



# **Cannabis Licensing Application Guide: Analytical Testing**

---

**Application Requirements and  
Process to Become a Holder of a  
Licence for Analytical Testing under  
the *Cannabis Act* and *Cannabis  
Regulations***



Government  
of Canada

Gouvernement  
du Canada

**Canada**

## FOREWORD

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 also 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.

Health Canada is committed to protecting personal information as well as confidential business information that is under its control. Ensuring the confidentiality, integrity, and availability of information is essential to government decision making and the delivery of services, and Health Canada recognizes that the protection of this information is an essential element in maintaining public trust in government. Health Canada has a systematic process in place to protect this information, including the identification and categorization of information, implementation of appropriate privacy training for personnel and information technology safeguards consisting of restricting access, including the level of access, to information in the Cannabis Tracking and Licensing System (CTLS) to those who need access to perform their duties. There may be instances where personal and/or confidential business information contained in applications made to Health Canada may be disclosed; however, only as required or permitted by law.

In addition to protecting your personal information, the Privacy Act gives you the right to request access to and correct your personal information. For more information about these rights, or about our privacy practices, please contact the Privacy Coordinator at 613-946-3179 or [privacy-vie.privee@hc-sc.gc.ca](mailto:privacy-vie.privee@hc-sc.gc.ca). You also have the right to file a complaint with the Privacy Commissioner of Canada if you think your personal information has been handled improperly.

### Disclaimer

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* shall prevail.

Publication Date : December 5, 2022

Également disponible en français sous le titre : Guide des demandes de licences liées au cannabis : Essais analytiques

© His Majesty the King in Right of Canada, as represented by the Minister of Health, 2022

This publication may be reproduced without permission provided the source is fully acknowledged.

ISBN: 978-0-660-46384-1

Cat: H134-11/1-2022E-PDF

## Table of Contents

|  |    |
|--|----|
| Purpose .....  | 1  |
| Background .....   | 1  |
| Scope .....  | 1  |
| Getting Started: the Application Process .....   | 2  |
| Step 1: Confirm the need for analytical testing licence.....   | 2  |
| Step 2: Create an account in the Cannabis Tracking and Licensing System (CTLS) .....   | 3  |
| Create an individual account in the CTLS.....  | 4  |
| Associated individuals create accounts in the CTLS.....  | 4  |
| Step 3: Develop your application .....   | 7  |
| I. Licence Ownership (Licence Holder).....   | 8  |
| II. Mailing Address .....  | 8  |
| III. Site Details (including activities) .....   | 8  |
| IV. Site Personnel.....  | 9  |
| V. Destruction .....   | 10 |
| VI. Physical Security .....  | 11 |
| VII. Record Keeping.....   | 12 |
| Step 4 - Submit your Application.....  | 12 |
| Submitting your application .....  | 12 |
| Following submission.....  | 13 |
| Service Standards .....  | 13 |
| Administrative procedures .....  | 13 |
| Contact Us .....   | 15 |
| Feedback – Help Us Improve.....  | 16 |
| Appendix A: Qualifications of the proposed Head of Laboratory or alternate Head of Laboratory for an analytical testing licence form ..... | 17 |
| Appendix B: Physical Security Plan (suggested template) .....  | 1  |
| Appendix C: Record Keeping Attestation .....   | 2  |
| Appendix D: Submission Checklist.....  | 4  |

## Purpose

This document provides information on the application requirements to obtain a licence to conduct analytical testing on cannabis from Health Canada under the *Cannabis Act* and *Cannabis Regulations*.

## Background

The *Cannabis Act* and *Cannabis Regulations* provide, among other things, the framework for legal access to cannabis and control and regulate its production, distribution and sale. Under this framework, a person is required to obtain a licence issued by Health Canada in order to conduct various activities with cannabis, among them analytical testing. Applicants and licence holders are responsible for compliance with the *Cannabis Act* and *Cannabis 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 an analytical testing 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 you in preparing your application. 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.

## Scope

This document provides guidance to anyone wishing to apply for a licence (“the applicant”) under the *Cannabis Act* and *Cannabis Regulations* to conduct activities in relation to analytical testing involving cannabis.

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

---

<sup>1</sup> Throughout this guide, there are references to actions that would be taken by the Minister under the *Cannabis Act* and *Cannabis 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 is employed in a capacity appropriate to making the decision and who has been delegated that responsibility in accordance with the *Salaries Act*.

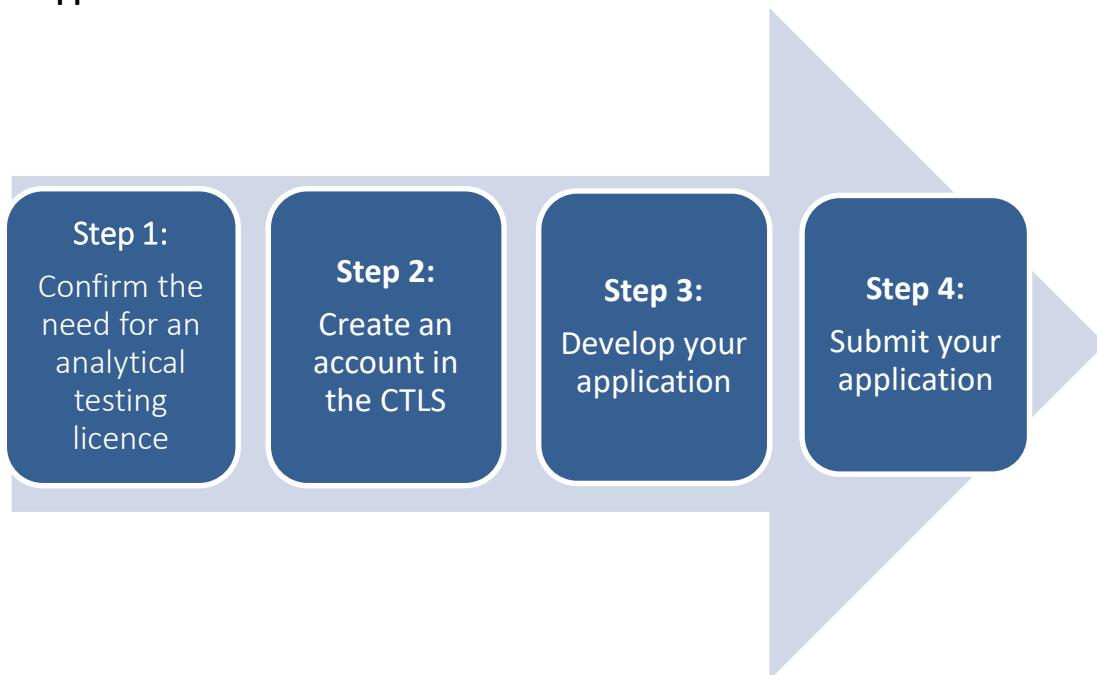
This guide does not include information on additional licensing requirements that may be required by the Canada Revenue Agency or provinces and territories.

Health Canada has established an online licence application system, referred to as the Cannabis Tracking and Licensing System (CTLS), to be 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@hc-sc.gc.ca](mailto:cannabis@hc-sc.gc.ca).

## Getting Started: the Application Process

This guide is separated into four steps to help you navigate the application process. The process flow outlined in Figure 1 provides a general summary, with references to the relevant parts of this guide.

**Figure 1: Application Process**



### Step 1: Confirm the need for analytical testing licence

Before applying for a licence, first determine whether an [analytical testing licence](#) is the appropriate class of licence needed. Individuals and corporations who wish, for the purposes of testing, to produce, distribute and sell reference standards, and to manufacture or assemble and distribute and sell test kits and to alter the chemical or physical properties of cannabis by any means for the purposes of testing may apply for an analytical testing licence (see below for definition of cannabis). Analytical testing activities may include, but are not limited to, any

combination of the following testing processes: chemical contaminants, microbial contaminants, cannabinoid content, dissolution or disintegration, sterility, stability testing and/or pesticides, including ensuring requirements are met by licence holders bound by the [Mandatory cannabis testing for pesticide active ingredients requirements](#).

If you or your organization hold(s) another licence under the *Cannabis Act*, you may already be authorized to conduct analytical testing activities under the terms of that licence (for example, in-house testing for THC or CBD). Contact Health Canada at [hc.sp-licensing-cannabis-licences-sp.sc@canada.ca](mailto:hc.sp-licensing-cannabis-licences-sp.sc@canada.ca) if you need to clarify your current authorizations.



**Important:** As per the *Cannabis Act*, cannabis (including hemp) means:

- Any part of a cannabis plant, including the phytocannabinoids produced by, or found in, such a plant, regardless of whether that part has been processed or not, other than a part of the plant referred to in Schedule 2;
- Any substance or mixture of substances that contains or has on it any part of such a plant; or
- Any substance that is identical to any phytocannabinoid produced by, or found in, such a plant, regardless of how the substance was obtained.

The term cannabis DOES NOT include:

- A non-viable seed of a cannabis plant;
- A mature stalk, without any leaf, flower, seed or branch, of such a plant;
- Fibre derived from a mature stalk; or
- The root or any part of the root of such a plant.



**Important:** Analytical testing licences cannot be applied for through an amendment to an existing cannabis licence, nor can a new cannabis licence (e.g., cultivation, processing) be added to an analytical testing licence through an amendment. Licence Holders wishing to apply for these licences must submit a new licence application.



**Important:** In order for your application to be considered, your facility should be already built.

## Step 2: Create an account in the Cannabis Tracking and Licensing System (CTLS)

Health Canada's CTLS, is a public facing web application that enables the submission of new license applications, requests for amendments, and licence renewals in addition to the submission of monthly tracking reports for those licence holders required to submit them.

## Create an individual account in the CTLS

In order to submit a licence application in the CTLS, you must first request access. In order to do so, basic information is required including your full name and salutation, email, phone number, date of birth, language preference and security information. Health Canada will then provide an Account ID that can be used to enter the CTLS. You can use the same Account ID for each licence application for which you may be associated.

For more information on the steps to create an account please refer to the [CTLS Getting Started Guide](#).



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

## Associated individuals create accounts in the CTLS

User accounts are also required for additional individuals associated with an analytical testing licence application (see Table 1). These individuals must create their own accounts in the CTLS before an application can be completed and submitted to Health Canada.

**Table 1: Individuals who require user accounts in the CTLS when applying for an analytical testing licence**

| Role               | Account IDs Required                   | Responsibilities and Qualifications   |
|--------------------|--|---|
| Licence Holder     | Only if the applicant is an individual | <ul style="list-style-type: none"><li>• Overall responsibility for the licence.</li></ul>   |
| Responsible Person | For all applicants                     | <ul style="list-style-type: none"><li>• A licence holder must identify an individual, known as the Responsible Person, who has the authority to bind the licence holder (often the CEO or Director of the organization, or someone delegated by that person).</li><li>• The Responsible Person will be the point of contact with Health Canada and through the CTLS.</li><li>• They are responsible for submitting the application.</li><li>• They are responsible for the activities conducted by the licence holder.</li><li>• Must have sufficient knowledge of provisions of the Act and Regulations that apply to the holder of a licence.</li></ul> |

**Table 1: Individuals who require user accounts in the CTLS when applying for an analytical testing licence**

| Role               | Account IDs Required                   | Responsibilities and Qualifications   |
|--------------------|--|---|
| Head of Laboratory | For all applicants                     | <ul style="list-style-type: none"> <li>A holder of a licence for analytical testing must retain the services of one individual as the Head of Laboratory. The Head of Laboratory must work at the licensed site and be responsible for the testing activities under section 90-91.1 of the <i>Cannabis Regulations</i> (testing for each lot/batch for composition).</li> <li>This person must have sufficient knowledge of the provisions of the <i>Cannabis Act</i> and the <i>Cannabis Regulations</i> that apply to the holder of a licence for analytical testing and have knowledge and experience relevant to the duties of the position (further guidance can be found in <b>table 4</b>).</li> </ul> <p>A holder of a licence for analytical testing may designate one or more individuals as the alternate Head(s) of Laboratory who are qualified to replace the Head of Laboratory. These alternates must be identified and credentials included.</p> |
| Directors          | Only if the applicant is a corporation | N/A   |
| Officers           | Only if the applicant is a corporation | N/A   |



**Tip:** A single individual may hold one or multiple roles within the company (e.g., be both the Licence Holder and the Responsible Person), for one or more classes of licences at one site, or in some cases, multiple sites, assuming they meet all the requirements.

### Creating a corporate profile

An application for an analytical testing licence can be created for an individual or a corporation. Applicants that are corporations (any incorporated organization) must ensure that a corporate profile for the organization has been created in the CTLS.




In order to create a corporate profile, individuals associated with the corporation (i.e., directors and officers) must create user accounts and those Account IDs must be linked to the corporate profile. Once the corporate profile has been created, a new Account ID is created for the corporation. This Account ID can then be used to create the analytical testing licence application, where the corporation can be specified as the licence holder.

Creating a corporate profile has some additional requirements, as outlined in Table 2. Some requirements are needed to create a corporate profile in the CTLS, while others are required before an application is submitted.

| Table 2: Corporate Profile Requirements  |   |
|--|---|
| Requirement  | Required details to include   |
| 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.  |
| 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.   |
| Certificate of incorporation   | As part of an application, certificate of incorporation documents are required.   |
| Corporate organizational chart   | As part of submitting an application, a corporate organizational chart is required. The organizational chart: <ul style="list-style-type: none"> <li>• Must demonstrate the relationships between senior positions within the organization and the various controlling individuals or entities, if applicable.</li> <li>• Must include all names and titles of senior management positions such as directors and officers of the organization and any controlling individual or entity, if applicable.</li> </ul> |
| 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 must be included as part of the corporate profile.  |

**Important:** The CTLS requires at least one director or officer be named per corporate

**Table 2: Corporate Profile Requirements**

| Requirement | Required details to include   |
|-------------|---|
|             |  profile. In the case where there is no director or officer for the organization, the Responsible Person should be identified as an officer in this section of the CTLS. |



**Tip:** 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 a licence has been granted and there is a change of details in the corporate profile, these changes may trigger an automatic amendment, or may require a notification under Section 34 of the *Cannabis Regulations*.

## Step 3: Develop your application

Once you have the appropriate Access IDs to the CTLS, you are ready to start developing your application. There are six main sections of an analytical testing licence application:

- I. Licence ownership (licence holder)
- II. Mailing address
- III. Site details (including activities)
- IV. Site personnel
- V. Destruction
- VI. Physical security
- VII. Record keeping

Each of these sections must be complete prior to submitting an application to Health Canada. If your application does not fulfill all of these requirements, Health Canada may refuse to consider your application.



**Important:** Many sections of the application require a document, or several documents, to be uploaded. File names should clearly identify the name of the application requirement outlined in this guide. For example: Responsible Person Government ID, Record Keeping Attestation, etc. A maximum of 5 documents can be uploaded per section, each with a maximum size of 10 MB per document. Applicants should combine documents where suitable and minimize extraneous content in order to submit the required documents.



**Tip:** You are not required to complete the application process in one session. The application may be started in the CTLS and left in Draft status until you are ready to submit.

## I. Licence Ownership (Licence Holder)

In this section of the application, you are required to identify the licence holder. An application can be created for an individual or a corporation. If you apply as a corporation, you must ensure that you have completed a corporate profile for the organization in the CTLS as outlined in Step 2.

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. You may designate one individual as an alternate Responsible Person who is qualified to replace the Responsible Person.

A copy of government-issued identification must be provided in order to verify the identities of the Licence Holder, Responsible Person, and Head of Laboratory.


## II. Mailing Address

This section of the application allows you to enter a mailing address identifying a Canadian address where you would like to receive official mailed correspondence (e.g., the licence when issued).

## III. Site Details (including activities)

This section of the application seeks information about the site where the proposed analytical testing will take place as well as information on the proposed testing to be conducted. Table 3 outlines the Site Detail requirements that must be provided.

**Table 3: Site Detail Requirements for an Analytical Testing Licence Application**

| Requirement  | Required details to include   |
|--|---|
| Complete site address  | Primary Canadian site at which the analytical testing is proposed to occur (cannot be a P.O. Box).  |
|  <b>Important:</b> Licensed activities cannot be conducted in a dwelling house (i.e., a place of residence) |   |
| Analytical testing processes to be conducted   | Identify the purposes of all analytical testing activities that the applicant is proposing to conduct.<br><br>For example, testing for: <ul style="list-style-type: none"><li>• Chemical contaminants (e.g., heavy metals, solvent residues)</li><li>• Microbial contaminants* (e.g., yeast, molds, bacteria, aflatoxins)</li><li>• Cannabinoid content (e.g., delta-9-tetrahydrocannabinol [THC], tetrahydrocannabinolic acid [THCA], cannabidiol [CBD], and cannabidiolic acid [CBDA])</li><li>• Dissolution/Disintegration</li></ul> |

- Pesticides
- Sterility
- Stability (e.g., if the licence holder proposes to include a product expiry date)
- Other (e.g., seed viability testing, reference standards, test kits)

*\*Sterility appears as an independent item in the CTLS*

#### IV. Site Personnel

As outlined in Step 2, as part of the application you will need to identify the individuals that must have CTLS accounts. These individuals will differ based on the type of analytical licence holder (e.g., individual or a corporation). Identified individuals will need to create CTLS accounts and provide their Account IDs to you. The majority of these individuals need to be identified if you are creating a corporate profile.

The only individual required to be identified within the “Site Personnel” section of the application is the Head of Laboratory. Table 4 includes information on what information should be provided to confirm the qualifications of this individual. This information should be provided via a document or documents, uploaded in this section of the application process.

**Table 4: Site Personnel Requirements for an Analytical Testing Licence**

| Requirement                               | Required details to include  |
|---|--|
| Qualifications for the Head of Laboratory | <p>Submit details of the individual’s qualifications, and any designated alternate Head(s) of Laboratory, as they relate specifically to the duties of the position using the Qualifications of the proposed Head of Laboratory or alternate Head of Laboratory for an analytical testing licence form, included in Appendix A.</p> <p>Note that the Head of Laboratory must hold a diploma, certificate or credential awarded by a post-secondary educational institution in Canada in a field or occupation that is relevant to the duties of the position, such as chemistry, biology, pharmaceutical or scientific regulatory affairs laboratory management, or laboratory technician. If awarded by a foreign institution, an equivalency assessment must be issued by an organization or institution that is responsible for issuing equivalency assessments and is recognized by a province. Examples of the candidate’s proof of qualifications should include, but is not limited to:</p> <ul style="list-style-type: none"> <li>• Copy of a diploma, certificate or credential awarded by a post-secondary educational institution in Canada in a field</li> </ul> |

**Table 4: Site Personnel Requirements for an Analytical Testing Licence**

| Requirement | Required details to include   |
|-------------|---|
|             | <p>or occupation that is relevant to the duties of the position, such as chemistry, biology, laboratory technician, pharmaceutical or scientific regulatory affairs, or laboratory management. If awarded by a foreign institution, an equivalency assessment must be issued by an organization or institution that is responsible for issuing equivalency assessments and is recognized by a province.</p> <ul style="list-style-type: none"><li>• Resume/CV.</li></ul>  |
|             | <p>Below are examples of some details that may be included in the description of qualifications for the Head of Laboratory in the form. Do not copy-paste these examples into your completed form.</p> <ul style="list-style-type: none"><li>• The proposed head of laboratory holds a bachelor’s degree in chemistry from University since 2010. During their academia, they developed and executed analytical testing methods including, but not limited to HPLC, GC-MS/MS, LC-MS/MS, ICP-MS.</li><li>• The proposed head of laboratory has worked 6 years as a Quality Control manager at Analytical Testing Co. They have prepared protocols, evaluated obtained data and interpreted it, prepared and approved certificate of analysis, and write reports for methods transfer and validation.</li><li>• The proposed head of laboratory has worked 2 years as a supervisor at Analytical Testing Co. They have supervised a team, delegated task to ensure proper workflow, evaluated laboratory procedures and policies and drafted standard operating procedures.</li></ul> |

## V. Destruction

Analytical testing licence holders must destroy the sample of a lot or batch of cannabis that has been distributed to them, and all cannabis obtained from that sample, within 90 days of the testing of the sample of the lot or batch being completed.

If testing of the sample of a lot or batch of cannabis distributed to the Licence Holder for analytical testing is not initiated within 120 days of its receipt, the Licence Holder must, by the end of that period, either destroy the sample or distribute it to another holder of a licence for

analytical testing or to the individuals referred to in section 4 of the *Cannabis Regulations*<sup>2</sup>. The destruction of cannabis samples of a lot or batch must be carried out in a manner that fulfills the requirements of section 43 of the *Cannabis Regulations*.

Table 5 provides a summary of the information that must be provided as part of an analytical testing licence application to demonstrate how the destruction requirements will be met.

| Table 5: Destruction Requirements for Analytical Testing Licences |  |
|---|--|
| Requirement   | Required details to include  |
| Description of destruction method                                 | <p>A description of the destruction method to be used to that meets the requirements of the <i>Cannabis Regulations</i>, including:</p> <ul style="list-style-type: none"> <li>An attestation that at least two individuals who are qualified to witness the destruction (e.g., employees of the Licence Holder) will be present.</li> </ul> |

## VI. Physical Security

A description of the physical security plan must include a brief description of the site, including its perimeter and storage areas.

A site plan should also be provided, including clear identification of the perimeter and the delineation of storage areas.

Table 6 provides a summary of the information that must be provided as part of an analytical testing licence application to demonstrate how the physical security requirements will be met.

| Table 6: Physical Security Requirements for Analytical Testing Licences |   |
|---|---|
| Requirement   | Required details to include   |
| Prevention of unauthorized access                                       | <p>A description of how the storage areas are designed to prevent unauthorized access to cannabis. Include such details as:</p> <ul style="list-style-type: none"> <li>Who accesses the storage areas and how their presence in the area is required by their duties</li> <li>How access to the storage areas is controlled</li> <li>The physical barriers surrounding the storage areas</li> </ul> <p>A template can be found in Appendix B.</p> |
| Site plan and floor plans   | The overall site plan must include the following details:   |

<sup>2</sup> Note that the distribution to another holder of a licence for analytical testing or to the individuals referred to in section 4 of the *Cannabis Regulations* is only permitted following October 17, 2019

**Table 6: Physical Security Requirements for Analytical Testing Licences**

| Requirement | Required details to include  |
|-------------|--|
|             | <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) or units within a building must be clearly identified; and</li><li>• An indication 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 as well as company name, if possible.</li></ul> |

If there are areas (including buildings) that will not be used exclusively by the applicant, these areas must be outside of the proposed site perimeter. If there are areas inside the proposed site perimeter that will be used to conduct activities other than activities with cannabis, these activities must be clearly indicated in an appendix to the site and/or floor plan(s).

Additionally, the applicant must also include a floor plan for each building including clear delineation of rooms where storage activities will take place.

## VII. Record Keeping

There are a number of regulatory requirements for record keeping that must be met by a licence holder. Table 7 provides a summary of the information that must be submitted as part of an analytical testing licence application.

**Table 7: Record Keeping Requirements for Analytical Testing Licences**

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

## Step 4 - Submit your Application

### Submitting your application

Once all required information has been entered/uploaded in the CTLS, the application is ready to be submitted.

Use the checklist in Appendix D to ensure that all required pieces have been completed and are included in your submission. Once an application is submitted, no further changes can be made.

Once the application is submitted, it will appear 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.



**Important:** If all items included in Appendix D are not included in your submission, the review of your application will be delayed until that information is received via a “request for more information” (see below).

## Following submission

Once an application is submitted in the CTLS, there are a series of steps Health Canada undertakes to review the licence and take a decision. Applicants are encouraged to check the status of their application using the CTLS at any time during the application process. Table 8 below provides an explanation of the four categories in the CTLS that denote the status of the application.

| Status              | Explanation   |
|---------------------|---|
| Draft               | The application has not yet been submitted. 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           | Once the application is received by Health Canada, the application is considered “submitted” and remains at this stage until the screening of the application commences.  |
| In progress         | Health Canada has begun review of the application.  |
| Pending information | A request for more information has been sent to you and Health Canada is waiting for a response.  |



**Important:** For assistance related to a specific licence application, an email may be sent to: [hc.sp-licensing-cannabis-licences-sp.sc@hc-sc.gc.ca](mailto:hc.sp-licensing-cannabis-licences-sp.sc@hc-sc.gc.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.

## Service Standards

Health Canada commits to a non-binding 180 business days service standard to issue a decision for analytical testing licence applications.

## Administrative procedures

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



Under subsection 62(5) of the *Cannabis Act*, Health Canada may request the submission of any additional information pertaining to an application.

It is the applicant's responsibility to meet all 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 will ask the applicant for clarification through a Request for More Information (RMI). To avoid such a request, ensure your application is as detailed as possible and addresses all items in the checklist included in Appendix D.

When an RMI is sent, Health Canada strives to be clear about what information is needed from the applicant and a deadline to respond is provided. If the applicant is unclear about what is required to respond to the request for more information, they may contact Health Canada by email for further guidance (see Contact Information Section of this guide). 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 within the timeframe requested. Responses should be comprehensive and comment on each of the elements noted in the request for more information. A revised version of the original documents should not be resubmitted unless requested to do so.



**Important:** Be as specific and as detailed as possible when addressing each question. Incomplete responses may delay processing or lead to a refusal to consider an application. A lack of response to Health Canada's request for more information may delay processing and lead to a refusal to consider an application.



**Tip:** If the applicant wishes another representative to be the primary recipient of communications or receive a copy of all communications, a written and signed consent to Health Canada must be submitted that permits Health Canada to communicate details about the application to the third-party individual. The consent must indicate the name(s) of the individuals, the application number and be sent to [hc.sp-licensing-cannabis-licences-sp.sc@hc-sc.gc.ca](mailto:hc.sp-licensing-cannabis-licences-sp.sc@hc-sc.gc.ca) from the email address captured within the CTLS for the Responsible Person, with the subject line "Consent to Communicate".

### Refusals and withdrawals

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

- Issuing the licence is likely to create a risk to public health or public safety, including the risk of cannabis being diverted to an illicit market or activity;
- There are reasonable grounds to believe that false or misleading information or false or falsified documents were submitted in, or in support of, the application;

- Within the last 10 years, the applicant has contravened a provision of *the Cannabis Act*, the *Controlled Drugs and Substances Act* or the *Food and Drugs Act* or of any regulation made under any of those Acts;
- There are reasonable grounds to believe that, within the last 10 years, the applicant has contravened an order made under the *Cannabis Act*, [the Controlled Drugs and Substances Act](#) or the [Food and Drugs Act](#), or a condition of another licence or permit issued to the applicant any of those Acts;
- The applicant is a young person (as defined in the *Cannabis Act*), an individual who does not ordinarily reside in Canada, or is an organization that was incorporated, formed or otherwise organized outside Canada;
- The Minister is of the opinion that it is in the public interest to do so;
- Any prescribed grounds for refusal exist.

In the cases mentioned above, Health Canada may send a Notice of Intent to Refuse. This Notice will provide the applicant with a timeframe within which to respond, after which a Notice of Refusal will be issued.

The Notice of Refusal 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 will not be returned to the applicant.

At any time during the review of an application, the applicant may withdraw the application through the CTLS. Withdrawal of an application is without prejudice to re-filing the application. If an applicant wishes to resubmit an application at a future time, the application will be processed as a new application.

### **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.sp-licensing-cannabis-licences-sp.sc@hc-sc.gc.ca](mailto:hc.sp-licensing-cannabis-licences-sp.sc@hc-sc.gc.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.

## **Contact Us**

For questions related to a specific licence application, an email may be sent to: [hc.sp-licensing-cannabis-licences-sp.sc@hc-sc.gc.ca](mailto:hc.sp-licensing-cannabis-licences-sp.sc@hc-sc.gc.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 *Cannabis Regulations* outside of a specific application, including those related to the CTLS, email: [cannabis@hc-sc.gc.ca](mailto:cannabis@hc-sc.gc.ca).

---



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

## **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 *Cannabis 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@hc-sc.gc.ca](mailto:cannabis@hc-sc.gc.ca) and indicate in the subject line: “Feedback on Analytical Testing Licence Application Guide”.

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

## Appendix A: Qualifications of the proposed Head of Laboratory or alternate Head of Laboratory for an analytical testing licence form

Complete the required information. If a section isn't applicable, indicate as such.

For each section that applies, fields indicated by an asterisk (\*) are mandatory.

Submit a separate form for each proposed head of laboratory and alternate head of laboratory, if applicable.

For more information on application requirements for a proposed head of laboratory, refer to the [Application requirements for cannabis analytical testing](#).

| Applicant or licence holder information*  |  |
|---|--|
| APP # (for new applicants) or LIC # (for licence holders)*  |  |
| Company name (corporation or individual)*   |  |
| Addition of head of laboratory or alternate head of laboratory  |  |
| Name of the proposed head of laboratory or alternate head of laboratory, as it appears in their CTLS account* |  |
| Proposed role*  | <input type="checkbox"/> Head of laboratory<br><input type="checkbox"/> Alternate head of laboratory   |
| Proposed head of laboratory or alternate head of laboratory's CTLS Account ID*                                |  |
| Proposed head of laboratory or alternate head of laboratory's date of birth*                                  | Click or tap to enter a date.  |
| Change(s) to the head of laboratory or alternate head of laboratory   |  |
| Are you changing an existing head of laboratory or alternate head of laboratory's role?*                      | <input type="checkbox"/> Yes, I'm designating my alternate head of laboratory (named above) to be the head of laboratory<br><input type="checkbox"/> Yes, I'm designating my head of laboratory (named above) to be the alternate head of laboratory |

|  |  |
|--|--|
| Name of the head of laboratory or alternate head of laboratory who is being replaced                           |  |
| <b>Removal(s) of the head of laboratory or alternate head of laboratory</b>                                    |  |
| Name of the head of laboratory or alternate head of laboratory to remove, as it appears in their CTLS account* |  |
| CTLS account ID for the head of laboratory or alternate head of laboratory to remove*                          |  |

|  |   |
|--|---|
| <b>Background of the proposed head of laboratory or alternate head of laboratory</b>   |   |
| Complete the section below with the required information.  |   |
| <b>Previous approval from Health Canada (if applicable)</b>  |   |
| Has the proposed head of laboratory or alternate head of laboratory previously been approved by Health Canada as a head of laboratory or alternate head of laboratory for an analytical testing licence holder?* | <input type="radio"/> Yes<br><input type="radio"/> No |
| If <b>yes</b> , date of prior approval (approximately)   |   |
| If <b>yes</b> , name of affiliated licence holder  |   |

|   |   |
|---|---|
| <b>Qualifications of the proposed head of laboratory or alternate head of laboratory</b>  |   |
| You must provide the following information in this section if the proposed head of laboratory or alternate head of laboratory has not been previously approved by Health Canada.  |   |
| You <b>do not</b> need to provide the following information in this section if the proposed head of laboratory or alternate head of laboratory has been previously approved by Health Canada. If this is the case, please indicate "N/A" below. |   |
| <b>Resume or Curriculum Vitae (CV)</b>  |   |
| Copy of résumé or CV*   | <input type="radio"/> Added to the CTLS<br><input type="radio"/> Not applicable |
| File name: HOL_APPorCHG-#_CVResume_YYYY-MM-DD.PDF   |   |
| <b>Education and training</b>   |   |
| Copy of diploma, certificate or credential awarded by a post-secondary educational institution in Canada in a   | <input type="radio"/> Added to the CTLS<br><input type="radio"/> Not applicable |

field or occupation that is relevant to the duties of the position, such as chemistry, biology, laboratory technician, pharmaceutical or scientific regulatory affairs, or laboratory management\*

**Note:** If awarded by a foreign institution, an equivalency assessment must be issued by an organization or institution that is responsible for issuing equivalency assessments and is recognized by a province.

File name: HOL\_APPorCHG-#\_Education\_YYYY-MM-DD.PDF

#### Other supporting documents

Copies of training certificates, official academic transcripts, letters of reference, etc.

File name: HOL\_APPorCHG-#\_SupportingDocs\_YYYY-MM-DD.PDF

- Added to the CTLS
- Not applicable

You must provide a detailed description of the proposed head of laboratory’s or alternate head of laboratory’s knowledge of, experience with, and training in each of the following areas including when, where and how the knowledge, training or experience was obtained. Complete every requirement with clear, concrete examples and details of how they’ll be able to fill all head of laboratory roles and responsibilities, and meet the requirements of [section 23 of the Cannabis Regulations](#).

The approval of the proposed personnel will depend on the **overall assessment** of their **ability** to conduct their responsibilities as per [section 23 of the Cannabis Regulations](#).

If you don’t have enough space, include the additional information on a separate page using the same format. In this case, include the completed page as a separate attachment with the file name “HOL\_APPorCHG-#\_Qualifications.PDF”.

#### Qualifications

##### 1. Managing a laboratory\*

|  |
|--|
|  |
|--|

## 2. Familiarity with analytical procedures listed in the application\*

|  |
|--|
|  |
|--|

### Declarations and signatures\*

I, the undersigned, declare that:

- the head of laboratory will work at the site set out in the licence and is responsible for the testing referred to in sections 90 to 91.1 of the *Cannabis Regulations*.
- the head of laboratory has sufficient knowledge of the provisions of the *Cannabis Act* and its Regulations that apply to the holder of the licence for analytical testing.
- all information provided in this document is correct and complete to the best of my knowledge.

|                                      |  |
|--------------------------------------|--|
| Responsible person's name (printed)* |  |
| Responsible person's signature*      |  |
| Date (YYYY-MM-DD)*                   |  |



---

## Appendix B: Physical Security Plan (suggested template)

Description of Site

---

What are the physical barriers surrounding the storage areas?

---

How will the physical security of the storage areas prevent unauthorized access to the cannabis?

---

Who will have access to storage areas and how is their presence in the area is required by their duties?

---



## Appendix C: Record Keeping Attestation

| PART 11 – RETENTION OF DOCUMENTS AND INFORMATION   |                            |
|--|----------------------------|
| <b>APPLICANT INFORMATION</b>   |                            |
| <b>Applicant Name:</b>   | <b>Application Number:</b> |
| <b>INSTRUCTIONS</b>  |                            |
| 1. Complete the “General Information” and “Responsible Person Attestation Signature” fields in the attestation form provided below.<br>2. Upload the completed attestation form as an attachment under the “Record Keeping Example Section” in the Cannabis Tracking and Licensing System (CTLS).  |                            |
| <b>GENERAL INFORMATION</b>   |                            |
| 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:   |                            |
| <b>REGULATORY ATTESTATION</b>  |                            |
| It is incumbent on the applicants to meet <b>all</b> applicable 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, as these may represent a greater risk in the event of non-compliance. |                            |
| <b>REGULATION</b>  |                            |
| <b>GENERAL PROVISIONS</b>  |                            |
| 221 Manner of Retention  |                            |
| 222 Requirement to continue to retain  |                            |
| <b>INVENTORY AND DISTRIBUTION</b>  |                            |
| 224 Inventory - cannabis other than oil  |                            |
| 225 Inventory – cannabis oil   |                            |
| 226 Receipt of cannabis  |                            |
| 227 Sale, distribution and export of cannabis  |                            |
| <b>DESTRUCTION</b>   |                            |
| 229 Destruction of cannabis  |                            |
| <b>RESEARCH AND DEVELOPMENT</b>  |                            |
| 237 Research and Development   |                            |

**RESPONSIBLE PERSON ATTESTATION SIGNATURE**

I, the undersigned, attest that:

- **All** applicable documents and information pertaining to *Part 11 – Retention of Documents and Information of the Cannabis Regulations*, as required by the analytical testing licence and activities being applied for at the time of licensing, will be retained accordingly for the noted retention period(s) as outlined by the respective regulation(s).
- With respect to section 221 of the *Cannabis Regulations*, **all** applicable documents and information will be retained in a manner that will enable an audit to be made of it in a timely manner.
- All information or documents under section 221 will be retained 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.

**Responsible Person Name (Printed):**

**Responsible Person Name (Signature):**

**Date:**

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

# Appendix D: Submission Checklist

## Analytical Testing Licence Application Checklist

### Licence Ownership

- Copy of the Licence Holder/Head of Laboratory/Responsible Person's Government-issued ID (e.g., driver's licence).
- A copy of the Certificate of Corporation (if applying as a corporation).

### Site Details

- Complete address of your site including:
  - ✓ Unit number, if applicable
  - ✓ Street number
  - ✓ Street Name
  - ✓ City
  - ✓ Province
  - ✓ Postal code
- Confirmation that the proposed site is not a dwelling house (i.e., residential) or an alternative address of your proposed site.

### Site personnel

- Qualifications of the proposed Head of Laboratory as well as those for any designated alternate Head(s) of Laboratory, as they relate specifically to the duties of the position. Note that the Head of Laboratory must hold a diploma, certificate or credential awarded by a post-secondary educational institution in Canada in a field or occupation that is relevant to the duties of the position, such as chemistry, biology, pharmaceutical or scientific regulatory affairs, laboratory management or laboratory technician. If awarded by a foreign institution, an equivalency assessment must be issued by an organization or institution that is responsible for issuing equivalency assessments and is recognized by a province.

The candidate's proof of qualifications should include, but is not limited to:

- Copy of a diploma, certificate or credential awarded by a post-secondary educational institution in Canada in a field or occupation that is relevant to the duties of the position, such as chemistry, biology, laboratory technician, pharmaceutical or scientific regulatory affairs, or laboratory management. If awarded by a foreign institution, an equivalency assessment must be issued by an organization or institution that is responsible for issuing equivalency assessments and is recognized by a province.
- Resume/CV.

*See Appendix A for form.*

### Destruction

- A description of the destruction method to be used to that meets the requirements of the *Cannabis Regulations*, including:
  - Attestation that at least two individuals who are qualified to witness the destruction (e.g. employees of the Licence Holder) will be present.

### Physical Security

- A physical security description for your site that includes:
  - how the physical security of the storage areas prevent unauthorized access to the cannabis.
  - who has access to storage areas and how their presence in the area is required by their duties.
  - the physical barriers surrounding the storage areas.

*See Appendix B for template.*

- A site plan with clearly identified perimeters and delineation of storage areas.

### Record Keeping

- Record Keeping attestation

*See Appendix C for attestation.*