GOOD PRODUCTION PRACTICES GUIDE FOR CANNABIS

Requirements under Part 5 of the *Cannabis Regulations*

Government of Canada
Gouvernement du Canada

Canada

Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health. Health Canada is committed to improving the lives of all of Canada's people and to making this country's population among the healthiest in the world as measured by longevity, lifestyle and effective use of the public health care system.

Disclaimer: This document does not constitute part of the *Cannabis Act* or its associated Regulations. It should be read in conjunction with relevant sections of the Act and its Regulations. The information in this document is not intended to substitute for, supersede or limit the requirements under the legislation. In the event of discrepancy between the legislation this document, the legislation shall prevail.

The reader is advised to consult other legislation that may apply to them or their activities, such as applicable provincial or territorial legislation.

This document may be updated from time to time so the reader is encouraged to check back periodically.

Good Production Practices Guide for Cannabis

Également disponible en français sous le titre :

Lignes directrices sur les Bonnes Pratiques de Production du Cannabis

Publication date:

PRINT

Cat.: H14-271/2018E-PDF

Pub.: 180390

ISBN: 978-0-660-25850-8

Table of contents

1.0 Purpose

The purpose of this document is to provide guidance to federally regulated holders of a licence under the *Cannabis Act* (hereafter referred to as licence holders) on the application of Part 5: Good Production Practices (GPP) of the *Cannabis Regulations.* It is designed to help licence holders understand the GPP requirements for cannabis that is produced, distributed and sold in Canada, as well as cannabis that is to be exported from Canada.

2.0 Background

The *Cannabis Act* (hereafter referred to as "the Act") and its Regulations provide, among other things, the framework for legal access to cannabis and the control and regulation of its production, distribution and sale.

Part 5 of the *Cannabis Regulations* include the requirements for GPP to help ensure that cannabis meets quality standards appropriate to its intended use. These standards and other requirements are backed by rigorous compliance and enforcement by Health Canada, including unannounced inspections where inspectors verify adherence to the regulations.

In the case that Health Canada finds a licence holder to be non-compliant with any or all of the requirements in Part 5 of the *Cannabis Regulations*, a range of compliance and enforcement measures may be taken, including but not limited to the following:

- Issuance of a warning letter
- Issuance of public advisories or other forms of risk communications
- Seizure or detention
- Refusal, suspension or revocation of an authorization, including a licence or a permit
- Issuance of an administrative monetary penalty up to $1 million
- Issuance of a ministerial order to recall products from the market, to conduct tests or studies, produce information or documents or take other measures

For more information, refer to the *Compliance and enforcement policy for the Cannabis Act* on Health Canada's website.

Guidance documents are administrative instruments not having force of law and, as such, allow for flexibility in approach. This guide is one of a series of guidance documents written as an accompaniment to the *Cannabis Regulations* under the Act. Health Canada publishes other guidance documents and information on its website that licence holders may use in conjunction with this document to maintain their compliance. For consistency and transparency, this guide and other guidance documents and information are updated as required to reflect changes to policies and/or operations.

3.0 Scope

This guide pertains to federally licensed production activities (including production, packaging, labelling, distribution, storage, sampling and testing) conducted with cannabis by licence holders, and compliance of those activities with the GPP provisions set out in Part 5 of the *Cannabis Regulations*.

The scope of this guide includes the following classes of cannabis, as set out in Schedule 4 of the Act:

- Dried cannabis
- Cannabis oil
- Fresh cannabis
- Cannabis plants
- Cannabis plant seeds

In accordance with the *Cannabis Regulations*, the GPP regulatory requirements outlined in this guide are broken down as follows:

- General requirements: Applicable to all cannabis, including all classes of cannabis , and all cannabis products of those classes that are to be sold, distributed or exported by a licence holder.
- Testing requirements: Applicable to cannabis within the following classes: dried cannabis, cannabis oil, and fresh cannabis that will become cannabis products that are to be sold or exported by a licence holder.

Additionally, the appendices in this guide provide information on additional requirements outlined in other parts of the *Cannabis Regulations* as they pertain to GPP, namely Part 2: Licensing, Part 6: Cannabis Products, and Part 11: Retention of Documents and Information.

4.0 Definitions and abbreviations

4.1 Definitions

The *Cannabis Act* and its Regulations should be referred to for definitions. The definitions in this section are provided for greater clarity and ease of reference.

Adverse reaction: As defined in s. 248(3) of the *Cannabis Regulations*, means a noxious and unintended response to a cannabis product.

Bulk cannabis: For the purpose of this guide, means any cannabis that has not yet been packaged as a cannabis product.

Cannabis: As defined in s. 2(1) of the Act, means a cannabis plant and anything referred to in Schedule 1 of the Act, but does not include anything referred to in Schedule 2 of the Act. For the purpose of this guide, the term cannabis includes any class of cannabis listed in Schedule 4 to the

Act, as well as any cannabis accessory that contains cannabis, a discrete unit of cannabis, or a cannabis product.

Cannabis accessory: As defined in s. 2(1) of the Act means:

(a) A thing, including rolling papers or wraps, holders, pipes, water pipes, bongs and vaporizers, that is represented to be used in the consumption of cannabis; or
(b) A thing that is deemed under subsection 3 to be represented to be used in the consumption of cannabis.

Cannabis oil: As defined in s. 1(1) of the *Cannabis Regulations* means an oil that contains anything referred to in items 1 and 3 of Schedule 1 to the Act, and that is in liquid form at room temperature of 22 ± 2°C.

Cannabis plant: As defined in s. 2(1) of the Act, means a plant that belongs to the genus *Cannabis.*

Cannabis plant seed: For the purpose of this guide, means any seed of a cannabis plant.

Cannabis product: As defined in s. 1(2) of the *Cannabis Regulations,* means cannabis of only one of the classes that are set out in Schedule 4 to the Act—or a cannabis accessory if that accessory contains such cannabis—after it has been packaged and labelled for sale to a consumer at the retail level, but does not include a drug containing cannabis.

Class of cannabis: For the purpose of this guide, means any one of the classes outlined in Schedule 4 to the Act (i.e., dried cannabis, cannabis oil, fresh cannabis, cannabis plants, or cannabis plant seeds).

Contamination: For the purpose of this guide, means the presence of any microorganism or chemical that exceeds the identified generally acceptable tolerance limits required for herbal medicines for human consumption, as established in any publication referred to in Schedule B to the *Food and Drugs Act*.

Discrete unit: For the purpose of this document, means a convenience form of cannabis, ready to use by the consumer.

Dried cannabis: As defined in s. 2(1) of the Act, means any part of a cannabis plant that has been subjected to a drying process, other than seeds.

Extraneous substances: For the purpose of this guide, means anything other than cannabis intended to be distributed, sold or exported, but does not include contaminants.

Fresh cannabis: As defined in s. 1(1) of the *Cannabis Regulations*, means freshly harvested cannabis buds and leaves, but does not include plant material that can be used to propagate cannabis.

Immediate container: As defined in s. 105 of the *Cannabis Regulations*, means the container that is in direct contact with a cannabis product.

Licence holder: For the purpose of this document, means the holder of a licence, as listed in s. 8 of the *Cannabis Regulations.*

Pest control product: As defined in s. 2(1) of the *Pest Control Products Act* (PCPA) means:

(a) A product, an organism or a substance, including a product, an organism or a substance derived through biotechnology, that consists of its active ingredient, formulants and contaminants, and that is manufactured, represented, distributed or used as a means for directly or indirectly controlling, destroying, attracting or repelling a pest or for mitigating or preventing its injurious, noxious or troublesome effects;
(b) An active ingredient that is used to manufacture anything described in paragraph (a);
(c) Any other thing that is prescribed to be a pest control product.

Produce: As defined in s. 2(1) of the Act, means to obtain cannabis by any method or process, including by:

(a) manufacturing;
(b) synthesis;
(c) altering its chemical or physical properties by any means; or
(d) cultivating, propagating or harvesting it or any living thing from which it may be extracted or otherwise obtained.

Serious adverse reaction: As defined in s. 248(3) of the *Cannabis Regulations*, means a noxious and unintended response to a cannabis product that requires inpatient hospitalization or a prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life threatening or results in death.

Validation: For the purpose of this guide, means establishing documented evidence that will provide a high degree of assurance that the testing methods will consistently, and reproducibly, lead to the predetermined specifications and quality results in tested cannabis.

4.2 Abbreviations

CBD	cannabidiol
CBDA	cannabidiolic acid
FDA	*Food and Drugs Act*
GPP	good production practices
OOS	out-of-specification
Part 5	Good Production Practices of the *Cannabis Regulations*
Part 6	Cannabis Products of the *Cannabis Regulations*
Part 11	Retention of Documents and Information of the *Cannabis Regulations*
PCP	pest control product
PCPA	*Pest Control Products Act*
QAP	quality assurance person
SOP	standard operating procedure

s.	section number in the *Cannabis Regulations*
THC	delta-9-tetrahydrocannabinol
THCA	delta-9-tetrahydrocannabinolic acid
The Act	the *Cannabis Act*

4.3 Icons

The following icons are used throughout this guide to highlight information of interest.

Important: Key or cautionary information.

Tip: Supplementary information that could be helpful, including references to external documents.

5.0 Good Production Practices: Regulatory requirements

Part 5 of the *Cannabis Regulations* establishes requirements pertaining to GPP, in order to ensure that cannabis is produced consistently by licence holders and controlled in such a way that it meets quality standards appropriate to its intended use.

This part of the guide is organized into two sections:

- Section 5.1: The general requirements that must be met in order to sell, distribute or export any cannabis.
- Section 5.2: The testing requirements that must be met in order to sell or export cannabis products.

Additionally, GPP-related requirements set out in Part 2: Licensing, Part 6: Cannabis Products, and Part 11: Retention of Documents and Information of the *Cannabis Regulations* are also included.

Each licence holder is responsible for understanding and complying with all GPP requirements that apply to their licence and range of activities. They must be able to demonstrate that cannabis has been produced, distributed and sold in accordance with the *Cannabis Regulations*.

Appendix A and Appendix B provide a summary of the GPP requirements by licence class and class of cannabis, respectively.

This guide provides examples of principles and practices that may be used to achieve compliance with sections of Part 5; however, these are not intended as exhaustive lists.

Alternate approaches to the principles and practices described in this guide may be acceptable if they meet the requirements of the *Cannabis Regulations.*

5.1 General requirements

As per s. 79 of the *Cannabis Regulations*, licence holders must not sell, distribute or export cannabis unless the applicable requirements set out in s. 80 to 88 of the *Cannabis Regulations* have been met. This section of the guide outlines these requirements in further detail.

5.1.1 *Standard operating procedures*

As per s. 80 of the *Cannabis Regulations,* cannabis must be produced, packaged, labelled, distributed, stored, sampled and tested in accordance with standard operating procedures (SOPs). These SOPs must be designed to ensure that those activities are conducted in accordance with the requirements of Part 5.

The SOPs should include all steps necessary to be in compliance with GPP in order to avoid the quality of the cannabis from becoming adversely affected (e.g., where there is an increased likelihood of the cannabis being contaminated, or of extraneous substances being added).

Examples of SOPs that may be developed in relation to key operational elements include, but are not limited to:

- Sanitation of the building or part of a building, equipment, and employee hygiene;
- Distribution, including transfer, and receipt of cannabis;
- Production and processing of cannabis including, but not limited to:
    - Cloning of cannabis plants or sowing cannabis plant seeds
    - Trimming or pruning
    - Additions of nutrients, fertilizers and pest control products
    - Harvesting
    - Drying, curing or burping
    - Extraction processing
    - Encapsulation and other discrete unit production
- Sampling and testing of cannabis;
- Packaging and labelling (e.g., for bulk cannabis, samples, immediate container and discrete units); and
- Storage (e.g., for bulk cannabis, quarantined product, product on hold, product approved for sale, product in transit and product destined for destruction).

Examples of **principles or practices** that may demonstrate compliance with s. 80 are as follows:

- The licence holder has a system in place to review procedures on a regular basis and revise them as needed.
- If a licence holder needs to deviate from an SOP, details of the deviation (e.g., the reason for the deviation, whether it was planned and assessment of GPP impacts) are documented in a report in accordance with an SOP.
- All personnel who conduct the activities described within a SOP are provided with training on the SOP.
- Training is provided and documented prior to the implementation of a new or revised SOP.

Licence holders should refer to section 5.1.6 of this guide for additional information regarding approval of the SOPs by the quality assurance person (QAP), where applicable, prior to use at the site.

Licence holders may consider using the following elements to develop their SOPs:

- Purpose
  - Includes a brief statement indicating the reason for the procedure
- Scope
  - Defines the area covered and any relevant exclusion
- Responsibility
  - Defines, as an overview, the functional unit(s) or individuals responsible for carrying out the procedure
- References
  - Includes, as appropriate, reference to the corresponding chapter in a quality manual, applicable quality system standard, regulation or other related procedure
- Terminology
  - Definitions to eliminate uncertainty over any words or terms used within the procedure
- Procedures, instructions, methods, actions
  - Describes the step-by-step actions that need to be taken
- Documentation
  - Includes the kinds of records associated with the procedure; indicates where these records are filed; and indicates the length of time the records are retained; (note that record retention time periods may alternatively be stated in general procedures for control of documentation and data and simply be referred to in individual procedures)
- Revision sheet/table

- Includes the revision level (letter, number or combination), the date of the revision, the effective date of the revision, and a brief description of the change(s); tracking of revisions may alternatively be maintained as part of general documentation control procedures

- Attachment
  - Includes forms to be used in carrying out the procedure; (e.g., the procedure may refer to the specific attachment that includes the relevant form (e.g., "For this procedure, a recall reporting form [Attachment X] is recommended.")

Other **good documentation practices** that licence holders may consider when developing their SOPs include:

- Involving the users in writing, reviewing, testing and modifying the procedures.
- Printing the names of individuals who prepare and approve procedures.
- Including signatures and the approval dates of those indicating their approval of the procedure.
- Numbering sections, paragraphs and pages to facilitate reading and discussion.
- Using text that is clear, simple and concise.

The record keeping requirements associated with this GPP requirement are found under s. 232 of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix E.

5.1.2 *Pest control product*

As per s. 81 of the *Cannabis Regulations,* cannabis must not be treated with a pest control product (PCP) unless the product is registered for use on cannabis under the *Pest Control Products Act* (PCPA), or is otherwise authorized for use under the PCPA.

Further requirements related to PCPs are found in s. 93 (2) of Part 6 of the *Cannabis Regulations* and in the document Health Canada has published that sets out the requirements for mandatory testing of cannabis for pesticide active ingredients. For more information on these requirements, which are effective as of January 2, 2019, refer to Appendix D and the *Mandatory cannabis testing for pesticide active ingredients - Requirements* page on Health Canada's website.

The record keeping requirements associated with this GPP requirement are found under s. 231(1)(c) and (2)(b) of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix E.

5.1.3 *Storage and distribution*

5.1.3.1 Storage

As per s. 82 of the *Cannabis Regulations,* cannabis must be stored under conditions that maintain its quality.

Examples of **principles or practices** that may demonstrate compliance with s. 82 are as follows:

- Storage areas are designed or adapted to ensure good storage conditions including orderly storage and prevention of cross-contamination of the various categories of materials and cannabis (e.g., in-process; bulk cannabis; cannabis in immediate containers and cannabis accessories; samples; material that is quarantined, approved for sale, rejected, returned or recalled; and material awaiting destruction). In particular, these areas are clean, dry and have adequate air circulation. To reduce human error, general storage areas are well lit and labelled accordingly.
- All cannabis including samples are stored according to the recommended storage conditions that are set out on the cannabis product label. When specified on the label, controls for temperature, humidity and light are in place and monitored using calibrated monitoring devices.
- Records of temperature and humidity deviations are maintained, where applicable. Adherence to these conditions are verified periodically.

The record keeping requirements associated with this GPP requirement are found under s. 231(1)(a) and (2)(a) of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix E.

The following are examples of storage records that may be maintained by a licence holder to demonstrate their compliance with Part 5:

- Records of temperature, humidity and lighting generated from the storage locations.
- Records of temperature and humidity deviations.
- Records demonstrating adequate maintenance and calibration, if applicable, for the temperature, humidity and lighting monitoring devices.

5.1.3.2 Distribution

As per s. 83 of the *Cannabis Regulations*, cannabis must be distributed in a manner that maintains its quality.

Examples of **principles or practices** that may demonstrate compliance with s. 83 are as follows:

- Vehicles used in the distribution (e.g., transferring, transporting, sending, delivering, providing) of cannabis are equipped with the necessary means to maintain its quality. For example, the vehicle may require temperature and humidity monitoring as well as temperature control when it is being used to transport cannabis that is sensitive to temperature and humidity (e.g., cannabis plants). The vehicles are clean, dry and capable of maintaining air quality.
- Cannabis is packaged and shipped in accordance with approved SOPs.

In addition, when distributing cannabis, a licence holder must take any steps that are necessary to ensure the safekeeping of cannabis when distributing it, as per the requirement under s. 47.

The record keeping requirements associated with this GPP requirement are found under s. 227 of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix E .

The following are examples of distribution records that may be maintained by a licence holder to demonstrate their compliance with Part 5:

- Records indicating that cannabis was packaged and shipped in accordance with applicable SOPs.
- Records tracking all personnel handling the product during distribution.
- Records demonstrating adequate sanitation, maintenance, and environmental conditions of the carrier.

5.1.4 *Building/part of a building, air filtration and equipment*

5.1.4.1 Building or part of a building

As per s. 84 of the *Cannabis Regulations*, cannabis must be produced, packaged, labelled, stored, sampled and tested in a building or part of a building that is designed, constructed and maintained in a manner that permits those activities to be conducted appropriately and under sanitary conditions.

In particular, the building or part of the building must be designed, constructed, and maintained in a manner that permits it to be kept clean and orderly, permits effective cleaning of all its surfaces, prevents the contamination of cannabis and prevents the addition of extraneous substances to the cannabis. This requirement does not apply to outdoor cultivation, propagation, or harvesting of cannabis.

Licence holders who choose to grow outdoors must ensure that all activities with cannabis post-harvest (e.g., drying, trimming) are conducted within a building or part of a building and are conducted in compliance with this section.

Examples of **principles or practices** that may demonstrate compliance with s. 84 are as follows:

- Design and construction of the building or part of building (e.g., doors, windows, ceilings, floors, pipes, light fittings, ventilation points):
    - The building or part of the building is designed or constructed in a manner that facilitates maintenance, cleaning and sanitary operations, which includes the repeated application of cleaning and disinfecting agents.
    - Brick, cement block and other porous materials are sealed and surface materials that shed particles are not used.
    - The building or part of the building may be designed or constructed in a manner that prevents entry of insects and other animals, facilitates waste treatment and disposal, and prevents mix-ups and cross-contamination.
    - Floor plans and the building or part of the building design is laid out to allow production to take place in areas connected in a logical order, corresponding to the sequence of the operations and to the requisite cleanliness levels.
    - A potable water source is available in sufficient volume to support the sanitary operation of the facility.
- Maintenance program
    - The building or part of the building is regularly monitored and carefully maintained.
    - Regular maintenance is performed to prevent deterioration of the building or part of the building.
    - Repair and maintenance operations does not present any hazard to the quality of the cannabis.

The record keeping requirements associated with this GPP requirement are found under s. 231(1)(a) and (2)(a) of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix E.

Examples of records pertaining to s. 84 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 are records of maintenance and service generated from the upkeep of the building or part of the building.

5.1.4.2 Air filtration

As per s. 85 of the *Cannabis Regulations*, the building or part of the building where cannabis is produced, packaged, labelled and stored must be equipped with a system that filters air to prevent the escape of odours. All conditions under which activities with cannabis are being conducted should maintain the quality of the cannabis.

Examples of **principles or practices** that may demonstrate compliance with s. 85 are as follows:

- Filters and ventilation
  - The building or part of the building used for the production, packaging, labelling and storage of cannabis is equipped with an adequate ventilation system that is capable of maintaining air quality within it.
  - The number and quality of air filters is sufficient for preventing the escape of odours from the building or part of the building where all activities with cannabis are taking place, as well as to maintain air quality within these areas.
- Maintenance program
  - Ventilation and air filtration is maintained in accordance with a schedule.
  - Maintenance operations are carried out in a manner that does not present any risk to the quality of the cannabis.
  - The presence of odours surrounding the facility is monitored in accordance to a schedule and responded to if necessary.
  - Inspection and repair activities occur when required.

The record keeping requirements associated with this GPP requirement are found under s. 231(1)(a) and (2)(a) of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix E.

Examples of records pertaining to s. 85 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 are records of maintenance and service of filtration systems and replacements of filters.

5.1.4.3 Equipment

As per s. 86 of the *Cannabis Regulations,* cannabis must be produced, packaged, labelled, stored, sampled and tested using equipment that is designed, constructed, maintained, operated and arranged in a manner that permits the effective cleaning of its surfaces, permits it to function in accordance with its intended use, prevents the contamination of the cannabis, and, except in the case of outdoor cultivation, propagation or harvesting, prevents the addition of an extraneous substance to the cannabis.

Examples of **principles or practices** that may demonstrate compliance with s. 86 are as follows:

- Design, construction, operation and arrangement of equipment and utensils
    - Equipment is stored in clean and dry conditions that optimize the flow of material while minimizing the movement of personnel. Clean or sanitized equipment is stored in an area separate from used or dirty equipment and in a manner that prevents re-contamination. Any equipment deemed defective is removed or clearly labelled as defective when removal is not feasible.
    - Balances and measuring equipment of an appropriate range, precision and accuracy are used.
    - Repairs are permanent and durable in nature. Temporary repairs (e.g., with tape) are avoided.
    - Repair and maintenance operations are performed in a manner that does not present a risk to the quality of the cannabis, taking into consideration the location of the repairs relative to the cannabis.
- Maintenance program
    - Written maintenance and calibration programs are implemented and include a list of equipment and utensils with their locations requiring regular maintenance and calibration (e.g., balances and pH meters). These programs include instructions on how to perform such activities, frequencies of such activities, measures to be taken if equipment does not function as intended, identification of the individuals who are assigned the responsibility for the maintenance and calibration procedures and names of external companies conducting such activities if applicable.

The record keeping requirements associated with this GPP requirement are found under s. 231(1)(a) and (2)(a) of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix E.

Examples of records pertaining to s. 86 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 are records of maintenance and servicing of equipment (e.g., cleaning, repair and calibration) used during all steps of production, packaging, labelling, storage, sampling and testing.

5.1.5 *Sanitation program*

As per s. 87 of the *Cannabis Regulations,* cannabis must be produced, packaged, labelled, stored, sampled and tested in accordance with a sanitation program. The sanitation program must set out:

- Procedures for effectively cleaning the building or part of the building where those activities with cannabis are conducted (this does not apply to outdoor cultivation, propagation or harvesting of cannabis);
- Procedures for effectively cleaning the equipment used in those activities with cannabis;
- Procedures for handling any substance used in those activities; and
- Any health and hygiene requirements for personnel necessary to ensure sanitary conditions.

Examples of **principles or practices** that may demonstrate compliance with s. 87 are as follows:

- The building (where applicable), equipment and utensils (e.g., pruning shears, pots, trays, extractors, beakers) is cleanable and capable of withstanding repeated sanitizing or disinfecting (e.g., be smooth, non-reactive, corrosion-resistant, non-toxic) as per approved SOPs.
- The sanitation program specifies the locations and/or equipment to be cleaned, the cleaning agents to be used, the mixing instructions, the temperature controls, the person(s) responsible, the frequency of each activity and the detailed procedures for cleaning and/or sanitizing.
- The effectiveness of the sanitation program is monitored and verified. Where applicable, the QAP responsible for overseeing the implementation and effectiveness of the sanitation program. Any changes that may affect the cleaning process are assessed and documented.
- Approved SOP(s) listing the basic health and hygiene requirements are made available to all personnel involved in cleaning the building or part of the building and equipment or in handling substances used in those activities with cannabis.
- Effective pest control programs are in place to prevent the entry of pests to any part of the building, to detect and eliminate pests and to prevent the contamination of cannabis.

The record keeping requirements associated with this GPP requirement are found under s. 231(1)(a) and (2)(a) of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix E.

Examples of records pertaining to s. 87 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 are as follows:

- Building and equipment cleaning records.
- Equipment maintenance records.
- Employee training records.

- Cleaning solution usage and preparation records.

5.1.6 *Quality assurance*

The information in section 5.1.6 applies only to processing licence holders.

The licensing requirements related to the QAP are found in s. 19 of Part 2 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix C and the Cannabis Licensing Application Guide. The record keeping requirements associated with the QAP's training, experience and technical knowledge licensing requirement are found under s. 231(1)(e) and (2)(d) of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix E.

A licence holder may have employees in addition to the QAP (or alternate QAP) who carry out activities related to the Quality Assurance requirements under s. 88 of the *Cannabis Regulations*. The QAP may assign duties to a person who has the relevant knowledge, training and experience; however, the QAP remains responsible for the quality of the cannabis produced and investigating complaints as per s. 19 of the *Cannabis Regulations*.

The QAP should be able to demonstrate that each individual who has been assigned duties has the training, experience and technical knowledge related to the licensed activities, as well as appropriate knowledge of the requirements of Part 5 in relation to the duties and responsibility assigned to them. This may include letters of reference, a copy of a diploma or certificate and any other documentation supporting their qualifications, training and experience.

In order to demonstrate that the QAP maintains accountability and overall responsibility of the requirements, the QAP may:

- Follow a written program to assess and train these individuals;
- Record specific duties for all staff who have been assigned quality assurance activities in a written work description;
- Ensure that the assignment of duties to any one individual is such that quality is not put at risk or compromised; and
- Periodically assess that licensed activities are conducted in accordance with the requirements of Part 5, including a review of performance of individuals who have been assigned duties. This may include random verification of various quality processes, such

as approval of lots or batches of cannabis, ensuring that SOPs are reflective of actual practices, or reviewing documents and interviewing staff to ensure duties are being conducted appropriately.

5.1.6.1 Investigation of quality-related complaints

As per s. 19(2) and 88(1) of the *Cannabis Regulations*, licence holders must have a QAP who is responsible for investigating every complaint received in respect of the quality of the cannabis and, if necessary, take corrective and preventative measures.

All complaints and other information concerning the quality of the cannabis must be reviewed according to approved procedures established by the licence holder. The complaint should be recorded with all the original details and thoroughly investigated. The complaint must be evaluated, an investigation must be conducted, and appropriate corrective and/or preventative action(s) must be taken (e.g., putting the lot or batch on hold until the investigation is completed). Complaint records should be routinely verified to ensure that all adverse reactions (including serious adverse reactions) are documented and reported in accordance with s. 248 of the *Cannabis Regulations*.

Licence holders may choose to keep additional samples of a lot or batch for their own purposes in order to investigate quality-related complaints and make a determination on whether a recall may be required.

Licence holders are required to report adverse reactions. Reports on serious adverse reactions must be submitted to the Minister within 15 days after the licence holder becomes aware of them; all other adverse reactions must be recorded in an annual summary report.

For more information on adverse reactions and recall reporting requirements, refer to the *Cannabis recalls, adverse reactions and reporting* page on Health Canada's website. Information on requirements related to voluntary recalls of cannabis and cannabis products can also be found in Health Canada's *Cannabis voluntary recall guide* .

The record keeping requirements associated with this GPP requirement are found under s. 231(1)(e) and (2)(e) of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix E.

5.1.6.2 Methods and procedures

As per s. 88(2) of the *Cannabis Regulations,* cannabis must be produced, packaged, labelled, distributed, stored, sampled and tested using methods and procedures that, prior to their implementation, have been approved by the QAP.

If circumstances require a deviation from an approved SOP, the QAP must ensure that the deviation is assessed and documented and that all GPP requirements are still being met.

Licence holders should refer to section 5.1.1 of this guide for additional information regarding SOPs.

The record keeping requirements associated with this GPP requirement are found under s. 232 of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix E.

5.1.6.3 Approval prior to sale

As per s. 88(3) of the *Cannabis Regulations*, every lot or batch of cannabis must be approved before it is made available for sale.

The QAP must ensure that the composition and pesticide testing results are reviewed and assessed to confirm the results are within the identified specification(s). Additionally, the QAP must ensure that the documentation for each lot or batch is reviewed and verified, and that the documentation demonstrate that the lot or batch has been produced in accordance with the approved SOPs. Only when there is confidence that the lot or batch was produced, packaged, labelled, distributed, stored, sampled and, where applicable, tested in accordance with Part 5 should the lots or batches be approved for sale.

The record keeping requirements associated with this GPP requirement are found under s. 231(1)(a) and (2)(a) of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix E.

5.2 Testing requirements

As per s. 89 of the *Cannabis Regulations,* licence holders must not sell cannabis products to a person authorized to sell under s. 69 of the Act or to a holder of a licence for sale and licence holders must not export cannabis products, unless the applicable requirements set out in s. 90 to 92 of the *Cannabis Regulations* have been met. This section of the guide outlines these requirements in further detail.

5.2.1 *Composition testing*

As per s. 91 of the *Cannabis Regulations,* composition testing must be conducted on each lot or batch of cannabis, other than cannabis plants or cannabis plant seeds that will become a cannabis product or that will be contained in a cannabis accessory that is a cannabis product.

The mandatory components to be tested using validated methods are as follows:

- Residues of solvents referred to in s. 93(3)
- Microbial and chemical contaminants referred to in s. 94
- Dissolution and disintegration tests referred to in s. 95
- Quantity or percentage of THC, THCA, CBD and CBDA, as the case may be

Additional requirements associated with the composition testing requirement are found under s. 93(3), 94, 95, 91(d) and 99 of Part 6 of the *Cannabis Regulations*. For more information on these requirements, refer to Table 6, Appendix D.

Testing must be performed against the identified pharmacopeial specification(s) before a lot or batch of cannabis product is made available for sale. The specification(s) for the cannabis to be tested against should be identified, documented, supported by adequate justification and, where applicable, approved by the QAP prior to testing.

The testing must be conducted using validated methods (as per s. 90 of the *Cannabis Regulations).* Licence holders are responsible for demonstrating that the methods used for testing were validated prior to being used. The results of validation studies must be documented and maintained in accordance with s. 231 of the *Cannabis Regulations*.

Guidance for validation can be obtained in publications such as the *Q2B: Validation of Analytical Procedures: Methodology*, published by Health Canada or any standard listed in *Schedule B to the Food and Drugs Act (FDA).*

Licence holders must have an approved SOP in place to describe the testing activities. The SOP may include information on reference standards and controls. Licence holders must also maintain records summarizing testing protocols followed (including the Schedule B standard chosen, and the test methods and associated specifications to be used) and detailed testing results for each batch or lot of cannabis.

Licence holders may either conduct composition testing in-house, or rely on a third party that holds a Health Canada licence for analytical testing to perform testing of their cannabis. However, if testing is performed by a third party, it is the licence holder's responsibility to:

- Ensure that the third-party testing facility holds a valid Health Canada licence for analytical testing and is eligible to possess and conduct activities with cannabis.

- Ensure that the third-party testing facility is using validated methods. This may include assessing the third-party testing facility's method validation(s) to ensure its suitability and maintaining records of this assessment.
- Ensure that the third-party testing facility uses the appropriate analytical methods that correspond to the licence holder's approved specifications captured in its approved SOP(s).
- Establish a list of the specifications and provide it to the third-party testing facility prior to any composition testing being conducted.

The samples used for testing must be representative of the lot or batch being tested and intended for sale. Licence holders should refer to section 5.2.2 of this guide for additional information regarding representative sampling.

The samples sent for testing should have undergone all required processing (e.g., drying, milling, freezing) and, subject to completion of the testing, should otherwise be ready for assessment (where applicable) prior to the lot or batch being approved for sale.

If a test result is outside of the identified specification, the product must not be approved for sale. Licence holders should not disregard test results that are out-of-specification (OOS) without scientific justification. OOS test results should be documented and investigated to determine the cause. The steps to be taken as part of an investigation in response to an OOS result (e.g., root cause, description of corrective actions and preventative actions carried out, and conclusions) should be outlined in the licence holder's approved SOP for testing.

Licence holders should not repeatedly test the product until result(s) are within the identified specification(s) (e.g., microbial and chemical contaminant testing) or until the desired result is obtained (e.g., quantity or percentage of THC or CBD content). If licence holders choose to conduct multiple tests, they must do so in accordance with an approved SOP that outlines pre-determined criteria for when additional testing, including retesting, would be required. If retests (whether retesting the same sample, or testing a new sample) are permitted by the licence holder, the maximum number of retests that can be performed should be documented in the SOP along with the criteria for when a retest would be permitted. When conducting testing, licence holders must always ensure that their validated methods are being followed.

Any additional processing, alterations or secondary treatments, and subsequent testing, that might be done on a lot or batch of cannabis after initial testing has been conducted should be justified in accordance with pre-determined criteria that have been outlined in an SOP, indicating when these additional activities would be permitted. In addition, the cannabis that has been processed, altered or treated after initial testing should undergo full composition testing and evaluation against all specifications prior to being made available for sale as a cannabis product.

The release specification(s) for the cannabis product to be approved for sale should be identified, documented, supported by adequate justification and, where applicable, approved by the QAP prior to the cannabis product being released for sale.

The quality of the cannabis could be adversely affected during processing activities (e.g., packaging) conducted after compositional testing. The licence holder is responsible for ensuring the quality of the cannabis after composition testing and until it is sold.

Licence holders should be aware that testing is only one component of GPP. As such, they must ensure that all GPP requirements are met throughout all stages, regardless of the test results of any lot or batch.

In addition to the testing required under Parts 5 and 6 *of the Cannabis Regulations*, the licence holder must be able to determine the following:

- Whether any PCPs were used on a lot or batch (s. 81 and 93(2)). For more information, refer to the *Mandatory cannabis testing for pesticide active ingredients - Requirements* page on Health Canada's website.
- That all of the components of the cannabis product are fit for the intended use, if the product is intended to be administered orally, rectally, vaginally or topically (s. 96).
- The THC yield quantities, taking into consideration the potential to convert THCA into THC, of the following:
    - Each discrete unit of a cannabis product (milligrams of THC) intended to be administered orally, rectally or vaginally (s. 97)
    - Cannabis oil that is a cannabis product or contained in a cannabis accessory that is a cannabis product (milligrams of THC per milliliter) (s. 101)
    - Each activation of a cannabis accessory that dispenses cannabis oil and that is packaged with a cannabis product that is cannabis oil or of a cannabis accessory that contains the oil, if the oil is intended to be taken by ingestion (milligrams of THC) (s. 102)

Additional information associated with the maximum yield quantity requirements is found under s. 97, 101 and 102 of Part 6 of the *Cannabis Regulations*. Refer to Table 7, Appendix D.

The record keeping requirements associated with this GPP requirement are found under s. 231(1)(a)(d) and (2)(a)(c) of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to Appendix E.

5.2.2 *Representative sample and quantity*

As per s. 92 of the *Cannabis Regulations,* a representative sample of each lot or batch must be taken for the purposes of the testing referred to in s. 90 to 91. A portion of this sample must be retained for at least one year after the date of the last sale of any portion of the lot or batch and must be of sufficient quantity to enable a determination of whether the lot or batch meets the following requirements:

- Residues of solvents and their limits used in the production of cannabis oil, (s. 91(a) and 93(3) of the *Cannabis Regulations*)
- Microbial and chemical contaminants (s. 91(b) and 94 of the *Cannabis Regulations*)
- Dissolution and disintegration (s. 91(c) and 95 of the *Cannabis Regulations*)
- Quantities or percentages of THC, THCA, CBD and CBDA (s. 91(d) of the *Cannabis Regulations*)
    - Maximum yield quantity—discrete unit (s. 97 of the *Cannabis Regulations*)
    - Maximum yield quantity—cannabis oil (s. 101 of the *Cannabis Regulations*)
    - Maximum yield quantity—activation of accessory (s. 102 of the *Cannabis Regulations*)
- Pest control product (s. 81 and 93(2) of the *Cannabis Regulations*)

The sample used for testing must be representative of the lot or batch (i.e., a quantity of cannabis whose characteristics represent, as accurately as possible, the entire lot or batch) that would be sold or exported. The quantity and quality of the samples should be proportional to and reflective of the total lot or batch.

Additional guidance on sampling procedures may be obtained in pharmacopeias (e.g., Herbal Drugs: Sampling and Sample Preparation of the British Pharmacopeia).

The samples must be collected according to the licence holder's approved SOP(s), and sampling procedures must be carried out under sanitary conditions, as per Part 5 of the *Cannabis Regulations*.

The samples must be maintained in accordance with an approved SOP. The samples should be retained in the same immediate containers in which they are sold, or in containers that are equivalent with respect to stability. The samples must be stored under appropriate conditions that do not adversely affect their integrity. Additionally, they should be stored according to the conditions set out on the label, and in a manner that enables immediate identification

Table 1 provides the minimum suggested sample sizes that may be considered sufficient for Health Canada to enable the testing required under s. 92 (2) of the *Cannabis Regulations*.

Table 1: Sample sizes: Minimum quantities that may be sufficient for laboratory testing			
	Dried and fresh cannabis	Cannabis oil	Discrete units
Residues of solvents	N/A	2g or mL	10 units (or equivalent of 2g of cannabis product)
Microbial contaminants	70g	70g	Equivalent to 70g of cannabis product
Chemical contaminants	15g	15g or mL	50 units (or equivalent of 15g of cannabis product)
Disintegration	N/A	N/A	20 units
Dissolution	N/A	N/A	24 units
Quantity or percentage of THC, THCA, CBD, and CBDA	5g	5g or mL	20 units (or equivalent of 5g of cannabis product)
TOTAL	90g	92g	Equivalent to 92g of cannabis product (or 80 units + 70g) + 20 units or 24 units for disintegration or dissolution respectively

In the case where there are no remaining portions of a lot or batch of cannabis that could be used for testing, retained samples may be required for testing (e.g. when conducting investigations pertaining to quality-related complaints). A sample must be maintained to allow Health Canada to conduct additional testing as required, until the one year period after the date of the last sale of any portion of the lot or batch elapses. The licence holder may also choose to keep a sample for their own testing purposes.

6.0 Contact us

Licence holders who have questions about the information or requirements in this guide are invited to contact the Controlled Substances and Cannabis Branch at cannabis@canada.ca .

For questions related to Health Canada inspections, licence holders may contact the Regulatory Operations and Enforcement Branch at HC.Inspections-Cannabis-Inspections.SC@canada.ca .

7.0 Feedback—Help us improve

Health Canada is committed to providing all stakeholders with timely, accurate and reliable information. This includes providing applicants and licence holders with the information they need to comply with the *Cannabis Act* and its Regulations.

We would appreciate receiving your feedback on whether this guide was useful, and we welcome your suggestions for improvement. Email your feedback to us at cannabis@canada.ca and indicate in the subject line Feedback on the Good Production Practices Guide for Cannabis.

Your comments will help us improve this guide.

Appendix A: GPP requirements by licence class

Tables 2 provides a general summary of the GPP requirements that apply for each licence class. However, different GPP requirements may apply depending on the activities associated with each individual licence. Refer to the *Cannabis Regulations* for further information.

Table 2 : General GPP requirements by licence class

GPP requirement (section of the *Cannabis Regulations*)	Cultivation: standard, micro & nursery	Processing: standard & micro	Sale for medical purposes	Analytical testing
Standard operating procedures (s. 80)	Required	Required	Required	N/A[1]
Pest control product (s. 81)	Required	Required	N/A	N/A
Storage (s. 82)	Required	Required	Required	N/A[1]
Distribution (s. 83)	Required	Required	Required	N/A
Building or part of a building (s. 84)	Required[2]	Required	Required	N/A[1]
Filtration of air (s. 85)	Required	Required	Required	N/A[1]
Equipment (s. 86)	Required[3]	Required	N/A	N/A[1]
Sanitation program (s. 87)	Required[4]	Required	N/A	N/A[1]
Quality assurance (s. 88(1))	N/A	Required	N/A	N/A
Methods and procedures (s. 88(2))	N/A	Required	N/A	N/A
Approval prior to sale (s. 88(3))	N/A	Required	N/A	N/A

[1] Analytical testing licence holders should take the necessary steps to comply with the GPP requirements associated with the activities they are conducting.

[2] This requirement does not apply to cultivation licence holders who obtain cannabis by cultivating, propagating or harvesting it outdoors; however, it does apply to cultivation licence holders who conduct those activities indoors.

[3] Section 86(1)(d) of this requirement does not apply to the outdoor cultivation, propagation or harvesting of cannabis; however, it does apply to those activities being conducted indoors, and to all other activities with cannabis.

[4] Section 87(1)(a) of this requirement does not apply to the outdoor cultivation, propagation or harvesting of cannabis; however, it does apply to those activities being conducted indoors, and to all other activities with cannabis.

Appendix B: GPP requirements by class of cannabis

Tables 3 and 4 provide a general summary of the GPP requirements that apply for each class of cannabis. However, different GPP requirements may apply depending on the activities associated with each individual licence. Refer to the *Cannabis Regulations* for further information.

Table 3: General GPP requirements by class of cannabis

GPP requirement[2] (section of the *Cannabis Regulations*)	Dried cannabis	Fresh cannabis	Cannabis oil	Cannabis plants	Cannabis plant seeds
Standard operating procedures (s. 80)	Required	Required	Required	Required	Required
Pest control product (s. 81)	Required	Required	Required	Required	Required
Storage (s. 82)	Required	Required	Required	Required	Required
Distribution (s. 83)	Required	Required	Required	Required	Required
Building or part of a building (s. 84)	Required	Required	Required	Required	Required
Filtration of air (s. 85)	Required	Required	Required	Required	Required
Equipment (s. 86)	Required	Required	Required	Required	Required
Sanitation program (s. 87)	Required	Required	Required	Required	Required
Quality assurance (s. 88(1))	Required[1]	Required[1]	Required[1]	Required[1]	Required[1]
Methods and procedures (s. 88(2))[1]	Required[1]	Required[1]	Required[1]	Required[1]	Required[1]
Approval prior to sale (s. 88(3))[1]	Required[1]	Required[1]	Required[1]	Required[1]	Required[1]

[1] This GPP requirement must be met by holders of a processing licence only.
[2] Cannabis that is produced in an intermediate step between two classes of cannabis (e.g., resin) is also subject to the applicable GPP requirements.

Table 4: Testing GPP requirements by class of cannabis					
GPP requirement (section of the *Cannabis Regulations*)	Dried cannabis	Fresh cannabis	Cannabis oil	Cannabis plants	Cannabis plant seeds
Validated methods (s. 90)	Required	Required	Required	N/A	N/A
Composition (s. 91)	Required	Required	Required	N/A	N/A
Representative sample (s. 92(1))	Required	Required	Required	N/A	N/A
Quantity (s. 92(2))	Required	Required	Required	N/A	N/A
Microbial and chemical contaminants (s. 94)	Required	Required	Required	N/A	N/A
Dissolution and disintegration (s. 95)	Required	Required	Required	N/A	N/A
Residues of solvents (s. 93(3))	N/A	N/A	Required	N/A	N/A

Appendix C: Part 2 – Licensing requirements related to GPP

This appendix provides requirements and additional information pertaining to the QAP - s. 19 of the *Cannabis Regulations.*

Table 5: Quality Assurance Person Requirements	
Section of the *Cannabis Regulations*	Requirements and additional information
Quality assurance person (s. 19(1))	• Licence holders must retain the services of one individual as a QAP who has the training, experience, and technical knowledge related to the GPP requirements. • To qualify as a QAP, the individual must be able to demonstrate that they possess the training, experience and technical knowledge related to Part 5. • The QAP should be able to demonstrate how their qualifications pertain to the following: o SOP development and approval. o Pest control management, including appropriate use of PCPs and PCP testing. o Quality control relating to the storage and distribution of cannabis and other products/substances. o Implementation of GPP as they pertain to the building (including air filtration), equipment and sanitation. o Oversight of an effective sanitation program to ensure production, packaging, labelling, storage, sampling and testing activities involving cannabis are conducted under sanitary conditions. o Complaint management. o Approval of cannabis quality prior to it being made available for sale. o Validation and suitability of methods for composition testing. o Solvent residue testing for cannabis oil. o Microbial and chemical contaminants, and their generally accepted tolerance limits for herbal medicines for human consumption. o Dissolution and disintegration testing of discrete units, such as capsules or other similar dosage forms, and assessment of results. o Quantity or percentage of THC, THCA, CBD, and CBDA, as well as the maximum yield test results for cannabis oil, discrete units, and accessories containing cannabis.

Table 5: Quality Assurance Person Requirements	
Section of the *Cannabis Regulations*	Requirements and additional information
	○ Sample collection and retention. ○ Handling recalls and adverse reaction reports.
Responsibilities (s. 19(2))	• The QAP is responsible for: ○ Assuring the quality of the cannabis before it is made available for sale ○ Investigating every complaint received in respect of the quality of the cannabis, and taking corrective and preventative measures when necessary • More information on quality assurance can be found in section 5.1.6 of this guide.
Alternate (s. 19(3))	• Licence holders may have up to two alternate QAPs who are qualified to replace the QAP (e.g., during vacation, illness, etc.). • At any given time, there can only be one person acting as the QAP for a licence holder.

Appendix D: Part 6 – Cannabis Products requirements related to GPP

Table 6 provides requirements and additional information pertaining to the composition testing requirements – s. 91, as well as PCP residual limit requirements – s. 93 (2) of the *Cannabis Regulations.* Table 7 provides additional details on maximum yield quantities of various cannabis forms.

Table 6: Cannabis Products – Composition Testing under s. 91 and PCP residual limits under s. 93(2) of the *Cannabis Regulations*	
Section of the *Cannabis Regulations*	Requirements and additional information
Maximum Residue Limit – pest control product (s. 93(2))	• Applicable class(es) of cannabis that are cannabis products or that are contained in a cannabis accessory that are cannabis products: o Dried cannabis o Cannabis oil o Fresh cannabis o Cannabis plants o Cannabis plant seeds • Specification: PCP residues (including its components or derivatives) must be within the maximum residue limit, in relation to cannabis, specified for the PCP (including its components or derivatives) under s. 9 or 10 of the PCPA. • Reference document(s): o s. 9 or 10 of the PCPA o *Mandatory cannabis testing for pesticide active ingredients - Requirements*
Cannabis oil (s. 93(3))	• Applicable class(es) of cannabis that are cannabis products or that are contained in a cannabis accessory that are cannabis products: o Cannabis oil • Specification: Cannabis oil may only contain: o Acceptable residues of pest control product set out in s. 93(2). o Carrier oil. o Residues of solvents listed in the document entitled *Limits for Residual Solvents in Cannabis Products.*, published by the Government of Canada and amended from time to time, that do not exceed the limits established in that document.

Table 6: Cannabis Products – Composition Testing under s. 91 and PCP residual limits under s. 93(2) of the *Cannabis Regulations*	
Section of the *Cannabis Regulations*	Requirements and additional information
	○ Other substances that are necessary to maintain the oil's quality and stability. • Residue limits: ○ Licence holders must be able to demonstrate that no residues exceeding the maximum limits established are present in their cannabis oil that is a cannabis product. ○ Limits for residual solvents are listed in the *Limits for Residual Solvents in Cannabis Products*. • Additional information: ○ Testing requirements may differ depending on the solvent class. Refer to the *Limits for Residual Solvents in Cannabis Products* for more information. ○ The licence holder's records should clearly identify the established residual solvent limit (to which the testing results will be compared) and the validated method(s) used for testing. ○ The licence holder's records should identify the carrier oil used. ○ The licence holder's records should identify any solvents used in the production of cannabis oil or in the cleaning of equipment or surfaces that come in contact with the cannabis or any substances added to the cannabis oil product. ○ If the licence holder is using other substances that maintain the quality and stability of the cannabis oil, they should be able to provide evidence that supports the use of those substances.
Microbial and chemical contaminants (s. 94)	• Applicable class(es) of cannabis that are cannabis products or that are contained in a cannabis accessory that are cannabis products: ○ Dried cannabis ○ Cannabis oil ○ Fresh cannabis • Specification: Must be within generally accepted tolerance limits of microbial and chemical contaminants for herbal medicines for human consumption, as established in any publication referred to in Schedule B to the FDA. • Reference document(s):

Table 6: Cannabis Products – Composition Testing under s. 91 and PCP residual limits under s. 93(2) of the *Cannabis Regulations*	
Section of the *Cannabis Regulations*	Requirements and additional information
	○ Schedule B of the FDA • Additional information: ○ Schedule B of the FDA lists recognized international publications that set technical specifications for pharmaceutical drugs, herbal medicines and dietary supplements. ○ Licence holders should maintain consistent specifications for their products according to these publications, and assess each lot or batch of cannabis against those specifications before approving it for sale. ○ The methods used for testing should correspond to the specifications chosen (e.g., a specification of absence in 10 g for E. coli should be tested using 10 g of cannabis rather than 1 g). The release specifications should be consistent with the pharmacopeial specification and method chosen, or tighter. ○ It is the licence holder's responsibility to establish the appropriate specifications and methods to be used for testing. ○ Methods should be validated in accordance with the applicable method and specification in the chosen pharmacopeia.
Dissolution and disintegration (s. 95)	• Applicable class(es) of cannabis that are discrete units of cannabis products that are intended to be administered orally, rectally or vaginally: ○ Dried cannabis ○ Cannabis oil ○ Fresh cannabis • Specification: Must meet the requirement(s) of a dissolution or disintegration test that is applicable to the formulation of the discrete unit. • Reference document(s): ○ Schedule B of the FDA • Additional information: ○ The established disintegration tolerance limits state the number of discrete units to be tested to demonstrate acceptable disintegration of the product.

Table 6: Cannabis Products – Composition Testing under s. 91 and PCP residual limits under s. 93(2) of the *Cannabis Regulations*	
Section of the *Cannabis Regulations*	Requirements and additional information
Quantity or percentage of THC, THCA, CBD and CBDA (s. 91(d) & 99)	• Applicable class(es) of cannabis that are cannabis products or that are contained in a cannabis accessory that are cannabis products: o Dried cannabis o Cannabis oil o Fresh cannabis • Specification: o The quantity or percentage of THC, THCA, CBD and CBDA, must be determined using validated methods to establish the levels present in each batch or lot of cannabis that will become a cannabis product. o THC or THCA must not be added to dried or fresh cannabis that will become a cannabis product, or that is or will be contained in a cannabis accessory. • Additional information: o Documentation on methods, test limits, results and calculations used should be maintained with information on each lot or batch. o The quantity or percentage of THC and CBD, as well as the quantities of THC and CBD that could be yielded, taking into consideration the potential to convert THCA into THC and CBDA into CBD, must be set out on each individual label on the cannabis product package in accordance with s. 124 to 127, where applicable.

Table 7: Specification details		
Section of the *Cannabis Regulations*	Applicable class(es) of cannabis	Specification
Discrete unit (s. 97)	o Dried cannabis o Cannabis oil o Fresh cannabis	Each discrete unit of a cannabis product that is intended to be administered orally, rectally or vaginally must not exceed a maximum yield quantity of 10 mg of THC, taking into account the potential to convert THCA into THC.
Cannabis oil (s. 101)	o Cannabis oil	Cannabis oil that is a cannabis product or contained in a cannabis accessory that is a cannabis product must not exceed a maximum yield quantity of 30 mg of THC per millilitre of the oil, taking into account the potential to convert THCA into THC.
Cannabis accessory (s. 102)	o Cannabis oil	Each activation of a cannabis accessory that dispenses cannabis oil and that is packaged with a cannabis product that is cannabis oil or of a cannabis accessory that contains the oil, if the oil is intended to be taken by ingestion, must not dispense more than a maximum yield quantity of 10 mg of THC, taking into account the potential to convert THCA into THC.
Additional Information		
The maximum yield of THC should be calculated using the established conversion factor for the decarboxylation of the THCA into THC (i.e., the decarboxylated equivalent mass). The conversion factor used should be documented, supported by adequate justification and approved by the QAP prior to use. It is not acceptable to report the percentage of THC using an anhydrous conversion factor. An anhydrous conversion factor calculates the cannabinoid content of cannabis on its dry mass matter content; it removes the water content of the cannabis from the calculations, and determines the cannabinoids as a percentage of the remaining dry components. The final result of this calculation is an increased cannabinoid percentage, as compared to a calculation using the whole cannabis, water included; it does not reflect cannabis as it is consumed by a patient or client.		

Appendix E: Part 11 – Retention of Documents and Information requirements related to GPP

This appendix summarizes the record keeping requirements pertaining to GPP. It provides the relevant section references between Parts 5 and 11.

Table 8: Retention of documents and information under Part 11 associated with GPP requirements		
GPP reference (Section of the *Cannabis Regulations*)	Retention of documents and information Section # of the *Cannabis Regulations*	Requirements and additional information
Distribution (s. 83)	s. 227	Licence holders must document the information set out in s. 227 regarding the sale, distribution and export of cannabis. These documents must be retained for at least two years after the day on which they were prepared.
Storage (s. 82) Building or part of a building (s. 84) Filtration of air (s. 85) Equipment (s. 86) Sanitation (s. 87) Approval prior to sale (s. 88(3)) Validated methods (s. 90) Composition (s. 91)	s. 231(1)(a) and (2)(a)	For each lot or batch of cannabis that has been sold or exported, a licence holder must retain records demonstrating that cannabis was produced, packaged, labelled, distributed, stored, sampled and tested in accordance with the requirements of Part 5. These records should allow traceability back to the specific lot or batch, such that each lot or batch can be easily identified, allowing for quick referencing of testing methods, test results, and, where applicable, the decision to approve or disapprove that lot or batch for sale. These records must be retained for at least two years after the day the last sale or export of any portion of the lot or batch took place.
Pest control product (s. 81)	s. 231(1)(c) and (2)(b)	Licence holders must retain records demonstrating their use of PCPs applied directly or indirectly to cannabis, including the name of the substance, the quantity used, the method and date of application and the rationale for the use of the PCP.

Table 8: Retention of documents and information under Part 11 associated with GPP requirements		
GPP reference (Section of the *Cannabis Regulations*)	Retention of documents and information Section # of the *Cannabis Regulations*	Requirements and additional information
		These documents must be retained for two years after the day on which they were prepared.
Validated methods (s. 90) Composition (s. 91)	s. 231(1)(d) and (2)(c)	Licence holders must retain documentation describing the validated test methods used and any assessment made by the licence holder ensuring the methods are validated. In addition, licence holders must retain documentation containing the test results for each lot or batch tested. For any lot or batch that has undergone additional processing, alteration(s) or secondary treatments(s) after the initial testing is conducted, associated documentation must be maintained on that additional activity. In addition, all test results of that lot or batch must be maintained. Any investigations that occurred in response to an OOS test result should also be retained and an explanation should be recorded. Documentation describing the validated test methods used must be retained for at least two years after the day on which they are replaced. Records demonstrating compliance with Part 5, as well as the original testing results along with any subsequent testing results must be retained for at least two years after the day the last sale or export of any portion of the lot or batch took place.
Quality assurance person (s. 19 & 88)	s. 231(1)(e) and (2)(d)	Where applicable, licence holders must retain a document that describes the qualifications of the QAP and any alternate QAP, demonstrating their training, experience and technical knowledge related to the licensed activities and the requirements of Part 5. This should include letters of reference, a copy of the diploma/certificates and any other documentation

Table 8: Retention of documents and information under Part 11 associated with GPP requirements		
GPP reference (Section of the *Cannabis Regulations*)	Retention of documents and information Section # of the *Cannabis Regulations*	Requirements and additional information
		supporting the qualifications, training and experience of the QAP. These records must be retained for the period during which the QAP or alternate QAP acts in that capacity and for at least two years after the day on which the person ceases to be in the role.
Investigation of quality-related complaints (s. 88(1))	s. 231(1)(e) and (2)(e)	Where applicable, licence holders must retain documentation concerning every complaint received in respect of the quality of cannabis and of any corrective or preventative measures taken. This documentation must be retained for at least two years after the day on which it was prepared. Details of investigations must be recorded (e.g., information on the assessment of the quality of the corresponding lot or batch, the decision of whether to take further corrective and preventative actions and the justification of that decision, etc.). All decisions and measures taken in response to a complaint should be recorded and referenced to the corresponding lot or batch records. Complaint records should be regularly reviewed for any indication of specific or recurring problems that require attention.
Standard operating procedures (s. 80) Methods and procedures (s. 88(2)) Sanitation (s. 87)	s. 232	Licence holders must maintain documentation describing the SOPs and the sanitation program that are in use at the site. This should include proof of the QAP's approval of the methods and procedures prior to use at the site, where applicable. Documentation of SOPs, the sanitation program, and records of their approval (if applicable) must be retained for the period during which they are current and for an additional period of two years after the day on which they are replaced by a new version.

Table 8: Retention of documents and information under Part 11 associated with GPP requirements		
GPP reference (Section of the *Cannabis Regulations*)	Retention of documents and information Section # of the *Cannabis Regulations*	Requirements and additional information
		To demonstrate compliance, details of any deviation from an SOP (e.g., the reason for the deviation, whether it was planned, assessment of GPP impacts, etc.) should be recorded and retained for the period during which the corresponding SOP is current and for at least two years after the day on which it is replaced by a new version.