



Islands Agricultural Show
Controlled Substances and Cannabis Branch
Licensing and Security Division

Health Canada



Government
of Canada

Gouvernement
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 all licences offered within the Controlled Substances and Cannabis Branch;
- Provide an overview of the cannabis licensing process for cultivation, processing and sale for medical purposes licence types;
- Help potential and in-progress applicants navigate the licensing process;
- Provide details on cultivation licence classes and key requirements.

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

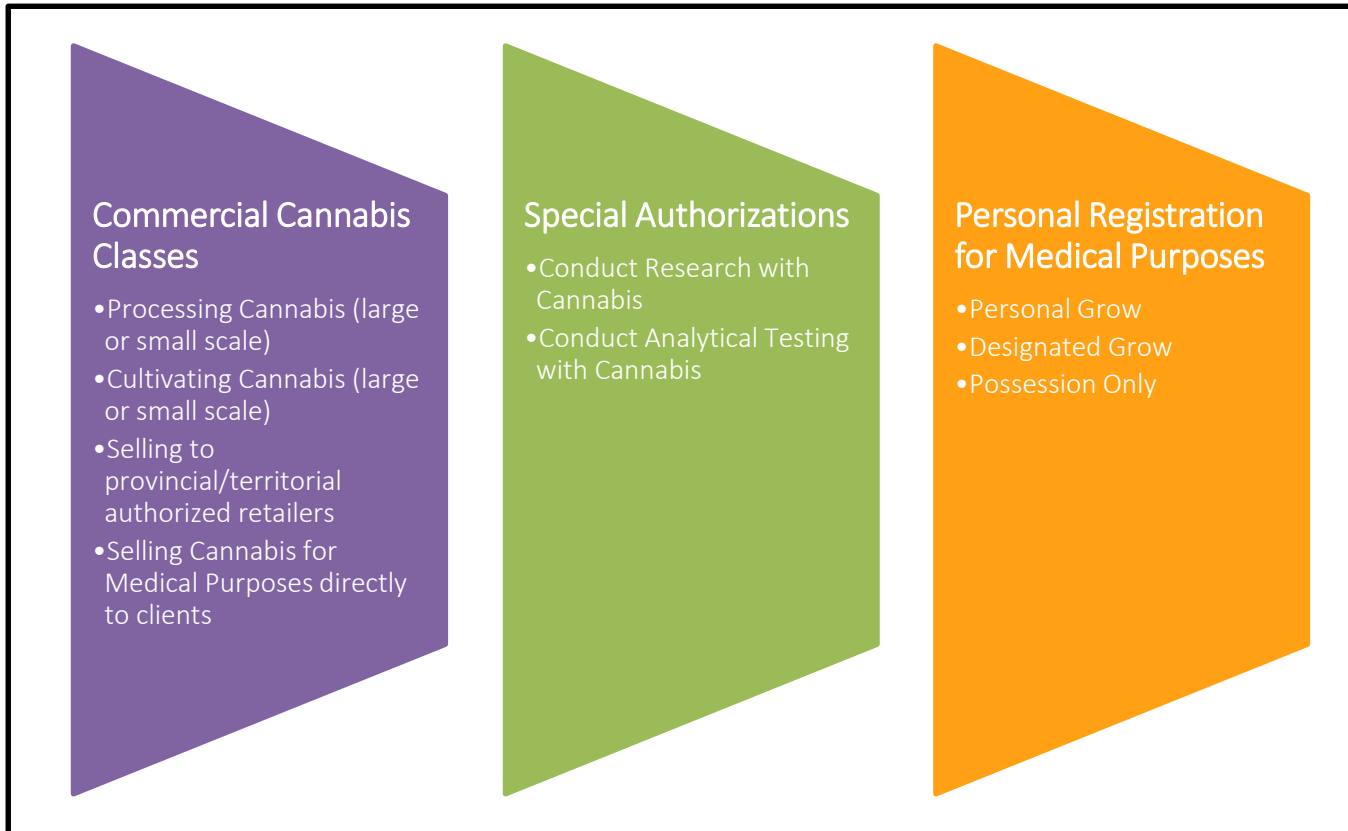
Regulatory Operations and the *Cannabis Act*

- ❖ Regulated parties operating in the cannabis industry are expected to:
 - Understand the *Cannabis Act* and Regulations and their obligation with respect to all regulated activities;
 - Demonstrate compliance through the licensing process and inspection program;
 - Apply understanding to all activities, process and products at all times

Authorized activities under the *Cannabis Act*

❖ The *Cannabis Act* regulates various activities with cannabis under these two frameworks:

Cannabis Regulations



Industrial Hemp Regulations



Commercial Cannabis Classes

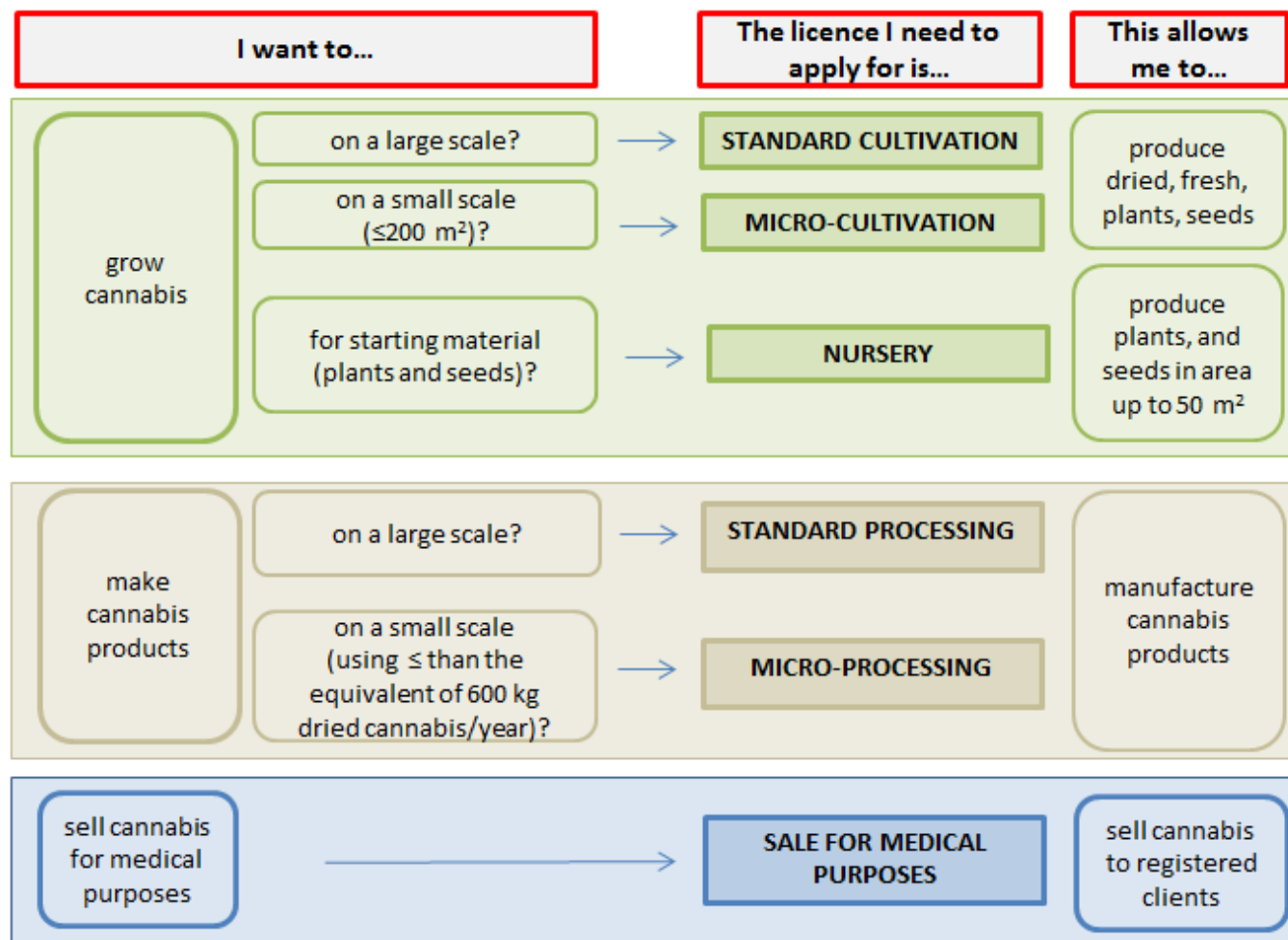
- ❖ Under the framework of the *Cannabis Act* and its Regulations, a person is required to obtain a licence issued by Health Canada to do various activities with cannabis such as:
 - Processing cannabis commercially for sale (large or small scale)
 - Cultivating cannabis commercially for sale (large or small scale) and/or (indoor or outdoor)
 - Sell cannabis to provincial/territorial authorized retailers
 - Sell cannabis for medical purposes

- ❖ Cannabis **products** covered under the commercial cannabis licence classes:
 - cannabis plants,
 - cannabis plant seeds,
 - dried and fresh cannabis,
 - cannabis extracts,
 - cannabis topicals and
 - edible cannabis.

- ❖ Reminder that applicants applying for a cultivation and/or processing licence are also required to apply for a cannabis licence from the Canada Revenue Agency (CRA) simultaneously.

Commercial Cannabis Classes

- ❖ Applicants can determine which class of licence is needed based on their planned activities (Figure 2: *Cannabis Licensing Application Guide*):

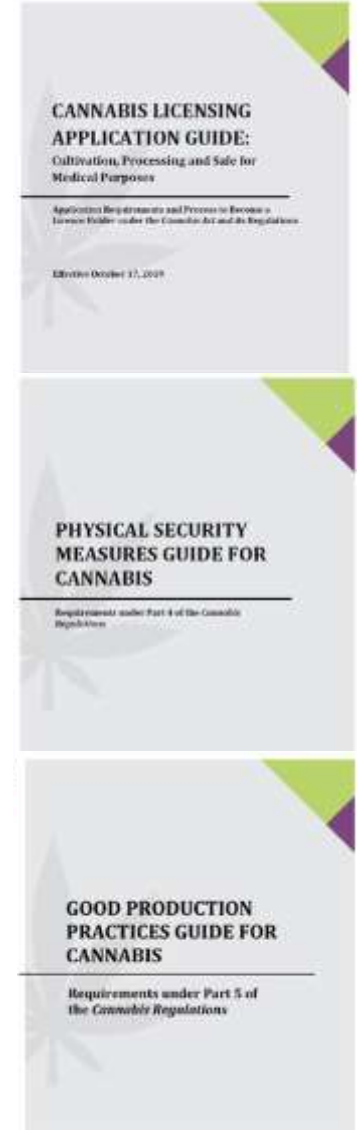


Licence Classes and Subclasses – Authorized Combinations

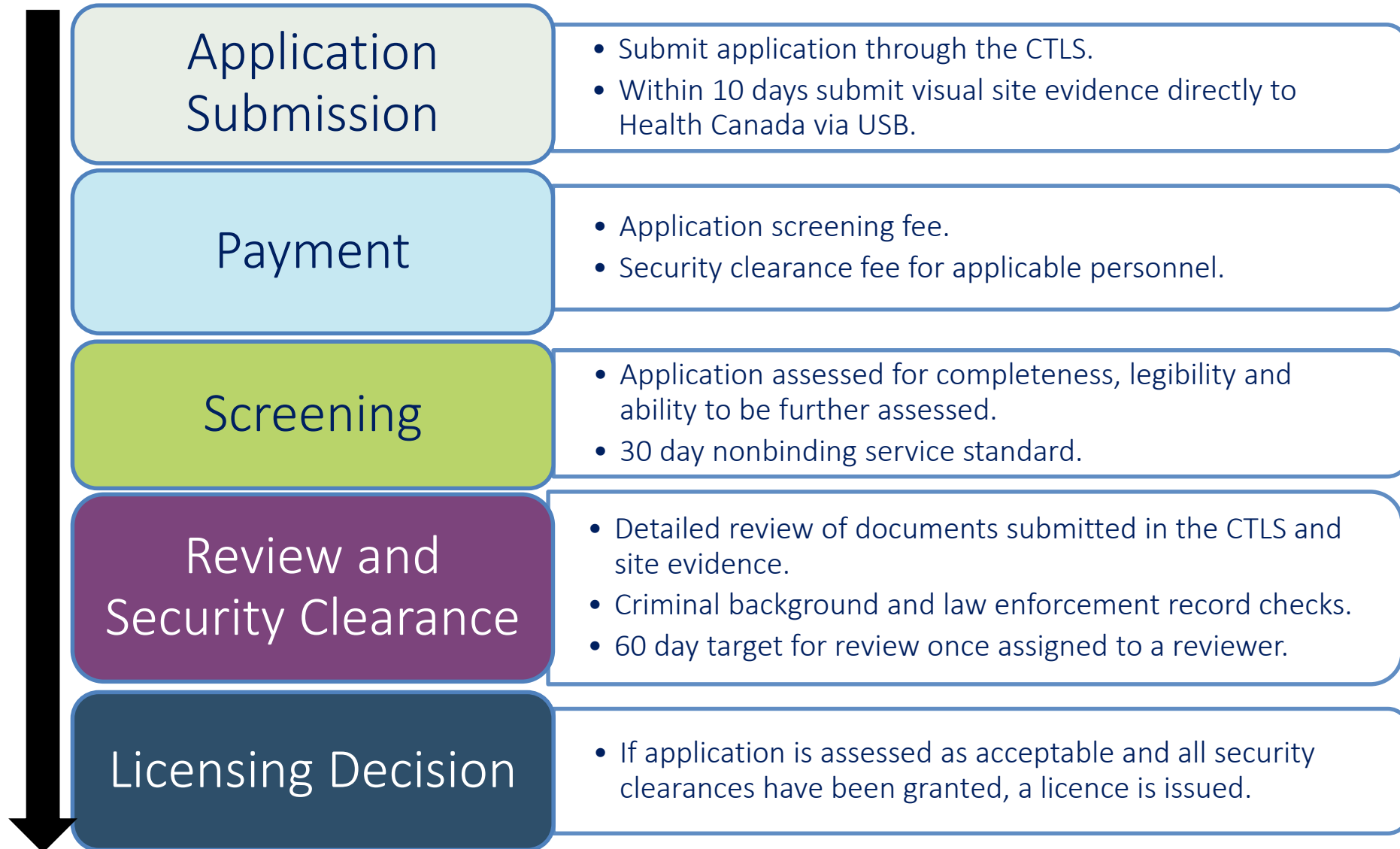
| General Guide for Combinations of Licence Classes and Subclasses at a Single Site | | | | | | |
|---|----------------------|-------------------|---------|---------------------|------------------|---------------------------|
| | Standard cultivation | Micro-cultivation | Nursery | Standard processing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

Commercial Cannabis Classes – Guidance Documents

- ❖ Health Canada has 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.



Licensing Process for a Commercial Cannabis Licence



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.

Key Personnel – Cultivation

- ❖ **Responsible Person:** Overall responsibility for the activities conducted and is responsible for submitting the application. They are the official point of contact with Health Canada. They must have sufficient knowledge of the provisions of the *Act* and *Regulations* that apply to the holder of the licence.
- ❖ **Head of Security:** Responsible for ensuring that the applicable physical security measures are complied with and the organizational security plan.
- ❖ **Alternate head of security (if applicable):** Qualified to replace the head of security.
- ❖ **Master Grower:** Responsible for the cultivation, propagation and harvesting of cannabis and must have sufficient knowledge of the provisions of the *Act* and its *Regulations* in relation to those activities
- ❖ **Alternate Master Grower (if applicable):** Qualified to replace the master grower

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.
- ❖ Please note that all security clearance applications are reviewed in parallel to the cannabis class application.

Cultivation Licence Class

- ❖ There are a few key factors that apply more specifically to a cultivation licence which we would like to highlight.
- ❖ The following slides highlight areas that are more specific to cultivation licence holders.

Production Capacity

❖ Section 6.4 of the Cannabis Licensing Application Guide

- ❖ Required details to submit for a Micro-cultivation or Nursery licence application:
 - Plant surface area cannot exceed 200m^2 for a micro-cultivation licence and 50m^2 for a nursery licence
 - The delineated area shown on the site plan and/or floor plan should include dimensions which demonstrate how the total surface area of the cannabis plants do not exceed the applicable threshold.
 - A sample calculation should be included to demonstrate how the total surface area does not exceed the applicable threshold.
 - Includes multiple surfaces such as surfaces vertically arranged.

Required Information in the Cannabis Tracking and Licensing System (CTLS)

| Required Information in the CTLS for a Standard Cultivation, Micro-Cultivation and Nursery Licence Application | |
|--|--|
| Requirement Area | Applicable Section of the Cannabis Application Guide |
| Proposed licence holder (Licence Ownership) | Section 6.1 |
| Mailing Address | Section 6.2 |
| Licence class and subclass | Section 6.3 |
| Site details (including activities) | Section 6.4 |
| Site Personnel | Section 6.5 |
| Site Ownership | Section 6.6 |
| Notice to local authorities | Section 6.7 |
| Physical Security (including Organizational Security Plan) | Section 6.8 |
| Good production practices (GPP) | Section 6.9 |
| Record Keeping (and reporting) | Section 6.10 |

Physical Security Measures – Cultivation

- ❖ 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, Micro-processing and Nursery Licence as per Part 4, Division 2 of the <i>Cannabis Regulations</i> | |
|---|-------------------------------|
| Required physical security measures | Micro-cultivation and Nursery |
| 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) | ✓ |

- ❖ Please refer to **Table 11** in the Cannabis Licensing Application Guide for the physical security measures as they relate to a Standard cultivation licence.

Good Production Practices (GPP) – Cultivation

| General GPP requirements for Micro-cultivation and Micro-processing Licences | |
|--|---|
| GPP requirement | Micro-cultivation, Standard cultivation and Nursery |
| 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.

Refer to **Table 13** of the Cannabis Licensing Application Guide for details on information to required for each of these sections.

Transitioning from a Personal Grow Site to a Commercial Cannabis Site

- ❖ A personal or designated grow site may be appropriate for a commercial cannabis site, however should you wish to conduct commercial cannabis activities as authorized under the *Cannabis Act* and Regulations, a licence must be applied for and granted through the Cannabis Tracking and Licensing System (CTLS).
- ❖ Activities under a personal or designated grow licence are permitted to be located at the same address as a commercial cannabis licence under the *Cannabis Act* and Regulations, provided the licence holder is the same as the holder of the personal or designated grow authorization and the licence holder is able to clearly demonstrate that they are in full compliance with the *Cannabis Act* and Regulations.
- ❖ This will mean keeping a clear distinction of the activities conducted under the commercial licence(s) and under the personal or designated production registration
- ❖ Examples of clear separation of activities include:
 - Separation of record keeping documents
 - Ensuring that there is no movement of product between the commercial licence and the personal or designated production registration

Outdoor Cultivation – Building Requirements

- ❖ Cultivation of cannabis may be conducted **indoors or outdoors**
- ❖ **Production, packaging, labelling, storing, sampling and testing** of cannabis must be conducted **indoors** (e.g., drying of fresh cannabis, storing cannabis plants, packaging cannabis seeds)
- ❖ A cultivation licence for outdoor growing requires that a building is present within the site perimeter.
- ❖ The building is required to be a permanent structure however is not required to have any operations related to cannabis conducted inside.
 - In this case, you would have to provide a description of how you intend to conduct harvesting activities such as storage, drying, etc. without using the building at the site.
- ❖ It is recommended to make use of the building on site for harvesting activities such as storage, drying etc.

Food and Cannabis on Site

- ❖ The prohibition under the *Cannabis Regulations* on producing food and cannabis in the same building and/or area within the site does not apply to cultivators.
- ❖ The *Cannabis Regulations* **prohibit a licensed processor** from producing, packaging, labelling and storing cannabis in the same building where food that is to be sold is also produced. However, a licensed processor may grow food (e.g., blueberries) intended to be used as ingredients in its cannabis products.
- ❖ This provision is a key strategy to mitigate against the food safety and public health concerns associated with multi-product manufacturing facilities, and in particular to mitigate against the risks of cross-contamination between ingredients and products, and the increased risk of mislabelling and product mix-ups.

Pest Control Products for use on cannabis

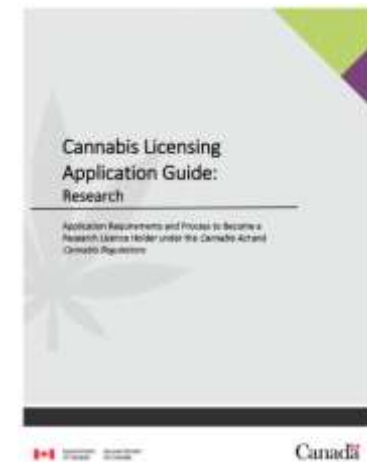
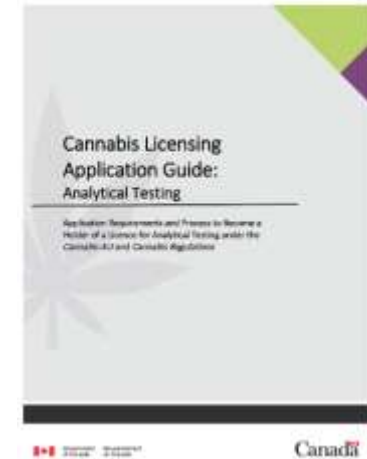
- ❖ Licence holders are only permitted to use [pest control products \(PCP\)](#) that are approved for use on cannabis under the [Pest Control Products Act \(PCPA\)](#).
- ❖ All products designed to manage, destroy, attract or repel pests that are used, sold or imported into Canada are regulated by the Pest Management Regulatory Agency (PMRA).
- ❖ The PMRA is responsible to administering the PCPA on behalf of the Minister of Health.
- ❖ The PMRA maintains the online [Pesticides Label Search](#) tool, which can be used to generate a list of PCPs currently registered for use on cannabis.

Special Authorizations: Analytical Testing Licence and Research Licence

- ❖ The Government of Canada recognizes the importance of cannabis research and analytical testing and is committed to promoting and enabling research and analytical testing while ensuring the overarching purpose of the *Cannabis Act* is respected
- ❖ Under the *Cannabis Act* there is a specific licence category for research and analytical testing, providing researchers and testers more flexibility to organize their work to suit their needs
- ❖ Since July 2019, research licence applications and analytical testing licence applications are being assessed using a risk-based approach to triage applications, which has resulted in a significant increase in the pace of licensing

Special Authorizations: Analytical Testing and Research Licence – Guidance Documents

- ❖ Health Canada has the following guidance documents to support applicants:
 - The [Cannabis Licensing Application Guide: Analytical Testing](#) and the [Cannabis Licensing Application Guide: Research](#) provides information on the application requirements.
- ❖ These guides should be used in conjunction with the *Cannabis Act* and its regulations.



Personal Registration for Medical Purposes

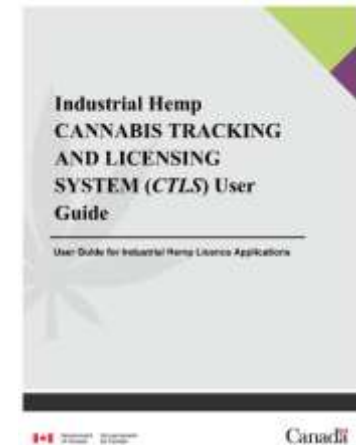
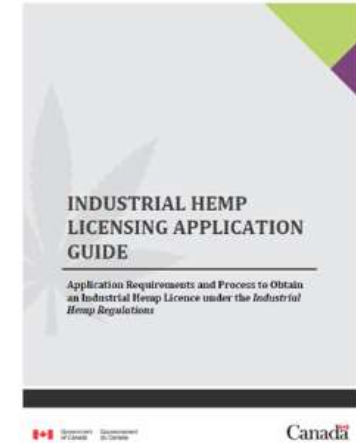
- ❖ Patients authorized by their health care practitioner are able to access cannabis for medical purposes by:
 - Buying directly from a federally licensed seller
 - Registering with Health Canada to produce a limited amount of cannabis for their own medical purposes
 - Designating someone to produce it for them
- ❖ For more information on registering to produce or possess cannabis for your own medical purposes: <https://www.canada.ca/en/health-canada/services/registering-produce-cannabis-own-medical-purposes.html>

Industrial Hemp Licence

- ❖ Under the *Cannabis Act*, the *Industrial Hemp Regulations* set out the regulatory framework for controlling and authorizing certain activities with industrial hemp.
- ❖ Industrial Hemp is defined under the *Industrial Hemp Regulations* as a cannabis plant, or any part of the plant, in which the concentration of THC is 0.3% w/w or less in the flowering heads and leaves
- ❖ The following activities may be conducted under a Industrial Hemp Licence:
 - Cultivation (including plant breeding/propagation)
 - Sale
 - Importation
 - Exportation
 - Cleaning
 - Preparing (conditioning)
 - Processing (including rendering non-viable and producing derivatives/products)

Industrial Hemp Licence – Guidance Documents

- ❖ Health Canada has the following guidance documents to support applicants:
 - The [Industrial Hemp Licensing Application Guide](#) and the **Industrial Hemp: Cannabis Tracking and Licensing System (CTLS) User Guide** provides information on the application requirements.
- ❖ These guides should be used in conjunction with the *Cannabis Act* and its regulations.



Contact Information

- General Cannabis Inbox: cannabis@canada.ca
- Cannabis Licensing: hc.licensing-cannabis-licences.sc@canada.ca
- Indigenous Navigator: hc.navigator-navigateur.sc@canada.ca
- Specialized Authorizations: hc.sp-licensing-cannabis-licences-sp.sc@canada.ca
- Import/Export: hc.import-export-cannabis-importation-exportation.sc@canada.ca
- Compliance: hc.compliance-cannabis-conformite.sc@canada.ca
- Industrial Hemp: hc.hemp-chanvre.sc@canada.ca
- Pest Management and Regulatory Agency: pmra.infoserv@hc-sc.gc.ca

Additional Guidance Resources

- [Mandatory cannabis testing for pesticide active ingredients - Requirements](#)
- [Mandatory cannabis testing for pesticide active ingredients – List and limits](#)
- [Cannabis Fees Order Guide](#)
- [Cannabis Tracking System - Monthly Reporting Guide \(Licence Holders and PTs\)](#)
- [Cannabis Voluntary Recall Guide](#)
- [Packaging and labelling guide for cannabis products](#)
- [Notice of new cannabis product guide](#)
- [Guide on composition requirements for cannabis products](#)
- CTLS User Guide: Available upon request to cannabis@canada.ca
- [CTLS Getting Started Guide](#)