batch at the expense of the licensee from the Analytical Service Provider Facility and the Authority shall reserve the right to oversee the retesting procedures.

(8) If the licensee wishes to reserve the option of requesting a retest from the Analytical Service Provider Facility then; twice the sample size needed to complete all testing shall be collected by the Analytical Service Provider Facility with one of the samples remaining at the laboratory in a tamper proof package.

Sample testing and disposal

150. (1) Immediately before packaging -

(a) A licensee conducting a cannabis cultivation operation shall segregate all harvested medicinal cannabis into homogenised lots of flower and trim, respectively, and submit to an Analytical Service Provider Facility a representative sample for testing from each lot and the sampling shall be done immediately before the packaging of any medicinal cannabis for sale to another licensee;

(b) the Analytical Service Provider Facility that performs the test shall collect the samples unless it has arranged sample delivery pursuant to these Regulations;

(c) if the licensee has segregated the lot of harvested material into packages or container sizes smaller than the entire lot, the laboratory shall sample and test each package containing harvested material from the lot presented for testing;

(d) for concentrated medicinal cannabis, edible medicinal cannabis infused products or topical medicinal cannabis products, a licensee shall submit to a Analytical Service Provider Facility, a random sample from each production for testing by the facility;

(e) a licensee shall use tamper resistant packaging products, and shall record the lot or production run, the batch number, and the weight or quantity, of harvested material or production run submitted for testing.

(2) An Analytical Service Provider Facility that receives a sample pursuant to this regulation shall -

(a) test the sample in accordance with these Regulations;

(b) report the test to the Authority, and to the licensee.

(3) From the time that a lot or production run has been homogenised for sample testing and eventual packaging and sale to a licensee until the analytical service provider facility provides the results from its tests and analyses, the licensee which provided the sample for testing shall segregate and withhold from use the entire lot or production run, except the samples that have been removed by the laboratory for testing.

(4) Pursuant to subregulation (3), during this period of segregation -

(a) the licensee that provided the sample shall maintain the lot or production run in a secure, cool and dry location so as to prevent the sample from becoming contaminated or losing its efficacy and shall maintain the product in quarantine;

(b) under no circumstances shall the licensee that provided the sample offer the medicinal cannabis to any person for sale until the Analytical Service Provider Facility has completed its testing and analysis and provided the results, in writing, to the licensee who provided the sample;

(c) the Analytical Service Provider Facility shall keep all failed samples and all random samples collected by the Authority, for confirmation testing, for up to thirty (30) days after testing and thereafter such samples should be stored in an approved manner;

(d) following this retention period, the samples shall be destroyed by the Analytical Service Provider Facility according to its disposal policy.

(5) Subject to subregulation (4)(d) an Analytical Service Provider Facility shall immediately dispose of any sample received pursuant to this regulation upon the completion of any testing, use or research and where the laboratory disposes of a sample received pursuant to this section, it shall document the disposal of the sample using its inventory control system pursuant to Regulation 94.

(6) Except as otherwise provided in these Regulations, if a sample provided to an Analytical Service Provider Facility pursuant to this Regulation does not pass the testing required by these Regulations, the licensee that provided the sample to be tested shall dispose of the entire lot or production run from which the sample was taken and document the disposal of the sample using its inventory control system and the Authority may require advanced written notice of lot or production run disposal.

(7) If a sample provided to an Analytical Service Provider Facility pursuant to these regulations passes the testing required by this Part, the Authority, having examined the COA, shall release the entire lot or production run for immediate manufacturing, packaging and labelling for sale.

(8) An Analytical Service Provider Facility shall file with the Authority, in the manner provided in Form 1 of Schedule 4, a copy of all Analytical Service Provider Facility test results and the time they are

obtained and compiled, regardless of the outcome of the test, including all testing required under these Regulations.

Certificate of Analysis (COA)

151. (1) An Analytical Service Provider Facility shall generate a COA, in accordance to ISO/IEC 17025, for each representative sample that the laboratory analyses.

(2) The Analytical Service Provider Facility shall ensure that the COA contains the result of all required analyses performed for the representative sample.

(3) The Analytical Service Provider Facility shall, within one (1) day of completing all analyses of a sample, transmit the COA to the Authority by electronic means or as otherwise advised in writing.

(4) The Analytical Service Provider Facility 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 and no text or images shall appear above the term "Regulatory Compliance Testing" on any page of the COA;

(b) the name and address of the Analytical Service Provider Facility;

(c) the name of the licensee who requested the test sample;

(d) the batch number of the batch from which the sample was obtained and, for medicinal cannabis products that are already packaged at the time of sampling, the labelled batch number on the packaged medicinal cannabis product shall match the batch numbers on the COA;

(e) the sample identifying information, including matrix type and unique sample identifiers;

(f) the sample history, harvest or production date, including the date collected, the date received by the Analytical Service Provider Facility, 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 a 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 employees 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.

(6) The Analytical Service Provider Facility shall report the 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 Analytical Service Provider Facility shall indicate "pass" or "fail";

(c) when reporting quantitative results for each analyte, the Analytical Service Provider Facility shall use the appropriate units of measurement as required under this Part;

(d) when reporting results for each test method, the Analytical Service Provider Facility 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 detected or detected below the LOD, indicate "ND"; and

(g) indicate "NT" for any test that was not performed.

(7) The relevant supervisory staff of the Analytical Service Provider Facility shall verify the accuracy of the information contained on the COA and sign and date the COA.

Subdivision 6

Post Testing Procedures

Remediation and retesting

152. (1) A licensee who requested a test sample may arrange for remediation of a batch of medicinal cannabis product that failed the testing, and if the batch cannot be remediated, the batch shall be destroyed at the cost of the licensee and in an authorised manner.

(2) A medicinal cannabis product batch that has been additionally processed after failed testing shall be retested and successfully shall pass all the analyses required under this Part, before the medicinal cannabis product is offered for sale.

(3) If a failed batch is not remediated or reprocessed in any way it cannot be retested and any subsequent COAs produced without the remediation or reprocessing of the failed batch shall not supersede the initial regulatory compliance testing COA.

(4) A medicinal cannabis product 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 and this destruction shall be witnessed by the Authority.

(5) Within one (1) day of completing the required analyses of a representative sample obtained from a remediated medicinal cannabis product batch, the Analytical Service Provider Facility shall transmit the COA to the Authority by electronic means or as otherwise advised in writing.

(6) Nothing in this regulation shall be interpreted to prevent a medicinal cannabis product batch from being retested when the COA is ten (10) or more months old.

Post testing sample retention

153. (1) The Analytical Service Provider Facility shall retain the reserve sample, consisting of any portion of a sample that was not used in the testing process and, the reserve sample shall be kept, for at least thirty (30) days after the analyses, after which time it may be destroyed and denatured to the point the material is rendered unrecognisable and unusable.

(2) The Analytical Service Provider Facility shall securely store the reserve sample in a manner that prohibits sample degradation, contamination, and tampering.

(3) The Analytical Service Provider Facility shall provide the reserve sample to the Authority, upon request.

Random quality assurance compliance checks

154. (1) Upon the request of the Authority, a licensee shall provide for an Analytical Service Provider Facility designated by the Authority, a sample of medicinal cannabis or a medicinal cannabis product in an amount determined by the facility to be sufficient for random quality assurance compliance checks.

(2) Where the Analytical Service Provider Facility receives a sample pursuant to subregulation (1), it shall, as directed by the Authority –

(a) screen the sample for pesticides, chemical residues, herbicides, growth regulators and unsafe levels of metals;

(b) perform any other quality assurance test deemed necessary by the Authority; and

(c) report its results to the Authority.

(3) Pursuant to subregulation (1) the licensee that is requested by the Authority to provide the sample for testing shall be responsible for all costs involved in screening or testing performed.

Medicinal cannabis at Analytical Service Provider Facility

155. An Analytical Service Provider Facility is not limited in the amount of usable medicinal cannabis and medicinal cannabis products which it may have on its premises at any given time, but the facility shall maintain records to prove that all usable medicinal cannabis on its premises are for testing purposes only.

Authorised use of medicinal cannabis upon failure of quality assurance test: Requirements For Retesting

156. (1) If a sample from a licensee fails a quality assurance test, the entire production run from which the sample was taken automatically is deemed to have failed the quality assurance test.

(2) At the request of a licensee, the Authority may, on a case-by-case basis, authorise a retest to validate the results of a failed test and the licensee shall be responsible for all costs involved in a retest performed pursuant to this Regulation.

(3) A licensee may not request a retest pursuant to this regulation unless, at the time samples are initially taken for testing, two samples are collected at the same time by the Analytical Service Provider Facility using tamper-resistant packaging.

(4) Pursuant to subregulation (4), one of the samples shall be taken by the Analytical Service Provider Facility for testing and the facility

shall place the other sample in a secure quarantine storage area at the premises for further testing as approved by the Authority.

(5) A licensee shall submit a request for retesting to the Authority in writing, on a form designated by Authority.

(6) If the Authority grants a request for retesting, the Authority will select the Analytical Service Provider Facility that will perform the retest.

(7) Except as otherwise provided in this subregulation, a licensee may submit a request for retesting of not more than 50 lots each calendar year.

(8) For any subsequent failure of a quality assurance test in a calendar year, licensee shall destroy the lot or the entire production run, as applicable.

(9) Upon approval of the Authority, a lot of medicinal cannabis flower which fails a microbial screening, may be used to make an extract using such remediation methods such as irradiation and ultrasonification and, after processing, the extract shall undergo the required quality assurance tests.

(10) A lot which only fails a quality assurance test for moisture content shall not be counted for the purpose of this regulation.

(11) A failed quality assurance test for pesticide residue shall be reported to the Authority.

(12) If a sample passes the same quality assurance test upon retesting, the licensee need not destroy the lot or production run and may sell the lot or production run to another licensee as applicable.

(13) If a sample fails the same quality assurance test upon retesting and the Authority denies a request for retesting or the licensee does not request retesting after a sample fails a quality assurance test, the licensee shall destroy the entire lot or production run from which the sample was taken.

Analytical Service Provider Facility Records

157. All analytical records developed by the Analytical Service Provider Facility and described in this Part shall be input into the Saint Vincent and the Grenadines Track and Trace System and shall be maintained in accordance with these Regulations.

Division 2

Research

Promoting research

158. The Authority shall promote and commission, objective scientific research to be completed within Saint Vincent and the Grenadines.

General obligations of a Research Licensee

159.(1) A research licensee shall develop research programmes and conduct studies for the purpose of improving or further developing cannabis for medicinal or scientific purposes.

(2) Any personnel involved in an approved research programme shall be approved by the Authority.

(3) A research licensee shall make every effort to recruit qualified personnel from Saint Vincent and the Grenadines.

(4) A research licensee shall keep a log of all persons entering and exiting the premises on which the subject of the licence is carried out and all other security guidelines as provided by the Authority in accordance with the Act and its Regulations.

(5) A research licensee may conduct research activities that may include but are not limited to, *in vivo* and *in vitro* studies, clinical trials, plant genetics, cannabis product development and educational programmes.

(6) A research licensee is authorised to conduct experiments and testing on every form and derivative of cannabis, including live plants, fresh and dried plant material, seeds, oil, and manufactured items.

(7) A research licensee may conduct the scientific and clinical operations of the research programmes if there is a clinician or scientist with expertise to conduct the required studies-

(a) partly at university campuses and partly at the hospitals;

(b) at other public or private institutions; and

(c) a facility approved by the Authority.

(8) Research studies into the medical efficacy and safety of medicinal cannabis and its derivatives shall employ, where possible, state-of-the-art research methodologies.

(9) Studies conducted pursuant to this Regulation shall include the greatest amount of new scientific research possible on the medical use of, and medical hazards associated with, cannabis.

(10) A research licensee is required to follow all applicable laws of the State which govern research involving human and animal subjects and must be granted approval from the Research Ethics Committee prior to the commencement of the research.

(11) A research licensee shall ensure that all medicinal cannabis used in the human and animal studies is of the appropriate quality and shall be obtained from an entity licensed by the Authority.

(12) A research licensee may only sell cannabis material which include seeds, plants or tissue culture, for the purpose of this subregulation, developed by approved research activities, to entities licensed or authorised by Authority and all sales must be approved by the Authority.

(13) A research licensee shall only purchase medicinal cannabis from an entity licensed by the Authority.

(14) A licensee shall follow the guidance of the Authority in relation to the testing, development and use of new drug formulations.

(15) A medicinal cannabis product developed during research must be approved and registered by the Authority prior to use in Saint Vincent and the Grenadines.

(16) A research licensee may import or export medicinal cannabis related to the approved research activities in accordance with the Act and its Regulations.

(17) A research licensee is authorised to transport medicinal cannabis, medicinal cannabis waste and waste, relating to its licensed activities and shall transport a sample in accordance with the Act and its Regulations.

(18) A research licensee shall transport medicinal cannabis samples within a locked, secured area, shielded from view from the exterior of the vehicle.

(19) A research licensee shall dispose of medicinal cannabis or its waste in the manner prescribed in these Regulations.

The award of grants for medicinal cannabis research studies

160. (1) The Authority may award grants for the development of research programmes and in so doing, the Authority shall under this Part, implement principles and parameters of the other well-tested international or regional research programmes administered by various universities or hospitals, modelled after programmes that follow international guidelines, including peer review evaluation of the scientific merit of applications.

(2) Criteria for the selection of research programmes to award grants, shall give particular weight to the organisational plan, leadership qualities of the programme director, and plans to involve investigators and patient populations from multiple sites.

(3) The funds received by the research licensee shall be allocated to various specific research studies in accordance with a scientific plan.

(4) The size, scope, and number of studies funded shall be commensurate with the amount of appropriated and available programme funding.

Research involving human subjects

161. (1) A research programme or a medicinal cannabis drug trial, that proposes to use human subjects in its undertaking, shall first meet all of the conditions as follows –

(a) have written and signed consent from each subject to be involved;

(b) have written and signed approval for the proposed research programme or medicinal cannabis drug trial, by the Research Ethics Committee through the minister responsible for health;

(c) have written and signed authorisation for the proposed research programme or medicinal cannabis drug trial from the Advisory Council; and

(d) have a medical doctor leading the research programme or medicinal cannabis drug trial.

(2) Programme requirements to be used when evaluating responses to a 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 programme of research regarding the medical efficacy and safety of medicinal cannabis;

(b) proposals shall contain procedures for outreach to patients with various medical conditions who may be suitable participants in research on medicinal 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 analyse data that accrues as part of clinical trials;

(e) proposals shall contain protocols suitable for research on medicinal cannabis, such as addressing patients with qualifying medical conditions;

(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; and

(h) proposals shall demonstrate the use of an Analytical Service Provider facility capable of analysing medicinal cannabis, for purity and cannabinoid content and the capacity to detect contaminants.

(3) To ensure objectivity in evaluating proposals, the programme shall use a peer review process that follows international guidelines regarding the avoidance of the funding of 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 declared 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 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.