

# **CANNABIS LICENSING APPLICATION GUIDE:**

## **Cultivation, Processing and Sale for Medical Purposes**

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**Application Requirements and Process to Become a  
Licence Holder under the *Cannabis Act* and its Regulations**



Government  
of Canada

Gouvernement  
du Canada

**Canada**

The *Cannabis Act* establishes that an application for a licence must be filed with the Minister in the form and manner specified by the Minister and must include the information required by the Minister. This guide sets out the application process including the form and manner for submitting an application for a licence and the information that is required to be submitted. In accordance with the *Cannabis Act*, the Minister may request any additional information that pertains to the information contained in an application and that is necessary to consider it. It is important to note that in the case where any information required to be submitted is not provided, the Minister may refuse to consider an application.

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This document should be read in conjunction with relevant sections of the *Cannabis Act* and its Regulations. In the case of any discrepancies between this document and the *Cannabis Act* and its Regulations, the latter shall prevail. In cases of discrepancy between the Cannabis Tracking and Licensing System (CTLS) and the Regulations or guidance, the *Cannabis Regulations* and this guide should be referred to for the established requirements and terminology.

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## 1.0 Purpose

This document (the “Guide”) provides information on the application requirements to obtain certain licences from Health Canada under the *Cannabis Act* and its Regulations.

## 2.0 Background

The *Cannabis Act* and its Regulations provide, among other things, the framework for legal access to cannabis and control and regulate its production, distribution and sale.

The oversight of the cannabis supply chain is a shared responsibility across federal and provincial and territorial governments, municipalities, industry and other stakeholders. One of Health Canada’s responsibilities is to provide the licensing and oversight framework for legal production of cannabis. Under this framework, a person is required to obtain a licence issued by Health Canada in order to conduct various activities with cannabis. Applicants and licence holders are responsible for compliance with the *Cannabis Act* and its Regulations as well as compliance with other applicable federal, provincial and territorial legislation and municipal by-laws.

The *Cannabis Act* establishes that an application for a licence must be submitted to Health Canada in the form and manner specified by the Minister<sup>1</sup> and must include the information required by the Minister. This guide sets out the application process including the form and manner for submitting an application for a licence and the information that is required.

Health Canada publishes other guidance documents and information on its website that may be used in conjunction with this document to assist applicants in preparing their applications. In order to maintain consistency and transparency, this guide, as well as other guidance documents and information, will be updated, as required, to reflect changes to policies and/or operations.

## 3.0 Scope

This document provides guidance to anyone wishing to apply for a licence (“the applicant”) under the *Cannabis Act* and its Regulations to conduct activities in relation to the following classes and subclasses of licences:

- Cultivation (including licences for micro- and standard cultivation and nursery)
- Processing (including licences for micro- and standard processing)
- Sale for medical purposes

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<sup>1</sup> Throughout this guide, there are references to actions that would be taken by the Minister under the *Cannabis Act* and its Regulations, often in the context of decision-making. In many cases, it is anticipated that the decision-making function would not be exercised personally by the Minister, but instead by an official in the Department of Health who has been delegated that responsibility in accordance with the *Salaries Act*.

The following activities are not addressed in this guide:

- application for an [analytical testing licence](#)
- application for a cannabis drug licence
- application for an [industrial hemp licence](#)
- application for a [research licence](#)
- applications for [cannabis security clearances](#)
- test kit manufacturing
- [post-licensing applications](#) including licence amendments and renewals, notifications, and applications for import or export permits
- [reporting](#) including inventory, recall, and information related to promotions and adverse reaction reporting
- applications for registration by an individual to access cannabis for medical purposes as outlined in Part 14 of the *Cannabis Regulations*
- any other items identified as regulatory requirements outside the scope of these specific application requirements

For more information on requirements associated with the activities that are not addressed in this guide, applicants may refer to the *Cannabis Act* and its Regulations, additional guidance published on the [Health Canada website](#), or contact Health Canada as outlined in section 8.

In addition, this guide does not include information on additional licensing requirements that may be required by the Canada Revenue Agency or provinces and territories.

Of particular note, Health Canada has established a national cannabis tracking system, referred to as the Cannabis Tracking and Licensing System (CTLS), to enable the tracking of high-level movements of cannabis and to help prevent diversion from and inversion into the regulated supply chain. The system is also used by applicants to apply to Health Canada for a cannabis licence. Applicants should be familiar with the use of this system and should refer to the CTLS User Guide for more information, available upon request from [cannabis@canada.ca](mailto:cannabis@canada.ca). This guide is based on the CTLS release 2.2.

Supplemental information, including information on the [cost recovery for the regulation of cannabis fees](#), is provided on the Health Canada website.



In cases of discrepancy between the CTLS and the *Cannabis Regulations* or guidance, or if the use of the CTLS is not feasible, Health Canada should be contacted for further information. The *Cannabis Regulations* and this guide should be referred to for the established requirements and terminology.

## 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.

**Additional individual requiring a security clearance:** Individuals that exercise or are in a position to exercise direct control over the activities taking place at the licensed site (e.g., key investor).

**Cannabis extract:** As defined in 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:** means a plant that belongs to the genus *Cannabis*.

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

- a) cannabis that is intended for an animal;
- b) a cannabis accessory that contains cannabis that is intended for an animal; or
- c) a drug containing cannabis.

**Cannabis topical:** 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.

**Cannabis Tracking and Licensing System (CTLS):** The name of the national cannabis tracking system as referred to in the *Cannabis Act*, established and maintained by Health Canada to enable tracking of high-level movements of cannabis and to help prevent diversion from and inversion into the regulated supply chain. It is also the system that applicants should use to apply to Health Canada for a cannabis licence.

**Dried cannabis** means any part of a cannabis plant that has been subjected to a drying process, other than seeds.

**Edible Cannabis:** As defined in 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 to be consumed in the same manner as food. It does not include dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds.

**Fresh cannabis:** means freshly harvested cannabis buds and leaves, but does not include plant material that can be used to propagate cannabis.

**Ingredient,** as defined in the *Cannabis Regulations*, means

- (a) In the case of a cannabis extract or a cannabis topical, a substance, other than anything referred to in item 1 or 3 of Schedule 1 the Act, that is used to produce the cannabis extract or cannabis topical, including any substance used in the manufacture of that substance, and that is present in the final form of the cannabis extract or cannabis topical.
- (b) In the case of edible cannabis,
  - i. a substance, other than anything referred to in item 1 or 3 of Schedule 1 to the Act,
    - A) that is used to produce the edible cannabis if the use of the substance 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 that Schedule that is used to produce the edible cannabis if the use of the mixture 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 anything referred to in item 1 or 3 of Schedule 1 to the Act,
    - A) that is used to produce the edible cannabis if the use of the mixture 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 that Schedule that is used to produce the edible cannabis if the use of the latter mixture results, or may reasonably be expected to result, in the former mixture or its by-products becoming a part of, or affecting the characteristics of, the edible cannabis.

**Key investor:** As defined in the *Cannabis Regulations*, means, in respect of the holder of a licence, a person that exercises, or is in a position to exercise, direct or indirect control over the holder by virtue of:

- (a) having provided money, goods or services directly or indirectly to the holder; or

(b) holding an ownership interest or other right or interest in, or in respect of, a business operated by the holder or, if the holder is an organization, in or in respect of the organization.

Refer to Appendix E: Key Investors, for more information.

**Local government:** As defined in the *Cannabis Regulations*, includes:

- (a) an incorporated city, metropolitan area, town, village or other municipality;
- (b) an authority responsible for delivering municipal services that are related to the activities to be conducted under the licence to an unincorporated city, metropolitan area, town, village or other municipality;
- (c) a band, as defined in subsection 2(1) of the *Indian Act*; or
- (d) a First Nation, Métis or Inuit government that is party to a self-government or land claims agreement that is given effect by an Act of Parliament, or a First Nation, Métis or Inuit government established under a provincial Act.

**Organizational security plan (OSP):** The organizational security plan (OSP) captures the risk mitigation measures that are in place to prevent, identify and respond to potential incidents that could divert cannabis to or from the illicit market. It outlines security measures in place beyond physical security including people requiring a security clearance and standard operating procedures (SOPs).

**Organizational chart:** Visual representation of how authority, responsibility, and information are to flow within a formal organizational structure. It usually depicts different management functions (accounting, finance, human resources, marketing, production, research and development, etc.) and their subdivisions as boxes linked with lines along which decision making power travels downward and answerability travels upward.

**Corporate organizational chart (for corporations, cooperatives and partners):** Outlining the relationships of directors and officers (if a corporation or cooperative) or partners in a partnership, as well as any individuals, partnerships, cooperatives or corporations that directly control the licence holder.

**Reporter:** An individual granted authority to submit monthly reports in the CTLS.

**Security clearance:** As defined in the *Cannabis Regulations* means, except in paragraph 53(2)(g) of the Regulations, a security clearance granted by the Minister under section 67 of the Act and includes, for the purpose of paragraph 53(2)(e) of the Regulations, a security clearance granted under section 112 of the former *Access to Cannabis for Medical Purposes Regulations*.

**Site:** As defined in the *Cannabis Regulations* means, in respect of a holder of a licence, an area that is used exclusively by the holder that consists of at least one building or one part of a building. This typically includes:

**Storage area:** As defined in the Regulations means, in respect of a site set out in a licence, an area of the site where cannabis is stored.

**Grow area:** As defined in the Regulations means, in respect of a site set out in a licence, an area of the site where cannabis plants are cultivated, harvested or propagated.

**Operations area:** As defined in the Regulations means, in respect of a site set out in a licence, an area of the site — other than a storage area — where cannabis is present as a result of any activities conducted under the licence. It includes a grow area.

**Site plan:** A visual representation or diagram of the site. It must include the following:

- i. The location of the site perimeter, including the locations of, and area covered by the security and visual monitoring devices, if applicable
- ii. The location of and footprint of all buildings
- iii. The locations of all storage areas within each building, including the locations of, and area covered by the security and visual monitoring devices, if applicable
- iv. The locations of and footprint of all outdoor cultivation areas, if applicable

## 4.2 Abbreviations

CBD cannabidiol

CBDA cannabidiolic acid

CTLS Cannabis Tracking and Licensing System

*FDA Food and Drugs Act*

GPP good production practices

OSP organizational security plan

QAP quality assurance person

RCMP Royal Canadian Mounted Police

SOP standard operating procedure

THC delta-9-tetrahydrocannabinol

THCA delta-9-tetrahydrocannabinolic acid

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



**Important:** Key or cautionary information, in particular, around data required in the CTLS.



**Information:** Highlights that there may be differences in requirements among licence classes (e.g., different requirements for sale for medical purposes without possession licences).

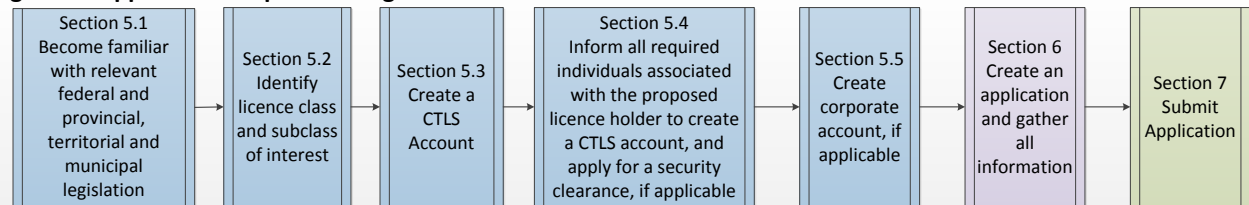


**Tip:** Information that could be helpful.

## 5.0 Application Requirements: Getting Started

There are some specific actions that applicants should undertake when creating an application to Health Canada. The CTLS User Guide may be referred to for more information. The process flow outlined in Figure 1 provides a general summary, with references to the relevant sections of this Guide.

**Figure 1: Application Steps – Getting Started**



The applicant is not required to complete the application process in one session. The application may be started in the CTLS and left in Draft status until the applicant is ready to submit it.

### 5.1 Knowledge areas

When applying for a licence, it is recommended that the applicant be familiar with the knowledge areas outlined below. This knowledge will help the applicant comply with the applicable requirements of the *Cannabis Act* and its Regulations as well as other federal and provincial or territorial legislation and regulations and/or municipal by-laws.

| Table 1: Knowledge areas                    |                                                                                                                                                                                                                                                     |
|---------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Key areas to be familiar with:              | Notes/References                                                                                                                                                                                                                                    |
| The <i>Cannabis Act</i> and its Regulations | Links may be found on <a href="#">Health Canada's website</a> .                                                                                                                                                                                     |
| Other federal Acts and Regulations          | Applicants are responsible for complying with applicable requirements of other Acts and Regulations such as the <i>Food and Drugs Act (FDA)</i> , the <i>Pest Control Products Act (PCPA)</i> , <i>Canada Consumer Product Safety Act (CCPSA)</i> , |

**Table 1: Knowledge areas**

| <b>Key areas to be familiar with:</b>                                                      | <b>Notes/References</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                            | <p><i>Tobacco and Vaping Products Act (TVPA)</i> and the <i>Fertilizers Act</i>, among others.</p> <p>Depending which activities will be conducted with cannabis, a cannabis licence under the <i>Excise Act</i> (2001) may also be required. For more information, consult the Canada Revenue Agency at:<br/><a href="http://www.canada.ca/cannabis-excise">www.canada.ca/cannabis-excise</a><br/><a href="mailto:cannabis@cra-arc.gc.ca">cannabis@cra-arc.gc.ca</a><br/>1-866-330-3304</p>                                                                         |
| Provincial or territorial legislation, and, municipal by-laws                              | <p>It is the applicant's responsibility to comply with all applicable provincial or territorial laws (e.g., environmental laws) as well as municipal by-laws (e.g., zoning and building permits).</p> <p>The provincial or territorial or municipal body may be contacted for more information.</p>                                                                                                                                                                                                                                                                  |
| The Cannabis Tracking and Licensing System (CTLS)                                          | <p>Health Canada has established that the CTLS is the primary manner in which licence applications should be submitted. If this is not feasible, applicants may contact Health Canada for more guidance.</p> <p>Applicants should be familiar with the use of the CTLS. The CTLS can be accessed directly (<a href="https://ctls-sscdl.hc-sc.gc.ca/">https://ctls-sscdl.hc-sc.gc.ca/</a>) or through the Health Canada website at <a href="http://www.canada.ca/cannabis">http://www.canada.ca/cannabis</a>. For more information, refer to the CTLS User Guide.</p> |
| The licensing application requirements and process found in this guide                     | All applicable requirements need to be met in order for a licence to be issued.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Additional Health Canada guidance (e.g., including on promotions, packaging and labelling) | The <i>Cannabis Act</i> and its Regulations include requirements and prohibitions which go beyond the scope of this guide. This includes prohibitions around promotions and requirements for packaging and labelling, among others. It is the responsibility of the applicant to read and understand all the applicable requirements and any associated guidance found on the Health Canada website before applying.                                                                                                                                                 |

## 5.2 Determine the type of licence to apply for

In order to select the correct licence class and subclass to apply for, it is important to know what activities you want to do with cannabis at your site, and which licence class and subclass allows those activities. Requirements differ based on the licence class or subclass. Appendix B:

Cannabis Classes and Subclasses of Licences should be referred to for details on each class and subclass, and Figure 2 can be used as a general reference.

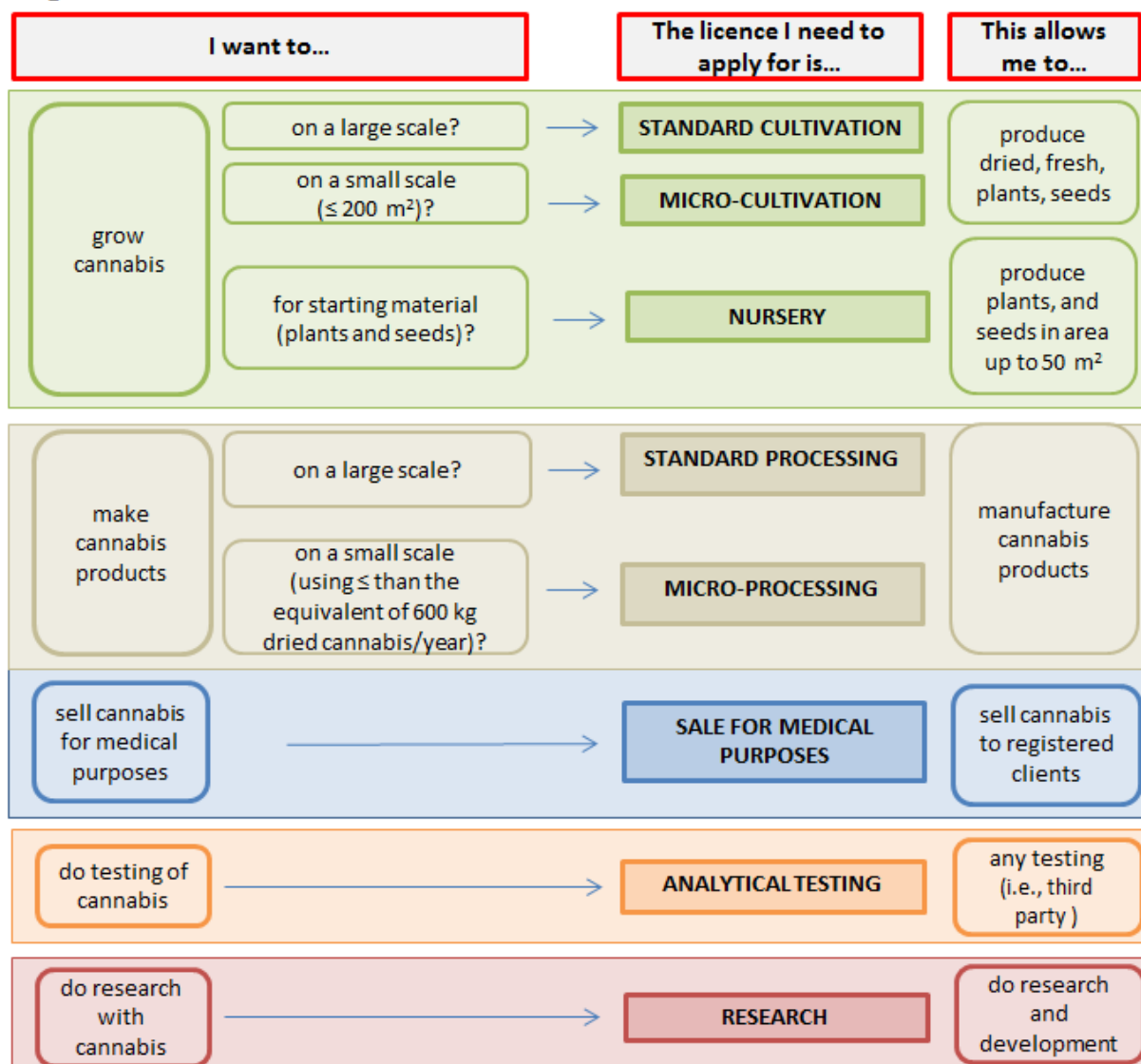


**Tip:** Applicants should be familiar with the classes and subclasses of licences to determine which class their activities of interest fall under.

For example, cultivation licence holders are only allowed to perform certain processing activities (for example, the drying of cannabis grown at their own site). If you want to conduct physical processes on cannabis such as sifting, beating, rubbing or other mechanical actions (for example, to separate trichomes from fresh or dried cannabis), you need to apply for a processing licence as this is extraction.

**Note:** Different product classes have different rules. Only cannabis products that are extracts, edibles or topicals can be made with cannabis that has been extracted. Products that are dried cannabis, for example, cannot be augmented by adding THC (such as by adding additional kief) and still be classified as dried cannabis. A product that contained a mixture of dried cannabis and kief could be classified as an extract, provided that it met the product rules, including the requirement that the cannabinoids and terpenes in the final product be uniformly distributed throughout the product.

**Figure 2: Cannabis Classes and Subclasses of Licences**



*An analytical testing licence, research licence, industrial hemp licence and cannabis drug licence are other types of licences, but are outside the scope of this guide. For more information on requirements for these licence classes, applicants may refer to the Cannabis Act and its Regulations, and additional guidance published on the Health Canada website.*



Applicants may apply for any combination of class or subclass of licences in relation to the same site; however, the Minister may refuse to issue a licence, depending on the combinations, in accordance with section 29 of the *Cannabis Regulations*. Refer to Table 2: General Guide for Combinations of Licence Classes and Subclasses at a Single Site.

**Table 2: General Guide for Combinations of Licence Classes and Subclasses at a Single Site**

|                      | Standard Cultivation | Micro-cultivation | Nursery | Standard Processing | Micro-processing | Sale <sup>2</sup> | Analytical Testing | Research |
|----------------------|----------------------|-------------------|---------|---------------------|------------------|-------------------|--------------------|----------|
| Standard Cultivation |                      |                   |         | ✓                   |                  | ✓                 | ✓                  | ✓        |
| Micro-cultivation    |                      |                   |         |                     | ✓                | ✓                 | ✓                  | ✓        |
| Nursery              |                      |                   |         |                     |                  | ✓                 | ✓                  | ✓        |
| Standard Processing  | ✓                    |                   |         |                     |                  | ✓                 | ✓                  | ✓        |
| Micro-processing     |                      | ✓                 |         |                     |                  | ✓                 | ✓                  | ✓        |
| Sale <sup>2</sup>    | ✓                    | ✓                 | ✓       | ✓                   | ✓                |                   | ✓                  | ✓        |
| Analytical Testing   | ✓                    | ✓                 | ✓       | ✓                   | ✓                | ✓                 |                    | ✓        |
| Research             | ✓                    | ✓                 | ✓       | ✓                   | ✓                | ✓                 | ✓                  |          |



Although an applicant may wish to apply for multiple licence classes or subclasses at the same site, the CTLS may not currently allow this, depending on the combination of licences sought (e.g., the CTLS will not allow an application for both an analytical testing licence and a processing licence to be submitted in the same application). In this case, a separate application may be submitted in the CTLS, or the applicant may contact Health Canada for more information.



Licence holders can conduct research and development activities within their authorized licensed activities. If the licence holder wishes to conduct research and development activities outside of their authorized licence activities, they must apply for a separate research licence. Refer to the [Cannabis Licensing Application Guide: Research](#) for more information on research licence applications.

## 5.3 Create an account in the CTLS

Health Canada has established the CTLS as the primary manner in which licensing applications should be submitted. The first step to create an application is to set up an individual user account in the CTLS (i.e., for the individual applicant or the person who will be submitting the application for an organization). The [CTLS Getting Started Guide](#) should be referred to for more information on the steps to create an account. To request an account, basic information is required including full name and salutation, email address, phone number, date of birth, language preference and security information. Health Canada then provides an access code that

<sup>2</sup> Sale for medical purposes

can be used to enter the CTLS. Once an account is established, the user will have an Account ID in the CTLS.



Part of the application process requires documents to be uploaded directly within the CTLS. For each section that requires documents to be uploaded, a maximum of 5 documents can be uploaded per section, each with a maximum size of 10MB per document. Applicants should combine documents where suitable and minimize extraneous content in order to submit the required documents. For assistance related to a specific licence application, an email may be sent to: [HC.licensing-cannabis-licences.SC@canada.ca](mailto:HC.licensing-cannabis-licences.SC@canada.ca). The email must clearly indicate the application file number, the applicant's name and the subject of the correspondence in the subject line of the email.



Should the CTLS (or internet) not be available, the applicant may contact Health Canada directly by phone at 1-866-337-7705 or by email at [cannabis@canada.ca](mailto:cannabis@canada.ca) for more guidance.



#### **For Indigenous Affiliated Applicants**

The Indigenous Navigator Service is designed to help Indigenous affiliated applicants effectively navigate the cannabis licensing process. This service is available to help guide self-identified Indigenous affiliated applicants through each step of the licensing process. Applicants who choose to self-identify in their CTLS application can also request a two-stage review that allows a licence application to be submitted without a fully built physical site. See section 7.1 Submitting an application for further information. Indigenous affiliated applicants who have any questions about the navigator service should contact Health Canada at [navig@canada.ca](mailto:navig@canada.ca).

## **5.4 Associated individuals create accounts in the CTLS**

User accounts are required for a number of individuals associated with an application. These individuals must create their own individual accounts in the CTLS before an application can be submitted to Health Canada. Individuals can use the same account information for each licence application that they may be associated with. Refer to Table 3: Individuals to be Identified.



The CTLS requires that individuals who require a security clearance submit their security clearance application form before a licence application can be submitted in the CTLS. For information on application requirements related to personnel security clearances, refer to the [Cannabis security clearances](#) webpages.

The applicant must ensure that the persons identified have the knowledge, qualifications, experience and ability to fulfill their responsibilities, as applicable. For more information on these elements, refer to Appendix A: Key Individuals at the Site.



The applicant should create a list of all Account IDs of individuals associated with an application. Account IDs are used to link individuals to an application in the CTLS.



An individual may hold one or multiple roles within the company, for one or more classes of licences at one site, or in some cases, multiple sites, assuming they meet all the requirements.



The CTLS requires at least one director or officer be named per corporate profile.

**Table 3: Individuals to be Identified**

| Role                                              | Account IDs required                                                                | Security Clearance Application Required prior to Submitting Application |
|---------------------------------------------------|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------|
| Directors                                         | For all licence classes if the applicant is a corporation or a cooperative          | Yes                                                                     |
| Officers                                          | For all licence classes if the applicant is a corporation or a cooperative          | Yes                                                                     |
| Partners                                          | For all licence classes if the applicant is a partnership                           | Yes                                                                     |
| Licence holder (where applicant is an individual) | For all licence classes if the applicant is an individual                           | Yes                                                                     |
| Responsible person and alternate if applicable    | For all licence classes. Note: this can be the individual who is the licence holder | Yes                                                                     |
| Head of security and alternate if applicable      | For all licence classes                                                             | Yes                                                                     |

**Table 3: Individuals to be Identified**

| Role                                                                                                                                                                                                                                                       | Account IDs required         | Security Clearance Application Required prior to Submitting Application |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|-------------------------------------------------------------------------|
| Master grower and alternate if applicable                                                                                                                                                                                                                  | For cultivation licence only | Yes                                                                     |
| Quality assurance person (QAP) and alternates if applicable                                                                                                                                                                                                | For processing licence only  | Yes                                                                     |
| Any individual, partnership (partners), corporation (directors and officers), or cooperative (directors and officers) in a position to directly control the applicant (for additional information refer to Appendix F: Direct Control-Security Clearances) | For all licence classes      | Yes                                                                     |
| Additional individuals requiring a security clearance                                                                                                                                                                                                      | For all licence classes      | Yes, if applicable                                                      |
| Reporter                                                                                                                                                                                                                                                   | For all licence classes      | Yes, if applicable                                                      |

## 5.5 Create a corporate profile for organizations (partnership, cooperative or corporation)



The CTLS does not have a distinct section for organizations such as partnerships or cooperatives. In these cases, the “Corporate Profile” section must be used in the CTLS to provide the information required in this guide about the organization. In the “Other Registered Names” section of the CTLS corporate profile section, the applicant must clearly indicate whether they are a corporation, partnership, or cooperative.

Applicants that are partnerships, cooperatives, and corporations (in essence any applicant that is not an individual/sole proprietor) also need to create a corporate profile. Once a corporate profile is created, the individual who creates the corporate profile will have access to an Account ID for the organization. When creating a corporate profile, the applicant lists and links (using their respective Account IDs) all the directors and officers of the corporation or cooperative, and the partners if a partnership. Once a corporate profile is created in the CTLS, the applicant can use that profile to create an application.

Creating a corporate profile has some additional requirements, as outlined below. Some requirements must be met to create a corporate profile in the CTLS, while others must be met before an application is submitted.

**Table 4: Corporate Profile Requirements**

| <b>Requirement</b>                                                                   | <b>Required details to include</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| The full legal name(s) of the organization                                           | Any other name(s) registered federally or provincially under which the entity intends to do business, if applicable.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| The incorporation number                                                             | As provided on the certificate of incorporation. In the case of a partnership or cooperative, if there is not an identification number, indicate “Not applicable.”                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Business address and contact details                                                 | The business address and the contact details used for correspondence with the corporation, not the individual applicant (e.g., head office).                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Controlling organizations (noted as “Parent Corporation” in the CTLS), if applicable | The Corporation ID of each controlling organization. Note that any controlling organization will be required to create a corporate profile as per these requirements.<br><br>Refer to Appendix F: Direct Control – Security Clearances for more information.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Certificate of incorporation (or partnership agreement)                              | As part of an application, certificate of incorporation documents are required. In the case of a partnership or cooperative, a partnership/cooperative agreement is required.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Corporate organizational chart                                                       | You need to identify the individuals in your corporate organizational chart. This includes: <ul style="list-style-type: none"> <li>• all individuals requiring a security clearance from the: <ul style="list-style-type: none"> <li>○ parent (owning) company, if applicable <ul style="list-style-type: none"> <li>▪ individuals that directly control or are in a position to directly control any partnership, corporation or cooperative <ul style="list-style-type: none"> <li>• directors</li> <li>• officers</li> <li>• other positions</li> </ul> </li> </ul> </li> <li>○ applicant <ul style="list-style-type: none"> <li>▪ individuals that directly control or are in a position to directly control any partnership, corporation or cooperative <ul style="list-style-type: none"> <li>• directors</li> <li>• officers</li> <li>• other positions</li> </ul> </li> </ul> </li> </ul> </li> </ul> |

**Table 4: Corporate Profile Requirements**

| <b>Requirement</b>     | <b>Required details to include</b>                                                                                                                                                                                  |
|------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Organization personnel | As part of an application, specific organization personnel must be identified. These individuals must have individual CTLS accounts created so that their Account IDs can be associated with the corporate profile. |

Directors or officers of corporations or cooperatives, and partners in a partnership must be included as part of the corporate profile.



The CTLS does not have a specific section for partners in the case of a partnership. These should be included in the officers section.

Any directors and officers of a corporation must hold a security clearance. It is the responsibility of the applicant to identify all directors and officers of an organization accurately.

Prior to submitting an application in the CTLS, these individuals will also be required to submit an application to obtain a security clearance in the CTLS.

In addition, all directors, officers, partners and individuals who exercise or are in a position to exercise, direct control over the applicant must be identified and will require security clearances.

Consult the *Cannabis Regulations* and the [Cannabis security clearances](#) webpages for details regarding security clearance requirements, and the application process.



Changes may be made to the corporate profile before and after an application has been submitted. Changes to the corporate profile will be updated in any associated application that has not yet been granted a licence.

If you've submitted your application in the CTLS and you need to add new individuals in your corporate organizational chart, you need to add them to your corporate profile and email [hc.licensing-cannabis-licences.sc@canada.ca](mailto:hc.licensing-cannabis-licences.sc@canada.ca). The subject line of the email should be "New Corporate Profile Personnel for APP#". Include the person's full name, their CTLS account ID, their HSC or SEC number and their position. If you do not notify Health Canada, it may result in delays in processing your application.

If a licence has been granted and there is a change of details in the corporate profile, these changes that may trigger an automatic amendment or may require

a notification under Section 34 of the *Cannabis Regulations*. Please refer to the [Manage your cannabis licence](#) webpages for more information.

Once an application is submitted, changes are not permitted within the licence application in the CTLS. If a change to an application is required after submission, applicants should refer to section 7.3.3 Changes to an Application/Unsolicited Information for more information.

## 6.0 Application Requirements: Creating an Application

This section of the guide includes the application requirements that are required for each class of licence. The requirements in this section are categorized by Requirement Areas which are found in the CTLS.

All applications are strictly and thoroughly reviewed by Health Canada against the application requirements outlined in this guide. Licences may be issued once all applicable requirements are met.

Applicants are expected to comply with applicable requirements of the Regulations, and compliance may be verified at any time by Health Canada.



### **For Processing, Cultivation and Sale for Medical Purposes with Possession Licences**

In addition to documents submitted as a part of a CTLS application, applicants are required to submit a site evidence package with visual evidence to demonstrate the completion and functionality of their facility. Applications will only be processed once both the document portion of the application is submitted within the CTLS and the site evidence package is received by Health Canada. Instructions for how to submit a site evidence package are found in section 7.1.1 Submitting Site Evidence.

When creating a new licence application in the CTLS, the applicant must first identify the licence class they are applying for in the CTLS. The licence classes within the scope of this guide include:

- Cultivation (micro, standard, nursery)
- Processing (micro, standard)
- Sale for medical purposes (with possession, without possession)

Refer to Appendix B: Cannabis Licence Classes and Subclasses for more information.

The following classes of licences are not addressed in this guide:

- Analytical testing licence
- Cannabis drug licence
- Industrial hemp licence

- Research licence

For more information on requirements for these licence classes, applicants may refer to the *Cannabis Act* and its Regulations, and additional guidance published on the [Health Canada website](https://www.healthcanada.gc.ca/healthcanada/).



As noted in section 5.2, applicants may apply for more than one class or subclass of licence at the same site depending on the licence class or subclass. For example, applicants may apply for a cultivation, processing and sale for medical purposes licence in one application. However, the design of the CTLS requires a separate application be submitted for other cannabis licences (e.g., analytical testing and research)



This guide establishes the application requirements to obtain cultivation, processing or sale for medical purposes licences under the *Cannabis Act*. It is up to the applicant to confirm that all application requirements set out in this guide are met. This guide also provides details on how to submit this information into the CTLS and, if required, how to submit a site evidence package, directly to Health Canada. Table 5 outlines the relevant sections of this guide where required information must be submitted to Health Canada, according to licence class.



When the applicant uploads a document into the CTLS, or submits the site evidence package (if required) the file names should clearly identify the name of the application requirement outlined in this guide. For example, Site Survey, OSP, Security Reports.

**Table 5: Application Guide Sections with Required Information in the CTLS, by Licence Class**

| Guide Section | Requirement Area                                                         | Cannabis Licence Class                 |                              |                                                         |                                                            |
|---------------|--------------------------------------------------------------------------|----------------------------------------|------------------------------|---------------------------------------------------------|------------------------------------------------------------|
|               |                                                                          | Cultivation (Micro, Standard, Nursery) | Processing (Micro, Standard) | Sale for medical purposes (with possession of cannabis) | Sale for medical purposes (without possession of cannabis) |
| 6.1           | Proposed licence holder (Licence Ownership)                              | ✓                                      | ✓                            | ✓                                                       | ✓                                                          |
| 6.2           | Mailing address                                                          | ✓                                      | ✓                            | ✓                                                       | ✓                                                          |
| 6.3           | Licence class and subclass (identified as "Site Activities" in the CTLS) | ✓                                      | ✓                            | ✓                                                       | ✓                                                          |

**Table 5: Application Guide Sections with Required Information in the CTLS, by Licence Class**

| Guide Section | Requirement Area                                           | Cannabis Licence Class                                           |                                                                  |                                                                  |                                                            |
|---------------|------------------------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------------|------------------------------------------------------------|
|               |                                                            | Cultivation (Micro, Standard, Nursery)                           | Processing (Micro, Standard)                                     | Sale for medical purposes (with possession of cannabis)          | Sale for medical purposes (without possession of cannabis) |
| 6.4           | Site details (including activities)                        | ✓                                                                | ✓                                                                | ✓                                                                | ✓                                                          |
| 6.5           | Site personnel                                             | ✓                                                                | ✓                                                                | ✓                                                                | ✓                                                          |
| 6.6           | Site ownership                                             | ✓                                                                | ✓                                                                | ✓                                                                | N/A                                                        |
| 6.7           | Notice to local authorities                                | ✓                                                                | ✓                                                                | ✓                                                                | N/A                                                        |
| 6.8           | Physical security (including organizational security plan) | ✓<br>Additional visual evidence to be submitted outside the CTLS | ✓<br>Additional visual evidence to be submitted outside the CTLS | ✓<br>Additional visual evidence to be submitted outside the CTLS | ✓<br>Only organizational security plan is required         |
| 6.9           | Good production practices (GPP)                            | ✓<br>Additional visual evidence to be submitted outside the CTLS | ✓<br>Additional visual evidence to be submitted outside the CTLS | ✓<br>Additional visual evidence to be submitted outside the CTLS | N/A                                                        |
| 6.10          | Record keeping                                             | ✓                                                                | ✓                                                                | ✓                                                                | ✓                                                          |
| 6.11          | Key investors report <sup>3</sup>                          | ✓                                                                | ✓                                                                | ✓                                                                | ✓                                                          |
| 6.12          | Self identification <sup>4</sup>                           | ✓                                                                | ✓                                                                | ✓                                                                | ✓                                                          |
| 6.13          | Associated individuals <sup>4</sup>                        | ✓                                                                | ✓                                                                | ✓                                                                | ✓                                                          |



For a sale for medical purposes licence where there will be possession of cannabis, after selecting the licence class and subclass, the applicant should select “Site Details” and in the “room activity” area of the CTLS, add “sale with possession of cannabis.” This opens the Site Ownership, Notice to Local Authorities and GPP sections in the CTLS.

<sup>3</sup> You are required to keep a record of key investors unless you are an organization whose equity securities are listed on a public market.

<sup>4</sup> Optional section.

## 6.1 Proposed licence holder (licence ownership)

An application can be created for an individual or an organization. If the applicant is an organization, they must ensure that they have completed a corporate profile for the organization in the CTLS as outlined in section 5.5.

A responsible person must be designated for all applications. The responsible person has the authority to bind the licence holder, has overall responsibility for the activities conducted and is responsible for submitting the application. The responsible person is the official point of contact with Health Canada. Refer to Appendix A: Key Individuals at the Site for more information.



As per the *Cannabis Regulations*, the applicant may designate one individual as an alternate responsible person who is qualified to replace the responsible person. However, only one responsible person may be designated in the CTLS. To change the responsible person after an application has been submitted, email [HC.licensing-cannabis-licences.SC@canada.ca](mailto:HC.licensing-cannabis-licences.SC@canada.ca), with the subject line “Request to change responsible person” and the application number and details. Health Canada will contact the applicant for additional details.

## 6.2 Mailing address

The mailing address entered must be the Canadian address where the applicant would like to receive official mailed correspondence (e.g., the licence when issued).



This is not necessarily the same as the site address or corporate address.

## 6.3 Licence class and subclass (identified as “Site Activities” in the CTLS)

The applicant must select the licence classes and subclasses for which they are applying. For processing licence applications, applicants are asked to identify the cannabis class(es) for which they intend to conduct activities with at their site. This information is collected solely for statistical purposes. Please note the sale and distribution of the cannabis classes identified at this stage will not necessarily be authorized by Health Canada on the initial licence.



Although there is an option in the CTLS to select “Sale – Non-Medical Online,” this should not be selected.



As noted in Section 5.2, licence holders can conduct research and development activities within their authorized licensed activities. If the licence holder wishes to conduct research and development activities outside of their authorized licence activities, they must apply for a separate research licence. Refer to the [Cannabis Licensing Application Guide: Research](#) for more information on research licence applications.

**For cultivation licence applicants:** Provide the authorized source of starting material (e.g. federally authorized licence holder). In the case where the applicant intends to use cannabis plants or cannabis plant seeds that were not obtained in accordance with the former *Access to Cannabis for Medical Purposes Regulations*, the former *Industrial Hemp Regulations*, the *Industrial Hemp Regulations* or with the *Cannabis Regulations* or from a person authorized to sell cannabis under a provincial Act, they must select “Declaration under 10(2) of the Cannabis Regulations” as their source. This option needs to be selected even if the applicant also intends to use cannabis starting material from an authorized source. The declaration under section 10(2) of the *Cannabis Regulations* should be signed and dated by the Responsible person, indicating the quantity of cannabis plants and cannabis plant seeds that they will have in their possession on the effective date of the licence. The declaration must be uploaded in the CTLS. If the source of starting material is not known at the time of application, the information may be requested at a later date.

## 6.4 Site details (including activities)

There is certain information required for a site. Requirements differ depending on the licence class (e.g., sale for medical purposes applicants are not required to submit information on their production capacity). Table 6 shows the site detail requirements.



Licensed activities cannot be conducted in a dwelling-house (i.e., a place of residence).




Licences are site specific, if an applicant intends to conduct licensed activities at more than one site, a separate application must be submitted for each site.




**Table 6: Site Detail Requirements**

| Requirement           | Required details to include                                                                                                                                                                                                                                                                                                                                                              |
|-----------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Complete site address | <p>Include Canadian address as well as latitude and longitude.</p> <p>The CTLS allows for entry of a single address in relation to a site. Should the site have multiple addresses (e.g., several buildings in an area used exclusively by the licence holder), all site details as outlined in this section must be uploaded into the CTLS as a separate document titled Additional</p> |

**Table 6: Site Detail Requirements**

| <b>Requirement</b>                                                                                                                                                                                                                                                                                     | <b>Required details to include</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                                                                                                                                                                                                                                        | Site Details. This must be uploaded in the “Site Survey” section of the CTLS.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| Site survey                                                                                                                                                                                                                                                                                            | A building location survey, location certificate or similar document, prepared and certified by a person qualified to do so in the jurisdiction where the site is located, such as a qualified land surveyor. The survey must accurately depict the site at the point of submission.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Aerial view                                                                                                                                                                                                                                                                                            | A clear and legible aerial view of the proposed site and surrounding lots to within 500 metres. The aerial view must accurately depict the site at the point of submission.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Production capacity<br>(Not required for sale for medical purposes)                                                                                                                                                                                                                                    | <p>An estimate of the proposed annual production amount (e.g., kg per year, number of plants or seeds per year) for each applicable cannabis class as found in Schedule 4 of the Act.</p> <p>The total combined area (m<sup>2</sup>) of the grow areas and the total combined area (m<sup>2</sup>) of the operations areas excluding grow areas that are being proposed for licensing. For the grow areas, the total combined area should include all surface areas, taking into account if multiple surfaces are being utilized (e.g., vertically arranged).</p>                                                                                                                                                                                                                                                                                                                                                                                                               |
| <div>  <p><b>NOTE:</b> There is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the “Site Survey” section.</p> </div> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Areas (buildings and rooms, outdoor areas) and activities                                                                                                                                                                                                                                              | <p>Each outdoor area (if applicable) and indoor area (building or part of building) including rooms, must be named and this name must be provided. The names used to identify each area must match all other information submitted (e.g., names used on the site and floor plans). All activities conducted, and the room in which they are conducted must also be identified (e.g., operations area [either cultivation or non-cultivation], testing area, storage area or sales with possession area or sales without possession area). There is no requirement to identify areas and rooms in the CTLS in which no activities with cannabis will take place (e.g., lavatory) or transitory areas (e.g., hallways). However, these areas and rooms should still be identified on the floor plan(s).</p> <p>More than one activity can occur in each area. Additional information may be requested to assess how the proposed activities meet all regulatory requirements.</p> |

**Table 6: Site Detail Requirements**

| <b>Requirement</b>                                                                | <b>Required details to include</b>                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>As noted in section 6.0, for a sale for medical purposes licence where there will be possession of cannabis</p> <p>The applicant should first select “Site Details” and in the “room activity” area of the CTLS, add “sale with possession of cannabis.” This will open the Site Ownership, Notice to Local Authorities and GPP sections in the CTLS. All rooms where cannabis is present must be included and room details must be provided.</p> |
|  | <p>Each site must have at least one indoor area (building or part of a building).</p> <p>Cultivators may also have outdoor areas to cultivate, propagate or harvest cannabis.</p>                                                                                                                                                                                                                                                                    |
|  | <p><b>For Processing Licences:</b> It is prohibited to produce, package, or label food for sale within a site unless those activities are conducted in a building that is separate from any building where the processor conducts activities with cannabis.</p>                                                                                                                                                                                      |

## 6.5 Site personnel

As outlined in section 5.4, as part of the application the applicant should identify individuals that must have accounts and [security clearances](#). The individuals will differ based on the licence class or subclass as well as the type of licence holder (i.e., if it is an individual or a corporation, cooperative or partnership). These individuals should create CTLS accounts and provide their Account IDs to the applicant. Some of these individuals need to be identified if the applicant is creating a corporate profile. Other individuals need to be identified within the “Site Personnel” section of the CTLS. The applicant must ensure that the persons identified have the knowledge, qualifications, experience and ability to fulfill their responsibilities, as applicable. For more information, refer to Appendix A: Key Individuals at the Site.



Qualifications are only required to be submitted for the QAP (and alternate QAP, if applicable) for a processing licence.



An individual may hold one or multiple roles for a licence, for one or more classes of licences at one site, or in some cases, multiple sites, assuming they meet all the requirements.



The CTLS requires that a security clearance application form be submitted for at least one individual in each position that requires a security clearance.

In the case where an applicant wishes to designate an alternate, as authorized under the Regulations, this may be done at any time. However, any alternate must also hold a valid security clearance, as applicable, before assuming the duties of the position. The Minister may also specify other individuals that must hold a security clearance, either by name or position. Should this occur, the licence holder or applicant will be notified in writing.

**Table 7: Site Personnel Requirements**

| <b>Requirement</b>                                   | <b>Required details to include</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Identification of personnel                          | <p>Specific individuals must be identified that are associated with an application in the CTLS, as follows:</p> <p><b>Cultivator (standard, micro or nursery):</b> Head of security, alternate head of security if applicable; master grower, alternate master grower if applicable</p> <p><b>Processor (standard or micro):</b> Head of security, alternate head of security if applicable; QAP, alternate QAP if applicable</p> <p><b>Sale for medical purposes:</b> Head of security, alternate head of security if applicable<br/>The responsible person must be identified within the “Licence Ownership” section of the CTLS as noted in section 6.1.</p> <p>To associate these individuals with an application, their Account IDs need to be included in the CTLS.</p>                                                                                                                                                                                                                                                                                                                                        |
| Qualifications for the QAP (Processing licence only) | <p><b>For cultivation, processing and sale for medical purposes with possession licences:</b><br/>An individual who holds a security clearance must be present at the site when activities are being conducted by other individuals in an operations area or a storage area.</p> <p>Submit details of the proposed individual’s qualifications, and any proposed alternate QAP, along with an explanation of how their training, experience and technical knowledge relate to the requirements in Part 5 (GPP requirements) and Part 6 (Cannabis Products) of the <i>Cannabis Regulations</i> as they pertain to the classes of cannabis for which activities will be conducted, including, but not limited to:</p> <ul style="list-style-type: none"><li>• development and approval of SOPs</li><li>• pest control management and pesticide testing</li><li>• quality control relating to the movement, storage and distribution of substances</li><li>• GPP as they pertain to facilities (including air filtration and ventilation, lighting, water supply, temperature and humidity control, and waste</li></ul> |

**Table 7: Site Personnel Requirements**

| Requirement | Required details to include                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
|-------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|             | disposal), equipment (including conveyances), sanitation and employee hygiene and protection                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|             | <ul style="list-style-type: none"><li>• investigations and risk mitigation pertaining to:<ul style="list-style-type: none"><li>○ cannabis or ingredients which pose a risk of injury to human health</li><li>○ the requirements of Part 5 or 6 not being met</li></ul></li><li>• complaint management and investigation</li><li>• approving product quality prior to release for sale analytical testing and validation of testing methods</li><li>• microbial and chemical contaminants</li><li>• disintegration/dissolution testing, if applicable</li><li>• cannabinoid content, including variability (THC, THCA, CBD and CBDA, as applicable)</li><li>• sample collection and retention</li></ul> |
|             | In addition, the QAP typically handles recalls (including recall simulation) and adverse reaction reports.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |



**For Processors Conducting Activities with Cannabis Extract and/or Edible Cannabis**

In addition to the requirements listed above, the QAP must possess the training, experience and technical knowledge related to biological, chemical and physical hazard identification and analysis as well as the preparation and implementation of preventive control plans. These requirements will not be assessed at initial licensing; however compliance may be verified at any time by Health Canada.



**For Processors Conducting Activities with Edible Cannabis**

In the event the QAP does not possess the training, experience and technical knowledge related to the requirements of Parts 5 and 6 of the *Cannabis Regulations* that are applicable to edible cannabis, the services of another individual who has that training, experience and technical knowledge must be retained. There is no requirement to submit the qualifications of this individual within the CTLS, however please note that compliance may be verified at any time by Health Canada.

Include clear, concrete examples and details of how the QAP and any alternate meets the technical knowledge, training, and experience requirement, including when, where and how the knowledge, training and, experience was obtained. The applicant should also submit the QAP's and any alternate's resume and any other information that supports their qualifications such as a letter of reference or a copy of their diploma, degree, certificate or transcripts that may be applicable.

**Table 7: Site Personnel Requirements**

| <b>Requirement</b> | <b>Required details to include</b>                                                                                                                                                                                                                                                                                     |
|--------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                    | A proposed work schedule and a summary of the roles and responsibilities of the QAP and any alternate if applicable (including if they are employed as a QAP at another licensed site) should also be provided to demonstrate how the QAP will be able to complete all the required activities to maintain compliance. |



For more information regarding the roles and responsibilities of the QAP and any alternate refer to the [Good Production Practices Guide](#) for Cannabis.

## 6.6 Site ownership



This section does not apply to sale for medical purposes without possession licences.

The following information is required to confirm site ownership:

**Table 8: Site Ownership Requirements**

| <b>Requirement</b>                                                                            | <b>Required details to include</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Site owner                                                                                    | <p>If the site is owned by the individual or the corporation applying for the licence, this must be indicated by linking their Account ID in the CTLS.</p> <p>If the site is owned by another individual(s) or corporation, a site owner consent form is required (see section below).</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| Site owner consent form, if the site or any portion of the site is not owned by the applicant | <p>A declaration, signed and dated by all the site's owners— or, if the owner is a corporation, by an authorized representative of the owner — consenting to activities with cannabis being conducted at the site.</p> <p>The consent form must contain:</p> <ul style="list-style-type: none"><li>• the full address of the site or any portion of the site for which the owner is not the applicant</li><li>• the class and subclass if applicable of the licence being applied for, and the proposed activities to be conducted on-site</li><li>• a declaration signed by all owners of the site stating that they:<ul style="list-style-type: none"><li>a) are the owner(s) of the site, as described</li><li>b) are aware of the activities with cannabis that the applicant proposes to conduct at the site</li><li>c) consent to those activities with cannabis being carried out at that site</li></ul></li></ul> |

## 6.7 Notices to local authorities



Notice to local authorities is not required for sale for medical purposes without possession licences.

Prior to submitting an application in the CTLS, applicants for licences to cultivate, process and sell for medical purposes (with possession of cannabis) must provide a written notice to local authorities who are located in the area of the proposed site, and submit a copy of this notice as part of their application.

More specifically, the notice must be provided to a senior official of the following local authorities:

- the local government
- the local fire authority
- the local police force or Royal Canadian Mounted Police detachment (RCMP) that is responsible for providing policing services to that area

The content of the notice must include:

- the name of the applicant
- the expected date on which the applicant will submit the application to Health Canada
- the class and subclass if applicable of licence that is being sought and the cannabis-related activities that are expected to be conducted under that licence
- the site address, and address of each building on site if applicable, at which the applicant is expecting to conduct cannabis-related activities

In order to submit an application, the following information is required:

**Table 9: Notice to Local Authorities Requirements**

| <b>Requirement</b>          | <b>Required details to include</b>                                                                                                                                                                                                                                                                                                                                                                                                          |
|-----------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Notice to local authorities | <p>The date each notice was sent or provided, and the name, title and address of the senior official to whom it was addressed.</p> <p>A copy of the actual notices provided to:</p> <ul style="list-style-type: none"><li>• the local government</li><li>• the local fire authority</li><li>• the local police force or Royal Canadian Mounted Police detachment that is responsible for providing policing services to that area</li></ul> |

## 6.8 Physical security including organizational security plan

The requirement for an [organizational security plan](#) applies to all licence classes, but the physical security requirements differ depending on the licence class, and subclass if applicable. For instance, licences for sale for medical purposes without possession are not required to demonstrate physical security measures. They are however, required to submit an organizational security plan (OSP).

For more information on the required physical security measures, refer to the *Cannabis Regulations*, and [The Physical Security Measures Guide for Cannabis](#).

Tables 10, 11, and 12 provide the information that must be submitted as part of the licence application by licence class to demonstrate how the OSP requirements and physical security requirements under the *Cannabis Regulations* will be met.




The nomenclature of the site and floor plans must be consistent with the information submitted in the “Site Details” section of the CTLS (i.e., for outdoor areas and indoor areas including rooms) and the information submitted with the security reports and visual evidence in the site evidence package, if applicable.



The individuals identified as being associated with an application must accurately align with all information provided in the Organizational Security Plan (OSP), Key Investor information, and the information included in the Cannabis Tracking and Licensing System (CTLS) application. Discrepancies or inconsistencies in the information provided may result in delays in the processing of your application.


**Table 10: Organizational Security Plan Requirements**

| Requirement                  | Required details to include                                                                                                             |
|------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------|
| Organizational security plan | Refer to the <a href="#">Cannabis organizational security plan</a> webpage for details on what must be submitted as a part of your OSP. |





**NOTE:** For Sale for Medical Purposes without possession, there is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the “Record Keeping Description” section.

**Table 11: Physical Security Requirements for Standard Processing, Standard Cultivation and Sale for Medical Purposes with Possession Licences**

| <b>Requirement</b>                                    | <b>Required details to include</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
|-------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Site plan<br>(includes storage areas)                 | <p>The overall site plan must include the following details:</p> <ul style="list-style-type: none"> <li>• The perimeter of the site must be clearly identified. Indicate whether the site perimeter is defined by a fence or the building envelope.</li> <li>• The locations of, and area covered by the security devices and visual monitoring devices for the site perimeter. All security devices must be clearly identifiable and uniquely labeled.</li> <li>• The footprint of any building(s) must be clearly identified.</li> <li>• The locations of all storage areas within each building must be clearly identified (this may also be captured on the floor plan).</li> <li>• The locations of, and area covered by the security devices and visual monitoring devices for each storage area (this may also be captured on the floor plan). All security devices must be clearly identifiable and uniquely labeled.</li> <li>• The location of any outdoor cultivation area must be clearly identified. For any outdoor area, the latitude and longitude coordinates for all four corners must be indicated.</li> </ul> <p>If there are areas, including buildings, that will not be used exclusively by the applicant, or areas that will be used by the applicant to conduct activities other than activities with cannabis, these areas must be outside of the proposed site perimeter.</p> |
| Additional site information<br>(includes floor plans) | <p> <b>NOTE:</b> There is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the “Aerial View” section.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                                       | <p>Include the following (it may be captured on the site plan)</p> <ul style="list-style-type: none"> <li>• The locations of, and area covered by the security devices and visual monitoring devices for any outdoor cultivation area. All security devices must be clearly identifiable and uniquely labeled.</li> <li>• Indicate if the building is a multi-unit building or a stand-alone site (i.e., single unit). If it is a multi-unit building, the site perimeter should be identified accordingly and all units must be labelled with information on their current use (i.e., company name).</li> </ul> <p>Floor plans must also be included for each building and include the following details:</p> <ul style="list-style-type: none"> <li>• Clear delineation of rooms where operations, grow and storage activities, as applicable, take place.</li> <li>• Clear identification of storage area(s) and the areas it is located within that meet the requirements of section 67 of the <i>Cannabis Regulations</i> as applicable.</li> </ul>                                                                                                                                                                                                                                                                                                                                                 |

**Table 11: Physical Security Requirements for Standard Processing, Standard Cultivation and Sale for Medical Purposes with Possession Licences**

| Requirement      | Required details to include                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                  | <ul style="list-style-type: none"> <li>The locations of and area covered by the security devices and visual monitoring devices as they relate to any operations area, (including grow areas) and the areas that any storage area is located within (section 67 of the <i>Cannabis Regulations</i>), as applicable. All security devices must be clearly identifiable and uniquely labeled.</li> <li>Cannabis flow between the rooms must be identified.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|                  | <div>  <p><b>NOTE:</b> There is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the “Aerial View” section.</p> </div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
| Security reports | <p>Provide the following information to demonstrate how the intrusion detection system requirements will be met.</p> <ul style="list-style-type: none"> <li>Alarm test reports for all intrusion detection devices for the site perimeter, all operations areas (including indoor and outdoor grow areas and the areas that any storage area is located within [section 67 of the regulations]), and storage areas. These reports must contain the date and time of the test, the name of the device and location of the device.</li> <li>A list of which alarm partition each intrusion detection device is assigned to.</li> <li>Access (entry and exit) log reports for all doors leading to and from storage areas. These reports must contain the date and time of each access, the name of the device, location of the device and the identity of the individual entering and exiting from each storage area.</li> </ul>                                                          |
|                  | <div>  <p><b>NOTE:</b> There is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the “Organizational Security Plan” section.</p> </div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Visual evidence  | <p>Provide the following information in the site evidence package.</p> <ul style="list-style-type: none"> <li>Guided video tour of entire site (including both indoor and outdoor areas), highlighting all security features of the site perimeter, operations areas (including all grow areas) and storage areas. All devices must correspond to their location as indicated on the site plan and all floor plans.</li> <li>Photographic overview of each side of the defined site perimeter.</li> <li>Visual recording device footage that includes the front, back and sides of the defined site perimeter (e.g., east, west, south and north walls). Complete coverage may be best demonstrated by displaying multiple visual recording device feeds that capture an individual walking around the perimeter.</li> <li>Footage from all visual recording devices in each operations areas (including the entry and exit points of the grow areas) and all storage areas.</li> </ul> |

**Table 11: Physical Security Requirements for Standard Processing, Standard Cultivation and Sale for Medical Purposes with Possession Licences**

| <b>Requirement</b>     | <b>Required details to include</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                        | <p>All video and images must meet the following criteria:</p> <ul style="list-style-type: none"> <li>• Have sufficient resolution to clearly visualize the area (not a pixelated image).</li> <li>• Capture the entirety of the areas identified (i.e. no blind spots and/or obstructed views).</li> <li>• Demonstrate the visual recording devices ability to capture the required information in both low light and night time conditions.</li> </ul> <div data-bbox="289 646 406 762"> </div> <div data-bbox="456 646 1513 800" style="background-color: #FFD700; padding: 5px;"> <p>Due to limitations on file size within the CTLS, site evidence packages are not able to be submitted as a part of the CTLS application. The site evidence package must be submitted to Health Canada outside of the CTLS. Refer to 7.1.1 Submission of Site Evidence for more information on how to submit site evidence.</p> </div>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| Additional Information | <p>Provide the following information to demonstrate how physical security requirements will be met.</p> <ul style="list-style-type: none"> <li>• Physical Barrier and Site Design <ul style="list-style-type: none"> <li>○ Description of the site and how it will prevent unauthorized access. Include any access controls at entry or exit points of the site such as windows, doors and vents.</li> <li>○ Description of materials used in the construction of the physical barriers, as applicable, for the site perimeter and for all of the operations areas (including all grow areas) and storage areas, this may include fences, walls, floors, ceilings, and doors to ensure prevention of intrusion.</li> </ul> </li> <li>• Visual Monitoring Devices <ul style="list-style-type: none"> <li>○ The type and specifications of the visual monitoring devices installed and operating, and how the devices meet the requirements (including operating temperature range, and any special features such as infrared or night vision and weatherproofing).</li> <li>○ Description of how monitoring will be maintained at all times (e.g., during a power outage).</li> </ul> </li> <li>• Intrusion Detection Devices <ul style="list-style-type: none"> <li>○ The type and specifications of the system installed and operating for intrusion detection (including operating temperature range, motion detection range if applicable, intended use, and any special features such as weatherproofing, tamper-resistance).</li> <li>○ Description of how intrusion detection system will be maintained at all times (e.g., during operating hours and a power outage).</li> <li>○ Description of how any attempted or actual tampering with the system will be detected.</li> </ul> </li> <li>• Restricted Access</li> </ul> |

**Table 11: Physical Security Requirements for Standard Processing, Standard Cultivation and Sale for Medical Purposes with Possession Licences**

| <b>Requirement</b>        | <b>Required details to include</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                           | <ul style="list-style-type: none"> <li>○ Description of how the access to operations areas (including grow areas), and storage areas will be restricted to individuals whose presence is required by their duties.</li> <li>○ Details on the types, specifications, and locations of access control or restriction devices installed and operating (e.g., Proximity card readers or keypads with electric door strikes or electromagnetic locks, door lock and key, combination lock, padlock).</li> <li>○ Information on how and which personnel will be given access (e.g., issued cards, fobs, PINs, keys).</li> </ul>                          |
| • Access Log              | <ul style="list-style-type: none"> <li>○ Description of how access to storage area will be logged.</li> <li>○ Method used to record the identity of every individual entering or exiting a storage area and the information that will be recorded (i.e. the date and time of entry and exit, the name of the area being accessed, the identifier for the access point used [e.g., door, gate, etc.]).</li> </ul>                                                                                                                                                                                                                                   |
| • Monitoring and Response | <ul style="list-style-type: none"> <li>○ Information on how the intrusion detection devices will be monitored continuously (i.e. 365 days a year, 7 days a week and 24 hours a day), either on-site or off-site (e.g., use of a ULC-certified monitoring company).</li> <li>○ Information on the procedure in place for when the intrusion detection system's alarm is triggered, and the procedure for responding to such incidences, including creating and retaining records of detected occurrences (i.e. the date and time of the occurrence and the measures taken in response to it and the date and time when they were taken).</li> </ul> |



**NOTE:** There is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the "Organizational Security Plan" section.

**Table 12: Physical Security Requirements for Micro-Cultivation, Micro-Processing, and Nursery Licences**

| <b>Requirement</b>                     | <b>Required details to include</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Site plan<br>(including storage areas) | <p>The overall site plan must include the following details:</p> <ul style="list-style-type: none"> <li>• The perimeter of the site must be clearly identified. Indicate whether the site perimeter is defined by a fence or the building envelope.</li> <li>• The footprint of any building(s) must be clearly identified.</li> <li>• The locations of all storage areas within each building must be clearly identified (this may also be captured on the floor plan).</li> <li>• The location of any outdoor cultivation area must be clearly identified. For any outdoor area, the latitude and longitude coordinates for all four corners must be indicated.</li> </ul> |




If there are areas, including buildings, that will not be used exclusively by the applicant, or areas that will be used by the applicant to conduct activities other than activities with cannabis, these areas must be outside of the proposed site perimeter.



**NOTE:** There is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the “Aerial View” section.

|                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Additional site information<br>(including floor plans) | <p>Include the following:</p> <ul style="list-style-type: none"> <li>• Indicate if the building is a multi-unit building or a stand-alone site (i.e., single unit). If it is a multi-unit building, the site perimeter should be identified accordingly and all units must be labelled with information on their current use (i.e., company name).</li> </ul> <p>Floor plans must also be included for each building and include the following details:</p> <ul style="list-style-type: none"> <li>• Clear delineation of rooms where operations, grow and storage activities, as applicable, take place.</li> <li>• Clear identification of storage area(s).</li> <li>• Cannabis flow between the rooms must be identified.</li> </ul> <p>In the case of cultivation licences, delineate the respective surface areas to demonstrate how the site meets the surface area threshold (including both indoor and outdoor grow areas). This can be indicated on the site plan and floor plans as applicable. As well, indicate whether the surface area is comprised of multiple surfaces (e.g., is vertically arranged).</p> <ul style="list-style-type: none"> <li>• The delineated area should include dimensions which demonstrate how the total surface area of the cannabis plants do not exceed the applicable threshold.</li> </ul> |
|--------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**Table 12: Physical Security Requirements for Micro-Cultivation, Micro-Processing, and Nursery Licences**

| <b>Requirement</b>                                                                  | <b>Required details to include</b>                                                                                                                                                                                                                                                                                                                                                                                                        |
|-------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                                                     | <ul style="list-style-type: none"> <li>A sample calculation should be included to demonstrate how the total surface area does not exceed the applicable threshold.</li> </ul>                                                                                                                                                                                                                                                             |
|    | For micro-cultivation, plant surface area cannot exceed 200 m <sup>2</sup> (includes multiple surfaces such as surfaces vertically arranged). For nursery seed production the total surface area cannot exceed 50 m <sup>2</sup> (for all the parts of budding or flowering plants).                                                                                                                                                      |
|    | <b>NOTE:</b> There is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the “Aerial View” section.                                                                                                                                                                                                                                            |
| Visual Evidence                                                                     | <p>Provide the following information in the site evidence package.</p> <ul style="list-style-type: none"> <li>Guided video tour of entire site (including both indoor and outdoor areas), highlighting the entire site perimeter and all storage areas.</li> <li>Visual footage showing entire physical barrier for the site and all storage areas.</li> <li>Photographic overview of each side of the defined site perimeter.</li> </ul> |
|  | Due to limitations on file size with the CTLS, site evidence packages are not able to be submitted as a part of the CTLS application. The site evidence package must be submitted to Health Canada outside of the CTLS. Refer to 7.1.1 Submission of Site Evidence for more information on how to submit site evidence.                                                                                                                   |

**Table 12: Physical Security Requirements for Micro-Cultivation, Micro-Processing, and Nursery Licences**

| <b>Requirement</b>     | <b>Required details to include</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
|------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Additional Information | <p>Provide the following information to demonstrate how physical security requirements will be met.</p> <ul style="list-style-type: none"> <li>• Physical Barrier and Site Design <ul style="list-style-type: none"> <li>○ Description of the site and how it will prevent unauthorized access. Including any access controls at entry or exit points of site such as windows, doors and vents.</li> <li>○ Description of materials used in the construction of the physical barriers, as applicable, this may include fences, walls, floor/ceiling and doors to ensure prevention of intrusion (include this for both site perimeter and for all of the storage areas).</li> </ul> </li> <li>• Restricted Access <ul style="list-style-type: none"> <li>○ Description of how the access to storage areas will be restricted to individuals whose presence is required by their duties.</li> <li>○ Details on the types, specifications, and locations of access control or restriction devices installed and operating (e.g., Proximity card readers or keypads with electric door strikes or electromagnetic locks, door lock and key, combination lock, padlock).</li> <li>○ Information on how and which personnel will be given access (e.g., issued cards, fobs, PINs, keys).</li> </ul> </li> </ul> |



**NOTE:** There is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the “Organizational Security Plan” section.

## 6.9 Good Production Practices



GPP requirements apply to a number of activities across many licence classes.

Compliance with some of these must be demonstrated at the time of application. However, GPP compliance may be verified at any time by Health Canada. Applicants for sale for medical purposes without possession licences do not need to demonstrate compliance with GPP as part of the licensing application process.

As part of the licensing application process, the applicant is required to provide a Good Production Practices Report that clearly demonstrates how the GPP requirements will be met. Table 13 provides the information that must be submitted to demonstrate how the GPP requirements under the *Cannabis Regulations* will be met.

For more information on the GPP requirements, refer to the *Cannabis Regulations* and the [Good Production Practices Guide](#) for Cannabis.

**Table 13: GPP Requirements for Cultivation, Processing, Sale for Medical Purposes with Possession Licences**

| <b>Requirement</b>               | <b>Elements to demonstrate that GPP requirements will be met:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
|----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Good Production Practices Report | <p>Provide the following information as a part of the Good Production Practices Report.</p> <ul style="list-style-type: none"> <li>• Storage <ul style="list-style-type: none"> <li>○ Description of how and where cannabis and anything used as an ingredient will be stored, including conditions of any storage area(s) (e.g., presence of temperature and/or humidity control) and how the requirements of section(s) 82 and 88.2, if applicable, of the <i>Cannabis Regulations</i> are met.</li> <li>○ Include a description of the storage procedure for cannabis and anything used as an ingredient (e.g., in-process, bulk, immediate containers, samples, quarantined, product approved for sale, rejected, returned or recalled product, and material awaiting destruction) and how these procedures will ensure that the requirements of section 82 of the <i>Cannabis Regulations</i> are met.</li> </ul> </li> <li>• Building or part of building <ul style="list-style-type: none"> <li>○ Description and/or depiction of the building detailing the construction of the surfaces such as walls, ceilings, (e.g., non-porous panels, sealant), floors (e.g., polished concrete, epoxy sealant), and seams (e.g., caulking, joints between floor, walls, and ceiling) demonstrating how the requirements of section 84 of the <i>Cannabis Regulations</i> are met.</li> <li>○ Process flow diagram and/or a “step-by-step” description showing the movement of cannabis, cannabis products and/or anything used as an ingredient through the building and the separation of operations areas (including grow areas), storage areas and non-cannabis areas.</li> </ul> </li> <li>• System - filtration and ventilation <ul style="list-style-type: none"> <li>○ Description of filtration and ventilation system, demonstrating how it will filter air to prevent the escape of odours associated with cannabis plant material to the outdoors.</li> <li>○ Description of how the filtration and ventilation system will provide sufficient air exchanges in order to prevent the contamination of the cannabis or thing that will be used as an ingredient (does not apply to a building or part of a building where the only activities being conducted with cannabis or anything that will be used as an ingredient are its cultivation, propagation or harvesting [e.g., cultivation of blueberries that will be used as an ingredient in an edible product]).</li> </ul> </li> </ul> |

**Table 13: GPP Requirements for Cultivation, Processing, Sale for Medical Purposes with Possession Licences**

| <b>Requirement</b> | <b>Elements to demonstrate that GPP requirements will be met:</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|--------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                    | <ul style="list-style-type: none"> <li>○ Description of how the filtration and ventilation system is accessible for cleaning, maintenance, or inspection, is capable of withstanding repeated cleaning and functions in accordance with its intended use, if applicable (does not apply to a building or part of a building where the only activities being conducted with anything that will be used as an ingredient are its cultivation, propagation or harvesting).</li> <li>○ Include type, number and location of air filters installed (e.g., HEPA, carbon, charcoal, combination, portable filters).</li> <li>○ Provide a diagram and/or floor plan detailing the filtration and ventilation system (e.g., air intake and air exhaust locations and direction of air flow within the building(s)).</li> </ul> |
| • Supply of water  | <ul style="list-style-type: none"> <li>○ Description of water supply source; if the source is not municipal water, provide evidence that the water is appropriate for the activity being conducted (e.g., water for irrigation, sanitation and processing).</li> <li>○ Description of any non-potable water sources and how cross connection with potable water sources will be eliminated or the measures used to eliminate any risk of contamination of cannabis or anything that will be used as an ingredient (e.g., backflow valves, etc.).</li> </ul>                                                                                                                                                                                                                                                           |



**For Processing Licences:**

Any water, steam or ice that comes into contact with a cannabis extract, a cannabis topical, edible cannabis or anything that will be used as an ingredient must be potable water, and if the water is not potable the water must not present a risk of contamination of the cannabis extract, cannabis topical, edible cannabis or thing that will be used as an ingredient.

Potable water should meet the [Guidelines for Canadian Drinking Water Quality](#).

- Lighting
  - Description of lighting in operations areas (including grow areas) and storage areas, demonstrating how the cannabis or thing that will be used as an ingredient will not become contaminated in the event of breakage (e.g., constructed with shatter resistant materials, fixtures shielded with safety covers).

**Table 13: GPP Requirements for Cultivation, Processing, Sale for Medical Purposes with Possession Licences**

| Requirement     | Elements to demonstrate that GPP requirements will be met:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                 | <ul style="list-style-type: none"> <li>○ Description of how light fixtures can withstand repeated cleaning and sanitizing (if necessary) to prevent contamination of the cannabis or thing that will be used as an ingredient (e.g., constructed from material that can be repeatedly cleaned and sanitized).</li> <li>● Sanitation program               <ul style="list-style-type: none"> <li>○ Description of the sanitation program demonstrating how the requirements of section 87 of the <i>Cannabis Regulations</i> are met for all operations areas (including grow areas), storage areas, transitory areas (e.g., hallway), areas where anything that will be used as an ingredient is produced, packaged, labelled, distributed, stored, sampled and tested, and non-cannabis areas (e.g., lavatory, office space). This should include the frequency or schedule.</li> <li>○ Description of how verification of cleaning effectiveness will be conducted.</li> </ul> </li> <li>● Hand cleaning and sanitizing stations and lavatories (if necessary)               <ul style="list-style-type: none"> <li>○ Indicate on any floor plan the location of all hand cleaning, sanitizing stations and lavatories.</li> </ul> </li> </ul> |
| Visual Evidence | <p>Video and photographic evidence must include the following details.</p> <ul style="list-style-type: none"> <li>● Guided video tour of entire site (including both indoor and outdoor areas), highlighting all GPP features of the building, including all operations areas (including grow areas) and storage areas.</li> <li>● Close-up images of the surfaces (including walls, floors, ceilings and joints) of all operations areas (including grow areas) and storage areas demonstrating that they meet the requirements of section 84 of the <i>Cannabis Regulations</i>.</li> <li>● A video of an individual entering and moving through different areas of the facility demonstrating the intended production process flow through the facility.</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |



Due to limitations on file size within the CTLS, site evidence packages are not able to be submitted as a part of the CTLS application. The site evidence package must be submitted to Health Canada outside of the CTLS. Refer to 7.1.1 Submission of Site Evidence for more information on how to submit site evidence.

**Table 13: GPP Requirements for Cultivation, Processing, Sale for Medical Purposes with Possession Licences**

| <b>Requirement</b>                                                     | <b>Elements to demonstrate that GPP requirements will be met:</b>                                           |
|------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| Good Production Practices Attestation<br><br>(Processing licence only) | Include a completed and signed attestation form found in Appendix G: Good Production Practices Attestation. |



NOTE: There is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the “Good Production Practices” section.



**For Processing Licences:**

As noted in section 6.4, it is prohibited to produce, package, or label food for sale within a site unless those activities are conducted in a building that is separate from any building where the processor conducts activities with cannabis.

## 6.10 Record keeping



Required for all licence types, based on the regulatory requirements.

There are a number of regulatory requirements for record keeping that must be met by a licence holder. The applicant is encouraged to refer to the *Cannabis Regulations* and Appendix C: Record Keeping Attestation for details about record keeping required for the licensing process, and to consult the *Cannabis Regulations* to obtain an understanding of the post-licensing regulatory record keeping requirements.

**Table 14: Record Keeping Requirements**

| <b>Requirement</b>         | <b>Required details to include</b>                                                               |
|----------------------------|--------------------------------------------------------------------------------------------------|
| Record keeping attestation | Include a completed and signed attestation form found in Appendix C: Record Keeping Attestation. |



**NOTE:** There is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the “Record Keeping Examples” section.

Detailed description of the record keeping methods proposed for additional requirements for sale for medical purposes (Sale for medical purposes licence only)

Include a description of the record keeping methods that will capture the following information:

- medical client registration information
- filling of orders and refusal to fill orders
- medical documents provided by clients
- communication with provincial or territorial professional licensing authorities

Examples of the following should also be provided

- the medical practitioner verification process
- an example of the registration document that will be provided to clients upon registration
- a description of how the system will ensure that the quantity of cannabis distributed or sold will not exceed the equivalent of 150g of dried cannabis (calculated in accordance with Schedule 3 of the *Cannabis Act*)



**NOTE:** There is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the “Record Keeping Description” section.



**For cultivation and processing licences:** There is no requirement to submit a description of your record keeping methods. Please upload a blank document in the “Record Keeping Description” section.

## 6.11 Key Investor Reports

An applicant seeking a licence for cultivation, processing or sale for medical purposes that does not trade its shares on the public market must provide information on key investors as part of an application. Refer to Appendix E: Key Investors for more information. The record of key investors must include the following information:

- The key investor's name and mailing address.
- A description of how the key investor exercises, or is in a position to exercise, control over the applicant.
- Details regarding each instance where the key investor provides money, goods or services to the applicant.
- Details regarding any benefit that the key investor receives as a result of being an investor.
- Details regarding each instance where money is repaid or goods are returned to the key investors.
- Whether the controlling interest has been, will be, or could be assigned, pledged, mortgaged, hypothecated or sold, in whole or in part, to any person.

Refer to section 241 of the *Cannabis Regulations* for the specific report details, and the [Report on your licence](#) webpage for reporting requirements relating to investors once licensed.

If there are no key investors, an attestation that has been signed and dated by the Responsible person must be uploaded.

## 6.12 Self Identification

The CTLS includes an opportunity to self-identify as Indigenous affiliated.<sup>5</sup> A no response includes not wanting to self-identify.

Indigenous affiliated applicants are able to request a two-stage review that allows a licence application to be submitted without a fully built physical site. A two-stage process would involve an in-depth paper-based review by Health Canada and upon completion of this review, Health Canada would issue a confirmation of readiness letter with a request for a site evidence package. After the build is completed and the site evidence package is received and reviewed by Health Canada, the application could be approved or refused.

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<sup>5</sup> Indigenous affiliation can include any person or persons of First Nation, Inuit and/or Métis descent or any community, corporation or business associated with a First Nation, Inuit and Métis government, organization or community.

## 6.13 Associated Individuals

### Reporter:

Applicants who wish to delegate [reporting](#) level access in the CTLS can add these individuals under the 'Associated Individuals' section in the CTLS.

### Individual Requiring Security Clearance:

For applicants requiring additional individuals to hold [security clearances](#) in addition to the other roles listed in [Table 3](#), the responsible person can add these individuals under the 'Associated Individuals' section in the CTLS. Please note that Health Canada will still need to verify and approve the need for these additional individuals to hold a security clearance. Provide a document with the person's full name, their CTLS account ID, their SEC number and the rationale for the request and upload it to the CTLS. Your rationale must include the reasoning why this individual requires a security clearance (e.g., the method by which they will exercise or be in a position to exercise direct control over activities taking place at the licensed site).



NOTE: There is no specific section in the current version of the CTLS to upload this information. This information should be uploaded as an attachment under the "Record Keeping Examples" section.

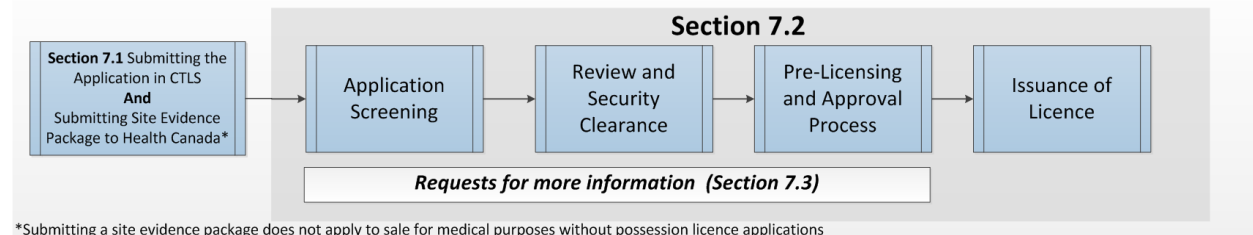
### Consent to Communicate:

If the applicant wishes to allow Health Canada to communicate with another representative regarding their application, the applicant must input that individual's CTLS account ID in the "Associated Individuals" section of their application. Applicants who have already submitted their application are no longer able to make changes. In this case, the responsible person must email [HC.licensing-cannabis-licences.SC@canada.ca](mailto:HC.licensing-cannabis-licences.SC@canada.ca) to request a **Cannabis Application Consent to Communicate Form**. The signed and completed form must be emailed to [HC.licensing-cannabis-licences.SC@canada.ca](mailto:HC.licensing-cannabis-licences.SC@canada.ca) from the e-mail address indicated in the Cannabis Tracking and Licensing System (CTLS) for the responsible person with the subject line "Consent to Communicate".

## 7.0 Submitting an Application and Administrative Procedures

Once the applicant has included all of the requirements in the application within the CTLS and is ready to submit the application, the additional steps in the licensing process will begin as outlined in Figure 3: Steps following submission of an application.

**Figure 3: Steps following submission of an application**



### 7.1 Submitting the application

Once the applicant has input all required information, they can submit their application. This involves the following steps:

- Submission (declarations and attestations) **for all licence classes:** Prior to submitting the application, the applicant, through their responsible person, must electronically attest within their CTLS application to the following:
  - That the proposed personnel submitted as part of the application are familiar with the provisions of the *Cannabis Act* and its Regulations that will apply to the licence.
  - That none of the activities that the applicant is proposing to conduct in the application will be conducted, or records of these activities maintained, at a dwelling-house.
  - That all information and documents submitted in support of the application, are, to the best of the applicant's knowledge, correct and complete.
  - That the person submitting the application has the authority to bind the application/applicant and has the overall responsibility for the management of the activities to be conducted under the licence.
- Submission (declarations and attestations) **for processing licences only:** Prior to submitting the application, the applicant, through their responsible person, must electronically attest within their CTLS application to the following:
  - Prior to conducting any activities with cannabis extracts or edible cannabis, all requirements to meet the relevant provisions of the *Cannabis Regulations* will be in place. This includes but is not limited to:

- Identifying and analyzing all 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.
- Using control measures that are shown by evidence to be effective, including any treatment or process, that prevent, eliminate or reduce to an acceptable level the biological, chemical and physical hazards.
- Preparing, retaining, maintaining and implementing a written preventive control plan for any activity conducted 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 Quality Assurance Person will ensure that all cannabis is approved prior to being made available for sale.
- In the event that the Quality Assurance Person does not have the required training, experience and technical knowledge related to the requirements of Parts 5 and 6 applicable to edible cannabis, the services of another individual with the required training, experience and technical knowledge will be retained.
- Cannabis will not be produced, packaged, labelled or stored in a building within a site if food that is to be sold is also produced, packaged or labelled in the same building.

Once the application is submitted, it appears in the “Submitted Licence Applications” section of the CTLS. Each application will have a unique Licence Application ID. All correspondence with Health Canada in relation to the application should include this identifier in the subject title. It is important to note that once an application is submitted, no further changes can be made in the CTLS by the applicant with the exception of changes to the corporate profile as indicated in Section 5.5 Create a corporate profile. If a change to an application is required after submission applicants should refer to section 7.3.3 Changes to an application/unsolicited information for more information.



An applicant may check the status of their application in the CTLS at any time during the application process. For more information, refer to Appendix D: Application Status Meanings in the CTLS.



#### **For Processing, Cultivation, and Sale for Medical Purposes with Possession Licences**

A site evidence submission must be received by Health Canada before an application can be considered. Site evidence package submissions must be received by Health Canada within 10 business days following the submission of their application in the CTLS. Applicants who do not submit their site evidence package within the timeframe may have their application refused as incomplete.

### **7.1.1 Submission of site evidence**

If you are applying for a **Processing, Cultivation, and Sale for Medical Purposes with Possession Licence**, you need to submit a site evidence package in one of the following ways:

1. **Electronic file transfer submission:** Once an application is submitted in the CTLS, the responsible person will receive an email from Health Canada with additional submission instructions. It can take up to **3 business days** to receive this email. The email will provide a unique and secure link provided by LiquidFiles in which to upload the site evidence package directly. Note, applicants must compress or zip all files into a single file for uploading. **This is the preferred method of submission as it reduces transit delays.** If you have any questions on how to use LiquidFiles email [CSCB.filetransfer-partagedefichiers.DGSCC@canada.ca](mailto:CSCB.filetransfer-partagedefichiers.DGSCC@canada.ca) with the subject line “LiquidFiles Submission Question for APP #”.
2. **USB storage device submission:** Once the application is submitted in the CTLS, the site evidence package can be saved to a USB device and this device can be sent to Health Canada. If you submitted your site evidence package on a USB and are using a courier service, please provide the Licensing and Medical Access Directorate with the tracking number for the package. The tracking number should be sent in an email to [HC.licensing-cannabis-licences.SC@canada.ca](mailto:HC.licensing-cannabis-licences.SC@canada.ca) with the APP number (APP-XXXXXXXXXX-20XX) provided by the CTLS listed in the subject line of the email.  
The USB submission package can be sent to the following address:

Licensing and Medical Access Directorate  
Health Canada  
Address Locator: 0301F  
Ottawa ON K1A 0K9

Please submit all visual evidence in accordance with the following:

- All submitted packages must be clearly identified with the APP number and applicant name (**APP-XXXXXXXXXX-20XX Site Evidence Submission\_Applicant Name**) associated with the CTLS portion of the licence application. Any packages which are inappropriately identified may result in a delay to the review process or refusal of the application.
- Photographic evidence must be provided in PDF-formatted files.
  - Visual evidence for each operations area (including grow areas) and storage areas identified must be submitted in separate files (e.g. Grow-Room.pdf, Facility-Perimeter.pdf).
- Visual evidence must show the area in question followed by images derived from the visual monitoring devices located in those areas.
- Video evidence must be submitted in any of the following supported formats:
  - MP4 Video file (.mp4, .m4v, .mp4v, .3g2, .3gp2, .3gp, .3gpp)
  - QuickTime Movie file (.mov)
  - Audio Visual Interleave (.avi)
  - Microsoft Digital Video Recording (.dvr-ms)

- Moving Pictures Experts Group (.mpg, .mpeg, .m1v, .mp2, .mp3, .mpa, .mpe, .m3u)

Due to Health Canada's internal IT security policy, any information submitted by CD ROM storage will be returned to the applicant. Alternative cloud storage hosting services other than LiquidFiles are not permitted.

## 7.2 After submission

Once an application is submitted in the CTLS, there are a series of steps Health Canada undertakes to review and issue the licence as outlined below. It is important to note that in accordance with subsection 62(5) of the *Cannabis Act*, the Minister may request the submission of any additional information that pertains to the information contained in the application and that is necessary for the Minister to consider the application. This would be in the form of a request for more information as outlined in section 7.3.1.

- **7.2.1 Application screening:** During screening, the application, attached documents and, if required, the submitted site evidence package are assessed for completeness, legibility and ability to be further assessed. For Processing, Cultivation, and Sale for Medical Purposes Licence applications there is a nonbinding 30 business day service standard for completion of screening of the application by Health Canada. Please note that application screening cannot take place until Health Canada receives the site evidence package (not applicable for sale for medical purposes without possession licences). The 30-day service standard will commence following payment of the applicable cost recovery fee for application screening and upon receipt of the complete application submission.
- **7.2.2 Review and security clearance:** Once an application has passed the screening stage, and security clearance applications are being processed, the application will undergo a detailed review of both documents submitted through the CTLS and, if required, visual evidence submitted as a part of the site evidence package to verify that the requirements are met. Refer to the [Cannabis security clearances](#) webpages for more information on the security clearance process.

**7.2.3 Pre-licensing and approval process:** Following the review of this information, an on-site pre-licence inspection by Health Canada inspectors may be deemed necessary prior to further licensing decisions. If an inspection is required, the inspection team will contact the applicant. In the case where an on-site pre-licence inspection is not required, the licence issuance will be based on the information submitted to Health Canada.

**7.2.4 Issuance of licence:** Once all information has been reviewed, including the results and observations from a pre-licence inspection, if necessary, and all security clearances have been granted, an initial licence for authorized activities is issued. A licence as well as an accompanying issuance letter detailing any conditions around the issued licence is

sent to the responsible person's email address in the CTLS. In addition, all individuals who have been granted a [security clearance](#) will be sent a security clearance letter.

Immediately after issuance of their licence, licence holders will generally be permitted to sell cannabis, as authorized by their licence as set out in the *Cannabis Regulations* and in accordance with any licence conditions. Cultivation and processing licence holders will generally be restricted to the sale of cannabis products that are cannabis plants and cannabis plant seeds to a holder of a licence for sale, and a person authorized to sell cannabis under a provincial Act by reason of subsection 69(1) of the *Cannabis Act*. The sale of cannabis products of all other cannabis classes will usually be restricted by a condition placed on the licence. For processing licence holders, to gain authorization for the sale of cannabis products of all other cannabis classes, an amendment application must be submitted to change the condition on the licence. Refer to the [Manage your cannabis licence](#) webpages for more information on how to complete an amendment submission.



Licence holders must ensure that the quality of cannabis products they produce, sell and distribute meet all applicable requirements. When a processing licence holder is first licensed, activities will usually be limited. This graduated licensing approach allows Health Canada to verify that the cannabis products intended for sale to the public meet all of the quality standards set out under the *Cannabis Regulations*.

## 7.3 Administrative procedures

### 7.3.1 Receiving and responding to a request for more information

It is the applicant's responsibility to meet all of the licensing requirements. If information submitted as part of the application is unclear or requires further detail to show how it meets the requirements, Health Canada may require the applicant to submit additional information. In these cases, Health Canada strives to be clear about what information is needed from the applicant. If the applicant is unclear about what is required to respond to the request for more information, they may contact Health Canada by email or phone for further guidance (refer to section 8.0). Note that it is not a requirement to retain the services of a third party (e.g., consultant) to prepare responses to Health Canada.

A request for more information will be emailed to the responsible person. The applicant must respond by email, generally within 10 business days of the request. Some requirements for responding to requests for more information include:

- Responses should be comprehensive and comment on each of the elements noted in the request for more information.
- The applicant should not resubmit a revised version of the original documents or visual evidence unless requested to do so, but should provide a clear and detailed response

specific to each point requested. This may include a tabular or report format or additional photographic or video evidence.

- It is important to be as specific and as detailed as possible when addressing each section. Incomplete responses may delay processing or lead to a refusal to consider an application.

### 7.3.2 Refusals and withdrawals

Health Canada may refuse to consider an application if any of the required information is not provided.

In addition, Health Canada may refuse to issue a licence under circumstances set out in the *Cannabis Act* and its Regulations. These include:

- Issuing a licence is likely to create a risk to public health or public safety including the risk of diversion.
- There are reasonable grounds to believe that false or misleading information has been submitted.
- The applicant has contravened the *Cannabis Act*, the *Controlled Drugs and Substances Act*, the *FDA* or any associated regulations, including an order or a condition of another licence under any of those Acts in the past 10 years.
- An applicant for a processing licence has been convicted of an offence under the *Safe Food for Canadians Act*, *Consumer Packaging and Labelling Act*, *Fish Inspection Act*, *Meat Inspection Act* or *Canada Agricultural Products Act*, in the past 10 years.
- The applicant is a young person (as defined in the *Cannabis Act*), an individual who is not ordinarily resident in Canada or an organization that was incorporated, formed or otherwise organized outside of Canada.
- A security clearance associated with the application has been refused or cancelled.
- An individual who is required to hold a security clearance does not hold one.
- The combination of classes or subclasses of licences proposed at the same site is not permitted. For further details, refer to Table 2: General Guide for Combinations of Licence Classes and Subclasses at a Single Site and section 29 of the *Cannabis Regulations*.
- The Minister is of the opinion that the refusal is in the public interest.

In these cases, Health Canada may send a notice of intent to refuse, either to refuse to consider an application, or to refuse to issue a licence. This intent to refuse notice will provide the applicant with a timeframe within which to respond, after which a decision on the refusal will be made.

The notice of refusal officially closes the file and sets out the specific reasons or deficiencies that resulted in the decision to refuse to consider the application or issue a licence. All decisions to refuse an application are without prejudice to filing a new application for a licence. If an applicant wishes to submit a new application at a future time, it will be processed as such. Information and data submitted to support an application that is refused will not be returned to the applicant.

At any time during the review of their application, the applicant may withdraw the application through the CTLS. Withdrawal of an application is without prejudice to submitting another application. If an applicant wishes to resubmit an application at a future time, the application will be processed as a new application. Information and data submitted to support the original application will not be returned to the applicant.

For the intent to refuse process for security clearances, refer to the [Cannabis security clearances](#) webpages.

### **7.3.3 Changes to an application/unsolicited information**

Once an application is submitted, changes cannot be made to the application within the CTLS. If a change is required, the applicant must contact [HC.licensing-cannabis-licences.SC@canada.ca](mailto:HC.licensing-cannabis-licences.SC@canada.ca). The email must clearly indicate the application file number, the applicant's name and the subject of the correspondence in the subject line of the email.

Any unsolicited information or submissions not clearly labelled with the above information may not be assessed by Health Canada.

## **8.0 Contact Us**

For questions related to a specific licence application, an email may be sent to: [HC.licensing-cannabis-licences.SC@canada.ca](mailto:HC.licensing-cannabis-licences.SC@canada.ca). The email must clearly indicate the application file number, the applicant's name and the subject of the correspondence in the subject line of the email. Meeting or teleconference requests are evaluated on a case-by-case basis.


For other general questions about the *Cannabis Act* and its Regulations outside of a specific application, including those related to the CTLS, email: [cannabis@canada.ca](mailto:cannabis@canada.ca).

Alternatively, the Controlled Substances and Cannabis Branch may be contacted by phone at 1-866-337-7705.

## **9.0 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 require in order to be compliant with the *Cannabis Act* and its Regulations.

Health Canada appreciates receiving your feedback on whether this guide was useful and would welcome your suggestions for improvement. Please send us your feedback by email to: [cannabis@canada.ca](mailto:cannabis@canada.ca) and indicate in the subject line: "Feedback on Application Guide".



Your feedback will help us improve this guide and better serve all applicants and licence holders.

## Appendix A: Key Individuals at the Site

\*Note that for the purposes of an application, other individuals may require accounts and/or security clearances in addition to the key individuals identified in this table. Refer to the *Cannabis Regulations* and Section 5 for more information.

✓ Required to be identified    SEC- Security Clearance Required

| Individuals                       | Responsibilities and Qualifications (as defined in the Regulations)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | Cultivation |       |         | Processing |       | Sale for Medical Purposes |
|-----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------|---------|------------|-------|---------------------------|
|                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Standard    | Micro | Nursery | Standard   | Micro |                           |
| Licence Holder (as an Individual) | <ul style="list-style-type: none"> <li>Overall responsibility for the licence</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | ✓SEC        | ✓SEC  | ✓SEC    | ✓SEC       | ✓SEC  | ✓SEC                      |
| Responsible Person                | <ul style="list-style-type: none"> <li>A holder of a licence must retain the services of one individual as the responsible person who has the authority to bind the licence holder</li> <li>Has overall responsibility for the activities conducted by the licence holder</li> <li>Must have sufficient knowledge of the provisions of the Act and Regulations that apply to the holder of the licence</li> </ul> <p><i>May designate one qualified alternate</i><br/> <i>Will be the official point of contact with Health Canada and through the CTLS</i></p> | ✓SEC        | ✓SEC  | ✓SEC    | ✓SEC       | ✓SEC  | ✓SEC                      |
| Head of Security                  | <ul style="list-style-type: none"> <li>Responsible for ensuring that the physical security measures comply with Part 4 of the <i>Cannabis Regulations</i></li> <li>Responsible for the OSP</li> </ul> <p><i>May designate one qualified alternate</i></p>                                                                                                                                                                                                                                                                                                       | ✓SEC        | ✓SEC  | ✓SEC    | ✓SEC       | ✓SEC  | ✓SEC                      |
| Master Grower                     | <ul style="list-style-type: none"> <li>Responsible for the cultivation, propagation and harvesting of cannabis</li> <li>Must be familiar with the provisions of the Act and Regulations that relate to his or her activities.</li> </ul> <p><i>May designate one qualified alternate</i></p>                                                                                                                                                                                                                                                                    | ✓SEC        | ✓SEC  | ✓SEC    |            |       |                           |

| Individuals | Responsibilities and Qualifications (as defined in the Regulations)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | Cultivation |       |         | Processing |       | Sale for Medical Purposes |
|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------|-------|---------|------------|-------|---------------------------|
|             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Standard    | Micro | Nursery | Standard   | Micro |                           |
| QAP         | <ul style="list-style-type: none"> <li>Responsible for ensuring that all cannabis is approved prior to being made available for sale</li> <li>Required to have the training, experience and technical knowledge related to the GPP and Cannabis Products requirements of the Regulations for the activities conducted with the applicable class of cannabis</li> <li>Responsible for investigating every complaint received in respect of the quality of the cannabis and, if necessary, taking measures to mitigate any risk</li> <li>Responsible for the immediate investigation if the cannabis or anything that will be used as an ingredient is suspected to present a risk of injury to human health or if the applicable requirements of Part 5 or 6 are not being met and immediately takes measures to mitigate any risk</li> <li>Responsible for approval of methods and procedures related to GPP</li> <li>Responsible for approving the preventive control plan for activities conducted with cannabis extract or edible cannabis</li> </ul> <p><i>May designate <b>up to two</b> alternate QAPs who can replace the QAP, if and when required. These alternates must be identified in advance and requires approval from Health Canada, because there are specified qualifications for this position</i></p> |             |       |         | ✓SEC       | ✓SEC  |                           |

## Appendix B: Cannabis Licence Classes and Subclasses

This table provides a summary of the cannabis licence classes and subclasses, and examples of activities that can be authorized under the *Cannabis Regulations*. The *Cannabis Regulations* should be referred to for additional detail. In order to conduct any of the activities, they must be authorized by the licence.

| Licence Class <sup>6</sup> | Subclass             | Restrictions                                                                                                                                                            | Authorized Activities (if authorized by licence) <sup>7</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Notes                                                                                                                                                                                                                                                                                                          |
|----------------------------|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Cultivation                | Standard Cultivation |                                                                                                                                                                         | <ul style="list-style-type: none"> <li>• Possess cannabis</li> <li>• Obtain dried or fresh cannabis, cannabis plants or cannabis plant seeds by propagating, cultivating, harvesting</li> <li>• For the purpose of testing, alter the chemical or physical properties of the cannabis</li> </ul>                                                                                                                                                                                                                                                                        | <ul style="list-style-type: none"> <li>• An applicant may apply for a standard cultivation licence, even with a proposed plant surface area of less than 200m<sup>2</sup> but standard cultivation requirements will apply in this case</li> <li>• Cultivation may be conducted indoors or outdoors</li> </ul> |
| Cultivation                | Micro-Cultivation    | <ul style="list-style-type: none"> <li>• Plant surface area cannot exceed 200m<sup>2</sup> (includes multiple surfaces such as surfaces vertically arranged)</li> </ul> | <ul style="list-style-type: none"> <li>• Sell and distribute dried cannabis, fresh cannabis, cannabis plants or cannabis plant seeds to other licence holders (cultivators, processors, analytical testers, researchers, cannabis drug licence holders), with the exception that dried cannabis or fresh cannabis cannot be sold to the holder of a nursery licence</li> <li>• Sell and distribute cannabis plants or cannabis plant seeds to a licensed nursery</li> <li>• Sell and distribute cannabis products that are cannabis plants or cannabis plant</li> </ul> | <ul style="list-style-type: none"> <li>• Cultivation may be conducted indoors or outdoors but the cannabis plant surface area includes any indoor/outdoor areas at any single time</li> </ul>                                                                                                                  |

<sup>6</sup> Should the user select 'Cannabis' as a licence class in the CTLS, they will then need to specify the cannabis licence class or subclass (as specified by the *Cannabis Regulations*) for which they intend to apply

<sup>7</sup> Licence holders can conduct research and development activities within their authorized licenced activities. If the licence holder wishes to conduct research and development activities outside of their authorized licence activities, they must apply for a separate research licence

| Licence Class <sup>6</sup> | Subclass | Restrictions                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Authorized Activities (if authorized by licence) <sup>7</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Notes                                                                                                |
|----------------------------|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------|
|                            |          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <p>seeds to a licence holder that is authorized to sell cannabis for medical purposes or to a person authorized to sell cannabis under a provincial or territorial Act</p> <ul style="list-style-type: none"> <li>• Send and deliver cannabis products that are cannabis plants or cannabis plant seeds to the purchaser at the request of a licence holder that is authorized to sell cannabis for medical purposes or of a person authorized to sell cannabis under a provincial or territorial Act</li> <li>• Conduct ancillary activities (e.g., drying, trimming, milling, etc.)</li> </ul>                                                                                                                                  |                                                                                                      |
| Cultivation                | Nursery  | <ul style="list-style-type: none"> <li>• For seed production, total surface area of no more than 50m<sup>2</sup> must contain all the parts of budding or flowering plants</li> <li>• Maximum of 5kg of flowering heads harvested from plants with the exception of cannabis plant seeds</li> <li>• Must destroy the flowering heads (with the exception of the cannabis plant seeds), leaves and branches of the plants within 30 days of harvesting them</li> </ul> | <ul style="list-style-type: none"> <li>• Possess cannabis</li> <li>• Obtain cannabis plants or cannabis plant seeds by propagating, cultivating, harvesting</li> <li>• For the purpose of testing, alter the chemical or physical properties of the cannabis</li> <li>• Sell and distribute cannabis plants or cannabis plant seeds to other licence holders (cultivators, processors, analytical testers, researchers, cannabis drug licence holders)</li> <li>• Sell and distribute cannabis products that are cannabis plants or cannabis plant seeds to a licence holder that is authorized to sell cannabis for medical purposes or to a person authorized to sell cannabis under a provincial or territorial Act</li> </ul> | <ul style="list-style-type: none"> <li>• Cultivation may be conducted indoors or outdoors</li> </ul> |

| Licence Class <sup>6</sup> | Subclass            | Restrictions                                                                                                                                                                                                                                                                                                                                                                                                      | Authorized Activities (if authorized by licence) <sup>7</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           | Notes                                                                                                                                |
|----------------------------|---------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------|
|                            |                     |                                                                                                                                                                                                                                                                                                                                                                                                                   | <ul style="list-style-type: none"> <li>Send and deliver cannabis products that are cannabis plants or cannabis plant seeds to the purchaser at the request of a licence holder that is authorized to sell cannabis for medical purposes or of a person authorized to sell cannabis under a provincial or territorial Act</li> <li>Conduct ancillary activities (e.g., drying )</li> </ul>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |                                                                                                                                      |
| Processing                 | Standard Processing |                                                                                                                                                                                                                                                                                                                                                                                                                   | <ul style="list-style-type: none"> <li>Possess cannabis</li> <li>Produce cannabis, other than obtaining it by propagating, cultivating, or harvesting</li> <li>For micro-processing, the cannabis cannot be obtained by synthesis.</li> <li>Sell and distribute cannabis to other licence holders (processors, analytical testers, researchers, cannabis drug licence holders)</li> <li>Sell and distribute to licensed micro-cultivators or standard cultivators: <ul style="list-style-type: none"> <li>dried cannabis, fresh cannabis, cannabis plants, or cannabis plant seeds</li> <li>cannabis produced for the purposes of testing that is necessary to determine the chemical characterization of cannabis, such as a reference standard</li> </ul> </li> <li>Sell and distribute to licensed nursery: <ul style="list-style-type: none"> <li>cannabis plants or cannabis plant seeds</li> <li>cannabis produced for the purposes of testing that is necessary to determine the chemical</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>Cannabis must be produced, packaged, labelled, stored, sampled and tested indoors.</li> </ul> |
| Processing                 | Micro-processing    | <ul style="list-style-type: none"> <li>Maximum of 600kg of dried cannabis (or equivalent) in 1 calendar year as per section 21 of the <i>Cannabis Regulations</i>.</li> <li>Cannabis cannot be obtained by synthesis.</li> </ul> <p>Note: If licence holder also holds a micro-cultivation licence for the same site and the cannabis comes exclusively from that site, this maximum quantity does not apply.</p> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                      |

| Licence Class <sup>6</sup> | Subclass                  | Restrictions                                                                                                                                    | Authorized Activities (if authorized by licence) <sup>7</sup>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 | Notes                                                                                                                                                                                                                                                         |
|----------------------------|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                            |                           |                                                                                                                                                 | <p>characterization of cannabis, such as a reference standard</p> <ul style="list-style-type: none"> <li>• Send and deliver cannabis products to a licence holder that is authorized to sell cannabis for medical purposes or to a person authorized to sell cannabis under a provincial or territorial Act</li> <li>• Send and deliver cannabis products to the purchaser at the request of a licence holder that is authorized to sell cannabis for medical purposes or of a person authorized to sell cannabis under a provincial or territorial Act</li> </ul>                                                                                            |                                                                                                                                                                                                                                                               |
| Sale                       | Sale for Medical Purposes | <ul style="list-style-type: none"> <li>• Must sell cannabis products in the packaging in which they were sold or distributed to them</li> </ul> | <ul style="list-style-type: none"> <li>• Possess cannabis products</li> <li>• Sell or distribute cannabis products to a client</li> <li>• Sell or distribute cannabis products to a licence holder (with the exception of a cultivator)</li> <li>• Sell or distribute cannabis products that are dried, fresh, plants or cannabis seeds to micro-cultivator or standard cultivator</li> <li>• Sell or distribute cannabis products that are plants or plant seeds to a licensed nursery</li> <li>• Sell or distribute cannabis products other than plants or seeds to a hospital employee for the purpose of, and in connection with, their duties</li> </ul> | <ul style="list-style-type: none"> <li>• Requirements for the application for a sale for medical purposes licence with possession of cannabis differ from those not applying for authorization to possess. Refer to Section 6 for more information</li> </ul> |

## Appendix C: Licensing Record Keeping Attestation

| PART 11 – RETENTION OF DOCUMENTS AND INFORMATION                                                                                                                                                                                                                                                                                                                                  |                     |
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| APPLICANT INFORMATION                                                                                                                                                                                                                                                                                                                                                             |                     |
| Applicant Name:                                                                                                                                                                                                                                                                                                                                                                   | Application Number: |
| INSTRUCTIONS                                                                                                                                                                                                                                                                                                                                                                      |                     |
| <ol style="list-style-type: none"> <li>1. Complete the 'General Information' and 'Responsible Person Attestation Signature' fields in the attestation form provided below.</li> <li>2. Upload the completed attestation form as an attachment under the 'Record Keeping Example Section' in the Cannabis Tracking and Licensing System (CTLS).</li> </ol>                         |                     |
| GENERAL INFORMATION                                                                                                                                                                                                                                                                                                                                                               |                     |
| Please confirm the proposed <b>record keeping method</b> :<br><input type="checkbox"/> Electronic-based ( <i>please specify any record keeping software to be used</i> ):<br><input type="checkbox"/> Paper-based<br><input type="checkbox"/> Other:                                                                                                                              |                     |
| ATTESTATION                                                                                                                                                                                                                                                                                                                                                                       |                     |
| While applicants are expected to meet <b>all</b> regulatory requirements pertaining to <i>Part 11 – Retention of Documents and Information</i> of the <i>Cannabis Regulations</i> , Health Canada has identified requirements (see below) for which we would like to emphasize and draw your attention to as these may represent a greater risk in the event of a non-compliance. |                     |
| REGULATION                                                                                                                                                                                                                                                                                                                                                                        |                     |
| INVENTORY AND DISTRIBUTION                                                                                                                                                                                                                                                                                                                                                        |                     |
| 224 Inventory                                                                                                                                                                                                                                                                                                                                                                     |                     |
| 225 Inventory – cannabis extract, etc.*<br><small>(*only applies to applicants applying for a processing licence)</small>                                                                                                                                                                                                                                                         |                     |
| 226 Cannabis obtained from another person                                                                                                                                                                                                                                                                                                                                         |                     |
| 226.1 Things to be used as ingredients                                                                                                                                                                                                                                                                                                                                            |                     |
| 227 Sale, distribution and export of cannabis                                                                                                                                                                                                                                                                                                                                     |                     |
| DESTRUCTION                                                                                                                                                                                                                                                                                                                                                                       |                     |
| 229 Destruction                                                                                                                                                                                                                                                                                                                                                                   |                     |
| SECURITY                                                                                                                                                                                                                                                                                                                                                                          |                     |
| 230 Organizational security plan                                                                                                                                                                                                                                                                                                                                                  |                     |
| PRODUCTION                                                                                                                                                                                                                                                                                                                                                                        |                     |
| 231 Good production practices                                                                                                                                                                                                                                                                                                                                                     |                     |
| 232 Standard operating procedures and sanitation program                                                                                                                                                                                                                                                                                                                          |                     |
| PACKAGING AND LABELING                                                                                                                                                                                                                                                                                                                                                            |                     |

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|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------|
| 233 Packages and labels                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |       |
| <b>SYSTEM OF CONTROL FOR RECALLS</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |       |
| 235 System of control                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |       |
| <b>RESPONSIBLE PERSON ATTESTATION SIGNATURE</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |       |
| <p>I, the undersigned, attest that:</p> <ul style="list-style-type: none"> <li>• <b>All</b> applicable documents and information pertaining to <i>Part 11 – Retention of Documents and Information</i> of the <i>Cannabis Regulations</i>, as required by the licence class(es) and activities being applied for at the time of licensing, will be retained as required by the regulation(s).</li> <li>• With respect to section 221 of the <i>Cannabis Regulations</i>, <b>all</b> applicable documents and information will be retained in a manner that will enable an audit to be made of it in a timely manner and will be available at the site of the licence holder, or, in the case of a person that does not hold a licence, at the person's place of business, or if they do not have one, at a place of business in Canada.</li> <li>• All information provided in this document is accurate</li> <li>• I have read and understand all of the requirements in the provisions of the <i>Cannabis Regulations</i> cited above.</li> </ul> |       |
| Responsible Person Name (Printed):                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |       |
| Responsible Person Name (Signature):                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Date: |

*Please review the regulations for the post licensing record keeping and reporting requirements.*

## Appendix D: CTLS Application Status

An applicant may check the status of their application in the CTLS at any time during the application process. The table below provides an explanation of what the status means.

| Status              | Explanation                                                                                                                                                                                                                                                  |
|---------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Draft               | The application has not yet been submitted by the applicant. Health Canada does not receive, nor process, draft applications. The applicant must complete all sections of the application in order to submit an application for processing by Health Canada. |
| Submitted           | Health Canada has received the application.                                                                                                                                                                                                                  |
| Payment             | Health Canada has issued the invoice but the required payment for the processing of the application, if applicable, has not yet been processed.                                                                                                              |
| In progress         | Payment, if applicable, has been processed by Health Canada. Health Canada will then begin the review of the application. Refer to section 7.2 for more information.                                                                                         |
| Pending information | A request for more information has been sent and Health Canada is waiting for a response from the applicant. Refer to 7.3.1 for more information.                                                                                                            |

## Appendix E: Key Investors

The Regulations provide the complete definition of a key investor. In essence, a key investor is a person who exercises, or is in a position to exercise, direct or indirect control over the licence holder. When the term “in a position to exercise, direct or indirect control over the holder” is used, an individual, partnership, cooperative or corporation will be considered to be controlled by another individual or organization at any time where, at that time, the controller has any direct or indirect influence that, if exercised, would result in control of the individual, partnership, cooperative or corporation.

As part of the licensing application, any person (except a corporation who trades its shares on a public market) who applies for a cultivation, processing or sale for medical purposes licence must provide certain information regarding key investors, such as the key investor’s name and mailing address; a description of the means by which the key investor exercises, or is in a position to exercise, control over the holder and, if known, whether the controlling interest has been, will be, or could be assigned, pledged, mortgaged, hypothecated or sold, in whole or in part, to any person.

A person may have control in fact of an organization even though that person does not have legal control of the organization. Legal or direct control of an organization generally entails the right to elect the majority of the board of directors based on having a sufficient number of voting shares.

Control includes the ability to control by any direct or indirect influence, and it may exist even without the ownership of any shares. It can take many forms such as the ability of a person to: change the board of directors or reverse its decisions; make alternative decisions concerning the actions of the organization in the short, medium or long term; directly or indirectly terminate the organization or its activities; or to appropriate its profits and property. The existence of such influence, even if it is not actually exercised, would be sufficient to result in control.

In order to determine whether an investor has control, and whether information about this investor needs to be reported, the following are some of the relevant general factors to consider:

- the percentage of ownership of voting shares (when such ownership is not more than 50 per cent) in relation to the holdings of other shareholders – although any ownership over 25 per cent, in combination with other factors would likely be a significant indication of control
- ownership of a large debt of an organization which may become payable on demand
- shareholder agreements including the holding of a casting vote
- commercial or contractual relationships of the organization, e.g., economic dependence on a single supplier or customer

Note that this list is not comprehensive. There may be other indicators of control that trigger key investor reporting requirements.

## Appendix F: Direct Control – Security Clearances

In some instances, an individual, partnership, cooperative or corporation that holds a licence can be controlled by an individual or another partnership, cooperative or corporation. The Regulations require that individuals, or directors and officers of cooperatives or corporations, must hold a valid security clearance when they directly control any partnership, cooperative or corporation that holds a cultivator, processor or sale for medical purposes licence.

With respect to partnerships, the terms of the partnership agreement may dictate who has control. Anyone who directly controls a partnership needs to hold a valid security clearance – this includes any individual, or if it is another partnership –those partners, and if a cooperative or corporation – then its directors and officers.

Cooperatives and corporations can also be controlled by others –individuals, partnerships, cooperatives or a corporation. In common language, is sometimes described as a “parent company”, which is a company that is able to control another company’s management and operations by influencing or electing its board of directors, among other things. The *Cannabis Regulations* require the directors and officers of any parent company, which is a cooperative or corporation that exercises or is in a position to exercise direct control over a licence holder, to hold security clearances.

If an individual exercises or is in a position to exercise direct control over a licence holder by holding an influential amount of voting stock or through the terms of a partnership agreement, they would require a security clearance.

## Appendix G: Good Production Practices Attestation for Processing Licences

| PART 5 - GOOD PRODUCTION PRACTICES                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                     |
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| APPLICANT INFORMATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                     |
| Applicant Name:                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Application Number: |
| INSTRUCTIONS                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                     |
| <ol style="list-style-type: none"> <li>1. Complete the 'Responsible Person Attestation Signature' field in the attestation form provided below.</li> <li>2. Upload the completed attestation form as an attachment under the 'Good Production Practices Section' in the Cannabis Tracking and Licensing System (CTLS).</li> </ol>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |                     |
| ATTESTATION                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |                     |
| <p>While applicants are expected to meet <b>all</b> regulatory requirements pertaining to <i>Part 5 – Good Production Practices</i>, Health Canada has identified requirements (see below) which may represent a greater risk in the event of a non-compliance.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |                     |
| RESPONSIBLE PERSON ATTESTATION SIGNATURE                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |                     |
| <ul style="list-style-type: none"> <li>• I, the undersigned, attest that: The quality assurance person will be responsible for investigating every complaint received in respect of the quality of the cannabis and 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 not being met and if necessary they will take immediate measures to mitigate any risk.</li> <li>• Prior to any individual conducting activities in relation to edible cannabis or anything that will be used as an ingredient in the production of edible cannabis, they will have the competencies and qualifications that are necessary to conduct those activities.</li> <li>• Temperature and humidity levels of any building or part of a building where cannabis or anything that will be used as an ingredient will be produced, packaged, labelled, stored or tested will be maintained at levels appropriate to the activities being conducted and for the cannabis and/or ingredients used.</li> <li>• If a building or part of a building is equipped with a heating, cooling or humidity-controlled system, and if necessary to prevent contamination of the cannabis or thing that will be used as an ingredient, it will be equipped with instruments to control and indicate the temperature and humidity levels. Additionally, it will be accessible and, if necessary for cleaning, maintenance and inspection, capable of being disassembled, capable of withstanding repeated cleaning and will function in accordance with its intended use.</li> <li>• Physical or other effective means will be used to separate incompatible activities in order to prevent the contamination of cannabis and anything used as an ingredient.</li> <li>• Physical or other effective means will be 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.</li> <li>• Anything that will be, or was intended to be, used as an ingredient that presents a risk of injury to human health will be identified as such and will be stored in a designated area within the site.</li> </ul> |                     |

- Any water, steam or ice that comes into contact with a cannabis extract, cannabis topical, edible cannabis or anything that will be used as an ingredient will be potable or will be made from potable water or if the water is not potable it will not present a risk of contamination.
- Animals will not be 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.
- If any land that forms a part of the site or if any land that is located near the site presents a risk of contamination of the cannabis or anything that will be used as an ingredient, measures will be taken to eliminate the risk.
- The building or part of a building where cannabis or anything that will be used as an ingredient will be produced, packaged, labelled or stored has means for the removal and disposal of contaminated materials and waste and, if necessary to prevent contamination of the cannabis or thing that will be used as an ingredient, the building or part of the building is equipped with a drainage, sewage and plumbing system that functions in accordance with its intended use.
- Any conveyance or equipment that will be used at the site set out in the licence to handle contaminated materials or waste will ensure that it will only be used for that purpose, it will be identified as being reserved for that purpose and it will meet all applicable requirements of section 86, unless it does not come into contact with the contaminated materials or waste.
- Any individual who enters or is in any 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 will wear clothing, footwear and protective coverings that are appropriate for the activity being conducted with cannabis and/or ingredients.

Responsible Person Name (Printed):

Responsible Person Name (Signature):

Date: