



Understanding the Federal Cannabis Licensing Process

Health Canada



Government
of Canada

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du Canada

Canada 

Objective

The Government of Canada is committed to a licensing framework that will enable a diverse, competitive legal industry that is comprised of a range of market participants, including small and large businesses, and Indigenous affiliated applicants.

The objectives of this session are to:

- Provide an overview of the cannabis licensing process for cultivation, process and sale for medical purposes licence types;
- Help potential and in-progress applicants navigate the licensing process;
- Increase the number of quality applications submitted to the commercial cannabis licensing process.

The Cannabis Act: An Overview

The Cannabis Act creates a framework that:

Restrict youth from accessing cannabis

- Youth under 18 years of age are prohibited from accessing cannabis
- Protects young people and others from advertising, promotional activities and enticements to use cannabis

Control access to cannabis for adults of legal age

- Limits adult possession to 30 grams of legal cannabis products (dried, fresh and oil)
- Limits home cultivation to 4 plants per residence

Provide oversight for the operation of the legal cannabis industry

- Permits, through federal licences, the production, cultivation and processing of cannabis
- Authorizes provinces and territories to distribute and sell cannabis, subject to federal conditions

Strictly regulate the supply chain

- Provides Canadians with access to a quality-controlled supply of cannabis
- Establishes strict product quality requirements (e.g., production standards, testing)
- Safeguards the integrity of the supply chain (i.e., Cannabis Tracking and Licensing System)

Establish strong penalties to protect public safety

- Creates new cannabis-related offences with serious penalties (i.e., selling cannabis to youth)
- Deters illegal activities through sanctions and enforcement measures

Regulatory Operations

- ❖ In order to meet the public health and safety objectives of the *Cannabis Act*, the commercial cultivation and processing of cannabis is a highly-regulated industry.
- ❖ Regulated parties operating in the cannabis industry are expected to:
 - Understand the *Cannabis Act* and *Regulations* and their obligations;
 - Demonstrate compliance through the licence application process and inspection program;
 - Apply understanding to all activities, processes and products at all times.

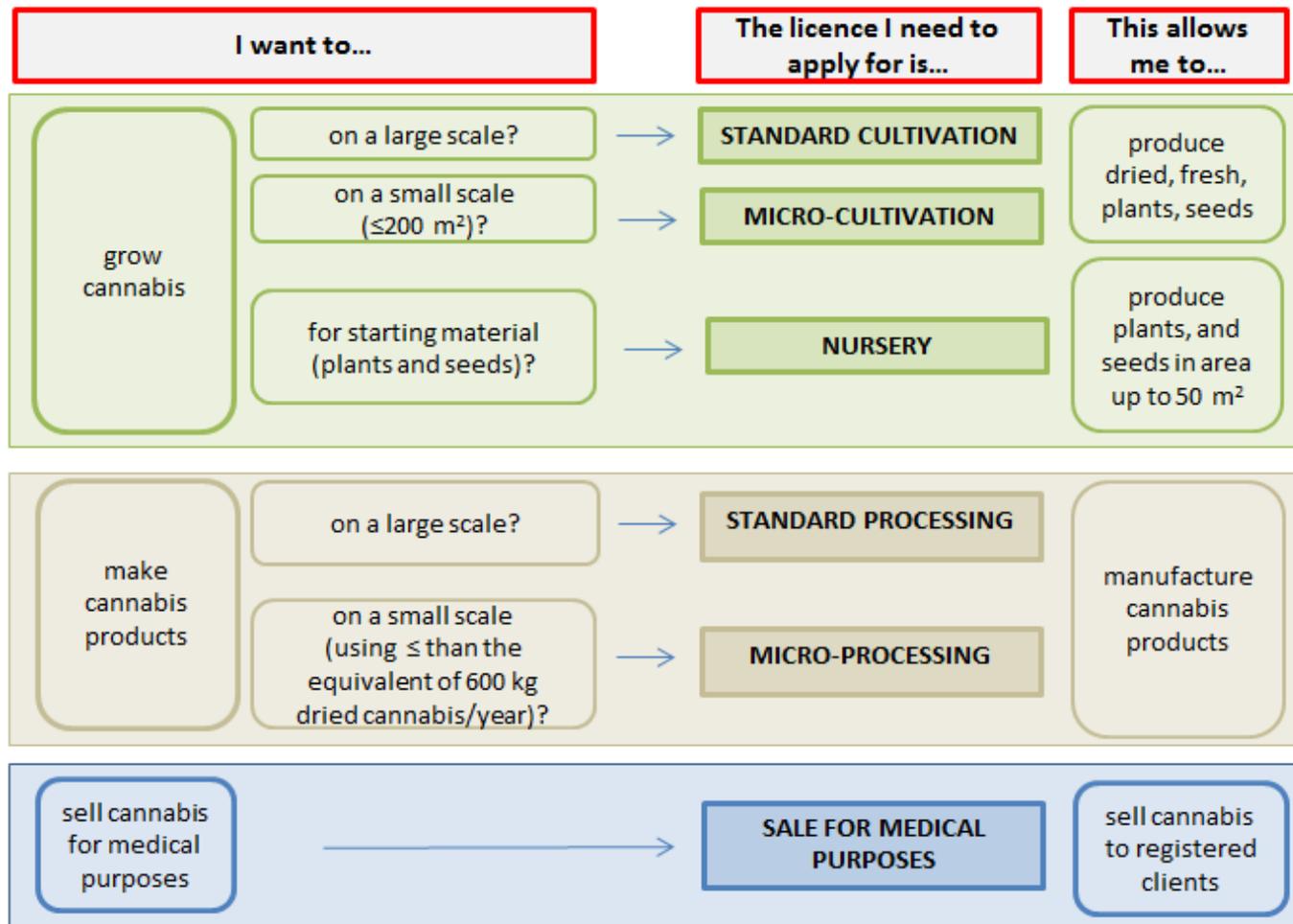
Licensing under the *Cannabis Act* and its Regulations

- ❖ Under the framework of the *Cannabis Act* and its Regulations, a person is required to obtain a licence issued by Health Canada to do various activities with cannabis such as:
 - Grow cannabis commercially for sale or produce cannabis products commercially (large or small scale);
 - Sell cannabis for medical purposes;
 - Conduct tests on cannabis;
 - Conduct research with cannabis.

- ❖ Cultivators and processors of cannabis products are also required to obtain a cannabis licence from the Canada Revenue Agency (CRA).

Determining Licence Class

- ❖ Applicants can determine which class of licence is needed based on their planned activities.



Licence Classes and Subclasses – Authorized Combinations

| General Guide for Combinations of Licence Classes and Subclasses at a Single Site | | | | | | |
|---|----------------------|-------------------|---------|---------------------|------------------|---------------------------|
| | Standard cultivation | Micro-cultivation | Nursery | Standard processing | Micro-processing | Sale for medical purposes |
| Standard cultivation | | | | ✓ | | ✓ |
| Micro-cultivation | | | | | ✓ | ✓ |
| Nursery | | | | | | ✓ |
| Standard processing | ✓ | | | | | ✓ |
| Micro-processing | | ✓ | | | | ✓ |
| Sale for medical purposes | ✓ | ✓ | ✓ | ✓ | ✓ | |

Licensing Process for a New Site

Application Submission

- Submit application through the CTLS.
- Within 10 days submit visual site evidence directly to Health Canada via USB.

Payment

- Application screening fee.
- Security clearance fee for applicable personnel.

Screening

- Application assessed for completeness, legibility and ability to be further assessed.
- 30 day nonbinding service standard.

Review and Security Clearance

- Detailed review of documents submitted in the CTLS and site evidence.
- Criminal background and law enforcement record checks.
- 60 day target for review once assigned to a reviewer.

Licensing Decision

- If application is assessed as acceptable and all security clearances have been granted, a licence is issued.

Application Submission: Site Evidence

- ❖ Like most federal site based licensing programs, Health Canada requires applicants submit evidence that demonstrates that they have a site which is **fully built** and meets all applicable requirements of the *Cannabis Regulations* at the time of application.
- ❖ A fully built site is considered:
 - operational and functional;
 - equipped with all **permanent** fixtures such as security features, facility lighting (excluding cultivation lights) ventilation and air filtration system as applicable.
- ❖ The fully built site is not required to have any cultivation or processing equipment (e.g., cultivation tables and lights, trimmers, scales etc.) on site nor have it present during the site evidence video walkthrough.
- ❖ Applicants may choose to only request a licence for a portion of a building, within the identified site perimeter. The applicant is only required to demonstrate compliance (physical security, GPP, etc.) for the areas that they would like approval for at this time, not the entire building. This is described in more detail on the following slide.

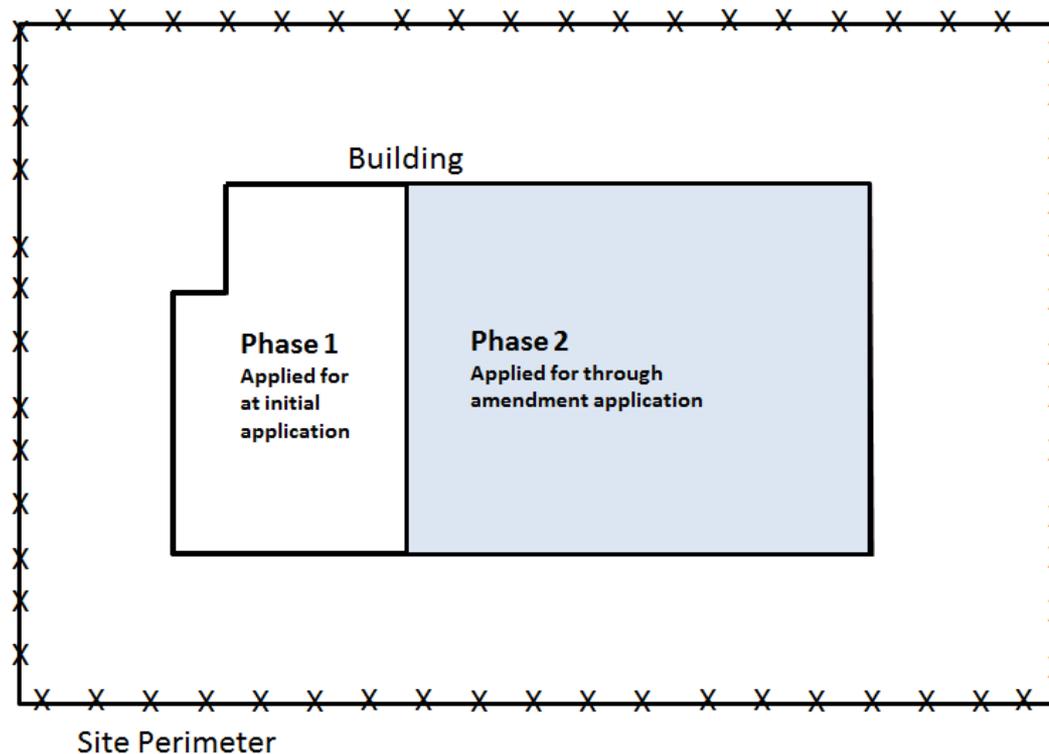
Phased Building Approach

❖ Phase 1

- Applicants may choose to request approval for and submit site evidence of only a portion of their building.

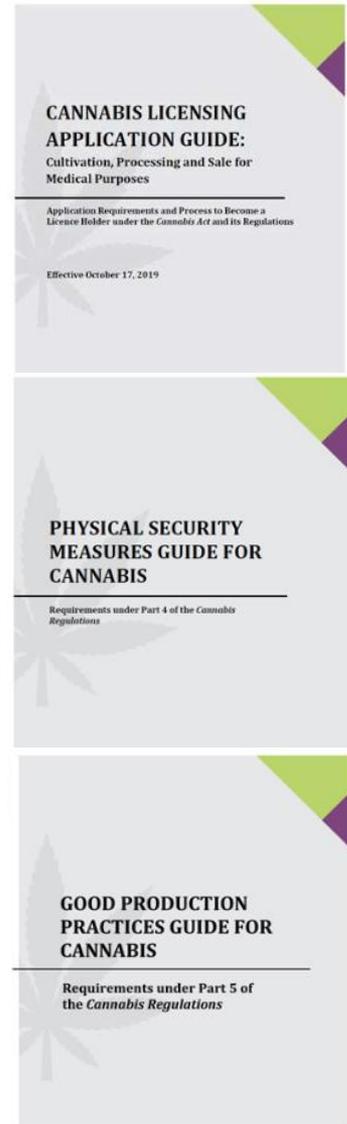
❖ Phase 2

- Licence holders may request to have their licence amended to add additional cannabis areas or move from a micro-class licence to a standard-class licence.



Available Guidance

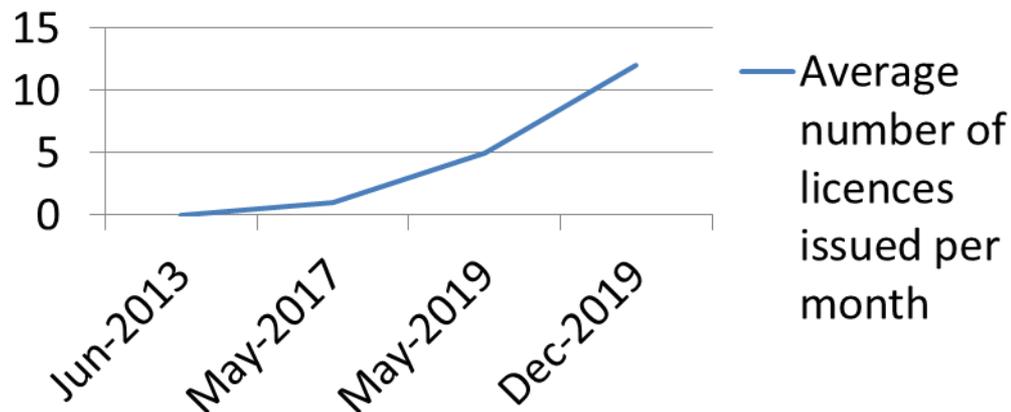
- ❖ Health Canada offers several guidance documents to support applicants:
 - The **Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes** provides information on the application requirements.
 - The **Physical Security Measures Guide for Cannabis** and the **Good Production Practices Guide for Cannabis** provide examples of principles and practices that may be used to demonstrate compliance.
- ❖ These guides should be used in conjunction with each other and the *Cannabis Act* and its regulations.



Current Licensing Statistics

- ❖ Health Canada continues to make improvements to its licensing process which can be seen in the following statistics:
 - From June 2013 to May 2017 Health Canada issued 44 licences for commercial cannabis production (~ **1 licence issued per month**).
 - In May 2017 Health Canada implemented a number of process improvements and from May 2017 until May 2019 Health Canada issued a further 129 licences (~**5 licences issued per month**).
 - Further process improvements were implemented in May 2019 and since that date Health Canada has issued a further 105 licences (~**13 licences issued per month**).

Impact of process improvements on licence issuance



Physical Security Measures - Micros

- ❖ Micro-class licence holders are required to meet physical security requirements in line with their risk profile, with no requirements for video recording or intrusion detection:

| Physical Security Requirements for Micro-cultivation and Micro-processing Licences as per Part 4, Division 2 of the <i>Cannabis Regulations</i> | | |
|--|--------------------------|-------------------------|
| Required physical security measures | Micro-cultivation | Micro-processing |
| Site Design Subsection 74(a) | ✓ | ✓ |
| Physical Barrier for the Site Subsection 74(b) | ✓ | ✓ |
| Physical Barrier for the Storage Area(s) Subsection 74(c) | ✓ | ✓ |
| Restricted Access for each Storage Area(s) Subsection 74(d) | ✓ | ✓ |

Good Production Practices (GPP) - Micros

| General GPP requirements for Micro-cultivation and Micro-processing Licences | | |
|--|-------------------|------------------|
| GPP requirement | Micro-cultivation | Micro-processing |
| Standard operating procedures Section 80 | ✓ | ✓ |
| Pest control product Section 81 | ✓ | ✓ |
| Storage Section 82 | ✓ | ✓ |
| Distribution Section 83 | ✓ | ✓ |
| Building or part of a building Section 84 | ✓ ¹ | ✓ |
| System – Filtration and ventilation Section 85 | ✓ | ✓ |
| Supply of water Section 85.1 | ✓ | ✓ |
| Lighting Section 85.2 | ✓ | ✓ |
| Equipment Section 86 | ✓ ² | ✓ |
| Sanitation program Section 87 | ✓ ³ | ✓ |
| Hand cleaning and hand sanitizing stations and lavatories Section 87.1 | ✓ | ✓ |

¹ Does not apply to cultivation licence holders who cultivate, propagate or harvest outdoors, only.

² Paragraph 86(1)(d) preventing addition of extraneous substances does not apply to outdoor cultivation, propagation or harvesting.

³ Paragraph 87(1)(a) requiring effective cleaning of building or part of a building does not apply to outdoor cultivation, propagation or harvesting.

Common Reasons for Delays

- ❖ Of the applications received and reviewed to date, Health Canada has identified a number of areas that commonly cause a delay in the review process.
- ❖ Key factors in application review times are the **quality** of the application and whether it contains **sufficient information and evidence** to demonstrate how it meets the security measures, the Good Production Practices, and the record-keeping requirements.
- ❖ The following slides highlight areas that are often insufficient for application review which can result in delays.

Production Capacity

❖ Section 6.4 of the Cannabis Licensing Application Guide

- Cultivation and Processing applicants only.

❖ Required details to submit:

- Estimate of the proposed annual production amount

- Kg per year per applicable cannabis class;
- Number of plants or seeds per year per applicable cannabis class.

- Total area of grow areas (m²).

- Total area of operations areas not including grow areas (m²).

QAP Qualifications

❖ Section 6.5 of the Cannabis Licensing Application Guide

- Required for **processors only**.

❖ Required details to submit:

- Clear concrete examples and details of how the QAP meets the technical knowledge, training and experience requirements.
- Details of when, where and how the knowledge, training and experience was obtained by the QAP.
- Resume or CV.
- Supporting documentation which may include letters of reference, diploma, degree, certificate or transcripts.

Site Ownership

❖ Section 6.6 of the Cannabis Licensing Application Guide

❖ Submission requirements depend on the ownership of the site:

Scenario 1: The site is owned by the individual or corporation applying for the licence → **Link Account ID in the CTLS.**

Scenario 2: The site is owned by another individual or corporation → **Submit a site owner consent form.**

- Site owner consent form must contain:
 - Address of site;
 - Class and subclass of licence;
 - Signed declaration by site owner stating:
 - » They are the owners of the site;
 - » They are aware of the activities with cannabis being conducted;
 - » They consent to those activities being carried out.

Notice to Local Authorities

❖ Section 6.7 of the Cannabis Licensing Application Guide

- Not required for Sale for Medical Purposes without possession.

❖ The notice must be submitted to:

- The local government;
- The local fire authority;
- The local police force.

❖ Notices must include the following:

- Date each notice was sent or provided;
- Name, title and address of senior official;
- Name of applicant;
- Expected date on which the applicant will submit application to Health Canada;
- The class and subclass of the licence being sought;
- The cannabis related activities that are expected to be conducted;
- The site address.

Site Plan

❖ Section 6.8 of the Cannabis Licensing Application Guide

- Not required for Sale for Medical Purposes without possession.

❖ Some of the required details to include:

- Clearly identified site perimeter;
- Clearly identified footprint of all buildings;
- Identification of the location of any outdoor grow areas if applicable;
- Indication of the locations and area covered by all security and visual monitoring devices if applicable (include both indoor and outdoor);
- Clear identification of all operations, grow and storage rooms or areas;
- Clear identification of the area the storage area is located within, if applicable.

This area must have the following:

- restricted access;
 - physical barrier;
 - visual monitoring;
 - intrusion detection system.
- Indication of how cannabis will flow through the site.

Guided Video Tour

- ❖ **Section 6.8 and 6.9 of the Cannabis Licensing Application Guide**
 - Not required for Sale for Medical Purposes without possession.

- ❖ Some of the required details to include in the video tour are:
 - Inclusion of the entire site highlighting all security features of the site perimeter, operations areas and storage areas, if applicable;
 - Highlighting all good production practices features of the buildings;
 - Inclusion of an individual moving through the areas of the facility to demonstrate the intended production flow process.

- ❖ Applicants should ensure that the video tour and site plans align.
 - Names given on tour and on site and floor plans should match.

- ❖ Narrative must be clear and audible.
- ❖ Video resolution must be sufficient to clearly see the areas.
- ❖ Special video equipment is not required.

Organizational Security Plan (OSP)

❖ Table 10 of the Cannabis Licensing Application Guide.

❖ Some of the required information to include is:

1. Head of security information

- Proposed work schedule, contact information

2. Business plan

- Description of business model including all activities and products sold
- Affiliations with other companies

3. Site organizational chart

- Outline of the organizational structure showing the relationships of directors, officers and management
- Description of roles for each individual listed in chart

4. Key individuals

- A complete list of all key individuals who require a security clearance

5. Cannabis tracking

- List of names, titles and contact information for all individuals who will input data into the CTLS

Organizational Security Plan (OSP) – cont.

6. Security awareness and training

- A description of the steps the head of security intends to take to ensure that guests and all employees/contractors are trained and aware of security procedures.

7. SOPs

- Include a list of SOPs and description of each demonstrating the procedures in place relative to each Priority Area outlined in Appendix D: Organizational Security Plan SOP Priority Areas.

8. Other security elements

- A description of any other security elements or features of the site

9. Attestations

- Submission of the physical security attestation and the OSP attestation

The Security Clearance Process

- ❖ All security clearance applications are subject to:
 - A criminal record check
 - A Law Enforcement Record Check (LERC)
- ❖ In order to allow a timely review Security Clearance requests, applicants should ensure that all information especially pertaining to past employment, education and travel history, and any past criminal convictions is complete and correct at the time of application submission.
- ❖ An individual cannot work in a role requiring a security clearance until after they have received their clearance.

Sale of Cannabis Products – A Graduated Licensing Process

A cannabis product is cannabis after it has been packaged and labelled for sale to a consumer at the retail level.

- ❖ Cultivators (micro, standard and nursery) can only sell **plants and seeds** that are packaged for sale to authorized retailers and/or holders of a licence for sale for medical purposes.
- ❖ Processors (micro, standard) can sell **all cannabis classes** that are packaged for sale to authorized retailers and/or holders of a licence for sale.

Prior to the sale of dried and fresh cannabis, edible cannabis, cannabis extracts, and/or cannabis topicals that are cannabis products, the processing licence holder must meet the following 2 requirements:

1. Amend licence to add activity of sale **and**;
2. Submit a new product notification (s.244).

Sale of Cannabis and Cannabis Products

| IF I HAVE A LICENCE FOR: | WHAT CLASS OF CANNABIS CAN I SELL? | AFTER LICENCE ISSUANCE WHO CAN I SELL ¹ TO? | | | | | |
|---------------------------------|--|--|------------------------|-------------------------------|--|--|---------------------------|
| | | Cultivator (micro or standard) | Nursery Licence Holder | Processor (micro or standard) | Sale for Medical Purposes ² | Provincially or territorially authorized retailer ² | Registered medical client |
| Cultivation (micro or standard) | Plants, Seeds | ● | ● | ● | ● | ● | |
| | Fresh, Dried | ● | | ● | | | |
| Nursery | Plants, Seeds | ● | ● | ● | ● | ● | |
| Processing (micro or standard) | Plants, Seeds | ● | ● | ● | ● | ● | |
| | Fresh, Dried | ● | | ● | ● | ● | |
| | Extracts, Topicals, Edibles | | | ● | ● | ● | |
| Sale for Medical Purposes | Plants, Seeds that are cannabis products | ● | ● | ● | ● | | ● |
| | Fresh, Dried that are cannabis products | ● | | ● | ● | | ● |
| | Extracts, Topicals, Edibles that are cannabis products | | | ● | ● | | ● |

¹Licence holders may also be authorized to sell cannabis to other parties as authorized by the *Cannabis Regulations*

²Any cannabis sold to a Sale for Medical Purposes licence holder or to a provincially or territorially authorized retail seller must be packaged and labelled according to Section 106 of the Cannabis Regulations.



Thank you!

Questions

Health Canada Licensing:
hc.licensing-cannabis-licences.sc@canada.ca

Additional Guidance Resources

| | |
|---|---|
| Mandatory cannabis testing for pesticide active ingredients - Requirements | https://www.canada.ca/en/public-health/services/publications/drugs-health-products/cannabis-testing-pesticide-requirements.html |
| Mandatory cannabis testing for pesticide active ingredients – List and limits | https://www.canada.ca/en/public-health/services/publications/drugs-health-products/cannabis-testing-pesticide-list-limits.html |
| Cannabis Fees Order Guide | https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/cannabis-fees-order/guide.html |
| Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes | https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/industry-licensees-applicants/licensing-summary.html |
| Change Summary - Cannabis Licensing Application Guide | https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/industry-licensees-applicants/licensing-summary/history.html |
| Physical Security Measures Guide for Cannabis | https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/laws-regulations/regulations-support-cannabis-act/guide-physical-security-measures.html |
| Cannabis Tracking System - Monthly Reporting Guide (Licence Holders and PTs) | https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/tracking-system/monthly-reporting-guide-federal/october-2019.html |
| Good production practices guide for cannabis | https://www.canada.ca/en/health-canada/services/cannabis-regulations-licensed-producers/good-production-practices-guide/good-production-practices-guide-october-2019.html |
| Cannabis Voluntary Recall Guide | https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/cannabis-voluntary-recall/guide/october-2019.html |
| Packaging and labelling guide for cannabis products | https://www.canada.ca/en/health-canada/services/cannabis-regulations-licensed-producers/packaging-labelling-guide-cannabis-products/guide.html |
| Notice of new cannabis product guide | https://www.canada.ca/en/health-canada/services/publications/drugs-health-products/notice-new-cannabis-product/guide.html |
| Guide on composition requirements for cannabis products | https://www.canada.ca/en/services/health/publications/drugs-health-products/composition-requirements-cannabis-products.html |
| CTLS User Guide | Available upon request to cannabis@canada.ca |
| CTLS Getting Started Guide | https://www.canada.ca/en/services/health/publications/drugs-health-products/getting-started-cannabis-tracking-licensing-system.html |