



GOOD PRODUCTION PRACTICES GUIDE FOR CANNABIS

**Requirements under Part 5 of
the *Cannabis Regulations***



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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

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Lignes directrices sur les Bonnes Pratiques de Production du Cannabis

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Table of contents

1.0 Purpose	3
2.0 Background	3
3.0 Scope.....	4
4.0 Definitions and abbreviations.....	5
4.1 Definitions.....	5
4.2 Abbreviations.....	9
4.3 Icons.....	9
5.0 Good production practices: Regulatory requirements.....	10
5.1 General requirements.....	12
5.2 Additional requirements – Holder of a licence for processing	29
5.3 Testing requirements.....	46
6.0 Contact us	55
7.0 Feedback—Help us improve	55
Appendix A: GPP requirements by licence class.....	56
Appendix B: GPP requirements by class of cannabis.....	59
Appendix C: Part 2 – Licensing requirements related to GPP.....	64
Appendix D: Part 6 – Cannabis Products requirements related to GPP	67
Appendix E: Part 11 – Retention of documents and information requirements related to GPP	74
Appendix F: Preventive control plan best practices.	78

1.0 Purpose

This document provides guidance to federally regulated holders of a licence under the *Cannabis Act* ("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, packaged, labelled, distributed, stored, sampled, tested and sold in Canada, as well as cannabis that is to be exported from Canada.



Please note that this Guide contains the GPP requirements of the *Cannabis Regulations* for holders of a licence for cultivation, processing or sale for medical purposes for activities conducted with cannabis, on, or after October 17, 2019, and for activities conducted with a cannabis extract, a cannabis topical or edible cannabis, or any accessory that contains any of these prior to October 17, 2019, which will be sold, distributed or exported as a cannabis product after this date.

Additionally, a 12-month transition period is provided for:

- Dried or fresh cannabis in relation to microbial and chemical contaminants, permitting that the tolerance limits may comply with the *Cannabis Regulations* as they read prior to October 17, 2019.
- Activities in relation to cannabis oil, permitting cannabis oil to be sold as a class of cannabis (by federal licence holders and provincially and territorially authorized distributors and sellers), subject to the *Cannabis Regulations* as they read prior to October 17, 2019.

Refer to [section 5.0](#) of this guide and sections 73 to 81 (i.e., the transitional provisions) of the *Regulations Amending the Cannabis Regulations (New Classes of Cannabis)* for the further information on the transitional provisions.

For further guidance on the GPP requirements of the *Cannabis Regulations* as they read prior to October 17, 2019, refer to the Good Production Practices Guide for Cannabis, as released on June 5, 2019.

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* addresses the GPP requirements that are designed 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 measures by

Health Canada, including unannounced inspections where inspectors verify adherence to the regulations.

When 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, such as:

- 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 permit
- Issuance of an administrative monetary penalty of up to \$1 million
- Issuance of a ministerial order to recall products from the market, conduct tests or studies, produce information or documents or take other measures

For more information on compliance and enforcement measures, 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 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 the compliance of those licence holders with the GPP requirements set out in Part 5 of the *Cannabis Regulations*.

As per section 3 of the *Cannabis Regulations*, the GPP requirements do not apply to the holder of a cannabis drug licence.

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

- [Dried cannabis](#)
- [Fresh cannabis](#)
- [Cannabis plants](#)
- [Cannabis plant seeds](#)
- [Edible cannabis](#)

- [Cannabis extracts](#)
- [Cannabis topicals](#)

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

- [General Requirements](#): Applies to all cannabis, including all [classes of cannabis](#), all [cannabis products](#) of those classes, and all things that will be considered as [ingredients](#) that are to be sold, distributed or exported by a licence holder other than a holder of a licence for analytical testing or a holder of a licence for research.
- [Additional Requirements - Holder of a licence for processing](#): Applies to cannabis and anything that will be used as an ingredient that is to be sold, distributed or exported by a holder of a licence for processing.
- [Testing Requirements](#): Applies to cannabis within the following classes: dried cannabis, fresh cannabis, edible cannabis, cannabis extracts, and cannabis topicals.

Additionally, the [appendices](#) 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. Some definitions that appear in the Act or in the Regulations are included in this section for ease of reference, and others appear for the purpose of the guide.

Acceptable level: As defined in subsection 78(1) of the *Cannabis Regulations*, means a level of a biological, chemical or physical hazard that does not present a risk of contamination of the cannabis or anything that will be used as an ingredient.

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

Agronomic input: An input that is used in growing of cannabis or an ingredient, and includes agricultural chemicals, biological controls, pollinators, commercial fertilizers, compost, compost tea, green manure, manure, mulch, row covers, soil amendments and pulp sludge.

Bulk cannabis: Any cannabis that has not yet been packaged as a cannabis product.

Cannabis: As defined in subsection 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 subsection 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 extract: As defined in subsection 1(1) of the *Cannabis Regulations*, means,

- (a) a substance produced by
 - (i) subjecting anything referred to in item 1 of Schedule 1 to the Act to extraction processing;
 - or
 - (ii) synthesizing a substance that is identical to a phytocannabinoid produced by, or found in, a cannabis plant; or
- (b) a substance or mixture of substances that contains or has on it a substance produced in a manner referred to in paragraph (a).

It does not include a cannabis topical or edible cannabis.

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

Cannabis plant seed: A seed of a cannabis plant.

Cannabis product: As defined in subsection 1(2) of the *Cannabis Regulations*, means cannabis of only one of the classes 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. It does not include cannabis intended for an animal, a cannabis accessory that contains cannabis that is intended for an animal, or a drug containing cannabis.

Cannabis topical: As defined in subsection 1(1) of the *Cannabis Regulations*, means a substance or mixture of substances that contains or has on it anything referred to in item 1 or 3 of Schedule 1 to the Act and that is intended for use, directly or indirectly, exclusively on external body surfaces, including hair and nails.

Class of cannabis: Any one of the classes outlined in Schedule 4 to the Act (i.e. dried cannabis, fresh cannabis, cannabis plants, cannabis plant seeds, edible cannabis, cannabis extracts, or cannabis topicals).

Contaminated: As defined in subsection 1(2) of the *Cannabis Regulations*, means, in respect of cannabis, a cannabis accessory or an ingredient, containing or having on it anything – including a micro-organism but excluding anything referred to in item 1 or 3 of Schedule 1 to the Act – that may render the cannabis or ingredient injurious to human health or unsuitable for human use.

Control measure: As defined in subsection 78.1 of the *Cannabis Regulations*, means a measure that can be applied to prevent or eliminate any biological, chemical or physical hazard that

presents a risk of contamination of the cannabis or anything that will be used as an ingredient, or to reduce the hazard to an acceptable level.

Critical control point: A step at which the application of a control measure is essential to prevent or eliminate any biological, chemical or physical hazard that presents a risk of contamination of the cannabis or anything that will be used as an ingredient, or to reduce the hazard to an acceptable level.

Discrete unit: Refers to, in the case where a single immediate container contains more than 1 unit of a cannabis product, each of those units. Examples could include multiple pre-rolled joints, capsules, separate edible pieces, etc.

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

Edible cannabis: As defined in subsection 1(1) of the *Cannabis Regulations*, means a substance or mixture of a substance that contains or has on it anything referred to in item 1 or 3 of Schedule 1 to the Act and that is intended to be consumed in the same manner as food. It does not include dried cannabis, fresh cannabis, cannabis plants or cannabis plant 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.

Food: As defined in subsection 1(2) of the *Cannabis Regulations*, has the same meaning as in section 2 of the *Food and Drugs Act*.

Food additive: As defined in subsection 1(2) of the *Cannabis Regulations*, means any substance the use of which results, or may reasonably be expected to result, in it or its by-products becoming a part of, or affecting the characteristics of, a food or edible cannabis, but does not include anything referred to in item 1 or 3 of Schedule 1 to the *Cannabis Act*; or anything that is excluded from the definition food additive in subsection B.01.001(1) of the *Food and Drug Regulations*.

Food allergen: As defined in section 105 of the *Cannabis Regulations*, has the same meaning as in subsection B.01.010.1(1) of the *Food and Drugs Regulations*.

Fresh cannabis: As defined in subsection 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 subsection 1(2) of the *Cannabis Regulations*, means the container that is in direct contact with cannabis that is a cannabis product or – if a wrapper is in direct contact with the cannabis – with the wrapper.

Ingredient: As defined in subsection 1(2) of the *Cannabis Regulations*, means

- (a) in the case of a cannabis extract or cannabis topical, a substance, other than a substance referred to in item 1 or 3 of Schedule 1 to the Act, that is intended to be present in the final form of the cannabis extract or cannabis topical; and
- (b) in the case of edible cannabis,

- (i) a substance, other than a substance referred to in item 1 or 3 of Schedule 1 to the Act,
 - (A) that is used to make the edible cannabis where the use results, or may reasonably be expected to result, in the substance or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis, or
 - (B) that is part of a mixture of substances referred to in item 2 of the Schedule that is used to make the edible cannabis where the use results, or may reasonably be expected to result, in the substance or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis, or
- (ii) a mixture of substances, other than a mixture of substances that are referred to in item 1 or 3 of Schedule 1 to the Act,
 - (A) that is used to make the edible cannabis where the use results, or may reasonably be expected to result, in the mixture or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis, or
 - (B) that is part of a mixture of substances referred to in item 2 of the Schedule that is used to make the edible cannabis where the use results, or may reasonably be expected to result, in the first mixture or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis.

Licence holder: The holder of a licence, as listed in section 8 of the *Cannabis Regulations*.

Non-food chemical agents: Chemicals at the site that are not considered to be cannabis, a food or an ingredient, including cleaning chemicals, detergents, lubricants, petroleum products, and pest control products.

Pest control product: As defined in subsection 1(2) of the *Cannabis Regulations*, has the same meaning as in subsection 2(1) of the *Pest Control Products Act*. In addition, for the purposes of this guide, a pest control product may either have been authorized for use on cannabis specifically, or have been authorized for use on crops more generally, or alternatively, an individual may seek an authorization under section 10 of the *Pest Control Products Act* specific to their production.

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

- manufacturing;
- synthesis;
- altering its chemical or physical properties by any means; or
- cultivating, propagating or harvesting it or any living thing from which it may be extracted or otherwise obtained

Sanitary condition: As defined in section 78.1 of the *Cannabis Regulations*, means a condition that does not present a risk of contamination, allergen cross-contamination or introduction of an extraneous substance to the cannabis or anything that will be used as an ingredient.

Serious adverse reaction: As defined in subsection 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: 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	<i>Food and Drugs Act</i>
GPP	good production practices
OOS	out-of-specification
Part 5	Good Production Practices of the <i>Cannabis Regulations</i>
Part 6	Cannabis Products of the <i>Cannabis Regulations</i>
Part 11	Retention of Documents and Information of the <i>Cannabis Regulations</i>
PCPA	<i>Pest Control Products Act</i>
QAP	quality assurance person
SOP	standard operating procedure
s.	section number in the <i>Cannabis Regulations</i>
THC	delta-9-tetrahydrocannabinol
THCA	delta-9-tetrahydrocannabinolic acid
The Act	the <i>Cannabis Act</i>

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* requires licence holders to follow GPP to help ensure cannabis is produced consistently and that all activities conducted by licence holders with cannabis meet quality standards appropriate to the intended use of the cannabis.

Section 5 of this guide is organized into three sections:

- Section [5.1](#): General requirements that must be met in order to sell, distribute or export any cannabis.
- Section [5.2](#): Additional requirements that must be met by a holder of a licence for processing in order to sell, distribute or export cannabis.
- Section [5.3](#): 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 included as accompanying information in the appendices.

Licence holders are responsible for understanding and complying with all GPP requirements that apply to their class of licence and range of authorized 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*.



Transitional Provisions

A transition period will exist for licence holders who were authorized to conduct certain activities prior to the amended *Cannabis Regulations* coming into force on October 17, 2019.

During this transition period, the following transitional provisions apply with respect to good production practices:

- Sale or distribution of cannabis oil, as per section 73 of the Transitional Provisions Part of the *Regulations Amending the Cannabis Regulations (New Classes of Cannabis)*.
 - A holder of a licence for processing or a licence for sale, conducting activities in relation to cannabis oil, are exempt from the application of the amended *Cannabis Regulations* if the holder was authorized to conduct these activities prior to October 17, 2019, and these activities are conducted in accordance with the *Cannabis Regulations* as they read prior to October 17, 2019.
 - This includes that the tolerance limits for residual solvents meet the requirements in the [*Limits for Residual Solvents in Cannabis Products*](#).
 - Twelve months following the coming into force of the amended *Cannabis Regulations*, the cannabis oil will be removed from Schedule 4 to the Act.
- Exemption – section 79 of the amended *Cannabis Regulations* as per section 74 of the Transitional Provisions Part of the *Regulations Amending the Cannabis Regulations (New Classes of Cannabis)*.
 - Holders of a licence that, before the day on which this section comes into force, initiated or completed activities with dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds, may sell, distribute or export cannabis, if these activities were conducted in accordance with Part 5 of the *Cannabis Regulations* as they read prior to October 17, 2019.
- As per subsection 75(1) of the Transitional Provisions Part of the *Regulations Amending the Cannabis Regulations (New Classes of Cannabis)*, dried cannabis and fresh cannabis are exempt from the contaminants limits of subsection 93(3) of the amended *Cannabis Regulations*, if the dried cannabis and fresh cannabis meet the generally accepted tolerance limits for microbial and chemical contaminants under subsection 94(1) of *Cannabis Regulations* as they read prior to October 17, 2019.

- Twelve months following the coming into force of the amended *Cannabis Regulations*, this exemption will cease to be in effect
- As per subsections 81(1) and 81(2) of the Transitional Provisions Part of the *Regulations Amending the Cannabis Regulations (New Classes of Cannabis)*, prior to October 17, 2019, it is prohibited for a holder of a licence to sell, distribute or export a cannabis extract, a cannabis topical or edible cannabis — or a cannabis accessory that contains any of these — that was produced, packaged, labelled, stored, sampled or tested prior to October 17, 2019, unless at the time these activities were conducted, the applicable requirements set out in Parts 5, 6 and 11 and subsections 19(1) and (1.1) of the amended *Cannabis Regulations* were met.

Refer to sections 73 to 81 in the transitional provisions of the *Regulations Amending the Cannabis Regulations (New Classes of Cannabis)* for the further information on the transitional provisions.

5.1 General requirements

As per section 79 of the *Cannabis Regulations*, licence holders must not sell, distribute or export cannabis unless the requirements set out in sections 80 to 88.94 of the *Cannabis Regulations* applicable to the activities they conduct have been met. As per section 79.1 of the *Cannabis Regulations*, the requirements of Part 5 do not apply to any activity that a person conducts in respect of anything that will be used as an [ingredient](#) unless the activity is conducted by a licence holder. Despite this section 79.1, licence holders are still responsible for ensuring that the final product, which may contain ingredients from a non-licence holder, is in compliance with the *Cannabis Regulations*. Furthermore, as per section 79.2 of the *Cannabis Regulations*, sections 80 to 87.1 do not apply to a holder of a licence for analytical testing or a holder of a licence for research.

These general requirements are outlined in further detail below.



Holders of a licence for cultivation, processing, and sale for medical purposes must meet the general requirements with respect to activities conducted with cannabis or anything that will be used as an ingredient.

5.1.1 Standard operating procedures

As per section 80 of the *Cannabis Regulations*, cannabis and anything that will be used as an ingredient must be produced, packaged, labelled, distributed, stored, sampled and tested in accordance with standard operating procedures (SOPs). The SOPs must be designed to ensure that those activities are conducted in accordance with the requirements of Part 5 and Part 6.

The SOPs should include all steps necessary to be in compliance with GPP with a view to avoiding adverse impacts on the quality of the cannabis (e.g., such as cannabis or an ingredient becoming [contaminated](#), or of [extraneous substances](#) being inadvertently added to the cannabis).

Examples of SOPs that may be developed in relation to key operational elements include:

- Sanitation of the building or part of a building and equipment
- Employee hygiene
- Distribution, including transfer, and receipt of cannabis and ingredients
- Production and processing of cannabis and ingredients include:
 - Cloning of cannabis plants or propagation of cannabis plant seeds
 - Trimming
 - Additions of nutrients, fertilizers and [pest control products](#)
 - Harvesting
 - Drying, curing or burping
 - Extraction processing
 - Encapsulation and other discrete unit production
 - Production of edible cannabis or an ingredient used to make edible cannabis
 - Production of a [cannabis extract](#) or cannabis topical, or an ingredient intended to be present in the final form of the cannabis extract or the cannabis topical
- Sampling and testing of cannabis
- Packaging and labelling (e.g., for [bulk cannabis](#), samples, [immediate container](#) and [discrete units](#))
- Storage (e.g., for bulk cannabis, ingredients, 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 section 80 include:

- Licence holders have 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 an assessment of GPP impacts) are documented in a report in accordance with an SOP.
- All personnel who conduct the activities described in a SOP are provided with training on the SOP.
- Training is provided and documented prior to the implementation of new or revised SOPs.

Licence holders should refer to section [5.2.1](#) of this guide for additional information regarding approval of the SOPs by the quality assurance person (QAP), where applicable, prior to SOPs being used at the site.

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

- Purpose
 - 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
 - List, 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 words or terms used in the procedure
- Procedures, instructions, methods, and actions
 - Describes the step-by-step actions that need to be taken
- Documentation
 - Includes the kinds of records associated with the procedure where they are filed, and the length of time the records are retained. Record retention time periods may alternatively be stated in general procedures for control of documentation and data and may simply be referred to in individual procedures.
- Revision sheet or 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.
- Attachments
 - Includes forms to be used in carrying out the procedure. The procedure should 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 section 232 of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to [Appendix E](#).

5.1.2 Pest control products, sanitizers, agronomic inputs and non-food chemical agents

5.1.2.1 Pest control product

As per subsection 81(1) of the *Cannabis Regulations*, cannabis must not be treated with a pest control product 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. Edible cannabis, however, may be treated during the course of production with a pest control product that is exempt from the PCPA pursuant to subparagraph 3(1)(b)(ii) of the *Pest Control Products Regulations* (i.e., a food preservative), as per subsection 81(2) of the *Cannabis Regulations*.



Further requirements related to pest control products are found in sections 92.1, 92.2, 93(2) and 94(1) of Part 6 of the *Cannabis Regulations* and in Health Canada's document entitled [Mandatory cannabis testing for pesticide active ingredients – Requirements](#) that sets out the requirements for mandatory testing of cannabis for pesticide active ingredients. For more information on these requirements, refer to it and [Appendix D](#).

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

5.1.2.2 Sanitizers, agronomic inputs and non-food chemical agents

As per section 81.1 of the *Cannabis Regulations*, any sanitizer, [agronomic input](#) or [non-food chemical agent](#) that is present at a site must be properly and clearly identified, must be suitable for its intended use and must not present a risk of contamination of the cannabis or anything that will be used as an ingredient. It also must be handled and used in a manner that does not present a risk of contamination of the cannabis or anything that will be used as an ingredient and that is in accordance with any manufacturer's instructions.

Examples of **principles or practices** that may demonstrate compliance with section 81.1 include the following:

- All sanitizers, agronomic inputs and non-food chemical agents that are present at the site are clearly identified (e.g., if labels or tags are used, they are clear and legible and if any sanitizer, agronomic input or non-food chemical agent is transferred to a different container, each subsequent container is identified).
- Oil that is used to lubricate equipment that comes into contact with cannabis or anything that will be used as an ingredient is food grade.
- Sanitizers and cleaners that are used on surfaces which will come into contact with cannabis or anything that will be used as an ingredient, are suitable for use on these contact surfaces and do not contaminate cannabis or anything that will be used as an ingredient.
- Non-food chemicals are used as appropriate for their application. For example, sanitizers are used to kill pathogens, and cleaning products are used to remove dirt and residues from cannabis, or anything that will be used as an ingredient, or used to remove other substances from surfaces which will come into contact with cannabis and anything that will be used as an ingredient.
- Agricultural chemicals that are used are approved for use on cannabis or anything that will be used as an ingredient, as applicable.
- Sanitizers, cleaners and disinfectants are used and handled in a manner that does not present a risk of contamination to cannabis or anything that will be used as an ingredient and are used according to the manufacturer's instructions (e.g., sanitizers, cleaners and disinfectants used on surfaces which come into contact with cannabis or anything that will be used as an ingredient, are used in a manner such that there is no contact, including residual contact with the cannabis or anything that will be used as an ingredient). Manufacturer's instructions on contact time, temperature and concentration for sanitizers and non-food chemical agents are followed.
- The manufacturer's instructions on the time interval and concentration for agricultural chemicals, including any pest control products are followed.



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

Examples of records pertaining to section 81.1 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 are records

indicating that the sanitizer, agronomic input or non-food chemical agents were handled and used in accordance with applicable SOPs and copies of usage instructions provided by the manufacturer or supplier.

5.1.3 *Storage and distribution*

5.1.3.1 *Storage*

As per section 82 of the *Cannabis Regulations*, cannabis and anything that will be used as an ingredient must be stored under conditions that maintain its quality.

Examples of **principles or practices** that may demonstrate compliance with section 82 include the following:

- Storage areas are designed and maintained to ensure good storage conditions. This includes orderly storage of cannabis and ingredients 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 materials and cannabis are labelled accordingly.
- All cannabis and anything to be used as an ingredient, including samples, are stored according to the recommended storage conditions that will be 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 is verified periodically.



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 83 of the *Cannabis Regulations*, cannabis and anything that will be used as an ingredient must be distributed in a manner that maintains its quality.

Examples of **principles or practices** that may demonstrate compliance with section 83 include the following:

- Vehicles used in the distribution (e.g., transferring, transporting, sending, delivering, providing) of cannabis and anything to be used as an ingredient 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.
- Vehicles are inspected to verify that they do not impact the quality of cannabis or anything to be used as an ingredient.
- Cannabis and anything to be used as an ingredient 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 safe-keeping of cannabis when distributing it, as per the requirement under section 47.



The record keeping requirements associated with this GPP requirement are found under paragraph 231(1)(a) 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 include:

- Records indicating that cannabis and anything that will be used as an ingredient 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

As per section 84 of the *Cannabis Regulations*, any building or part of a building where cannabis or anything that will be used as an ingredient is produced, packaged, labelled, stored, and tested must be 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 or anything that will be used as an ingredient and prevents the introduction of extraneous substances to the cannabis or anything that will be used as an ingredient.



Licence holders who choose to grow cannabis 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 section 84 include the following:

- 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. Joints between walls, ceilings and floors are sealed.
 - There are no holes or cracks in doors, windows, walls, ceilings and floors (other than those intended by design).
 - The building or part of the building prevents entry of insects and other animals or extraneous substances (or from one area to another), facilitates waste treatment and disposal, and prevents mix-ups and cross-contamination.
 - Floor plans and the building or part of the building design are 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.
 - Doors that give direct access to the exterior from manufacturing and packaging areas are used for emergency purposes only and these doors are properly sealed.
 - Receiving and shipping areas do not allow direct access to production areas.
 - Mechanical areas such as boiler rooms, generators, and other engineering areas are segregated from production areas.
 - Screen and trap floor drains. Drains do not cause water to pool.

- 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 do not present any hazard to the quality of the cannabis.



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 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 demonstrating the upkeep of the building or part of the building.

5.1.5 System – filtration and ventilation, supply of water, and lighting

5.1.5.1 System – filtration and ventilation

As per section 85 of the *Cannabis Regulations*, any building or part of a building where cannabis or anything that will be used as an ingredient is produced, packaged, labelled, stored or tested must be equipped with a system that must be able to:

- Filter air to prevent the escape of cannabis odours associated with cannabis plant material to the outdoors.
- Provide natural or mechanical ventilation with sufficient air exchange to provide clean air and to remove unclean air in order to prevent the contamination of the cannabis or thing that will be used as an ingredient, except in the case of any building or part of a building where the only activities being conducted in respect of cannabis and anything that will be used as an ingredient are its cultivation, propagation or harvesting.
- Be accessible and, if necessary for its cleaning, maintenance or inspection, be disassembled, except in the case of any building or part of a building where the only activities being conducted in respect of anything that will be used as an ingredient are its cultivation, propagation or harvesting;
- Withstand repeated cleaning, except in the case of any building or part of a building where the only activities being conducted in respect of anything that will be used as an ingredient are its cultivation, propagation or harvesting; and

- Function in accordance with its intended use, except in the case of any building or part of a building where the only activities being conducted in respect of anything that will be used as an ingredient are its cultivation, propagation or harvesting.

All conditions under which activities with cannabis or anything that is to be used as an ingredient are being conducted should maintain the quality of the cannabis or the ingredient.

Examples of **principles or practices** that may demonstrate compliance with section 85 include the following:

- System – filtration and ventilation
 - Any building or part of a building used for the production, packaging, labelling, storage, or testing of cannabis is equipped with an adequate system that is capable of maintaining air quality within it.
 - Is designed in a manner in which the air exchange is sufficient for maintaining the air quality of the building or any area of the building with the exception of any building or part of a building where the only activities being conducted are the cultivation, propagation and harvesting of cannabis or anything that will be used as an ingredient.
 - Prevents the accumulation of heat, steam, condensation or dust.
 - Is equipped with close-fitting screens or filters to prevent the entry of dust, smoke, steam, odours, and contaminated air.
- Maintenance program
 - Ventilation and air filtration should be maintained in accordance with a schedule.
 - Maintenance operations are carried out in a manner that do not present any risk to the quality of the cannabis or anything that will be used as an ingredient.
 - The presence of odours surrounding the building or part of a building are 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 paragraphs 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 records pertaining to section 85 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5:

- Records of installation
- Maintenance and service of the ventilation and filtration systems
- Replacements of filters

5.1.5.2 Supply of water

As per section 85.1 of the *Cannabis Regulations*, any system that supplies water to a site must be appropriate for the activities being conducted with cannabis and anything that will be used as an ingredient. In addition, any system that supplies potable water to a site must not be cross-connected with any other system, unless measures are taken to eliminate any risk of contamination of the cannabis or anything that will be used as an ingredient, resulting from the cross-connection.

Examples of **principles or practices** that may demonstrate compliance with section 85.1 include:

- Water supply
 - The water supply is appropriate for the intended use and is of a quantity and pressure sufficient for the operational needs of the site.
 - Measures to eliminate the risk of contamination of the cannabis or anything that will be used as an ingredient are in place, such as filtration or UV lights.
 - If water is reclaimed or reused, the water is treated and maintained in a manner that will not increase the risk of contamination of cannabis or anything that will be used as an ingredient.
 - Monitoring, including chemical and microbiological testing, is conducted on a periodic basis.
- Cross-connections:
 - Cross-connections only exist between potable water systems that are protected against contamination, or water systems that do not present a risk of contamination of cannabis or anything that will be used as an ingredient.
 - Hoses, taps and other similar sources of possible contamination are designed to prevent back-flow or back-siphonage and have prevention devices installed as applicable.
 - Visual inspection of non-mechanical (air gaps) and mechanical prevention devices and testing of back-flow preventers are conducted on a periodic frequency.



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 85(1) of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 are records of testing for source water, maintenance, service and sanitation records of water systems, including visual inspections.

5.1.5.3 Lighting

As per section 85.2 of the *Cannabis Regulations*, any building or part of the building where cannabis or anything that will be used as an ingredient is produced, packaged, labelled, stored or tested must be equipped with natural or artificial lighting that is appropriate for the activity being conducted.

Furthermore, any lighting fixtures in the building or part of the building where these activities are being conducted must be capable of withstanding repeated cleaning and, if necessary to prevent the contamination of the cannabis or thing that will be used as an ingredient, repeated sanitizing. The lighting fixture must not present a risk of contamination of the cannabis or thing that will be used as an ingredient in the event of a breakage.

Examples of **principles or practices** that may demonstrate compliance with section 85.2 include the following:

- Natural or artificial lighting:
 - The lighting used within the building or part of a building is appropriate in terms of placement and intensity for the cannabis or thing that will be used as an ingredient and the activity being conducted (e.g., areas where cannabis, ingredients or packaging materials are inspected, may require a higher intensity of light than storage areas).
 - The lighting used does not alter the natural colour, affect the quality, result in the production of natural toxins and microorganisms of cannabis or anything that will be used as an ingredient, or cause them to deteriorate.
 - The effectiveness of chemical sanitizers is unaffected, as applicable (e.g., certain chemical sanitizers deteriorate during storage and exposure to light, such as chlorine dioxide and sodium hypochlorite).
- Light fixtures are:
 - Constructed from shatter-resistant materials.
 - Shielded with safety covers when they have materials like glass that could break, so as to contain broken materials.
 - Constructed from material that can be repeatedly cleaned and, if necessary, sanitized.
 - Installed in a manner that permits for routine cleaning.
 - Cleaned, sanitized, and maintained in accordance with approved SOPs.



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 subsection 85(2) of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 are records cleaning, sanitization and maintenance of light fixtures, and supplier specification sheets indicating ingredient storage requirements.

5.1.6 Equipment

As per section 86 of the *Cannabis Regulations*, cannabis and anything that will be used as an ingredient 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;
- Is accessible and, if necessary for its cleaning, maintenance or inspection, is able to be disassembled;
- Prevents the contamination of the cannabis and anything that will be used as an ingredient;
- Except in the case of outdoor cultivation, propagation or harvesting, prevents the addition of an extraneous substance to the cannabis and anything that will be used as an ingredient; and
- Except in the case of outdoor cultivation, propagation or harvesting, protects the cannabis or anything that will be used as an ingredient against allergen cross-contamination.

In addition, cannabis and anything that will be used as an ingredient must be distributed using a conveyance that is designed, constructed, maintained and operated in a manner that prevents the contamination of the cannabis or anything that will be used as an ingredient. A conveyance includes anything within the licenced site to transport cannabis or ingredients within the site.

Examples of **principles or practices** that may demonstrate compliance with section 86 include the following:

- Use and function of equipment
 - Equipment is verified to be functioning as intended by the manufacturer before use.

- Equipment that is used for more than one class of cannabis or ingredient is appropriate for each substance.
- Design, construction and operation of equipment, including utensils, such as pruning shears, pots, trays, extractors, beakers, and conveyances (e.g., a forklift or a hand lift), and the arrangement of equipment
 - Where necessary, proper drainage is permitted from the equipment and, where applicable, is connected directly to drains.
 - Where necessary, equipment exhausts to the outside of the building or conveyance to prevent excessive condensation.
 - Equipment and conveyances have no internal horizontal ledges that have hidden or hard-to-clean areas.
 - Equipment and conveyances have protective shields, lids or covers to prevent contamination.
 - Equipment and conveyances do not contaminate cannabis or anything that will be used as an ingredient in the event of a failure of any parts.
 - Any equipment or conveyance determined to be 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.
 - Equipment is installed with sufficient space around it to permit its proper operation, maintenance, and cleaning.
 - 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 or anything that will be used as an ingredient, taking into consideration the location of the repairs relative to the cannabis or anything that will be used as an ingredient, and are performed at a prescribed frequency or as necessary to ensure that the equipment or conveyance continues to function as intended to reduce the risk of contamination.
- Accessibility for cleaning and sanitizing, maintenance and inspection of equipment:
 - Contact surfaces of equipment that comes into contact with cannabis and anything that will be used as an ingredient are accessible.
 - Equipment is installed and arranged in a manner such that it can be reached and there is sufficient room to clean them.

- Equipment can be disassembled for cleaning and sanitizing.
- 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 conveyances and in a manner that prevents re-contamination.
- Maintenance program
 - Written maintenance and calibration programs are implemented and include a list of equipment with its locations requiring regular maintenance and calibration (e.g., balances and pH meters). Instructions are included on how to perform such activities, the frequency of such activities, measures to be taken if equipment does not function as intended, identification of the individuals who are assigned 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 paragraphs 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 section 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.

5.1.7 Sanitation

5.1.7.1 Sanitation program

As per section 87 of the *Cannabis Regulations*, cannabis and anything that will be used as an ingredient must be produced, packaged, labelled, distributed, 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 or anything that will be used as an ingredient are conducted (this does not apply to outdoor cultivation, propagation or harvesting of cannabis or anything that will be used as an ingredient);
- Procedures for effectively cleaning the equipment and conveyances 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 section 87 include the following:

- The building (where applicable) and equipment are cleanable and capable of withstanding repeated sanitizing or disinfecting (e.g., they are 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 is 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 control programs are in place to prevent the entry of animals, such as insects, rodents, birds or other vermin to any part of the building, to detect and eliminate animals, and to prevent the contamination of cannabis.



The record keeping requirements associated with this GPP requirement are found under paragraphs 231(1)(a), and (2)(a) and 232 (1)(b) and (2) of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to [Appendix E](#).

A licence holder that is subject to Part 5 must maintain records describing the sanitation program referred to in section 87 of the *Cannabis Regulations* that is in use at the site described in the licence. Such records may include the following:

- Building and equipment cleaning records
- Equipment maintenance records
- Employee training records
- Cleaning solution usage and preparation records

5.1.7.2 Hand cleaning and hand sanitizing stations and lavatories

As per subsection 87.1 of the *Cannabis Regulations*, if necessary to prevent contamination of cannabis or anything that will be used as an ingredient, a site must be equipped with hand cleaning and hand sanitizing stations and lavatories.

The hand cleaning and sanitizing stations and lavatories must be:

- Appropriately equipped and adequate in number and size for the number of individuals using them;
- Located so that they are readily accessible to the individuals using them; and
- Capable of withstanding repeated cleaning and, if necessary to prevent contamination of the cannabis or anything that will be used as an ingredient, repeated sanitizing.

In addition, the hand cleaning and hand sanitizing stations must permit the effective cleaning and sanitation of hands and lavatories must be located and maintained so that they do not present any risk of contamination of cannabis or anything that will be used as an ingredient.

Examples of **principles or practices** that may demonstrate compliance with section 87.1 include:

- Hand cleaning, hand sanitizing stations and lavatories are:
 - Constructed in such a way that avoids splashing of water into cannabis or anything that will be used as an ingredient or any contact surfaces
 - Accessible for the use by employees at all times
 - Are durable, cleanable and maintained in a clean and sanitary condition
- In addition, hand cleaning and hand sanitizing stations:
 - Are located at entrances to production areas, in close proximity to the lavatories, and anywhere else deemed necessary (e.g., if outdoor production is taking place, in addition to lavatories, hand cleaning and hand sanitizing stations are accessible)
 - Not used for other purposes
 - Equipped to provide hot and cold, or premixed warm, running water, and cleaning or sanitizing agents, and are equipped with supplies or equipment that can dry hands in a sanitary manner
 - Equipped with a sign that explains proper hand washing procedures



The record keeping requirements associated with this GPP requirement are found under section 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 section 87.1 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 are records of cleaning or maintenance of hand cleaning and hand sanitizing stations and lavatories.

5.2 Additional requirements – Holder of a licence for processing

5.2.1 Quality assurance



Licensing requirements related to the QAP are found in section 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 paragraphs 231(1)(e) and (2)(d) of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to [Appendix E](#).

As per section 88 of the *Cannabis Regulations*, a holder of a licence for processing must ensure the following:

- All quality-related complaint investigations and risk mitigation measures and all cannabis or ingredient risk investigations and mitigation measures are conducted under the responsibility of the QAP referred to in section 19 of the *Cannabis Regulations*;
- If necessary, following an investigation, the QAP immediately cause measures to be taken to mitigate any risk;
- Cannabis or anything that will be used as an ingredient is produced, packaged, labelled, distributed, stored, sampled and tested using methods and procedures that, prior to their implementation, have been approved by the QAP;
- In the case of a cannabis extract or edible cannabis, the QAP approves the preventive control plan prior to its implementation; and
- Every lot or batch of cannabis is approved by the QAP before it is made available for sale.

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 section 88 of the *Cannabis Regulations*. The QAP may assign quality assurance duties to a person who has the relevant knowledge, training and experience that are applicable to the class of cannabis in respect of the activities being conducted; however, the QAP remains responsible for the quality of the cannabis produced and for investigating complaints as per section 19 of the *Cannabis Regulations*. If, however, the QAP does not have the training, experience and technical knowledge related to the requirements of Parts 5 and 6 that are applicable to edible cannabis, and the licence holder conducts activities for this class of cannabis, the licence holder must retain the services of another individual who has the training experience and

technical knowledge.

The QAP should be able to demonstrate that each individual who has been assigned quality assurance duties has the training, experience and technical knowledge related to the licensed activities, as well as appropriate knowledge of the requirements of Part 5 and Part 6 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.

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;
- List in a written work description specific duties for all staff who have been assigned quality assurance activities;
- 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 the performance of individuals who have been assigned quality assurance duties. This may include random verification of various quality processes, such as approval of lots or batches of cannabis, ensuring SOPs reflect actual practices, or reviewing documents and interviewing staff to ensure duties are being conducted appropriately.

Investigations are conducted under the responsibility of the QAP:

- All investigations, including those addressing quality complaints and those concerning a potential risk to public health, or those regarding a potential lack of compliance with the requirements of Parts 5 and 6 of the *Cannabis Regulations* must be conducted according to approved procedures established by the licence holder.
- Complaints and other information concerning a potential risk to public health, or that regarding a potential lack of compliance with the requirements of Parts 5 and 6 of the *Cannabis Regulations* should be recorded with all the original details and thoroughly investigated. The investigation must be evaluated, and if necessary, measures must be taken immediately to mitigate any risk (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 section 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 determine 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 paragraphs 231(1)(e) and (2)(e) of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to [Appendix E](#).

Methods, procedures and plans:

- Cannabis or anything that will be used as an ingredient 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 document that all GPP requirements are still being met.
- The QAP must ensure that the preventive control plan is approved prior to implementation. The QAP is responsible for ensuring that procedures are put into place to implement the plan.

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 sections 231(1)(d),3(b), and 232 of Part 11 of the *Cannabis Regulations*. For more information on these requirements, refer to [Appendix E](#).

Approval prior to sale:

- The QAP must ensure that the results of the required tests in sections 90 to 91.1 of the *Cannabis Regulations* and pesticide testing results are reviewed and assessed to confirm that 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 demonstrates 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 and Part 6, should the lots or batches be approved for sale.



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

5.2.2 *Competencies and Qualifications*

As per section 88.1 of the *Cannabis Regulations*, a licence holder must ensure that any individual that conducts activities in relation to edible cannabis or anything that will be used as an ingredient in the production of edible cannabis has the competencies and qualifications that are necessary to conduct those activities at the site set out in the licence.

Licence holders should be able to demonstrate that each individual who has been assigned duties has the appropriate competencies and qualifications related to the activities, as well as appropriate knowledge of the requirements of Part 5 and Part 6, in relation to the duties and responsibilities 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.

Examples of **principles or practices** that may demonstrate compliance with section 88.1 include the following:

- A written program is in place to assess and train individuals.
- Personnel who conduct the activities described in an SOP are provided with training on the SOP, and completion of the training is documented.
- Duties for all staff who have been assigned activities are specified in a written work description.
- There is a periodic assessment to ensure that activities related to edible cannabis or anything that will be used as an ingredient in edible cannabis are conducted in accordance with the requirements of Part 5 and Part 6. This may include a review of the performance of individuals who have been assigned duties; random verification of

various quality processes, such as approval of lots or batches of cannabis; ensuring that SOPs reflect actual practices; or reviewing documents and interviewing staff to ensure duties are being conducted appropriately.



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 88.1 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 include:

- Records of the training program
- Records of qualifications
- Records of verification checks, as applicable

5.2.3 Temperature and humidity, heating, cooling or humidity-control system

As per section 88.2 of the *Cannabis Regulations*, licence holders must ensure that the temperature and humidity of any building or part of a building where cannabis or anything that will be used as an ingredient is produced, packaged, labelled, stored or tested are maintained at levels that are appropriate for the activity being conducted with the cannabis or thing that will be used as an ingredient.

In addition, if the building or part of the building is equipped with a heating, cooling or humidity-control system, licence holders must ensure that the system has the following qualities:

- If necessary to prevent contamination of the cannabis or anything that will be used as an ingredient, it is equipped with instruments to control and indicate the temperature and humidity levels;
- Is accessible and, if necessary for its cleaning, maintenance or inspection, is able to be disassembled;
- Is capable of withstanding repeated cleaning; and
- Functions in accordance with its intended use.

Examples of **principles or practices** that may demonstrate compliance with section 88.2 include the following:

- Appropriate temperature and humidity of any building or part of building:
 - Production areas are maintained at a temperature that prevents the growth of bacteria.

- Cannabis and anything that will be used as an ingredient that requires refrigeration are stored at 4°C or less.
 - Cannabis and anything that will be used as an ingredient that requires freezing are stored at -18°C or less.
 - Humidity levels are maintained at a level that is low enough to prevent condensation, where condensation poses a risk to the safety of cannabis or anything that will be used as an ingredient.
 - Temperature and humidity are checked periodically to ensure that they are maintained at a level that is appropriate to the cannabis, the thing that will be used as an ingredient, and the activity being conducted.
 - Cannabis, and anything that will be used as an ingredient, is placed in refrigerated or freezer storage in a manner that does not restrict air flow, preventing them from reaching the required temperature.
- Heating, cooling and humidity-control system
 - A recording device, such as a thermometer, is used in the refrigerated and freezer storage area(s) that can monitor, record and control the temperature.
 - System ducts are equipped with cleanout doors to permit access for cleaning.
 - The system is made of material that is compatible with the chemicals and methods used for cleaning.
 - The capacity and design of the system is adequate for the conditions of the building.
 - The system's sensing device accurately measures the conditions in the building or part of a building. The device also activates and de-activates the system to maintain the temperature and humidity at pre-determined the levels.



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 88.2 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 include:

- Temperature and humidity records generated from production, packaging, labelling, storage or testing of cannabis or anything that will be used as an ingredient
- Records of temperature and humidity deviations
- Records demonstrating adequate cleaning, maintenance and calibration, if applicable, for the temperature and humidity monitoring devices

5.2.4 *Incompatible activities*

As per subsection 88.3(1) of the *Cannabis Regulations*, a licence holder must ensure that physical or other effective means are used to separate incompatible activities in order to prevent contamination of the cannabis or anything that will be used as an ingredient.

A licence holder must ensure that, if two or more activities were to occur simultaneously, sequentially, or in close proximity, they would not present a risk of contamination of the cannabis or anything that will be used as an ingredient. Physical or other effective means refers to a separation by time, space or preparation practices.

Examples of **principles or practices** that may demonstrate compliance with subsection 88.3(1) include:

- Cleaning and sanitizing activities are not conducted in the same area(s) where production, packaging and labelling of cannabis or anything that will be used as an ingredient is taking place, (e.g., cleaning and sanitizing of production equipment or conveyances are carried out in a dedicated room for cleaning and sanitization, or if cleaning must be carried out in the same area, it is not done while production, packaging or labelling activities are taking place.)
- Cleaning is done in-between the production of different lots or batches of cannabis or anything that will be used as an ingredient.
- Dedicated equipment that is identifiable, via colour coding, or by other means is used.
- Shipping of cannabis product is separated from receipt of incoming cannabis or ingredients either by having two separate areas, or by separating the activities to ensure they do not occur at the same time and as per approved SOP(s).
- Storage of contaminated materials and waste is separate from the production, packaging, labeling, storage (non-contaminated materials, such as cannabis products or ingredients) and testing of cannabis and ingredients.
- Any in-house testing, such as, microbiological and pathogen testing, is conducted in a separate area from production packaging, labelling and storage areas.
- SOPs and processes regarding handling of cannabis and ingredients with allergens are in place to prevent cross contamination of cannabis or ingredients without allergens.
- Positive air pressure directs air flow from highly sensitive areas, such as aseptic rooms, to less sensitive areas, such as raw ingredient handling rooms.
- As applicable, in the case of outdoor cultivation, propagation or harvesting of cannabis or anything that will be used as an ingredient, or materials, such as agronomic inputs, are stored separately from water sources, cannabis and ingredients.

The *Cannabis Regulations* explicitly prohibit one type of incompatible activity: the co-location of cannabis production and conventional food production. Specifically, subsection 88.3(2) of the *Cannabis Regulations* states that, a licence holder must not produce, package, label or store cannabis at a site set out in the licence if food that the licence holder intends to sell is also produced, packaged or labelled at that site.

However, if a licence holder chooses to process cannabis and food products on the same site, then the production, packaging, labelling, and storage of cannabis and the production, packaging, and labelling of food products must be conducted in a separate building within the site as per subsection 88.3(3) of the *Cannabis Regulations*.

Examples of **principles or practices** that may demonstrate compliance with subsection 88.3(2) in relation to the co-location of cannabis production and conventional food production include:

- Ingredients which may be used in the production of cannabis and food that is intended for sale, may be stored in an area of a building or part of a building that is part of the site together, as long as the necessary measures are taken to ensure that the ingredient will not be contaminated.
- If the site set out on the licence is a unit within a larger building or complex, measures should be taken to ensure that there is no contamination of cannabis and ingredients if there are shared systems, such as heating, ventilation and air conditioning, or water systems.
- For licence holders who manufacture other non-cannabis products such as cosmetics, methods and procedures are implemented to prevent the contamination of cannabis or ingredients.



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 88.3 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 include standard operating procedures preventing incompatible activities from occurring and site floor plans showing personnel and material flow.

5.2.5 *Separation of cannabis and ingredients from contaminants*

As per section 88.4 of the *Cannabis Regulations*, a holder of a licence for processing must ensure that physical or other effective means are used to separate cannabis or anything that will be used as an ingredient from anything that presents a risk of contamination of the cannabis or thing that will be used as an ingredient.

Examples of **principles or practices** that may demonstrate compliance with section 88.4 include:

- The presence of SOP(s) and practices which demonstrate that cannabis or anything that will be used as an ingredient is separated from:
 - Other cannabis or anything that will be used as an ingredient which contains allergens
 - Sanitizers, agronomic inputs and other non-food chemical agents
 - Contaminated material and waste, including cannabis intended for destruction.



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 88.4 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 include standard operating procedures and site floor plans showing personnel and material flow.

5.2.6 *Ingredient-related risk of injury to human health*

As per section 88.5 of the *Cannabis Regulations*, a holder of a licence for processing must ensure that anything that will be, or was intended to be, used as an ingredient that presents a risk of injury to human health is identified as such and placed in a designated area within the site.

This may include, but is not limited to, anything that will be, or was intended to be used as an ingredient which has been subject to a recall, requires further processing due to hazards, or which may be undergoing an investigation as the ingredient poses a risk to injury to human health. Such circumstances may include storage conditions not being met, or SOPs not being followed during the production of the ingredient.

The licence holder should have a designated area assigned for any ingredient undergoing investigation and a manner in which to identify the ingredient (e.g., via signage and through inventory controls) to ensure that the ingredient is not used until such time as a decision on its disposition can be made. In addition, ingredients or chemicals which may be used during production which may present a risk of injury to human health, are stored in designated area(s) and appropriately identified (e.g., chemicals used during production of cannabis extracts, or allergens, such as nuts being separated at a building or part of a building where nut-free cannabis products are produced).

[Control measures](#) may be taken to prevent the contamination of other cannabis or anything that will be used as an ingredient at the site as necessary.



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 88.5 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 include: Records of deviations and investigations including any risk mitigation measures taken and inventory records.

5.2.7 Potable water

As per section 88.6 of the *Cannabis Regulations*, a licence holder for processing must ensure that any water that might come into contact with a cannabis extract, cannabis topical, edible cannabis or anything that will be used as an ingredient is potable; and if the water is not potable, the licence holder must ensure that it does not present a risk of contamination of the cannabis extract, cannabis topical, edible cannabis or anything that will be used as an ingredient.

In addition, a holder of a licence for processing must ensure that any steam or ice that might come into contact with a cannabis extract, a cannabis topical, edible cannabis or anything that will be used as an ingredient is made from water that meets the requirements of subsection 88.6(1) of the *Cannabis Regulations*. If the steam or ice does not meet those requirements, the licence holder must ensure that it does not present a risk of contamination of the cannabis extract, cannabis topical, edible cannabis or thing that will be used as an ingredient.

Examples of **principles or practices** that may demonstrate compliance with section 88.6 include the following:

- Municipal water sources are used for any water that will come in contact with a cannabis extract, cannabis topical, edible cannabis or anything that will be used as an ingredient.
- If a water source other than municipal water is used, water samples are tested in order to determine that the water is potable; licence holders should consider using an accredited laboratory or similarly rigorous process.
- Recirculated or reclaimed water, is treated, monitored, and maintained to prevent contamination of a cannabis extract, cannabis topical, edible cannabis or anything that will be used as an ingredient, in accordance with SOPs.
- The water distribution system in the establishment is enclosed and protected from contaminants. If a well is used, this includes covering the well head and ensuring it is protected appropriately.
- Ice machine doors are kept closed when not in use and ice is stored in the machine.

For information on potable water standards, refer to [Guidelines for Canadians Drinking Water Quality – Summary Table](#). Licence holders may also consult [From Source to Tap: Guidance on the Multi-Barrier Approach to Safe Drinking Water](#) that provides operators of a water supply with a risk-based management plan for producing potable water.



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 88.6 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 include:

- Results from testing of the water source, including third-party labs, in-house testing or municipal reports.
- Maintenance and sanitation records pertaining to the system that supplies water as applicable.

5.2.8 No presence of animals

As per section 88.7 of the *Cannabis Regulations*, a holder of a licence for processing must ensure that no animal is present in any building or part of a building, where cannabis or anything that will be used as an ingredient is produced, packaged, labelled or stored.

Examples of **principles or practices** that may demonstrate compliance with section 88.7 include the following:

- Roof, air intakes, foundation, walls, floors, drains, doors and windows in any building or part of a building prevent the entry of animals, such as insects, rodents, birds or other vermin.
- Control measures and procedures (SOPs) are in place to discourage pests from harbouring in any building or part of building and in the surrounding area where production, packaging, labelling or storage is taking place, and measures are taken to detect pests in the building or part of a building, and to immediately eliminate pests when they are identified.
- Measures taken to comply with section 88.7 do not pose a risk of contamination to cannabis or anything that will be used as an ingredient which will be produced, packaged, labelled or stored (e.g., pest control products and devices are used in a manner that does not cause contamination, pest control devices are periodically checked in accordance with a schedule and emptied as necessary). Animals, such as cats, are not used as a means of pest control in the building or any part of the building. This does not prohibit a

licence holder who also possesses a licence for cultivation from using beneficial insects in the grow areas.



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 88.7 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 include records of building maintenance, including verification checks and third-party and internal pest control records, such as pest control product application records, as applicable.

5.2.9 *Land-related risk of contamination*

As per section 88.8 of the *Cannabis Regulations*, if any land that forms part of a site set out on a licence for processing, or any land that is located near such a site, presents a risk of contamination of cannabis or anything that will be used as an ingredient, the licence holder must take measures to eliminate the risk.

Examples of **principles or practices** that may demonstrate compliance with section 88.8 include the following:

- The land and surrounding area around any building or site is maintained to prevent animals, including pests, from harbouring around any building, by removing any debris and refuse, keeping grass trimmed and removing dead vegetation.
- Waste containers are cleaned regularly.
- Grading of the site surrounding any building is done to allow water to drain water away from the building(s).
- If the site is located near a source of contamination, such as sanitary landfills, oil refineries, chemical plants, paper and steel mills, any building air intakes are located away from those sources and the incoming air passes through filters to remove any contaminants.
- If propagation, cultivation and harvesting of anything that will be used as an ingredient takes place outdoors:
 - Sources of contamination are identified and the field is not used, or the ingredients are not harvested and brought into any building, until it is certain that the ingredient will not contaminate cannabis or anything else that will be used as an ingredient.

- Adjoining land is assessed for potential sources of contamination that may drift to the site. Where sources of contamination are identified, measures are taken to mitigate or eliminate the risk of contamination.



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 88.8 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 include building maintenance and verification check records.

5.2.10 Removal and disposal of contaminated materials and waste

As per subsection 88.9(1) of the *Cannabis Regulations*, a holder of a licence for processing must ensure that any building or part of a building where cannabis or anything that will be used as an ingredient is produced, packaged, labelled or stored has available the means for the removal and disposal of contaminated materials and waste and, if necessary to prevent contamination of the cannabis or anything that will be used as an ingredient, that the building or part of the building is equipped with a drainage, sewage and plumbing system that functions in accordance with its intended use.

In addition, the licence holder must ensure that contaminated materials and waste are removed and disposed of at a frequency that is sufficient to prevent contamination of the cannabis or anything that will be used as an ingredient and in a manner that does not present a risk of contamination of the cannabis or anything that will be used as an ingredient.

Examples of **principles or practices** that may demonstrate compliance with subsection 88.9(1) include:

- Drainage and sewage systems are in place that can accommodate the volume and type of effluent produced at the site, and are equipped with traps and vents to prevent backflow.
- Waste and contaminated materials are removed at a set frequency, or more often if necessary, so they do not overflow.
- Removal of contaminated materials and waste is done using predetermined routes (e.g., effluent or sewage lines are constructed so they do not pass directly over or through production areas, unless measures are taken to prevent risk of contamination of cannabis or anything that will be used as an ingredient, and the employees who remove the contaminated material and waste wear appropriate clothing, such as overalls, gloves and boots, when removing the contaminated materials and waste).



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 88.9 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 include building engineering drawings, sanitation records, destruction records and third-party waste removal contracts and records, as applicable.

5.2.11 Conveyances and equipment

As per section 88.91 of the *Cannabis Regulations*, a licence holder for processing must ensure that any conveyance or equipment used at the site set out in the licence to handle any contaminated materials or any waste, be used only for that purpose, be identified as being reserved for that purpose, and meet the applicable requirements of section 86 of the *Cannabis Regulations*, unless that conveyance or equipment does not come into contact with those materials or waste.

Examples of **principles or practices** that may demonstrate compliance with section 88.91 for conveyances and equipment used for handling contaminated materials or waste include:

- Conveyances and equipment are identified for the specific purpose of handling contaminated materials or waste by the use of labelling or colour coding, and are segregated from conveyances and equipment not intended for that purpose, to prevent the contamination of cannabis or anything that will be used as an ingredient.
- Employees are aware of the system used to identify equipment reserved for handling contaminated materials, waste, or other inedible things, via training or through the use of SOPs, as applicable.



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 88.91 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 include:

- SOPs and training records demonstrating that procedures are in place for handling contaminated materials or waste.

5.2.12 Clothing, footwear and protective coverings

As per section 88.92 of the *Cannabis Regulations*, a holder of a licence for processing must ensure that any individual who enters or is in a building or part of a building where cannabis or anything that will be used as an ingredient is produced, packaged, labelled, stored, sampled or tested wears clothing, footwear and protective coverings that are appropriate for the activity being conducted with the cannabis or anything that will be used as an ingredient. This includes gloves, a hairnet, a beard net, and a smock that are in a good, clean and sanitary condition.

Examples of **principles or practices** that may demonstrate compliance with section 88.92 include:

- To prevent contamination, a procedure is in place to ensure that appropriate clothing, footwear and protective coverings are worn by employees, visitors and contractors when entering and moving in the building or part of building where activities with cannabis or anything that will be used as an ingredient is taking place.
- Clothing, footwear and protective coverings are stored in designated, accessible locations and in a manner which prevents contamination (e.g., items required for production activities are stored in cabinets adjacent to production area).
- Measures are taken to ensure that clothing, footwear and protective coverings are in good condition (e.g., as required depending on the activity being conducted, clothing, footwear and protective coverings are removed during breaks and changed or cleaned as necessary throughout the course of a shift; and re-used items are made of materials that can be cleaned and sanitized and are regularly washed. Items intended for one-time use should not be re-used).



The record keeping requirements associated with this GPP requirement are found under paragraphs 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 section 88.5 of the *Cannabis Regulations* that may be maintained by a licence holder to demonstrate their compliance with Part 5 include an SOP listing the health and hygiene requirements for the facility and training records.

5.2.13 Identification and analysis of hazards - Prevention, elimination and reduction of hazards



The information in sections [5.2.13](#) and [5.2.14](#) apply only to holders of a licence for processing that produce cannabis extracts or edible cannabis.

As per section 88.93 of the *Cannabis Regulations*, a holder of a licence for processing that produces a cannabis extract or edible cannabis must identify and analyze the biological, chemical and physical hazards that present a risk of contamination of the cannabis or anything that will be used as an ingredient in the production of the cannabis extract or edible cannabis.

For each cannabis extract and edible cannabis, identify and describe any biological, chemical and physical hazards that may be reasonably expected to contaminate the cannabis extract and edible cannabis through:

- the inputs (e.g., ingredients and packaging materials),
- processing steps, and
- traffic flows

In addition, the licence holder must prevent, eliminate or reduce to an [acceptable level](#) these hazards by using control measures that are shown by evidence to be effective, including any treatment or process. Evidence of effectiveness should be kept up to date and take into consideration changes in formulations, new processing equipment, and emerging new information or processing data.

It is good practice to review and update the hazard analysis periodically to ensure any new hazards are identified and evaluated.



For more detailed information on the requirements of section 88.93 of the Cannabis Regulations associated with the identification, analysis, prevention, elimination and reduction of hazards refer to Table 10, [Appendix F](#).

5.2.14 *Preventive control plan*



A holder of a licence for processing that produces edible cannabis and cannabis extracts must identify hazards that pose a risk to the production of these cannabis products and then prepare, retain, maintain and implement a preventive control plan that is specific to the activities and operations that the processor conducts at their site. A preventive control plan is a written document which is prepared, kept, maintained and implemented by the licence holder. It describes how hazards related to the production of cannabis and cannabis products are controlled, including the ingredients used in production and how the regulatory requirements are met.



Before developing and implementing a preventive control plan, a holder of a licence for processing should:

- Assemble a team to identify microbial, chemical and physical hazards of the cannabis products being produced, technology and equipment used at the site, and process flow.
- Ensure the building(s) or part of building and site are operating and maintained as required by sections 79 to 88.92 of the *Cannabis Regulations*.

As per section 88.94 of the *Cannabis Regulations*, a licence holder that conducts activities in relation to a cannabis extract or edible cannabis must prepare, retain, maintain and implement a written preventive control plan for any activity they conduct in respect of the cannabis or anything that will be used as an ingredient in the production of the cannabis extract or edible cannabis.

The preventive control plan must include the following criteria:

- A description of the measures for ensuring that the applicable requirements of sections 101.3, 101.4, 102, 102.2, 102.3, 102.5 and 102.6 are met;
- In relation to the applicable requirements of these *Cannabis Regulations*:
 - A description of the biological, chemical and physical hazards that are identified under subsection 88.93(1) that present a risk of contamination of the cannabis extract, edible cannabis or anything that will be used as an ingredient in the production of the cannabis extract or edible cannabis;
 - A description of the control measures for preventing or eliminating the hazards referred to in subparagraph 88.93(1)(i) or reducing them to an acceptable level and the evidence that the control measures are effective;
 - A description of the [critical control points](#), of the related control measures and of the evidence that the control measures are effective;
 - A description of the critical limits for each critical control point;
 - The procedures for monitoring the critical control points in relation to their critical limits;
 - The corrective action procedures for each critical control point;
 - The procedures for verifying that the implementation of the preventive control plan results in compliance with these Regulations; and
 - Documents that substantiate that the preventive control plan has been implemented with respect to subparagraphs 88.93(1)(i) to (vii).
- Supporting documents that show evidence of the information recorded under subparagraphs 88.94(1)(a) and subparagraphs 88.94(1)(b)(i) to (vii).

In addition, each document referred to in subparagraph 88.94(1)(2)(b)(viii) must be retained for at least two years after the day on which it is prepared.



For more detailed information on the requirements of section 88.94 of the *Cannabis Regulations* associated with the preventive control plan refer to Table 10, [Appendix E](#).

5.3 Testing requirements

As per section 89 of the *Cannabis Regulations*, licence holders must not sell cannabis products to a person authorized under a provincial Act referred to in subsection 69(1) of the Act or to a holder of a licence for sale, or export cannabis products, unless the applicable requirements set out in sections 90 to 92 of the *Cannabis Regulations* have been met. This section of the guide outlines these requirements in further detail.

5.3.1 Testing Requirements

5.3.1.1 Testing for phytocannabinoids

As per section 90 of the *Cannabis Regulations*, testing for the quantity or concentration, as the case may be, of THC, THCA, CBD and CBDA must be conducted on each lot or batch of cannabis, other than cannabis plants or cannabis plant seeds, that is or will become a cannabis product or is or will be contained in a [cannabis accessory](#) that is or will become a cannabis product.

The testing must be conducted on the final form of the cannabis, either before or after it — or the cannabis accessory that contains it — is packaged and labelled as a cannabis product.

5.3.1.2 Testing for contaminants

As per section 91 of the *Cannabis Regulations*, testing for microbial and chemical contaminants (e.g., residual solvents, heavy metals, aflatoxins, etc.) — other than residues of a pest control product or its components or derivatives — must be conducted on the following:

- Each lot or batch of cannabis — other than cannabis plants, cannabis plant seeds, or edible cannabis — that is or will become a cannabis product, or, is or will be contained in a cannabis accessory that is or will become a cannabis product.
 - Testing on this lot or batch of cannabis must be conducted on the final form of the cannabis, either before or after it — or the cannabis accessory that contains it — is packaged and labelled as a cannabis product.
- Each lot or batch of cannabis — other than cannabis plant seeds — that is used to produce a lot or batch of cannabis — other than cannabis plants, cannabis plant seeds, or edible cannabis that is or will become a cannabis product, or is or will be contained in a

cannabis accessory that is or will become a cannabis product, or is used to produce edible cannabis that is or will become a cannabis product, or is or will be contained in a cannabis accessory that is or will become a cannabis product.

- Testing of this lot or batch of cannabis must be conducted after the final step in the production process during which the microbial and chemical contaminants – other than residues of a pest control product or its components or derivatives - could have been introduced or could be concentrated whichever is later.

The results of this testing must enable a determination of whether the contaminants, if any, are or will be within the tolerance limits referred to in subsection 93(3) or 94(2) or section 101.1 of the *Cannabis Regulations*, as the case may be.

The generally accepted tolerance limits for human use for a contaminant must be appropriate for the intended use and any reasonably foreseeable use of the cannabis product, except for edible cannabis which must be appropriate for product that is to be ingested, and they must be established in a publication referred to in Schedule B of the *Food and Drugs Act*.

There are a number of concepts that may be considered when determining whether a contaminant is or will be present at an acceptable level. These include, but are not limited to:

- Permitted daily exposure and concentration limits
 - The acceptable tolerance limits for some contaminants can be expressed as permitted daily exposures or concentration limits. In the event a permitted daily exposure has been determined for a contaminant, consideration must be given to whether the contaminant is present at a level at which the intended use and any reasonably foreseeable use of that product (i.e. the anticipated amount used daily, route of exposure) would not result in a permitted daily exposure being exceeded. Publications in Schedule B to the *Food and Drugs Act* outline how to go about determining an appropriate limit for contaminants so that a permitted daily exposure is not exceeded.
- Intended and reasonably foreseeable use of the cannabis product
 - Publications listed in Schedule B to the *Food and Drugs Act* contain general chapters for categories of products (e.g., European Pharmacopoeia (Ph. Eur.) 1433 Herbal Drugs) as well as for different types of contaminants (e.g., Ph. Eur. 5.20 Elemental Impurities). Some of these chapters may contain different quality specifications for the contaminant in question, thus it is important to consider the intended or reasonably foreseeable use of the cannabis product to determine whether the level of a contaminant would be within generally accepted tolerance limits. For example, the toxicity of heavy metals can vary greatly depending on the route of exposure and as such, generally accepted tolerance limits are different for products for orally ingested versus inhaled. While

the general chapter for herbal drugs Ph. Eur. 1433 contains specifications for heavy metals including cadmium, lead and mercury, these levels are appropriate as limits for products that are orally ingested; however, the general chapter for elemental impurities Ph. Eur. 2.20 contains specification for heavy metals for which the limits are more appropriate for products that may be reasonably foreseeably consumed via inhalation, such as dried cannabis intended to be smoked or vaporized.

- o Other contaminants must be similarly considered based on the cannabis product's intended use and reasonably foreseeable use, including route of administration or exposure. For example, a cannabis product intended for vaginal use may be considered contaminated if it contained *Candida albicans* since this microorganism would present the risk of causing a yeast infection. The licence holder may consider identifying a publication referred to in Schedule B of the *Food and Drugs Act* for which tolerance limit exists (e.g., the acceptance criterion is an absence of *Candida albicans* in vaginal products, as specified in Ph. Eur. 5.1.4, Microbiological Quality of Non-sterile Pharmaceutical Preparations and Substances for Pharmaceutical Use).
- o When selecting generally accepted tolerance limits, the licence holder must consider the intended use and the reasonably foreseeable use in which the cannabis product, except in the case of edible cannabis will be used. This assessment may include an evaluation of similar products available on the market, or common uses of the product.

It is the responsibility of licence holders to ensure that they periodically review the selected publications referred to in Schedule B of the *Food and Drugs Act* to ensure that the contaminant testing and selected tolerance limits meet the requirements of the *Cannabis Regulations*.

Refer to Table 1 for further details on the timing of testing for contaminants.

Table 1: Testing for contaminants – Time of testing

Class of cannabis	Input cannabis only (paragraph 91(2)(b))	Final form only (paragraph 91(2)(a))	Final form (paragraph 91(2)(a)) or Input cannabis (paragraph 91(2)(b))
Cannabis plant seeds	N/A	N/A	N/A
Cannabis plants	N/A	N/A	N/A
Fresh cannabis	N/A	N/A	Required ¹
Dried cannabis	N/A	N/A	Required ¹
Cannabis topicals	N/A	N/A	Required ¹
Cannabis extracts	N/A	N/A	Required ¹
Edible cannabis	Required ¹	N/A	N/A

Additional information

¹The holder of a licence, when conducting microbial and chemical contaminant testing (including solvent residue testing), with the exception of edible cannabis, the licence holder will have the option of conducting testing on either each lot or batch of the final form of cannabis that is or will become a cannabis product or is or will be contained in a cannabis accessory that is or will become a cannabis product, or of the cannabis used to produce the cannabis, that is or will become a cannabis product or is or will be contained in a cannabis accessory that is or will become a cannabis product at the final step in the production process during which the contaminants could be introduced or concentrated (i.e., on the input cannabis). For example, if a cannabis extract is used in the production of a cannabis topical, the holder of a licence for processing has the option of conducting testing on the cannabis extract or on the final form of the cannabis topical. However, for edible cannabis, contaminant testing must be conducted on the input cannabis.

Refer to section 91 of the *Cannabis Regulations* for further information.



Regardless of the time of testing, the tolerance limits established in subsection 93(3) and section 101.1 of the *Cannabis Regulations* with respect to microbial and chemical contaminants apply to cannabis that is a cannabis product – or that is contained in a cannabis accessory.

5.3.1.3 Dissolution and disintegration testing

As per section 91.1 of the *Cannabis Regulations*, if cannabis, or a cannabis accessory that contains cannabis, is or will become a cannabis product to which subsection 95(1) applies, testing must be conducted on each lot or batch of the cannabis or cannabis accessory to determine whether the requirements referred to in that subsection are, or will be, met.

The testing must be conducted on the final form of the cannabis, either before or after it – or the cannabis accessory that contains it – is packaged and labelled as a cannabis product.

5.3.1.4 Testing method

As per section 92 of the *Cannabis Regulations*, testing that is conducted under sections 90 to 91.1 — or to determine whether the requirements under Part 6 are, or will be, met — must be conducted using validated methods on a representative sample of each lot or batch of cannabis or cannabis accessory that contains cannabis.

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 the following:

- Whether the lot or batch meets the requirements of section 81 and the requirements of subsections 93(3), 94(2) or 95(1), or section 101.1, as applicable; and
- The quantity or concentration of THC, THCA, CBD, and CBDA.



Additional requirements associated with the testing requirement of Parts 5 and 6 of the *Cannabis Regulations* are found under sections 92.2, 93, 94, 95, 97, 97.1, and 101.1 of Part 6 of the *Cannabis Regulations*. For more information on these requirements, refer to Table 6, [Appendix D](#).

Refer also to the *Cannabis Regulations* for further information on all applicable requirements of Part 6.

Testing must be performed against the identified pharmacopeial specification(s), as applicable before a lot or batch of cannabis product is made available for sale. The specification(s) against which the cannabis is to be tested must be identified; documented; supported by adequate justification, including an assessment of the intended and reasonably foreseeable use as per

section [5.3.1.2](#); and, where applicable, approved by the QAP prior to testing. Licence holders should refer to section [5.3.1.2](#) for additional information on selecting tolerance limits.

The testing must be conducted using validated methods, as per subsection 92(1) 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 section 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 approved SOP(s) in place to describe the testing activities. The SOP(s) may include reference standards and controls. Licence holders must 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 testing for phytocannabinoids, contaminants (other than residues of pest control products), or dissolution and disintegration in-house, or rely on a third party who holds a Health Canada licence under the *Cannabis Act* for 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 that the licence holder 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 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 the licence holder's approved SOP(s)
- Establish a list of the specifications and provide it to the third-party testing facility prior to conducting any testing for phytocannabinoids, contaminants (other than residues of pest control products), or dissolution and disintegration testing

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 [5.3.2](#) 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 approving the lot or batch for sale or export.

If a test result is outside of the identified specification, the product must not be approved for sale or export. 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 SOPs for testing.

Licence holders should not repeatedly test the product until the result(s) fall within the identified specification(s) (e.g., microbial and chemical contaminant testing) or until the desired result is obtained (e.g., quantity or concentration 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 permitted. If licence holders permit retests (whether retesting the same sample, or testing a new sample), the maximum number of retests that can be performed should be documented in the SOP, along with the criteria for when the 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 may require full testing and evaluation against all specifications prior to being made available for sale as a cannabis product. Licence holders should refer to section [5.3.1.2](#) for additional information on the stage of testing.

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 testing. The licence holder is responsible for ensuring the quality of the cannabis after 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. For example, licence holders must not rely on irradiation and test results to approve the lot or batch for sale without respecting all applicable GPP requirements.

Further to some of the testing required under Parts 5 and to determine whether the applicable requirements in Part 6 of the *Cannabis Regulations* are, or will be, met, the licence holder must be able to determine the following:

- Whether any pest control products were used on a lot or batch [sections 81 and 92.2, 93(2), 93(4), 94(1), 101(3)(b), 102.1(2)(b)]. For more information, refer to the [Mandatory cannabis testing for pesticide active ingredients - Requirements](#).

- The THC quantities or concentrations, taking into consideration the potential to convert THCA into THC, of the following:
 - Each [discrete unit](#) of a cannabis product (milligrams of THC) intended for ingestion, or nasal, rectal or vaginal use (section 96)
 - Cannabis extract or cannabis topical that is a cannabis product or that is contained in a cannabis accessory that is a cannabis product (milligrams of THC per immediate container) (section 101.2)
 - Edible cannabis that is a cannabis product or that is contained in a cannabis accessory that is a cannabis product (milligrams of THC per immediate container) (section 102.7)
 - Each activation of the following cannabis accessories that dispenses cannabis extract (milligrams of THC) (section 103.2):
 - A cannabis accessory that is a cannabis product and that dispenses a cannabis extract that is intended for ingestion or nasal, rectal or vaginal use
 - A cannabis accessory that is packaged with, and that is intended to dispense, a cannabis extract that is a cannabis product and that is intended for ingestion or nasal, rectal or vaginal use
- Variability limits of a cannabis extract, a cannabis topical or edible cannabis that is a cannabis product - or that is contained in a cannabis accessory that is a cannabis product and variability of divisible cannabis products or of discrete units (sections 97 and 97.1).



Additional information associated with the maximum quantity and concentration requirements is found under sections 96, 97, 97.1, 101.2, 101.7, 102.7, and 103.2 of Part 6 of the *Cannabis Regulations*. Refer to Table 7, [Appendix D](#). Refer to the *Cannabis Regulations* for additional information on all applicable requirements of Part 6, as the above referenced sections is not an exhaustive list.

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

5.3.2 ***Representative sample and quantity***

As per section 92 of the *Cannabis Regulations*, a representative sample of each lot or batch of cannabis or cannabis accessory must be taken for the purposes of each test referred to in sections 90 to 91.1 or to determine whether the applicable requirements in Part 6 are, or will be,

met. 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:

- Microbial and chemical contaminants (subsections 91(1), 93(3), 94(2) and section 101.1 of the *Cannabis Regulations*)
- Dissolution and disintegration (section 91.1 and subsection 95(1) of the *Cannabis Regulations*)
- Quantities or concentrations of THC, THCA, CBD and CBDA (subsection 90(1) of the *Cannabis Regulations*)
- Pest control product (sections 81, 92.2, 93(2), 94(1) and 101(3)(b) 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) of cannabis or cannabis accessory that contains cannabis 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. In addition, the portion of sample(s) retained for one year from the last sale of any portion of each lot or batch of cannabis or cannabis accessory, must be representative of the sample(s) that were taken at the time of testing to meet the requirements of sections 90 to 91.1 for each required test. For example, for edible cannabis, the sample retained for microbial and chemical contaminants should be on each lot or batch of cannabis that was used to produce edible cannabis as per subparagraph 91(1)(ii) and testing for phytocannabinoids must be on the final form of cannabis.




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 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, as applicable, and in a manner that enables immediate identification. In the case where samples of cannabis product are retained, the licence holder may choose to keep samples in the same immediate containers in which they are sold, or in containers that are equivalent with respect to stability.

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 when conducting investigations, such as those 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. Licence holder may 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.inspectionscannabisinspections.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.

Health Canada appreciates receiving feedback on whether this guide was useful, and welcomes your suggestions for improvement. Email your feedback to 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

Table 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: GPP requirements by licence class			
GPP requirement (section of the <i>Cannabis Regulations</i>)	Cultivation: standard, micro & nursery	Processing: standard & micro	Sale for medical purposes
Standard operating procedures (s. 80)	Required	Required	Required ¹
Pest control product (s. 81)	Required	Required	N/A
Sanitizers, agronomic inputs and non-food chemical agents (s. 81.1)	Required	Required	N/A
Storage (s. 82)	Required	Required	Required ²
Distribution (s. 83)	Required	Required	Required ¹
Building or part of a building (s. 84)	Required	Required	Required ²
System – filtration and ventilation (s. 85)	Required	Required	Required ²
Supply of water & cross-connection (s. 85.1)	Required	Required	N/A
Lighting & light fixtures (s. 85.2)	Required	Required	Required ²
Equipment & conveyances (s. 86)	Required	Required	N/A
Sanitation program (s. 87)	Required	Required	N/A
Hand cleaning and sanitizing stations and lavatories (s. 87.1)	Required	Required	Required ²
Competencies and qualifications (s. 88.1)	N/A	Required	N/A
Temperature and humidity (s. 88.2)	N/A	Required	N/A

Table 2: GPP requirements by licence class

GPP requirement (section of the <i>Cannabis Regulations</i>)	Cultivation: standard, micro & nursery	Processing: standard & micro	Sale for medical purposes
Incompatible Activities (s. 88.3)	N/A	Required	N/A
Separation of cannabis and ingredients from contaminants (s. 88.4)	N/A	Required	N/A
Ingredients – risk of injury to human health (s. 88.5)	N/A	Required	N/A
Potable water & steam and ice from potable water (s. 88.6)	N/A	Required	N/A
No presence of animals (s. 88.7)	N/A	Required	N/A
Land – risk of contamination (s. 88.8)	N/A	Required	N/A
Removal and disposal of contaminated materials and waste & frequency and manner (s. 88.9)	N/A	Required	N/A
Conveyances and equipment (s. 88.91)	N/A	Required	N/A
Clothing, footwear and protective coverings (s. 88.92)	N/A	Required	N/A
Identification and analysis of hazards & Prevention, elimination and reduction of hazards (s. 88.93)	N/A	Required	N/A
Preventive Control plan (s. 88.94)	N/A	Required	N/A

¹ This requirement may apply to a holder of a licence for sale for medical purposes with respect to ensuring that the requirements section 83 of the *Cannabis Regulations* have been met.

Table 2: GPP requirements by licence class

GPP requirement (section of the <i>Cannabis Regulations</i>)	Cultivation: standard, micro & nursery	Processing: standard & micro	Sale for medical purposes
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²This requirement does not apply to a holder of a licence for sale for medical purposes without possession. However, these licence holders must ensure that the requirements of section 79 of the *Cannabis Regulations* have been met.

Appendix B: GPP requirements by class of cannabis

Tables 3, 4 and 5 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 (section of the <i>Cannabis Regulations</i>)	Dried cannabis	Fresh cannabis	Cannabis extracts	Edible cannabis	Cannabis topical	Cannabis plants	Cannabis plant seeds
Standard operating procedures (s. 80)	Required	Required	Required	Required	Required	Required	Required
Pest control product (s. 81)	Required	Required	Required	Required ¹	Required	Required	Required
Sanitizers, agronomic inputs and non-food chemical agents (s. 81.1)	Required	Required	Required	Required	Required	Required	Required
Storage (s. 82)	Required	Required	Required	Required	Required	Required	Required
Distribution (s. 83)	Required	Required	Required	Required	Required	Required	Required
Building or part of a building (s. 84)	Required	Required	Required	Required	Required	Required	Required
System – filtration and ventilation (s. 85)	Required	Required	Required	Required	Required	Required ²	Required ²
Supply of water & cross-connection (s. 85.1)	Required	Required	Required	Required	Required	Required	Required

Table 3: General GPP requirements by class of cannabis

GPP requirement (section of the <i>Cannabis Regulations</i>)	Dried cannabis	Fresh cannabis	Cannabis extracts	Edible cannabis	Cannabis topical	Cannabis plants	Cannabis plant seeds
Lighting & light fixtures (s. 85.2)	Required	Required	Required	Required	Required	Required	Required
Equipment & conveyances (s.86)	Required	Required	Required	Required	Required	Required ³	Required ³
Sanitation program (s. 87)	Required	Required	Required	Required	Required	Required	Required
Hand cleaning, sanitizing stations and lavatories (s. 87.1)	Required	Required	Required	Required	Required	Required	Required

Additional Information

¹As per subsection 81(2), edible cannabis may be treated during the course of production with a pest control product referred to in subparagraph 3(1)(b)(ii) of the *Pest Control Products Regulations*.

²Paragraph 85(1)(b) does not apply in respect of any building or part of a building where the only activities being conducted in respect of cannabis are its cultivation, propagation or harvesting.

³ Paragraph 86(1)(d) and (e) do not apply to the outdoor cultivation, propagation or harvesting of cannabis or anything that will be used as an ingredient.

Table 4: Additional requirements for a holder of a licence for processing by class of cannabis

GPP requirement (section of the <i>Cannabis Regulations</i>)	Dried cannabis	Fresh cannabis	Cannabis extract	Edible Cannabis	Cannabis topical	Cannabis plants	Cannabis plant seeds
Quality assurance (s.88)	Required	Required	Required	Required	Required	Required	Required
Competencies and qualifications (s. 88.1)	N/A	N/A	N/A	Required	N/A	N/A	N/A
Temperature and humidity (s. 88.2)	Required	Required	Required	Required	Required	Required	Required
Incompatible activities (s. 88.3)	Required	Required	Required	Required	Required	Required	Required
Separation of cannabis and ingredients from contaminants (s. 88.4)	Required	Required	Required	Required	Required	Required	Required
Ingredients – risk of injury to human health (s. 88.5)	Required	Required	Required	Required	Required	Required	Required
Potable water & steam and ice from potable water (s. 88.6)	N/A	N/A	Required	Required	Required	N/A	N/A
No presence of animals (s. 88.7)	Required	Required	Required	Required	Required	Required	Required
Land – risk of contamination (s. 88.8)	Required	Required	Required	Required	Required	Required	Required

Table 4: Additional requirements for a holder of a licence for processing by class of cannabis

GPP requirement (section of the <i>Cannabis Regulations</i>)	Dried cannabis	Fresh cannabis	Cannabis extract	Edible Cannabis	Cannabis topical	Cannabis plants	Cannabis plant seeds
Removal and disposal of contaminated materials and waste & Frequency and manner (s. 88.9)	Required	Required	Required	Required	Required	Required	Required
Conveyances and equipment (s. 88.91)	Required	Required	Required	Required	Required	Required	Required
Clothing, footwear and protective coverings (s. 88.92)	Required	Required	Required	Required	Required	Required	Required
Identification and analysis of hazards & Prevention, elimination and reduction of hazards (s. 88.93)	N/A	N/A	Required	Required	N/A	N/A	N/A
Preventive control plan (s. 88.94)	N/A	N/A	Required	Required	N/A	N/A	N/A

Table 5: Testing GPP requirements by class of cannabis

GPP requirement (section of the <i>Cannabis Regulations</i>)	Dried cannabis	Fresh cannabis	Cannabis extract	Edible Cannabis	Cannabis topical	Cannabis plants	Cannabis plant seeds
Testing for phytocannabinoids & Timing of testing (s. 90)	Required	Required	Required	Required	Required	N/A	N/A
Testing for contaminants, timing of testing and tolerance limits (s. 91)	Required	Required	Required	Required ¹	Required	N/A	N/A
Dissolution and disintegration & timing of testing (s. 91.1) ²	Required	Required	Required	N/A	Required	N/A	N/A
Testing procedure, retention period & sufficient quantity (s. 92)	Required	Required	Required	Required	Required	N/A	N/A

Additional Information

¹ In the case of edible cannabis, the contaminant testing requirements of subsection 91(1) of the *Cannabis Regulations* must be carried out on each lot or batch of cannabis — other than cannabis plant seeds — that is used to produce edible cannabis that is or will become a cannabis product or is or will be contained in cannabis accessory that is or will become a cannabis product.

² As per subsection 95(1) of the *Cannabis Regulations*, dissolution and disintegration testing is required for discrete units of a cannabis product that are intended for ingestion or nasal, rectal or vaginal. Testing must be conducted on a representative sample of the discrete unit. Refer to subsection 95(1) of the *Cannabis Regulations* for further information.

Appendix C: Part 2 – Licensing requirements related to GPP

Table 6 provides requirements and additional information pertaining to the QAP - section 19 of the *Cannabis Regulations*.

Table 6: Quality assurance person requirements	
Section of the <i>Cannabis Regulations</i>	Requirements and additional information
Quality assurance person (s. 19(1))	<ul style="list-style-type: none"> • Holders of a licence for processing must retain the services of one individual as a QAP who has the training, experience, and technical knowledge related to the GPP (Part 5) and cannabis products (Part 6) requirements of the <i>Cannabis Regulations</i>, that are applicable to the class(es) of cannabis for which activities will be conducted. • 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 and Part 6. • The QAP should be able to demonstrate how their qualifications pertain to the following: <ul style="list-style-type: none"> ○ SOP development and approval ○ Pest control management, including appropriate use of approved pest control products, as applicable, and pesticide residue testing ○ Quality control relating to the movement, storage and distribution of cannabis, anything that will be used as an ingredient and other products/substances ○ Implementation of GPP as they pertain to the building (including air filtration and ventilation, lighting, water supply, temperature and humidity control, and waste disposal), equipment, including conveyances, sanitation and employee hygiene and protection ○ Oversight of an effective sanitation program to ensure production, packaging, labelling, storage, sampling and testing activities involving cannabis are conducted under sanitary conditions ○ Approval of a preventive control plan for cannabis extracts and edible cannabis ○ Complaint investigation and management and implementation of measures to mitigate risk

Table 6: Quality assurance person requirements

Section of the <i>Cannabis Regulations</i>	Requirements and additional information
	<ul style="list-style-type: none"> ○ Approval of cannabis quality prior to it being made available for sale ○ Validation and suitability of methods for testing ○ Microbial and chemical contaminants, and their generally accepted tolerance limits for human use that are established in a publication referred to in Schedule B to the Food and Drugs Act and that are appropriate for the intended use and foreseeable use of the cannabis product, for all cannabis products other than edible cannabis which must be appropriate for a product that is ingested. ○ Dissolution and disintegration testing of discrete units as applicable, such as capsules or other similar dosage forms, and assessment of results ○ Quantity or concentration of THC, THCA, CBD, and CBDA, as well as the maximum quantity of THC and variability limits, as applicable for cannabis products ○ Sample collection and retention ○ Handling recalls, including recall simulation and adverse reaction reports
<p>Exception – Edible cannabis (s. 19(1.1))</p>	<ul style="list-style-type: none"> ● If the quality assurance person does not have the training, experience and technical knowledge related to the requirements of Parts 5 and 6 that are applicable to edible cannabis, the holder of a licence for processing that conducts activities in respect of that class of cannabis must retain the services of another individual who has that training, experience and technical knowledge.
<p>Responsibilities (s. 19(2))</p>	<ul style="list-style-type: none"> ● The QAP is responsible for: <ul style="list-style-type: none"> ○ Assuring the quality of the cannabis before it is made available for sale ○ Investigating every quality complaint received in respect of the quality of the cannabis, and if necessary, immediately taking measures to mitigate risk

Table 6: Quality assurance person requirements

Section of the <i>Cannabis Regulations</i>	Requirements and additional information
	<ul style="list-style-type: none"> ○ Conducting an immediate investigation and, if necessary, immediately taking measures to mitigate any risk, if they suspect, on reasonable grounds, that the cannabis or anything that will be used as an ingredient presents a risk of injury to human health or that the applicable requirements of Part 5 or 6 are otherwise not being met ● More information on quality assurance can be found in section 5.2.1 of this guide
Alternate (s. 19(3))	<ul style="list-style-type: none"> ● 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 7 provides some of the requirements and additional information pertaining to the cannabis product specifications outlined in sections 92 - 104 of Part 6 associated with the cannabis testing requirements outlined in sections 90 and 91 of Part 5 of the *Cannabis Regulations*. Table 8 provides additional details on maximum quantities of various cannabis forms.

Table 7: Cannabis testing and associated cannabis products specifications

Section of the <i>Cannabis Regulations</i>	Requirements and additional information
Residues of pest control products – s. 92.1, 92.2 93(2), 94 (1) and 101(3)(b)	<ul style="list-style-type: none"> • Applicable to: <ol style="list-style-type: none"> a) The following class(es) of cannabis that are cannabis products or that are contained in a cannabis accessory that are cannabis products: <ul style="list-style-type: none"> ○ Dried cannabis ○ Fresh cannabis ○ Edible cannabis ○ Cannabis extracts ○ Cannabis topicals ○ Cannabis plants ○ Cannabis plant seeds b) Cannabis that is referred to in item 1 or 3 of Schedule 1 to the <i>Act</i> and that is used in the production of a cannabis extract, cannabis topical, or edible cannabis, that will become a cannabis product or that will be contained in a cannabis accessory that will become a cannabis product. • Specifications: <ul style="list-style-type: none"> ○ Must not contain or have on them residues of a pest control product that is registered for use on cannabis under the PCPA, or that is otherwise authorized for use under that Act, unless the residues are within any maximum residue limits that are specified in relation to cannabis under section 9 or section 10 of that Act. • Reference document(s): <ul style="list-style-type: none"> ○ PCPA ○ Mandatory cannabis testing for pesticide active ingredients – Requirements

Table 7: Cannabis testing and associated cannabis products specifications

Section of the <i>Cannabis Regulations</i>	Requirements and additional information
<p>Microbial and chemical contaminants s. 93(3), 94(2), and 101.1</p>	<ul style="list-style-type: none"> • Applicable to: <ul style="list-style-type: none"> a) The following class(es) of cannabis that are cannabis products or that are contained in a cannabis accessory that are cannabis products: <ul style="list-style-type: none"> ○ Dried cannabis ○ Fresh cannabis ○ Cannabis extracts ○ Cannabis topicals b) Cannabis that is referred to in item 1 or 3 of Schedule 1 to the <i>Act</i> and that is used in the production of edible cannabis, if the edible cannabis will become a cannabis product or will be contained in a cannabis accessory that will become a cannabis product • Specification: Must be within generally accepted tolerance limits for human use that are: <ul style="list-style-type: none"> ○ Established in a publication referred to in Schedule B to the FDA; ○ Appropriate for the intended use and any reasonably foreseeable use of the cannabis product, in the case of dried cannabis, fresh cannabis and cannabis extract and cannabis topicals; and, ○ Appropriate for a product that is to be ingested, in the case of edible cannabis. • Reference document(s): <ul style="list-style-type: none"> ○ Schedule B of the FDA • Additional information: <ul style="list-style-type: none"> ○ In the case of dried and fresh cannabis, if there are generally accepted tolerance limits that apply in respect of the residues of a pest control product for which a maximum residue limit has been specified in relation to cannabis under the PCPA, the more stringent limit applies. ○ 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.

Table 7: Cannabis testing and associated cannabis products specifications

Section of the <i>Cannabis Regulations</i>	Requirements and additional information
	<ul style="list-style-type: none"> ○ 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.
<p>Dissolution and disintegration (s. 95(1))</p>	<ul style="list-style-type: none"> ● Applicable to the following class(es) of cannabis that are discrete units of cannabis products intended for ingestion or nasal, rectal or vaginal use: <ul style="list-style-type: none"> ○ Dried cannabis ○ Fresh cannabis ○ Cannabis extracts ○ Cannabis topicals ● Specification: <ul style="list-style-type: none"> ○ If the form of the unit is similar to a dosage form for which a dissolution or disintegration test is set out in a publication referred to in Schedule B to the FDA, the discrete unit must meet the requirement(s) of that test or, if there is more than one applicable test, the requirements of any such test that is suitable for demonstrating that the cannabis product will perform as intended. ● Reference document(s): <ul style="list-style-type: none"> ○ Schedule B of the FDA ● Additional information: <ul style="list-style-type: none"> ○ The established disintegration tolerance limits state the number of discrete units to be tested to demonstrate acceptable disintegration of the product.

Table 7: Cannabis testing and associated cannabis products specifications

Section of the <i>Cannabis Regulations</i>	Requirements and additional information
Quantity or concentration of THC, THCA, CBD and CBDA (s. 97 & 97.1)	<ul style="list-style-type: none"> • Applicable classes of cannabis that are or will become cannabis products or that are or will be contained in a cannabis accessory that are or will become cannabis products: <ul style="list-style-type: none"> ○ Dried cannabis ○ Fresh cannabis ○ Cannabis extracts ○ Cannabis topicals ○ Edible cannabis • Specification: <ul style="list-style-type: none"> ○ The quantity or concentration 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 are or will become cannabis products or that are or will be contained in a cannabis accessory that are or will become cannabis products. • Variability Limits <ul style="list-style-type: none"> ○ Cannabis extract, or cannabis topicals, that are a cannabis product — or that are contained in a cannabis accessory that are a cannabis product — must not contain, in respect of any quantity or concentration of THC or CBD that is displayed on the label, less than 85% or more than 115% of that quantity or concentration. ○ Edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain: <ul style="list-style-type: none"> ▪ if a quantity of THC or CBD that is displayed on the label exceeds 5 mg, less than 85% or more than 115% of that quantity; ▪ if a quantity of THC or CBD that is displayed on the label exceeds 2 mg but does not exceed 5 mg, less than 80% or more than 120% of that quantity; and ▪ if a quantity of THC or CBD that is displayed on the label does not exceed 2 mg, less than 75% or more than 125% of that quantity.

Table 7: Cannabis testing and associated cannabis products specifications

Section of the <i>Cannabis Regulations</i>	Requirements and additional information
	<ul style="list-style-type: none"> ○ If a cannabis product that is not in discrete units is represented as being able to be divided into discrete units, each represented unit must not contain a quantity of THC or CBD that is less than 75% or more than 125% of the quantity of THC or CBD in each of the other represented units, taking into account the potential to convert THCA into THC or CBDA into CBD respectively. ○ If a cannabis product is in discrete units that are represented as being able to be divided into discrete subunits, each represented sub-unit must not contain a quantity of THC or CBD that is less than 75% or more than 125% of the quantity of THC or CBD in each of the other represented sub-units, taking into account the potential to convert THCA into THC or CBDA into CBD respectively. ● Additional information: <ul style="list-style-type: none"> ○ Documentation on methods, test limits, results and calculations used should be maintained with information on each lot or batch. ○ The quantity or concentration 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 respectively, must be set out on each individual label on the cannabis product package in accordance with sections 124, 124.1, 125, 132.1, 132.11, 132.12, 132.15, 132.16, 132.1, and 132.19, where applicable.

Table 8: Specification details

Section of the <i>Cannabis Regulations</i>	Applicable class(es) of cannabis	Specification
Discrete unit (s. 96)	<ul style="list-style-type: none"> • Dried cannabis • Fresh cannabis • Cannabis extracts • Cannabis topicals 	Each discrete unit of a cannabis product that is intended for ingestion, nasal, rectal or vaginal use must not contain a quantity that exceeds 10 mg of THC, taking into account the potential to convert THCA into THC.
Cannabis extracts & cannabis topicals (s. 101.2)	<ul style="list-style-type: none"> • Cannabis extracts • Cannabis topicals 	A cannabis extract, or a cannabis topical, that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain a quantity of THC that exceeds 1000 mg per immediate container, taking into account the potential to convert THCA into THC.
Edible cannabis (s. 102.7)	<ul style="list-style-type: none"> • Edible cannabis 	Edible cannabis that is a cannabis product — or that is contained in a cannabis accessory that is a cannabis product — must not contain a quantity of THC that exceeds 10 mg per immediate container, taking into account the potential to convert THCA into THC.
Cannabis accessory (s. 103.2)	<ul style="list-style-type: none"> • Cannabis extracts 	Each activation of a cannabis accessory that is a cannabis product, or that is packaged with a cannabis product, that dispenses, or that is intended to dispense cannabis extract that is intended for use for ingestion or nasal, rectal or vaginal use, must not dispense a quantity of extract that contains greater than 10 mg of THC, taking into account the potential to convert THCA into THC. This is in addition to the variability limits of subsection 97(1) of the <i>Cannabis Regulations</i> .

Additional information

The maximum quantity 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

Table 9 summarizes the record keeping requirements pertaining to GPP. It provides the relevant section references between Parts 5 and 11.

Table 9: Retention of documents and information under Part 11 associated with GPP requirements		
GPP reference (Section of the <i>Cannabis Regulations</i>)	Retention of documents and information Section # of the <i>Cannabis Regulations</i>	Requirements and additional information
Distribution (s. 83)	s. 227	Licence holders must document the information set out in section 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.
s. 81.1, 82, s. 84 to 87.1, 88.2 to 88.92 and 90 to 92	s. 231(1)(a) and (2)(a)	For each lot or batch of cannabis where any portion of which has been sold or exported, a licence holder must retain records demonstrating that cannabis and anything that will be used as an ingredient was produced, packaged, labelled, distributed, stored, sampled and tested in accordance with the requirements of Parts 5 and 6. 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) Sanitizers, agronomic inputs and non-food	s. 231(1)(c) and (2)(b)	Licence holders must retain records demonstrating their use of substances, such as pest control products and agronomic inputs, applied directly or indirectly to cannabis, including the name of the substance, the

Table 9: Retention of documents and information under Part 11 associated with GPP requirements

GPP reference (Section of the <i>Cannabis Regulations</i>)	Retention of documents and information Section # of the <i>Cannabis Regulations</i>	Requirements and additional information
chemical agents (s. 81.1)		<p>quantity used, the method and date of application and the rationale for the use of the substance.</p> <p>These documents must be retained for two years after the day on which they were prepared.</p>
<p>Testing for phytocannabinoids (s. 90(1))</p> <p>Testing for contaminants (s. 91(1))</p> <p>Dissolution and disintegration testing (s. 91.1(1))</p>	s. 231(1)(d) and (2)(c) and (3)(b)	<p>Licence holders must retain documentation describing the validated test methods used and any assessment made by the licence holder ensuring the methods are validated.</p> <p>In addition, licence holders must retain documentation containing the test results for each lot or batch tested.</p> <p>For any lot or batch that has undergone additional processing, alteration(s) or secondary treatments(s) after the initial testing is conducted, the 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 out-of-specification test result should also be retained and an explanation should be recorded.</p> <p>Documentation describing the validated test methods used must be retained for at least two years after the day on which they are replaced.</p> <p>Records demonstrating compliance with Parts 5 and 6, 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.</p> <p>Each version of the validated test method must be retained for at least two years after the day on which the validated methods are replaced.</p>
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

Table 9: Retention of documents and information under Part 11 associated with GPP requirements

GPP reference (Section of the <i>Cannabis Regulations</i>)	Retention of documents and information Section # of the <i>Cannabis Regulations</i>	Requirements and additional information
		<p>alternate QAP, demonstrating their training, experience and technical knowledge related to the applicable classes of cannabis, licensed activities and the requirements of Parts 5 and 6.</p> <p>This should include letters of reference, a copy of the diploma/certificates and any other documentation supporting the qualifications, training and experience of the QAP.</p> <p>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.</p>
Investigation of quality-related complaints (s. 88(a))	s. 231(1)(e) and (2)(e)	<p>Where applicable, licence holders must retain documentation that describes every investigation of every complaint received in respect of the quality of cannabis, and the investigation of any cannabis or anything that will be used as an ingredient that the QAP suspects presents a risk of injury to human health or for which the requirements of Parts 5 or 6 are not being met. Any measures taken, including those to immediately mitigate any risk are documented.</p> <p>This documentation must be retained for at least two years after the day on which it was prepared.</p> <p>Details of investigations must be recorded (e.g., information on the assessment of the quality of the corresponding lot or batch, information regarding the potential risk, or Parts 5 or 6 requirement not being met, and the decision of whether to take immediate measures to mitigate the risk the justification of that decision, etc.). All decisions and measures taken in response to an investigation should be recorded and referenced to the corresponding lot or batch records, as applicable.</p>

Table 9: Retention of documents and information under Part 11 associated with GPP requirements

GPP reference (Section of the <i>Cannabis Regulations</i>)	Retention of documents and information Section # of the <i>Cannabis Regulations</i>	Requirements and additional information
		Investigation records should be regularly reviewed for any indication of specific or recurring problems that require attention.
<p>Standard operating procedures (s. 80)</p> <p>Methods and procedures (s. 88(c))</p> <p>Sanitation (s. 87)</p>	s. 232	<p>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.</p> <p>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.</p> <p>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.</p>

Appendix F: Preventive control plan best practices

Table 10 provides an overview of the GPP requirements for sections 88.93 and 88.94 of the Cannabis Regulations, specific to holders of a licence for processing that produce a cannabis extract or edible cannabis.

Table 10: Preventive control plan requirements (for holders of a licence for processing who produce cannabis extracts and edible cannabis)

Subsection 88.93(1)

Holders of a licence for processing that produce edible cannabis or cannabis extracts must identify and analyze the biological, chemical and physical hazards that present a risk of contamination to the cannabis or anything that would be used as an ingredient in the production of the edible cannabis or cannabis extract.

When conducting a hazard analysis, all hazards that present a risk of contamination of the cannabis extract and edible cannabis are identified and evaluated, and a determination is made as to how these hazards are controlled.

Biological hazards include microorganisms such as bacteria, viruses, parasites, fungi and molds.

Examples of sources of biological hazards may include, but are not limited to:

- Incoming ingredients, including raw materials
- Cross-contamination in the processing or storage environment
- Employees
- Cannabis extract, edible cannabis and ingredient contact surfaces
- Air
- Water
- Insects and rodents

Chemical hazards may occur naturally or may be introduced during any stage of cannabis extract or edible cannabis processing

Examples of chemical hazards may include, but are not limited to:

- Chemicals intentionally used in cannabis extract and edible cannabis processing such as ingredients, including food and [food additives](#) (as applicable)
- Chemicals that are by-products of processing such as nitrosamines, chloramines
- Chemical contamination from equipment such as lead-soldered seams

- Industrial chemicals such as cleaning agents, oils, gasoline, lubricants, ammonia
- Naturally occurring toxicants such as products of plant or microbial metabolisms, including mycotoxins or histamines
- Agricultural chemicals such as pesticides, antibiotics, fungicides, rodenticides, algacides, and fertilizers
- Nutrients, such as over-addition of vitamins and/or minerals
- [Food allergens](#) such as peanuts, tree nuts, sesame seeds, milk, eggs, fish, crustaceans, shellfish, soy, mustard and wheat, sources of gluten and sulphites

Physical hazards include many types of unwanted materials that may be introduced anywhere along the chain, from production through distribution. Unwanted materials can be introduced by anything or anyone coming in contact with the extract cannabis and edible cannabis, such as by people who handle the cannabis extract or edible cannabis, or during processing, distribution or storage. The unwanted materials are considered to be hazards if they can result in illness or injury to anyone who consumes the cannabis extract or edible cannabis.

Examples of physical hazards include:

- Stones, rocks and dirt
- Metal (commonly associated with processing activities such as milling, cutting, slicing or grinding operations, as well packaging materials or containers such as metal shards, staples and nails)
- Jewelry and personal items (resulting from poor food handling practices)
- Glass or other contaminants from packaging materials or containers, or from the processing environment (e.g., uncovered light fixtures)
- Wood splinters from broken pallets or packaging material
- Flaking paint from overhead structures or equipment
- Insect pieces

Incoming inputs, product formulations and processing steps and the hazards that may be reasonably expected to occur from the ingredients, packaging material and the environment, or steps in manufacturing, preparation, storage, and movement and labelling of your cannabis product are evaluated. Product formulations and specifications as well as processing steps should be documented in this analysis.

- Identification of all hazards
 - Identify all potential hazards for a cannabis extract and edible cannabis, and prepare a list of biological, chemical and physical hazards that may reasonably be expected or likely to occur from:

- Product formulations and all inputs (e.g., the raw materials, ingredients, food additives, packaging materials), and the intended end use of the cannabis extract and edible cannabis.
- Each step in the production of cannabis extract and edible cannabis as part the operation of the site, from receiving to storage and distribution.
- Hazard identification may come from a number of sources, including:
 - Employee knowledge and experience of the site and activities conducted by the licence holder.
 - Records of production issues such as files on investigations, deviations production rework, product quality complaints and recalls.
 - External references, such as reference texts, scientific publications, complaints, supplier or government advisories or notices, etc.
- The list of identified hazards includes the name of the pathogen (e.g., *Listeria monocytogenes*) or the type of physical hazard (e.g., metal fragments), the conditions that are associated with it (e.g., presence, survival, growth, contamination), and the reason for the hazard (e.g., contamination of allergen-free ingredients with allergens due to inadequate separation from allergen-containing ingredients in bulk storage).
- Evaluation of each hazard
 - A determination whether the hazards identified in Step 1 are reasonably likely to occur and the extent to which they would be injurious to human health or unsuitable for human use.
 - To evaluate the likelihood that a hazard will occur, consider the existing SOPs and control measures in place, and use a combination of experience, scientific literature, and corporate historical information on investigations, recalls and customer complaints.
 - Consideration may be given to the severity of the hazards evaluated, including factors, such as the impact on public health and public safety, including the duration and magnitude of illness or injury that the hazard may cause, and the susceptibility of certain consumers to be affected, based on population groups or age groups (e.g. medical clients).
 - A justification is documented for hazards not reasonably likely to occur, or those will reasonably occur but that are not significant.
- Determination of the control measures

- The measures that would control each hazard are described, including the tasks required to be carried out to effectively implement the control measure, how the tasks are carried out, the frequency at which the tasks will be carried out, the person responsible for carrying out the task, and the forms/records used for documenting the tasks and controls are described.
- If significant hazards do not have a control measure at the step where the hazard was identified, or at any other step, then the product or process is modified, at that step or at an earlier or later stage, to include a control measure.
- Evidence that shows that the control measures are capable of controlling the hazard is described.

Subsection 88.93(2)

Licence holders must prevent, eliminate or reduce to an acceptable level the hazards identified by implementing effective control measures that are shown by evidence to be effective, including any treatment or process.

The control measure(s) that control each hazard in the hazard analysis are identified and described. Include the following details in the description of the control measures:

- What: a description of the tasks involved
- How: details of how the task is carried out
- When: the frequency of the task
- Who: the person responsible for carrying out the task

Evidence may include scientific literature, validation studies and scientifically valid sampling and testing. The type and depth of evidence needed to show that a control measure (or combination of control measures) is effective depends on the nature of the hazard(s) being controlled and the level of the risk associated with the hazard.

- Control measures for significant hazards, such as those with critical limits at a critical control point, usually have a quantitative effect on specific hazards. The evidence required for these types of control measures is more substantive and is often based on the collection and assessment of scientific, technical and observational information.
- Pre-validated control measures (measures that have already been validated as effective) may be used. Re-validation is not required, provided the conditions of application are the same. For new or alternative approaches, a scientific validation study involving study design and collecting and analyzing the licence holder's own scientific data to generate the evidence needed to prove that these measures are effective may be required.

The process to obtain evidence on the effectiveness of a control measure requires:

- Knowledge of the cannabis extract or edible cannabis food, the hazards and control measures.

- Hazards that need to be controlled are identified. Licence holders should refer to subsection 88.93(1) of the *Cannabis Regulations* in this table for additional information on the hazard analysis.
- The intended goal(s) of the control measures are identified (e.g., reduce the level of *Listeria monocytogenes* in a ready-to-eat edible cannabis product to below 100 cfu/g for the durable life of the product).
- Control measure(s) for the hazards(s) are identified.
- Obtaining the evidence showing the control measures are effective.
- Documenting the evidence and where/how it was obtained.

1. Identify the control measure(s)

- Control measure(s) are identified to control the hazard(s) identified. For example, cooking at "x" degrees Celsius for "y" minutes to achieve a 5-log reduction in numbers of *Listeria monocytogenes*.
- Consider the following:
 - Has the control measure been validated (e.g., by a competent authority or other national or international organization)?
 - Is its performance well established for the application for which it is being considered?
 - Are the conditions of application in the operation the same as those under which the control measure was previously validated (e.g., are the raw materials, relevant hazards, combination of control measures, intended use, and distribution and consumption patterns the same)?

Note: If the answer is yes to all of these questions, most of the evidence needed to show the control measure is effective exists. Now it is only necessary to collect monitoring and verification data to confirm that the control measure is implemented as intended and is effective in achieving the desired outcome

2. Evidence is obtained that shows a control measure is effective

- Define parameters and acceptance criteria, such as:
 - The parameters (e.g., internal temperature, pressure, pH, concentration level or fill weight).
 - The acceptance criteria and variability.
 - The limit of precision or confidence level (e.g., the ability of a metal detector to detect metal fragments greater than or equal to 0.5 mm at a 95% confidence level).
 - Parameters and criteria may be obtained from sources such as, the instructions provided by the equipment manufacturer, peer-reviewed publications, scientifically valid experimental data and government guidelines and standards.

- Determine the approach to be followed to obtain evidence.
 - Some control measures require the use multiple approaches, such as:
 - A literature review (e.g., existing scientific or technical information, previous validations studies and documented historical knowledge of the performance of the control measure). It should be demonstrated that the conditions of the specific operation in question are the same as those of the original study or publication, or that any differences with the application would result in a safer outcome.
 - A period of time during regular operating conditions to collect specific data to assess the effectiveness of the control measures may be set. When collecting data, worst-case scenarios should be accounted for and sampling techniques used that lead to obtaining data that are representative of the cannabis extract or edible cannabis operation and of the control measure that is being assessed.
 - Challenge studies, such as a microbial challenge study to obtain scientifically valid experimental data showing the control measures are effective may be conducted. The study should be appropriate for the specific cannabis product and be designed to mimic process conditions.
 - Predictive modelling, such as mathematical models and equations to predict the growth and/or activity of a microorganism in a food product over time may be used.
 - Surveys may be used under certain circumstances in conjunction with other approaches to show that a control measure is effective in achieving the safety outcome.
 - Results are analyzed to confirm the effectiveness of the control measure(s).
 - Scientific, technical and observational information and results from the approaches(s) used are analyzed (e.g., process records, test results, certificates of analysis). The results of the analysis are used to assess the ability of the control measure to consistently address the hazard and achieve the intended outcome.
 - Re-validation of a control measure
3. The evidence is documented:
- Relevant information that was reviewed and/or obtained as evidence to validate the effectiveness of the control measures is documented. This may include where and/ or how the evidence was obtained. This information is maintained as part of the preventive control plan and should include the following, as applicable objectives; information used, study design and methodology, results analysis and conclusions.

Subsection 88.94(1)

Holders of a licence for processing who conduct activities in relation to cannabis extracts or edible cannabis must prepare, retain and implement a written preventive control plan for any activity that they conduct in respect to the cannabis or anything that will be used as an ingredient in the production of the cannabis extract or edible cannabis.

Paragraph 88.94(2)(a)

The preventive control plan must include a description for ensuring the following sections are met:

- Cannabis extracts
 - 101.3
 - Cannabis extracts - content
 - Prohibited ingredients
 - Exception – vitamins
 - Naturally-occurring substances
 - Permitted ingredients – inhaled cannabis extract
 - Ethyl alcohol – ingested cannabis extract
 - 101.4
 - Uniform distribution – cannabinoids and terpenes
- Edible cannabis
 - 102
 - Ingredients – edible cannabis
 - Temporarily marketed foods
 - Meat products, poultry products and fish
 - Self-produced foods
 - Food additives
 - Vitamins and minerals
 - 102.2
 - Caffeine
 - 102.3
 - Ethyl Alcohol
 - 102.5
 - Hermetically sealed containers
 - 102.6
 - Irradiation

For more information on the requirements related to sections 101.3, 101.4, 102, 102.2, 102.3, 102.5 and 102.6, refer to Part 6 of the *Cannabis Regulations*.

Subparagraph 88.94(2)(b)(i)

As part of their preventive control plan, a licence holder must include description of the biological, chemical and physical hazards that are identified under subsection 88.93(1) *Cannabis Regulations* that present a risk of contamination of the cannabis extract, edible cannabis or anything that will be used as an ingredient in the production of the cannabis extract or edible cannabis.

Licence holders should refer to subsection 88.93(1) of the *Cannabis Regulations* in this table for additional information on the hazard analysis.

Subparagraph 88.94(2)(b)(ii)

As part of their preventive control plan, licence holders must include a description of the control measures for preventing, eliminating or reducing to an acceptable level the hazards referred to in subparagraph 88.94(2)(b)(i) and the evidence that the control measures are effective.

Licence holders should refer to subsections 88.93(1) and 88.93(2) of the *Cannabis Regulations* in this table for additional information on the hazard analysis and evidence that control measures are effective.

Subparagraph 88.94(2)(b)(iii)

As part of their preventive control plan, licence holders must include a description of the critical control points, the related control measures and the evidence that the control measures are effective.

Critical control points are the steps in the process where a control measure is applied and is essential to prevent or eliminate a hazard that presents a risk of contamination of the cannabis or anything that will be used as an ingredient or to reduce the hazard to an acceptable level.

- The critical limits are described for each critical control point identified.
- Critical limits are the maximum and/or minimum set values that control a hazard at a critical control point (e.g., the time and temperature parameters used at a cooking step would be considered the critical limits).
- Critical limits are be specific and measurable.
- More than one step in a process may be involved in controlling a hazard, and more than one hazard may be controlled by a specific control measure.

Licence holders should refer to subsection 88.93(2) and subparagraph 88.94(2)(b)(iv) in this table for additional information relating to evidence that control measures are effective, and critical control limits associated with critical control points.

Subparagraph 88.94(2)(b)(iv)

As part of their preventive control plan, licence holders must include a description of the critical limits for each critical control point.

Critical limits are clear, specific and measurable criteria that distinguish between what is acceptable and/or unacceptable for a hazard identified by a critical control point. The effectiveness of control measures depends on their ability to keep hazards within critical limits.

Licence holders should define, how it will be determined that a hazard is prevented or reduced to an acceptable level at critical control point by establishing critical limits that are supported by scientific data and meet standards set out in legislative or regulatory requirements, such as the *Cannabis Regulations*, the *Food and Drug Regulations*, the *Pest Control Products Regulations*, and guidelines, as applicable.

Examples of critical control points and corresponding critical limits include:

Critical control points	Critical limits
Cooking	Time and temperature
Cooling	Time and temperature
Formulation	Concentration (ppm), pH
Dehydration	Water activity (Aw)
Freezing for parasite control	Time and temperature
Sifting	Mesh size
Chlorination	Concentration, volume
Filtration	Filter size

- Characteristics of a critical limit
 - Evaluation of a critical limit produces an immediate result to ensure a quick decision on whether the identified hazard is controlled to an acceptable level.
 - Critical limits may be quantitative (e.g., length, height, area, volume, weight, speed, time, temperature, humidity) or qualitative (e.g., other types of properties that can be confirmed by a visual inspection, such as colour of the food or presence of air bubbles). Critical limits that are based on qualitative data (subjective data) should be supported further with descriptions/ and instructions that help those responsible for monitoring the critical control point to understand the critical limit and apply it uniformly.
 - Rationale that supports the critical limits established, such as, scientific data or regulatory requirement is provided.
 - Critical control points are evaluated on an ongoing basis to ensure that the critical limits, which are measurable criteria, are not exceeded.
- Having specific and measurable critical limits supports the consistent application of the critical limit (e.g., for a cooking step, stating “cook product at high temperature” is not measurable, whereas stating “cook product to a temperature of not less than 75°C” is measurable).

- A combination of critical limits may be used to control a hazard at a particular critical control point. Critical limits may include a set of criteria, such as temperature, time (minimum time exposure), physical product dimensions, water activity and moisture level.
- More than one hazard may be identified at a critical control point. Different critical limits should be used to control each hazards as applicable.
- Critical limits are established by:
 - Determining the critical limit(s) for each critical control point, that prevents, eliminates or reduces the hazard to an acceptable level. This may include, identifying, minimum temperatures and times to ensure destruction of a pathogenic bacteria, a specific pH to prevent the growth of bacteria, the minimum size of detectable foreign substances to prevent extraneous matter hazards).
 - Evidence is obtained that validates each critical limit is effective. This evidence should be documented as per subparagraphs 88.94(2)(b)(viii) and 88.94(2)(c) of the *Cannabis Regulations*.

Critical limits may need to be re-evaluated, re-established and re-validated when a change is made to a production line (e.g., line speed, process step addition or elimination, new equipment), adjust a formulation (e.g., higher concentration of pathogens in the new ingredient or food) or learn new information (e.g., a previously unidentified hazard, change to accepted practice).

Subparagraph 88.94(2)(b)(v)

As part of their preventive control plan, licence holders must have a procedure for monitoring critical control points in relation to their critical limits.

Monitoring is done to detect any deviation from critical limits or standards indicating a loss of control over the process, and to provide this information in time for corrective action to be taken to regain control of the process before there is a need to reject the product.

- Monitoring activities are conducted to:
 - Ensure that control measures are effective.
 - Detect a loss of control before the product is sold, distributed or exported.
 - Produce an accurate record of the control measure for compliance and verification purposes.
 - Ensure that control measures used for hazards not part of a critical control point are correctly and consistently carried out and are effective.
- Monitoring procedures are established for each critical control point and these procedures specify, the tests, measurements or observation used to assess whether critical limits are met and that the control measures are functioning as intended.

Every written monitoring procedure should address the following questions.

- What: A description of the activities being done to monitor the critical limits is provided, including:
 - The tests performed
 - Measurements to be taken or observations to be made
- How: A detailed description of how the activities are being carried out is provided, including:
 - Test methods
 - Instructions on how to conduct the test, measurements or observations
- When: A monitoring frequency is established that is appropriate to ensure hazards are controlled, including:
 - Setting a frequency for carrying out the monitoring procedure.
 - Monitoring can be continuous or intermittent. If monitoring is intermittent, set a frequency that is sufficient to guarantee the critical control point is in control.
- Who: The job title of the person responsible for conducting the different activities under the monitoring procedures and evaluating the results is identified. Typically, monitoring activities are conducted by those responsible for applying the control measures.
- Records: Records used to document the results of the monitoring activities are listed.

Frequency of monitoring activities

- The frequency of monitoring activities is identified and is precise and measurable (e.g., "as required" is not an appropriate frequency). It may be time-based (e.g., hourly, daily, weekly, monthly, every six months, annually) or production-based (e.g., each lot or batch, or each shipment).
- The frequency of monitoring may need to be adjusted if something happens or changes (e.g., an increase in the frequency of monitoring may occur after a change in a critical limit, a change in the process, a deviation, or new validation data).

Some types of monitoring activities at a critical control point may include:

- Physical measurements:
 - time
 - weight
 - temperature

- belt speed
- Chemical measurements:
 - pH
 - water activity
 - salt
- Microbiological testing:
 - Microbiological analysis of critical ingredients before their use in processing (e.g., analytical results in dried milk used in chocolate products, or in starch used in canned foods)
 - Microbiological analysis of critical cannabis products before their release to highly sensitive consumers (e.g., medical clients).

The time required to obtain results is considered when deciding what monitoring procedures should be used in a critical control point. Rapid tests are preferable for monitoring procedures taking place on dynamic processing lines.

Some types of monitoring activities for control measures that are not part of a critical control point may include:

- Visual observation of:
 - Employee hygiene (e.g., hand washing, hair nets, appropriate clothing)
 - Incoming materials inspection (e.g., segregation of allergens)
 - Application of sanitizers (e.g., away from cannabis and ingredients)
- Sensory evaluation for flavour and odour as an extension of visual observation, including:
 - Detection of off-odours
 - Tactile evidence of textural deterioration

Subparagraph 88.94(2)(b)(vi)

As part of their preventive control plan, licence holders must have a corrective action procedure for every critical control point.

Corrective actions are an integral component of an effective preventive control plan. They are the steps taken to address any deviations from the critical limits or the control measures in the plan by:

- Identifying, isolating and evaluating the affected cannabis or ingredient, and addressing the non-compliance
- Determining the root cause of the deviation and preventing recurrence

- Documenting the deviations and all of the corrective actions taken

Deviations from critical limits and procedures may affect both the safety of the cannabis product and compliance with regulations. If adequate corrective actions are not taken when critical limits are not met, this could lead to unsafe cannabis product.

Designing and implementing corrective action procedures

When there is an indication that non-compliance or a deviation has occurred in the preventive control plan, whether through monitoring results, consumer complaints or some other means, steps should be taken to implement corrective actions to establish control over the cannabis extract, edible cannabis or ingredient. Corrective actions should follow a standard, documented approach that is flexible enough to deal with any deviation that may occur.

Every written corrective action procedure should answer some basic questions related to who, what, how, as well as what record to use to document corrective actions on.

Step 1. For each control measure, the person responsible for taking the corrective action is identified:

- The person(s) responsible for the corrective actions is identified, and is someone who is competent and qualified to determine what needs to be done and act on it.
- The person who implements the corrective action is identified. This may be the person performing the monitoring, or be their superior, or another qualified individual.

Step 2. The corrective actions to take for the non-conformance are documented. Namely, what needs to be done and how. Control the non-conformance:

- All cannabis or ingredient lots or batches that may be affected are immediately identified and isolated. This includes controlling all cannabis or ingredients back to any produced after the last acceptable monitoring result was taken.
- Production is stopped, if necessary, to prevent unsafe cannabis or ingredient from being produced.
- An investigation of the affected cannabis or ingredient should be conducted to assess the quality risk to public health. The assessment may include such things as sampling and testing. Evaluation of the assessment of the cannabis or ingredient to determine the appropriate disposition, including if the cannabis or ingredient is assessed as:
 - Safe to consume: The cannabis or ingredient may be sold, distributed and exported as cannabis extract or edible cannabis or be used as an ingredient, or cannabis that will become an edible cannabis or cannabis extract.
 - Not safe to consume but is able to be brought into compliance:

- The cannabis or ingredient is brought into compliance (e.g., heat treatment, repackaged, relabeled, reworked) before it is distributed or sold.
- Not safe to consume and cannot be brought into compliance:
 - It is disposed of appropriately (e.g., destroyed).

Step 3. The steps for investigating, identifying and following up and conducting a recall if a non-compliant cannabis extract, edible cannabis or an ingredient has entered the marketplace or has entered into a cannabis or food supply chain as an input material or ingredient for a cannabis product or food are documented.

Step 4. The steps for determining the root cause of the deviation and preventing any future recurrence are documented, including:

- An investigation and determination of what went wrong to cause the deviation
- Implementation of the corrective action(s) to restore control
- Once implemented, verification of the effectiveness of the corrective action(s) to ensure that the parameter(s) have been brought back under control
- If corrective actions were not effective in establishing control of the cannabis extract, edible cannabis or ingredient as above, additional corrective actions are developed, implemented and their effectiveness is verified.
- If during the process of determining the root cause and adjusting control measures to prevent recurrence, a hazard is identified that was not considered during the development of the preventive control plan, the plan is reviewed to determine whether the hazard needs to be controlled.

Step 5. A standardized record to document the details of the corrective actions as outlined in steps 1 to 4 is prepared, including:

- The date and time the deviation was observed or reported
- The nature of the deviation including, a detailed product description (e.g., example, lot or batch number and name of the product in question) and specifying if cannabis or ingredients or cannabis or ingredient contact surfaces were affected
- Whether an investigation of the affected cannabis or ingredient was completed, the outcome of that investigation and details of product disposition
- What corrective actions were or are to be taken
- The timeframe for completion of the corrective actions including:
 - A target date for completion of corrective actions

- The actual completion date for these corrective actions
- Control measures to be taken to prevent recurrence, including:
 - A target date for completion of these control measures
 - The actual completion date for these control measures
- Signature of the responsible employee
- Documentation, including verification date, time and signature indicating that the verifier approves that the activity (e.g., corrective action) were completed satisfactorily and that the corrective action was effective

Subparagraph 88.94(2)(b)(vii)

As part of their preventive control plan, licence holders must have procedures for verifying that the implementation of the preventive control plan result in compliance with the Cannabis Regulations.

Verification activities are used to confirm and demonstrate that all control measures and procedures outlined in the preventive control plan are consistently implemented and effective in achieving the intended outcome.

Verification procedures applied to:

- Critical control points and their control measures
- Control measures for hazards not part of a critical control point
- Measures taken to ensure that other regulatory requirements (e.g., labelling, maximum quantity of THC, contaminants) are met
- Monitoring procedures
- Corrective actions procedures

Verification SOPs detail how it is ensured that each control measure and procedure is consistently implemented and is effective at ensuring safe and compliant cannabis extract, edible cannabis and ingredient.

Every written verification procedure should answer the basic questions: who, when, what, why and how. The procedure should also identify the records used. Verification procedures may include the following:

- The responsible person who conducts the verification activities and the verification frequency is identified:
 - The person or team responsible, other than the person who conducts the monitoring or corrective actions is named.
 - External qualified third parties may be used when verification cannot be carried out by in-house staff

- A frequency is determined appropriate to the hazards associated with the cannabis extract, edible cannabis or ingredient and the process that is being verified
 - Verification of critical control points may be conducted at a higher frequency than verification of other control measures
 - The frequency of verification is adjusted in response to the identification of problems with monitoring or corrective actions
- The verification activities to be conducted are described, such as:
 - Employees are directly observed performing monitoring activities to ensure that the SOPs are being followed
 - Corrective actions taken by an employee are directly observed to ensure that the SOPs are being followed
 - Records documenting the monitoring activity are reviewed to ensure the proper version of the record is used, records are complete and filled out as per SOPs (e.g., review of temperature controls)
 - Records documenting the actions taken in response to a deviation
 - Samples and tests of the environment, or a cannabis extract, edible cannabis or ingredient to confirm the safety of the product are reviewed (e.g., swab equipment to verify the effectiveness of a sanitation program or testing of cannabis product for compliance to microbial and chemical contaminants)
 - Calibration of equipment is verified (e.g., thermometers, timing belts and pumps)
 - Employees are interviewed and observed to ensure that written policies and procedures are being followed
- Records to be completed to document the verification activities are completed and the results of those activities are described.
- Additional procedures are specified that relate to appropriate follow-up when problems are identified during verification. The procedure to follow may differ depending on the nature of the issue (e.g., monitoring or corrective actions, or if it is with the effectiveness of the preventive control plan itself in maintaining control).

Verification records are designed to include space to comment on the outcome of the verification including what corrective action (if needed) was taken.

Subparagraph 88.94(2)(b)(viii)

As part of their preventive control plan, a licence holder must have documents that substantiate that the preventive control plan has been implemented with respect to subparagraphs 88.94(2)(b)(i) to (vii) verifying that the implementation of the preventive control plan results in compliance with the *Cannabis Regulations*.

Paragraph 88.94(c)

As part of their preventive control plan, licence holders must have supporting documents to substantiate a preventive control plan (description of hazard identified, control measures, critical control points, procedures for monitoring, corrective action procedures, verification procedures) has been implemented and supporting information required in the *Cannabis Regulations* 88.94(2)(a) and (b) have been included.

Subsection 88.94(3)

Each document referred to in subparagraph 88.94(2)(b)(viii) of the *Cannabis Regulations* which substantiates that the preventive control plan has been implemented with respect to subparagraphs 88.94(2)(b)(i) to (v)(ii) must be retained for at least two years after the day on which it is prepared.