



CANNABIS LICENCE MANAGEMENT GUIDE:

Cultivation, Processing and Sale for Medical Purposes

**Guidance to Licence Holders under the *Cannabis Act* and
its Regulations**



Government
of Canada

Gouvernement
du Canada

Canada¹

The *Cannabis Act*, s. 62, establishes that an application for a licence or permit, or for its renewal or amendment, 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 applications for the issuance, renewal and amendment of licences and permits. 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.

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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* 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 holders of licences authorizing cultivation, processing and sale for medical purposes issued under the *Cannabis Act* and pursuant to the *Cannabis Regulations* with information on how to manage their licence after it has been issued, including how to renew their licence, how to amend their licence, and how to apply for an import or export permit, if applicable. It also outlines notification and reporting requirements.

2.0 Background

The *Cannabis Act* and its Regulations provide a licensing framework for the production, testing, packaging, labelling, sending, delivery, transportation, sale, possession or disposal, importation and exportation of cannabis or any class of cannabis. Licences are issued by Health Canada on behalf of the Minister after consideration of the application within the framework of the *Cannabis Act* and its Regulations.

After the licence is issued, it is the licence holder’s responsibility to continue to comply with all requirements in the *Cannabis Act* and its Regulations.

The *Cannabis Regulations* set out requirements to manage a licence, such as renewing or amending it. There are also notification and reporting requirements that a licence holder must follow. This guide provides licence holders with best practices to employ to meet these requirements.

Health Canada has established the Cannabis Tracking and Licensing System (CTLS) as the system through which applicants may apply for licences, amendments, renewals and security clearances and submit tracking reports. Licence holders may also be required to submit information to Health Canada by a means other than the CTLS, such as by email.

Health Canada publishes other guidance documents and information on its website that licence holders may use in conjunction with this document to assist in maintaining their compliance. For consistency and transparency, this guide and other guidance documents and information are updated as required to reflect changes to policies and/or operations.

3.0 Scope

This guide applies to those who hold licences for:

- Cultivation
- Processing
- Sale for medical purposes

It does not apply to industrial hemp licence holders under the *Industrial Hemp Regulations* or analytical testing, research or cannabis drug licence holders under the *Cannabis Regulations*.

This document provides guidance related to the following activities:

- Licence renewals
- Licence amendments
- Changes requiring Health Canada's approval¹
- Changes requiring notification to Health Canada
- Import and export permit applications and notification requirements
- Reporting and disclosure requirements including:
 - Notice to local authorities
 - Notice of cessation of activities
 - Reporting promotion-related information
 - Annual reporting of key investors
- Licence and permit refusals, suspensions and revocations

The following activities that are closely connected to licensing requirements are not addressed in this guide:

- Notices of new cannabis products have been removed from the earlier version of this guide and are now found in the "[Notice of New Cannabis Product Guide](#)".
- Applying for a licence under the *Cannabis Regulations*. Refer to "[Applying for a licence under the Cannabis Act and the Regulations](#)" page on the Health Canada website for more information
- Requirements for Access to cannabis for medical purposes, as outlined in Part 14 of the *Cannabis Regulations*
- Paying [cost recovery fees](#)

The following activities are mentioned in this guide but more detailed information is found in other guides on the Health Canada website:

- [Cannabis Tracking and Licensing System – Monthly Reporting Guide](#)
- [Reporting of loss or theft of controlled substances, precursors and cannabis](#)
- [Cannabis voluntary recall guide](#)
- [Serious adverse reaction reporting](#)
- [Physical security measures guide for cannabis](#)
- [Good production practices guide for cannabis](#)

For more information on these activities, licence holders may refer to the *Cannabis Act* and its Regulations and additional guidance published on the [Health Canada website](#) or may contact Health Canada as outlined in [section 9](#) of this guide.

¹Throughout 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, decision-making 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 is based on the CTLS release 2.0.



Important: In cases of discrepancy between the CTLS and the *Cannabis Regulations* or guidance, or if use of the CTLS is not possible, the licence holder should contact Health Canada. 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 this guide.

Amendment: As defined in section 32 of the *Cannabis Regulations*, a change related to the licence. Section 32 of the Regulations and this guide outline the specific circumstances that are defined as amendments.

Brand element: As defined in the *Cannabis Act*, includes a brand name, trademark, tradename, distinguishing guise, logo, graphic arrangement design or slogan that is reasonably associated with, or that evokes,

- a) cannabis, a cannabis accessory or a service related to cannabis; or
- b) a brand of any cannabis, cannabis accessory or service related to cannabis.

Brand name: The name, whether or not it includes the name of any licence holder, in English or French, that is assigned to the cannabis product, under which the cannabis product is sold or promoted, and that is used to distinguish the cannabis product.

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: As defined in the *Cannabis Act*, 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: 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 for use, directly or indirectly, exclusively on external body surfaces, including hair and nails.

Cannabis Tracking System (CTS): The system created under the authority of the *Cannabis Act* and established and maintained by Health Canada to track high-level movements of cannabis and help prevent diversion from and inversion into the regulated supply chain.

Cannabis Tracking and Licensing System (CTLS): The online portal used to apply to Health Canada for a cannabis licence and used by licence holders to manage their licence, including applying for amendments or changes to a licence and submitting monthly reports.

CTLS icons: The following icons are used to manage licences and applications in the CTLS:

Under the **Licences** tab in the CTLS

	<ul style="list-style-type: none"> • Initiate an application to amend a licence
	<ul style="list-style-type: none"> • Initiate an application to renew a licence (appears in the CTLS four months before the licence expires)
	<ul style="list-style-type: none"> • Request cancellation of the target licence. Note: This icon locks the licence record and sends a cancellation request to Health Canada. Do not choose this to withdraw an application or to amend a licence.

Licence applications tab in the CTLS

	<ul style="list-style-type: none"> • Edit a draft application
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- Withdraw a draft application
- Withdraw a submitted application

Dried cannabis: As defined in the *Cannabis Act*, 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: As defined in the *Cannabis Regulations*, 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;
- 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.

Licence application: The information that must be submitted through the CTLS to apply for, change, or renew a licence as follows:

- **New licence application:** To apply for a new licence
- **Licence amendment application:** To apply to change a licence or licensed site
- **Licence renewal application:** To apply to renew a licence for a licence that is within four months of the expiry date

Licence class: The *Cannabis Regulations* authorize activities related to cannabis by licence class, as follows:

- Cultivation
- Processing
- Sale for medical purposes
- Analytical testing
- Research
- Cannabis drug licence

Licence record: The complete record of all information related to a licensed site as approved by Health Canada. The record includes the information displayed on the physical (paper) licence as well as information regarding the site that is not displayed on the physical licence (e.g., activities and rooms within a building).

Licence subclass: The *Cannabis Regulations* outline specific licence subclasses, as follows:

For cultivation, a licence for:

- micro-cultivation
- standard cultivation

- nursery

For processing, a licence for:

- micro-processing
- standard processing

For sale, a licence for:

- sale for medical purposes

Promote: As defined in the *Cannabis Act*, in respect of a thing or service, means to make, for the purpose of selling the thing or service, a representation — other than a representation on a package or label — about the thing or service by any means, whether directly or indirectly, that is likely to influence and shape attitudes, beliefs and behaviours about the thing or service.

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.

4.2 Abbreviations

CBD : cannabidiol

CBDA: cannabidiolic acid

CTS: Cannabis Tracking System

CTLs: Cannabis Tracking and Licensing System

GPP: Good Production Practices

QAP: Quality Assurance Person

THC: delta-9- tetrahydrocannabinol

THCA: delta-9-tetrahydrocannabinolic acid

4.3 Icons

The following icons are used throughout this guide.



Important: Key or cautionary information.



Tip: Supplementary information that could be helpful, including references to external documents.

5.0 Licence Renewals and Changes

A licence holder must renew their licence before it expires. For a licence holder to continue to be authorized to conduct the activities authorized by the licence, the licence must be renewed on or before the expiry date. Refer to section 5.1 in this Guide for information on submitting licence renewals.

The licence holder may also wish to make changes to the licence, such as modifying information about their site, their activities, or their personnel. The *Cannabis Regulations* outline two types of changes that can be initiated by a licence holder, as follows:

- **Changes requiring approval** by Health Canada (see sections 20, 32 and 33 of the *Cannabis Regulations*). Refer to section 5.2 in this guide for more information about changes requiring approval.

For the purposes of this Guide, an application for a cultivation, processing or sale for medical purposes licence at an approved licensed site is also considered a change requiring approval.

- **Changes requiring notification** to Health Canada (see section 34 of the *Cannabis Regulations*). Refer to section 5.3 Changes Requiring Notification to Health Canada for instructions on submitting notifications.



Important: The CTLS does not distinguish between the different types of changes as defined in the *Cannabis Regulations*. Therefore, it is critical that licence holders be familiar with the regulatory requirements and follow the processes as outlined in this guide.

Licence holders are expected to comply with applicable requirements as outlined in the Regulations, and compliance may be verified at any time by Health Canada.

Table 1: Changes related to a licence lists the types of changes that may be made, as well distinguishes between those which require approval and those which require notification and how the changes must be submitted to Health Canada. Some changes only apply to certain licence types (e.g., change of Quality Assurance Person (QAP) only applies to licences for standard processing or micro-processing).

Table 1: Changes related to a licence				
Type of change	Example	Change requiring approval See section 5.2 of this guide	Change requiring notification See section 5.3 of this guide	Submission method
Contact and licence holder information	Change a mailing address or contact information		✓	Email
	Change licence holder name	✓		CTLS
	Change the address of the site or building within the site where the activity is authorized, but location stays the same	✓		CTLS
Licence classes and activities	Add a new licence class to a licensed site (i.e., cultivation, processing, sale for medical purposes)	✓		CTLS
	Change an authorized activity at the site or at each building within the site Remove an activity, such as no longer selling in a building	✓		CTLS
Personnel	Change the QAP	✓		CTLS

Table 1: Changes related to a licence


Type of change	Example	Change requiring approval See section 5.2 of this guide	Change requiring notification See section 5.3 of this guide	Submission method
changes	Change other individuals who require a security clearance such as corporate personnel or master grower		✓	Email
	Change to the responsible person		✓	CTLS
Site changes	Change to the site plan that requires physical security measures to be carried out in order to comply with Part 4 of the <i>Cannabis Regulations</i> (e.g., the addition of a grow or operations area, converting a grow or operations area into a storage area)	✓		CTLS
	Change to the site plan that does not require physical security measures to be carried out in order to comply with Part 4 of the <i>Cannabis Regulations</i> (e.g., the removal of extra cameras within a room not required by the Regulations or a change in nomenclature for areas on the site plan, converting a storage area to an operations area)		✓	Email
	Change an organizational security plan (e.g., updates to the business plan, change in the site organizational chart)		✓	Email


Table 1: Changes related to a licence				
Type of change	Example	Change requiring approval	Change requiring notification	Submission method
		See section 5.2 of this guide	See section 5.3 of this guide	
Licence conditions	Change the conditions on the licence to authorize a new cannabis class for sale to a provincially or territorially authorized retailer and/or holder of a licence for sale for medical purposes	✓		Email
Other	Change concerning good production practices or record keeping practices	No approval from or notification to Health Canada is required. Licence holders are responsible for ensuring that all of their activities comply with the <i>Cannabis Act</i> and <i>Cannabis Regulations</i> . This includes meeting good production practices and following record keeping requirements. Health Canada may verify compliance at any time.		N/A

5.1 Licence renewals

For the licence holder to continue to be authorized to conduct the activities authorized by the licence, the licence must be renewed on or before the expiry date shown on the licence.

The licence holder must apply to renew their licence through the CTLS. The option to renew a licence will appear in the CTLS four months before the licence expires and the licence holder is encouraged to apply for renewal at that time. The CTLS can be accessed directly (<https://ctls-sscdl.hc-sc.gc.ca/>) or through the Health Canada website at <http://www.canada.ca/cannabis>.

A licence renewal application is initiated by navigating to the **Licences** tab in CTLS and clicking the green arrow icon  next to the licence to be renewed. After pressing confirm, the status of the

target licence will change from “Issued” to “Renewal in progress”. To review and submit the licence renewal, navigate to the **Licence Applications** tab in CTLS and click the green pencil icon  next to the newly generated draft amendment application.

Only the responsible person named in CTLS is able to initiate and submit a licence amendment application in the CTLS.

Licence holders are not required to re-enter information to renew a licence. Health Canada assumes renewals are based on information provided in support of the current licence. Licence holders must, however, confirm that all the information in the CTLS is up to date at the time of the licence renewal. Licence holders should review all information captured in the CTLS to ensure its accuracy prior to the submission of the licence renewal. If information is captured incorrectly in the CTLS, please contact Health Canada at HC.licensing-cannabis-licences.SC@canada.ca.

Prior to renewing a licence, Health Canada may request additional information which may include but is not limited to:

- names of individuals in key positions at the licensed site
- corporate organizational chart and the names of directors and officers of the licence holder and parent company, if applicable
- updated site plan indicating the site perimeter and the names and locations of all buildings within the perimeter
- updated floor plans of the interior of each building indicating the names and locations of all rooms/areas in which cannabis may be present
- updated list of rooms within each building and the activities being conducted in each
- updated Organizational Security Plan
- Key Investor Report

Note: The names used to identify each room/area in the CTLS must match all other information submitted (e.g., site plan, floor plans).



Important: Licence holders who wish to also make changes to their licence when they renew it may do so by initiating a licence renewal application as described above and then follow the process(es) outlined in section 5.2 Changes Requiring Approval and/or section 5.3 Changes Requiring Notification to Health Canada of this Guide. However, they may be required to withdraw and resubmit a licence renewal application with the changes removed if it is determined that the processing time for one or more of the requested changes may extend past the expiry date of the licence.

When an application to renew a licence is received, Health Canada verifies:

- The security clearance status of the individuals involved
- The information in the licence record in the CTLS
- The status of fees paid, if applicable
- The status of licences issued under the *Excise Act, 2001* (by the Canada Revenue Agency)

- In the case of a licence for processing, that the licence holder has not been convicted of an offence under the *Safe Food for Canadians Act* or an Act referred to in subsection 374(2) of the *Safe Foods for Canadians Regulations*

An inspection may also be conducted to verify ongoing compliance with the requirements of the *Cannabis Act* and its Regulations. The licence holder may also be asked to provide additional information to help Health Canada plan the inspection.





Tip: Licence holders should ensure that the security clearances of their key personnel and their licence under the *Excise Act, 2001* are active, and that fees have been paid. Individuals whose security clearances are close to expiring should apply to renew these as soon as possible. A minimum of six months in advance of the expiry is recommended, but some clearances may take longer.

It is the licence holder's responsibility to ensure continued compliance with these security clearance requirements.

5.2 Changes requiring approval by Health Canada

Changes requiring approval must be submitted as a licence amendment application in the CTLS with the exception of an application to amend a licence to add sale of classes of cannabis which must be submitted via email, and must be approved by Health Canada before they are implemented. Once they are approved, Health Canada issues an amended licence or, where an update to the physical licence is not necessary, a letter approving the changes.

Only the responsible person is able to initiate and submit a licence amendment application in the CTLS.

A licence amendment application may be initiated by opening the **Licences** tab in the CTLS and clicking the green pencil icon  next to the licence to be amended. Click "Confirm" and the status of the target licence will change from "Issued" to "Amendment in Progress". To edit and submit the application, open the **Licence Applications** tab in the CTLS and click the green pencil icon  next to the newly generated draft amendment application.

Once the application is submitted, the licence holder can no longer view or edit it, and no other changes to the licence can be submitted in the CTLS until Health Canada has reviewed and accepted or refused the application.

A licence holder may check the status of their amendment application in the CTLS at any time.

There are three categories in the CTLS that denote the status of the application as follows:

Submitted: Health Canada has received the application

In Progress: Health Canada has begun the screening or review of the application

Pending Information: A request for more information has been sent and Health Canada is waiting for a response from the licence holder

Licence holders may withdraw and resubmit an application at any time if they wish to make significant changes to it. They are encouraged to email Health Canada at HC.licensing-cannabis-licences.SC@canada.ca when they change and resubmit an application in the CTLS. Applications that are withdrawn and resubmitted are likely to be subject to processing delays.



Licence holders may be asked to withdraw and resubmit a licence amendment application if the information submitted does not accurately reflect the information in the application (e.g., **Application for Approval of a Change to the Site Plan** [see Appendix J] indicates additional grow rooms but these were not added under the Site Details section of the application for an amendment in the CTLS).



Tip: New draft amendment or licence renewal applications will automatically have all required fields filled in with information from the most recent licence record. Therefore, it is only necessary to update information in the sections relevant to the changes being requested and upload the applicable form (see Appendix B or J) into the Record Keeping Description section before submitting the application.

Licence holders should ensure that the file name of all documents that they upload to the CTLS indicate the topic of the document and the date it was uploaded (e.g., SitePlan [Upload date YYYY-MM-DD]). Failing to provide a clear title and a date may result in processing delays.



Tip: Personnel changes requiring approval

Licence holders who wish to make personnel changes that require approval (e.g., QAP or alternate QAP), should send an email to HC.licensing-cannabis-licences.SC@canada.ca to identify the proposed new individuals as being linked to the licensed site, as well as identify any individuals who are no longer linked to the licensed site. Licence holders should confirm that they have applied for a security clearance through the CTLS prior to submitting the amendment application. This will allow licence holders to submit other amendment applications in the CTLS as they wait for the security clearance to be granted. Once the individual receives their clearance, an amendment application can be submitted in the CTLS.

Table 2 shows the changes that require a licence amendment application to be submitted to request approval, as well as the required information and the instructions on how to submit the application.

Table 2: Changes requiring approval by Health Canada		
Type of amendment	Required information	CTLS instructions
<p>A change to the name of the licence holder (if the licence holder is a corporation, partnership or cooperative).</p> <p>Note: This triggers an amendment to all licences held by the licence holder.</p>	<ul style="list-style-type: none"> • Cannabis Licence Attestation Form (see Appendix B) • A document that shows the name change, for example an amended certificate of incorporation or, in the case of a partnership or cooperative, updated agreement documents 	<p>In the Corporate Profile: Modify the legal name and upload a new certificate of incorporation, articles of incorporation or agreement documents.</p> <p>Draft licence amendment applications will be automatically initiated for each licence held by the corporate profile and each application will need to be completed and submitted by the responsible person and approved before a licence with the modified name can be issued.</p> <p>Update the following sections in the licence amendment application:</p> <p>In the Licence Holder section: Verify that the licence holder is accurate.</p> <p>In the Record Keeping Description section: Upload a Cannabis Licence Attestation Form (see Appendix B)</p>
<p>A change to the name of the licence holder (if the licence holder is an individual).</p> <p>Note: This triggers an amendment to all licences held by the licence holder.</p>	<ul style="list-style-type: none"> • Cannabis Licence Attestation Form (see Appendix B) • A document that shows the name change, such as the legal name change certificate, or marriage certificate 	<p>In the individual’s user account: Modify the name and email a colour copy of the government-issued ID showing the name change to HC.licensing-cannabis-licences.SC@canada.ca.</p> <p>Draft licence amendment applications will be automatically initiated for each licence held by the licence holder and each application will need to be completed and submitted by the responsible person and approved before a licence with the modified name can be issued.</p>

Table 2: Changes requiring approval by Health Canada

Type of amendment	Required information	CTLS instructions
		<p>Update the following sections in the licence amendment application:</p> <p>In the Licence Holder section: Verify that the licence holder is accurate.</p> <p>In the Record Keeping Description section: Upload a Cannabis Licence Attestation Form (see Appendix B)</p>
<p>Change to the address (not a location change) of the site or a building within the site where the activity is authorized.</p> <p>Note: A location change requires a new licence application.</p>	<ul style="list-style-type: none"> • Cannabis Licence Attestation Form (see Appendix B) • A document showing the address change, such as a bill addressed to the licence holder with the new address, or notification from the city confirming the address change. • An updated site survey, if applicable. 	<p>Initiate a licence amendment application and update the following sections:</p> <p>In the Site Details section: Modify the address of the site.</p> <p>If multiple addresses were provided in the original licence application, the information must be uploaded as a separate document. Changes must be clearly marked. This must be uploaded in the Site Survey section of the CTLS.</p> <p>In the Site Survey section: If the change in address results in a change to the site survey upload a new or revised site survey (see section 6.4 of the Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes).</p> <p>In the Record Keeping Description section: Upload a document showing the address change, and a Cannabis Licence Attestation Form (see Appendix B) describing the change.</p>
<p>Change to an authorized activity at the site or a change to an authorized activity</p>	<ul style="list-style-type: none"> • Cannabis Licence Attestation Form (see Appendix B) <p>Required information depends</p>	<p>Initiate a licence amendment application and update the following sections:</p> <p>In the Site Activities section: Indicate</p>

Table 2: Changes requiring approval by Health Canada

Type of amendment	Required information	CTLS instructions
<p>that may be conducted at each building within the site.</p> <p>Note: This also includes applying for a cultivation, processing or sale for medical purposes licence at the approved licensed site.</p>	<p>on the type of authorization requested. It could include evidence demonstrating:</p> <ul style="list-style-type: none"> • Physical security requirements • Organizational security plan updates • Good production practices • Record keeping and reporting <p>Sufficient information must be provided to demonstrate how the requirements would be met for the proposed change.</p> <p>Refer to sections 6.8, 6.9, and 6.10 as applicable of the Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes for instructions on the required details to include.</p>	<p>any licence classes to be added to the existing licensed site.</p> <p>Note: Applications to apply for a standard or micro processing licence will only be reviewed if the proposed QAP already holds a valid security clearance. As security clearance application processing timelines can vary greatly, licence holders may be required to withdraw their application and resubmit it <u>after</u> the proposed QAP has been granted a security clearance if there are other changes requiring approval that need to be submitted.</p> <p>In the Site Details section, indicate any changes to the specific activities conducted within each room or building.</p> <p>In the Physical Security and GPP sections upload all required information.</p> <p>In the Record Keeping Description section, upload a Cannabis Licence Attestation Form (see Appendix B) describing the changes.</p>
<p><i>Applies to a holder of a processing licence:</i> Replacing the QAP or designating or replacing an alternate (section 20 of the <i>Cannabis Regulations</i>)</p>	<ul style="list-style-type: none"> • Cannabis Licence Attestation Form (see Appendix B) • The name and birth date of the proposed QAP or alternate. • Details of the proposed QAP or alternate’s qualifications, demonstrating that they have the training, experience and technical knowledge related to all 	<p>Initiate a licence amendment application and update the following sections:</p> <p>In the Site Personnel section: Associate the account ID of the proposed QAP or alternate QAP with the licence.</p> <p>In the Quality Assurance Person Qualifications section: Upload the proposed QAP’s or alternate QAP’s qualifications, proposed work schedule and other supporting information (e.g., resume, transcripts).</p>

Table 2: Changes requiring approval by Health Canada

Type of amendment	Required information	CTLS instructions
	<p>relevant requirements in Part 5 (good production practices requirements) and Part 6 (cannabis products) of the <i>Cannabis Regulations</i>.</p> <p>Refer to Table 7 of the Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes for instructions on the required details to include.</p> <p>Note: The QAP or alternate must hold a valid security clearance before the application will be approved.</p>	<p>In the Record Keeping Description section, upload a Cannabis Licence Attestation Form (see Appendix B) describing the changes.</p>
<p>The following changes to the site plan that require physical security measures to comply with Part 4 of the <i>Cannabis Regulations</i>:</p> <ul style="list-style-type: none"> • Addition of new grow or operations area • Modification to an approved grow or operations area • Modification to an approved storage area • Modification to an approved 	<ul style="list-style-type: none"> • Application for Approval of a Change to the Site Plan (see Appendix J) and requested supporting documentation 	<p>Initiate a licence amendment application and update the following sections:</p> <p>In the Site Details section: Add or remove rooms as necessary. Add or remove activities being conducted within each room as necessary.</p> <p>In the Record Keeping Description section: Upload proposed new site plan with the security measures identified.</p> <p>In the Record Keeping Description section: Upload the completed Application for Approval of a Change to the Site Plan (see Appendix J).</p>

Table 2: Changes requiring approval by Health Canada

Type of amendment	Required information	CTLS instructions
<p>building in a manner that does not affect the site perimeter</p>		
<p>The following changes to the site plan that requires physical security measures to comply with Part 4 of the <i>Cannabis Regulations</i>:</p> <ul style="list-style-type: none"> • Addition of new building • Addition of new storage area • Modification to an approved building in a manner that affects the site perimeter • Change to the site perimeter 	<ul style="list-style-type: none"> • Cannabis Licence Attestation Form (see Appendix B) • The proposed site plan with security measures identified • A description of the changes, including updated information as required to demonstrate how the physical security requirements outlined in the <i>Cannabis Regulations</i> are met. Refer to Section 6.8 of the Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes for additional information on the required details to include. • Additional site evidence relevant to the proposed changes may need to be provided for review and approval. These may include, but are not limited to: <ul style="list-style-type: none"> ○ Alarm reports ○ Access control logs ○ Camera still-shots (day/night) ○ Sanitation programs ○ Construction 	<p>Initiate a licence amendment application and update the following sections:</p> <p>In the Site Details section: Add or remove buildings and rooms as necessary. Add or remove activities being conducted within each room as necessary.</p> <p>In the Physical Security and GPP sections: Upload all required information including the proposed new site plan with the security measures identified. In addition, provide an attestation, signed by the head of security and responsible person, that the organizational security plan has been updated.</p> <p>In the Record Keeping Description section: Upload the Cannabis Licence Attestation Form (see Appendix B) describing the changes.</p>

Table 2: Changes requiring approval by Health Canada

Type of amendment	Required information	CTLS instructions
	material and equipment specifications	
Change to amend a licence to add sale of classes of cannabis (e.g., authorization of a new cannabis class for sale to a provincially or territorially authorized retailer and/or holder of a licence for sale for medical purposes)	<ul style="list-style-type: none"> Application to Amend a Licence to Add Sale of Classes of Cannabis (see Appendix I) and requested supporting documentation <p>An on-site inspection by Health Canada may also be required.</p>	<p>Do not submit in the CTLS</p> <p>When a licence holder is applying to amend their licence conditions to add the authorization of sale of a new class of cannabis products, they must complete Application to Amend a Licence to Add Sale of Classes of Cannabis (see Appendix I). The completed form and all required documentation should be emailed directly to Health Canada at HC.licensing-cannabis-licences.SC@canada.ca. Licence holders should ensure that the file name of all documents that they include in the email indicate the topic of the document and the date it was submitted (e.g., Certificate of Analysis for lot X, Release SOP). Failing to provide a clear title may result in processing delays.</p>



Important: The Site Details section of every application must accurately reflect all of the buildings, rooms and activities previously approved by Health Canada, as well as any buildings, rooms and activities being added or removed as part of the application. If the information in this section does not match Health Canada’s records, or the information provided on the **Cannabis Licence Attestation Form** (see Appendix B), or **Application for Approval of a Change to the Site Plan** (see Appendix J), there will be a delay in processing the application and the licence holder may be asked to withdraw it in order to make the corrections.

When a licence holder is proposing a change to the site plan, they must first determine whether the proposed change requires physical security measures to comply with the *Cannabis Regulations*. If it does, a licence amendment application requesting the change must be submitted through the CTLS and approved by Health Canada before activities with cannabis can be conducted in the proposed areas and the licence record will be updated to reflect the change.

If the proposed change does not require physical security measures, it is considered a change requiring notification (see section 5.3 of this guide).

Health Canada reviews licence amendment applications for site plan changes that require physical security measures as per the requirements in the *Cannabis Act* and its Regulations. The [Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purpose](#) as well as the [Physical Security Measures Guide for Cannabis](#) provide more information. If all requirements are met and the application is approved in the CTLS, the licence record is updated to reflect the change and an amended licence and/or a letter approving the change(s) is issued to the licence holder.



Tip: Authorized activities vary depending on the class or subclass of a licence. A proposal to modify an authorized activity must fall within those permitted for the licence class or subclass.

For example, a holder of a micro-processing licence that wishes to synthesize cannabis cannot do so by applying for a licence amendment, as synthesizing cannabis is not an authorized activity under a micro-processing licence. Rather, the licence holder must apply for a new licence to be a standard processor.



Tip: Changes including, but not limited to, modifying production procedures (e.g., changing the production method for a cannabis extract or solvent used), modifying the destruction method or location, or changing packaging and labelling are not considered amendments or changes requiring approval or notification. The *Cannabis Regulations* specify the licence holder requirements for these.

5.2.1 Mergers and acquisitions

When an organization is purchased by, or merges with, another organization, amendments or changes requiring approval or notification may be required. Licence holders should email Health Canada at HC.licensing-cannabis-licences.SC@canada.ca and provide details of the proposed acquisition or merger, as well as contact information for follow up, and Health Canada will provide further instructions based on the context.



Tip: The *Cannabis Regulations* allow individuals to apply for a security clearance if they will be required to hold one after a pending business transaction is completed.

5.3 Changes requiring notification to Health Canada

As per section 34 of the *Cannabis Regulations*, some changes require the licence holder to notify Health Canada rather than obtain approval from Health Canada. In these cases, the licence holder must notify Health Canada within five calendar days of making the change. Changes that require notification are defined in section 34 of the *Cannabis Regulations* and are summarized in

Table 3: Changes Requiring Notification to Health Canada. To submit a notification, send an email with the supporting documentation listed in Table 3, and the **Notification Attestation Form** (see Appendix C) to HC.licensing-cannabis-licences.SC@canada.ca with the subject line: s.34 Notification – Corporation Name – Licence #.



Important: To replace the responsible person, licence holders should submit the notification to Health Canada through a licence amendment application in the CTLS. See **Table 4: Changes to the responsible person** for instructions on how to submit this change in the CTLS.



Tip: Other than when changing the responsible person, licence holders are not required to update information in the CTLS related to notifications. Certain information in the CTLS related to a notification, such as a new email address, will be updated by Health Canada following receipt and review of the notification.

Table 3: Changes requiring notification to Health Canada as per section 34 of the <i>Cannabis Regulations</i> (email notification)	
Type of change	Required supporting documentation
A change to the mailing address, telephone number, email address or facsimile number of the licence holder	(a) A description of the change; and (b) A Notification Attestation Form (see Appendix C), signed and dated by the responsible person indicating that all information provided in support of the notification is correct and complete to the best of their knowledge.
A change to the site plan that does not require physical security measures to comply with Part 4 of the <i>Cannabis Regulations</i>	(a) A description of the change; and (b) A Notification Attestation Form (see Appendix C), signed and dated by the responsible person, indicating that all information provided in support of the notification is correct and complete to the best of their knowledge.
Replacing or adding corporate personnel who must hold a security clearance (e.g., directors and officers). Replacing or adding a Head of Security or Master Grower.	(a) A description of the change; (b) The name, date of birth and the CTLS User Account ID for each of the new individuals; (c) If the individual replaced a director or officer, the certificate of incorporation or other amended incorporating instrument of the corporation or cooperative.

Table 3: Changes requiring notification to Health Canada as per section 34 of the *Cannabis Regulations* (email notification)

Type of change	Required supporting documentation
	<p>(d) A Notification Attestation Form (see Appendix C), signed and dated by the responsible person, indicating that all information provided in support of the notification is correct and complete to the best of their knowledge;</p> <p>Note: The individuals who have been identified to fill a role listed in s. 50 of the <i>Cannabis Regulations</i> must hold a security clearance prior to occupying the position.</p>
Updates to the organizational security plan for cultivation, processing and medical sales licences	<p>(a) A description of the change; and</p> <p>(b) A Notification Attestation Form (see Appendix C), signed and dated by the responsible person indicating that all information provided in support of the notification is correct and complete to the best of their knowledge.</p>

Table 4: Changes to the Responsible Person

Required information	CTLS instructions
The proposed new responsible person's CTLS User Account ID	<p>Initiate a licence amendment application and update the following sections:</p> <p>In the Licence Ownership section, designate the new responsible person using their CTLS Account ID.</p> <p>In the Record Keeping Description section, upload a Notification Attestation Form (see Appendix C) describing the change.</p> <p>NOTE: Only the current responsible person is able to initiate and submit a licence amendment application in the CTLS. If the responsible person is not able to complete this step for any reason (e.g., they left the company abruptly), licence holders must contact Health Canada for assistance.</p>

Any individual who is required to hold a security clearance under section 50 of the *Cannabis Regulations* must hold a valid clearance before assuming the duties of the position. In addition, the licence holder must ensure they have someone in the required positions at all times.



Tip: Personnel changes requiring notification

Licence holders who wish to make personnel changes that require notification (e.g., master grower, head of security, directors and officers), should send an email to HC.licensing-cannabis-licences.SC@canada.ca to identify any proposed new individuals as being linked to the licensed site, as well as identify any individuals who are no longer linked to the licensed site. Licence holders should confirm that all new personnel have applied for a security clearance through the CTLS. After the individual receives their clearance, a notification designating them to the position can be submitted by email.

A change to the responsible person cannot be submitted via email and requires the submission of an amendment application in the CTLS. Licence holders should send an email to HC.licensing-cannabis-licences.SC@canada.ca to identify the proposed new responsible person as being linked to the licensed site, and confirm that they have applied for a security clearance through the CTLS. Once the individual receives their clearance, an amendment application can be submitted in the CTLS. This will allow licence holders to submit other amendment applications in the CTLS as they wait for the security clearance to be granted.

In addition to the notification requirements defined in section 34 of the *Cannabis Regulations*, individuals who hold security clearances must immediately provide Health Canada with notice in writing if they are charged with, or found guilty of, an offence under the *Cannabis Act*, the *Controlled Drugs and Substances Act* or the Criminal Code. The written notice should be emailed to HC.licensing-cannabis-licences.SC@canada.ca.



Tip: Licence holders are responsible for ensuring that all changes they submit are accurate and meet the legal requirements. They should pay particular attention to changes requiring approval by Health Canada as these changes must be approved by Health Canada before they are implemented.

If a licence holder makes a change that does not comply with the requirements, Health Canada may take compliance and enforcement actions.

5.4 Multiple changes

Licence holders can request multiple changes in one licence amendment application in the CTLS. A summary of the changes must be provided using the **Cannabis Licence Attestation Form** (see Appendix B). The completed form is to be uploaded in the Record Keeping Description section of

the amendment application. All other applicable forms (e.g., Appendix J) and required supporting documentation must also be submitted as outlined in section 5.2 of this Guide.



Important: Applications for an amendment that request multiple changes cannot receive partial approval. Therefore, the amount of time from submission to final approval is dependent on the change that takes the most time to review and approve, as well as the number of changes requested. Licence holders are encouraged to prioritize and group their requests accordingly.

5.5 Amendments triggered by Health Canada

As per section 63 of the *Cannabis Act*, Health Canada may amend a licence or permit if Health Canada is of the opinion that this is necessary to protect public health or safety, including to prevent cannabis from being diverted to an illicit market or activity.

In this case, Health Canada sends a written notice to the licence holder that sets out the reasons for the proposed amendment and gives the licence holder an opportunity to be heard, prior to the amendment taking effect.

5.6 Requests for more information and refusal to issue

In accordance with subsection 62(5) of the *Cannabis Act*, Health Canada may ask a licence holder to submit additional information related to the application for a renewal or amendment. This is sent as a Request for More Information, as outlined in the [Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes](#).

Health Canada may refuse to consider an application for renewal or amendment if any of the required information is not provided. In addition, Health Canada may refuse to issue a renewal or amendment under a number of circumstances set out in section 62(7) of the *Cannabis Act* and may refuse to issue, renew or amend a licence under a number of circumstances set out in section 29 of the *Cannabis Regulations*.

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

The notice of refusal closes the file and sets out the specific reasons or deficiencies that resulted in the decision to refuse to consider the application or issue an amended licence.

All decisions to refuse an application are without prejudice to filing a new application. If the applicant wishes to submit a new application in the future, it will be processed as such. Health Canada does not return information and data submitted to support an application.



Important: If an application for renewal is refused and the licence expires, the licence holder is no longer authorized to conduct the activities specified in the licence and must stop all activities immediately as of the date of expiry. If activities are not stopped, Health Canada may take compliance and enforcement actions, or, in appropriate circumstances, may make a referral to law enforcement.

6.0 Import/Export Permits

6.1 Applications for an import or export permit for medical or scientific purposes

Under Part 10 of the *Cannabis Regulations*, licence holders who wish to import or export cannabis for medical or scientific purposes must hold an import or export permit for each shipment of cannabis that is imported or exported. Table 5: Import and export permit application requirements outlines the application requirements for an import or export permit.

Application requirement		Import permit application requirement	Export permit application requirement
Licence holder information	Name of licence holder	✓	✓
	Mailing address of licence holder	✓	✓
	Licence number	✓	✓
Transit details	The name and address of the importer		✓
	The name and address of the exporter	✓	
	The port of entry into Canada	✓	
	The port of exit from Canada and country of import		✓
	The address of the customs office where the shipment will be delivered	✓	
	The address of the customs office, sufferance warehouse or bonded		✓

Table 5 : Import and export permit application requirements

Table 5 : Import and export permit application requirements			
Application requirement		Import permit application requirement	Export permit application requirement
	warehouse where the shipment will be delivered, if applicable		
	Each mode of transport used	✓	✓
	Any country of transit or transshipment, if applicable	✓	✓
Shipment details	Anticipated shipment date, if known	✓	✓
	Description of the form of the cannabis (e.g., extract, seeds, plants) and description of the packaging if applicable	✓	✓
	Name and address of the exporter	✓	✓
	Intended use of the cannabis including a detailed description of what the imported/exported product will be used for	✓	✓
	Brand name, if applicable	✓	✓
	Quantity of the cannabis	✓	✓
	Percentage of THC weight by weight (w/w) and CBD w/w of the cannabis, except in the case of cannabis plants and cannabis plant seeds	✓	✓
Competent authority authorization	Valid import permit from the competent authority in the country of import		✓

An **Import or Export Permit Application for medical or scientific purposes Form**, as found in Appendix D and Appendix E respectively, should be used to apply for a permit. Email the completed form to HC.import-export-cannabis-importation-exportation.SC@canada.ca. The subject of the email and the file name should indicate **Import/Export Permit Application Form for LIC #**.

Additional information on the circumstances for permitting the importation or exportation of cannabis for medical or scientific purposes can be found on the Health Canada website.

Permits are valid only until the earliest of the date on which the:

- shipment is imported/exported
- permit expires or is revoked
- licence expires or is revoked
- date the import or export permit is revoked by the competent authority of the country of import/export pertaining to the shipment



Tip: Import and export permit holders are authorized to, in the case of import, possess, transfer, transport, send or deliver, or, in the case of export, sell, the shipment of cannabis to the extent necessary to import or export the cannabis.

6.2 Notification of shipment

An import or export permit holder must provide a copy of the import or export permit to the customs office at the time of import or export.

Within 15 days after the release of a shipment of cannabis in Canada or the export of a shipment of cannabis, the permit holder must provide Health Canada with information outlined in sections 209 (for import) and 218 (for export) of the *Cannabis Regulations* using the **Cannabis Shipment Detail Notification Form**, as found in Appendix F. Email the completed form to HC.import-export-cannabis-importation-exportation.SC@canada.ca. The subject line of the email and the file name should indicate **Import Notification of Shipment** or **Export Notification of Shipment**, as applicable, **the permit number and LIC #**.

The holder of an import permit must ensure that after the imported cannabis is released from the Canada Border Services Agency, it is transported directly to the site set out in the licence referred to in the permit.



Tip: Health Canada may provide information in the import or export permit application as well as the permit and the notification of shipment or the status (i.e., if the permit has been suspended or revoked) to a customs officer to verify compliance with the *Cannabis Regulations*.

6.3 Refusal to issue an import or export permit

Health Canada may refuse to consider an application for an import or export permit if required information is not provided.

In addition, Health Canada may refuse to issue an import or export permit under a number of circumstances as set out in subsection 62(7) of the *Cannabis Act* and as outlined in [section 5.6](#) of this guide.

Sections 206 and 215 of the *Cannabis Regulations* outline additional reasons that an import or export permit may be refused, including:

- The applicant does not hold a licence
- The Minister has reasonable grounds to believe that the shipment to which the permit application pertains contravenes the *Cannabis Regulations* or the laws of the country of import or export or any country of transit or transshipment
- In the case of import, the importation of the cannabis is for the purpose of exporting it
- In the case of export, it does not comply with the permit for importation issued by a competent authority of the country of import

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 permit. This notice will provide the licence holder with a timeframe within which to respond, after which a decision on the refusal will be made.

The notice of refusal 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 permit. All decisions to refuse an application are without prejudice to filing a new application for a permit. 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.

7.0 Other Notification and Reporting Requirements

This section details other notification and reporting requirements outlined in the *Cannabis Regulations*. Appendix A: **Summary of Other Notification and Reporting Requirements** summarizes these requirements, including the frequency and manner to submit them.

7.1 Notice to local authorities

As per section 35 of the *Cannabis Regulations*, holders of licences for cultivation, processing and sale for medical purposes that authorize the possession of cannabis must provide written notice to the local authorities within 30 calendar days of the following events:

- issuance of the licence
- amendment to the licence
- suspension, reinstatement or revocation of the licence

The notice must be provided to a senior official of the following local authorities:

- the local government, as defined by the Regulations
- the local fire authority
- the local police force or Royal Canadian Mounted Police detachment that is responsible for providing policing services to that area

The notice must include:

- the name of the licence holder
- the site address on the licence

- a description of the applicable circumstances including details of any amendment if applicable
- the effective date of the circumstance

Licence holders are also required to provide a copy of the notice to Health Canada by emailing HC.licensing-cannabis-licences.SC@canada.ca. The subject of the email and the file name should indicate **Post-Licensing Notification to Local Authorities for LIC #**.

7.2 Notice of cessation of activities

Section 36 of the *Cannabis Regulations* requires that licence holders notify Health Canada of their intent to cease authorized activities 30 calendar days before the activities cease.

Notification of intent to cease conducting activities is required if the cessation will occur before or on the date the licence will expire.

The notice must include the following information:

- The date on which the activities are expected to cease
- A description of the manner in which any cannabis remaining at the site as of the date will be disposed of by the licence holder, including
 - If it will be sold or distributed, the name and address of the person to which it will be sold or distributed to
 - If it will be destroyed, the day and location of the destruction
- The location at which the licence holders' records, reports, electronic data and other documents that are required to be retained will be retained after activities have ceased
- The contact information of a person from whom further information can be obtained after activities have ceased

The **Cannabis Notice of Cessation of Activities Form** found in Appendix G should be used to provide the required information to Health Canada. Email the completed form to HC.licensing-cannabis-licences.SC@canada.ca. The subject line and the file name should indicate **Notice of Cessation of Activities for LIC #**.

The licence holder may cancel a licence through the CTLS and this should be used once the form is submitted. Regardless, Health Canada will cancel the licence after receipt of the form.

If there are further changes after activities have ceased, the licence holder must submit an updated form to Health Canada using the process outlined above. Further changes could include changes to the address of the location where the records, reports and documents are stored, or a change to the person who can be contacted for more information.

As per section 222 of the *Cannabis Regulations*, documents or information that must be retained and for which the retention period has not yet ended must continue to be retained even if the individual ceases to hold a licence.

If cannabis inventory will be sold or distributed before cessation of activities, the person it is sold or distributed to must be authorized to conduct the specified activities. For example, if they are planning to possess or sell, they must be authorized for those activities.

7.3 Record of key investors



Tip: This requirement applies to licence holders for cultivation, processing and sale for medical purposes that are not organizations whose equity securities are listed on a published market. Further definition of key investors can be found in the *Cannabis Regulations* and the [Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes](#).

Section 241 of the *Cannabis Regulations* requires that licence holders for cultivation, processing or sale for medical purposes maintain a record of key investors.

A copy of this record must be provided to Health Canada no later than January 31 of each given year. Further information on the form and manner to submit this information will be provided by Health Canada at a later date.



Tip: The licence holder must retain a copy of the key investor record for at least two years after the day on which the licence holder ceases to be required to maintain it. In addition, the record must be available at the site specified in the licence and be maintained in a manner that enables an audit of it to be made in a timely manner.

Information related to former investors must continue to be retained in the record even if the person ceases to be an investor.

Licence holders must not delete any information from the record.

7.4 Notice of new cannabis products

As per section 244 of the *Cannabis Regulations*, licensed processors must notify Health Canada of their intent to sell a cannabis product, they have not previously sold in Canada, other than cannabis plants or cannabis plant seeds. This notification must be provided to Health Canada at least 60 calendar days before making the cannabis product available for sale. Please refer to the [“Notice of New Cannabis Product Guide”](#) for more information.

7.5 Reporting information related to promotions

The *Cannabis Act* outlines general prohibitions related to promoting cannabis, cannabis accessories and services related to cannabis. The purpose of the promotion prohibitions is to protect public health and public safety, including protecting young persons and others from inducements to use cannabis. For more information on promotion prohibitions, refer to the *Cannabis Act* and [Fact Sheet: The Cannabis Act - Promotion Prohibitions](#).

As per section 245 of the *Cannabis Regulations*, all licence holders, including those with research and/or analytical testing licences, are required to provide information about their promotional activities related to cannabis, cannabis accessories or services related to cannabis. Services related to cannabis include clinics where advice may be provided, or specialized delivery services for cannabis, among others. The information that must be submitted includes the total amount of money spent in a given calendar year on promotion, categorized into (1) promotions directed

to consumers who purchase cannabis at the retail level in Canada and (2) all other promotions that are not directed to consumers who purchase cannabis at the retail level. The information must also include a description of the types of promotion on which the money was spent.



Tip: “Consumers who purchase cannabis at the retail level” are those who purchase from a retailer authorized by their province or territory as well as those who purchase directly from a licence holder authorized for sale for medical purposes.

Activities not directed at consumers who purchase cannabis at the retail level could encompass a variety of individuals or companies, such as promotions targeted to health care practitioners.

Licence holders are responsible for ensuring that their report on promotions meets all of the requirements listed under section 245 of the *Cannabis Regulations*. Large corporate entities holding multiple licences may submit a combined report on behalf of all of their licence holders; however, this document must contain separate reports for each licence number or each brand (i.e., brand element). If an individual or corporation chooses to report their promotions expenses by brand, all licence numbers associated with the brand should be clearly identified, and any non-brand specific promotions also need to be included in the report in order to fully fulfill the requirements listed under section 245 of the *Cannabis Regulations*.

This information must be provided no later than March 31 of the year following the year when the promotion occurred. Licence holders are encouraged to submit nil reports if no promotional spending occurred to demonstrate compliance with the reporting requirements and to limit the possibility of follow-up requests for information from Health Canada.

Appendix H shows an **Annual Reporting Form: Reporting Information Related to Promotions** that may be used to submit information about promotions. Completed reports should be emailed to hc.ctls-bi-sscdl-ie.sc@canada.ca with the subject line “**Promotions Reporting**” and the associated licence number or numbers.

Health Canada may request additional information related to promotions, in accordance with section 43 of the *Cannabis Act*. This could include copies of promotional materials.



Tip: The licence holder must retain a copy of the information sent to Health Canada for at least two years after the date it is sent, as well as samples or copies of any promotional materials for at least two years after the event or promotion takes place as per section 236 of the *Cannabis Regulations*. Copies of the promotional material can be requested by Health Canada under section 43 of the *Cannabis Act*.

For more information on requirements associated with the promotions prohibitions and promotions reporting, licence holders are encouraged to refer to the *Cannabis Act* and its Regulations.

Licence holders are invited to contact Health Canada at hc.ctls-bi-sscdl-ie.sc@canada.ca if they have questions regarding promotions reporting or how to complete the promotions reporting form, with the term “Promotions” in the subject line of the email.

7.6 Other reporting requirements

The *Cannabis Act* and the *Cannabis Regulations* include several additional reporting requirements for licence holders. Details on these requirements can be found in other guidance documents on the Health Canada website.

Requirement
Monthly Inventory reporting into the Cannabis Tracking System (Part 6 of the <i>Cannabis Act</i> and Cannabis Tracking System Order)
Theft or loss of cannabis (section 246 of the <i>Cannabis Regulations</i>)
Recalls (section 247 of the <i>Cannabis Regulations</i>)
Adverse reactions (section 248 of the <i>Cannabis Regulations</i>)



Tip: Health Canada has annual reporting obligations to the International Narcotics Control Board. It may request information from licence holders to meet those obligations.

8.0 Licence Suspensions and Revocations

8.1 Suspension of a licence or permit

Health Canada may suspend a licence under subsection 64(1) of the *Cannabis Act* or section 30 of the *Cannabis Regulations* without prior notice if:

- Health Canada has reasonable grounds to believe that the suspension is necessary to protect public health or public safety, including preventing cannabis from being diverted to an illicit market or activity
- An individual who is required to hold a security clearance in respect of the licence does not hold such a security clearance
- The licence holder has failed to pay a fee in relation to the licence
- The licence issued under subsection 14(1.1) of the *Excise Act*, 2001 is suspended under subsection 23(2) of that Act

Health Canada may suspend an import or export permit without prior notice if Health Canada has reasonable grounds to believe that the suspension is necessary to protect public health or public safety, including preventing cannabis from being diverted to an illicit market or activity.

Where Health Canada intends to suspend a licence or import or export permit, Health Canada issues a notice of suspension that sets out the reasons for the suspension. The suspension takes effect immediately.

Licence holders may be heard by providing Health Canada with reasons why they believe the suspension is unfounded, by emailing HC.licensing-cannabis-licences.SC@canada.ca within 10 days of receipt of the notice. If the reasons for the suspension no longer exist or the licence holder provides sufficient information and evidence that might demonstrate that the suspension was unfounded, Health Canada may reinstate the licence or permit.

8.2 Revocation of a licence or permit

Health Canada may revoke a licence or permit under a number of circumstances as set out in section 65 of the *Cannabis Act*. Where Health Canada proposes to revoke a licence or permit, Health Canada sends a notice in writing that includes the reasons for the proposed revocation and provides the licence or permit holder with an opportunity to be heard.

9.0 Contact Us

For questions related to a specific licence application, email HC.licensing-cannabis-licences.SC@canada.ca and indicate the application file number, the applicant name and the subject of the correspondence in the subject line of the email. Requests for a meeting or teleconference will be evaluated on a case-by-case basis.

For general questions about the *Cannabis Act* and its Regulations, outside of a specific application but including those related to the CTLS, email cannabis@canada.ca or contact Health Canada by phone at 1-866-337-7705.

10.0 Feedback – Help Us Improve

Health Canada is committed to providing all stakeholders with timely, accurate and reliable information. This includes providing applicants and licence holders with the information they need to comply with the *Cannabis Act* and its Regulations.

We would appreciate receiving your feedback on whether this guide was useful, and we welcome your suggestions for improvement. Email your feedback to us at cannabis@canada.ca and indicate in the subject line: **“Feedback on Cannabis Licence Management Guide.”**

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

Appendix A: Summary of Other Notification and Reporting Requirements

This table summarizes the other notification and reporting requirements outlined in this guide. It does not include notifications regarding a licence under section 34 of the *Cannabis Regulations*; these are detailed in **Table 1: Changes to a cannabis licence**.

Table 6: Summary of notification and reporting requirements (as outlined in section 7 of this guide)		
Requirement (section of the <i>Cannabis Regulations</i>)	Frequency	Form and manner
Notice to local authorities (section 35)	Within 30 days of licence issuance, amendment, suspension, reinstatement or revocation	Email copy of notice to: HC.licensing-cannabis-licences.SC@canada.ca
Notice of cessation of authorized activities (section 36)	Within 30 days of intent to cease activities	Email Appendix G to: HC.licensing-cannabis-licences.SC@canada.ca
Record of key investors (section 241)	Annually, no later than January 31	Email information to: HC.licensing-cannabis-licences.SC@canada.ca
Notice of new cannabis products (section 244)	At least 60 days prior to making a new cannabis product available for sale	Refer to Notice of New Cannabis Product Guide
Reporting information related to promotions (section 245)	Annually, no later than March 31 of the year following the year when the promotion took place	Email Appendix H to: hc.ctls-bi-sscdl-ie.sc@canada.ca
Organizational security plan (sections 34 and 45)	At Health Canada's request and within 5 days of making a change to the plan	Email updated organizational security plan to: HC.licensing-cannabis-licences.SC@canada.ca
Monthly inventory reporting from cannabis licence holders (cultivators, processors and medical sales)	No later than the 15th of each month for the previous month	Refer to additional guidance documents on reporting requirements and procedures on the Health Canada website .
For other reporting requirements, such as on theft or loss, recalls, and adverse reactions, refer to the <i>Cannabis Regulations</i> and other guidance listed in section 7.6 of this guide.		

Appendix B: Cannabis Licence Attestation Form

This form must be included as part of the licence amendment applications referred to in section 2 of this form. The completed form should be uploaded in the Record Keeping Description section of the CTLS in the application.

Please see details in section 5.0 of the Licence Management Guide for other information required to assess the change.

SECTION 1: Administrative information	
Name of licence holder:	
Licence number:	
Responsible person name:	Contact details (email and phone number):

SECTION 2: Change being requested	
Change requiring Health Canada approval	<input type="checkbox"/> Change to the name of the licence holder <input type="checkbox"/> Change to the address of the site, or building within the site, where the activity is authorized <input type="checkbox"/> Change to the authorized activity at the site (e.g., addition of licence for cultivation, a licence for processing, or a licence for sale for medical purposes) or a change to the authorized activities that may be conducted at each building within the site. <input type="checkbox"/> Change to Quality Assurance Person <input type="checkbox"/> Change to the site plan that would require physical security measures to comply with Part 4 of the <i>Cannabis Regulations</i> of the following types: <ul style="list-style-type: none">• Addition of new building (e.g., adding a new building within the approved site perimeter);• Addition of a new storage area (e.g., adding a new storage area within an approved building);• Modification to an approved building in a manner that does affect the

	<p>site perimeter (e.g., addition of a new gate in a site perimeter fence or new exterior door in a building [where the building envelope is the site perimeter]);</p> <ul style="list-style-type: none"> • Addition or change to site perimeter (e.g., adding a new fence as the site perimeter when the site perimeter was previously the building envelope). <p>NOTE:</p> <ul style="list-style-type: none"> • Submit a completed Appendix J form for all other changes to site plan that would require physical security measures to comply with Part 4 of the <i>Cannabis Regulations</i>. • Submit a completed Appendix I form for an application to amend a licence to add sale of classes of cannabis.
Description of change	

SECTION 3: Attestation by responsible person

I hereby attest that all of the information provided is correct and complete to the best of my knowledge. By submitting the information in the CTLS, I attest that all changes are reflected on this form and no other changes have been made in the system.

Name of responsible person (print)	
Signature of responsible person	
Date	

Appendix C: Notification Attestation Form

This form must be emailed to Health Canada as notification of a change, as outlined in section 34 of the *Cannabis Regulations*.

Notifications related to **cultivation, processing and sale for medical purposes licences** should be sent to HC.licensing-cannabis-licences.SC@canada.ca.

Changes related to the responsible person should be submitted as a licence amendment application in the CTLS with this form being uploaded in the Record Keeping Description section of the CTLS in the application.

SECTION 1: Administrative information	
Name of licence holder:	
Licence number:	
Responsible person name:	Contact details (email and phone number):

SECTION 2: Change requiring notification
<input type="checkbox"/> Change to the mailing address, telephone number, email address or the facsimile number of the licence holder
<input type="checkbox"/> Change to the site plan that does not require physical security measures to comply with Part 4 of the <i>Cannabis Regulations</i> . For example: <ul style="list-style-type: none">○ Adding or upgrading visual monitoring recording devices, intrusion detection devices or alarm systems or relocating them, as long as the security in the area is not reduced;○ Replacing barriers (e.g., replacing a pre-existing door in an approved space, replacing a perimeter fence door or adding/upgrading access control devices);○ Upgrading equipment, such as the air filtration or other systems.
<input type="checkbox"/> Replacing an individual who must hold a security clearance referred to in any of paragraphs 50b) to g), 50i) and j) of the <i>Cannabis Regulations</i> , or adding another such individual,

other than an individual who is designated as an alternate for the position of quality assurance person referred to in section 19 of the *Cannabis Regulations*

A change to the organizational security plan

Description of change	
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SECTION 3: Attestation by responsible person

I hereby attest that all of the information provided is correct and complete to the best of my knowledge. By submitting the information through electronic mail, I attest that all changes are reflected on this form and no other changes requiring notification have been made at the site.

Name of responsible person (print)	
Signature of responsible person	
Date	

Appendix D: Application for Permit to Import Cannabis for Medical or Scientific Purposes

This form should be used to apply for a permit to import cannabis for medical or scientific purposes under the *Cannabis Regulations*. Email the completed form to HC.import-export-cannabis-importation-exportation.SC@canada.ca. The subject of the email and the file name should indicate **Import Permit Application Form and the LIC#**.

SECTION 1: Licence holder information	
Name of licence holder	
Mailing address	
Licence number	

SECTION 2: Transit details	
Name of exporter	
Country of export	
Address details	
Port of entry in Canada	
Address of customs office to which shipment is to be delivered	
Each mode of transportation used	
Any country of transit or transshipment, if applicable	

SECTION 3: Shipment details

Anticipated shipment date, if known	
Description of cannabis product form (e.g., extract/oil, seeds, plants) and description of the packaging if applicable	
Detailed description of the intended use of cannabis (i.e., what the imported product will be used for). <i>This information may be provided as an annex to this application.</i>	
Brand name, if applicable	
Quantity of cannabis	
The percentage of THC w/w and CBD w/w of the cannabis, except in the case of cannabis plants and cannabis plant seeds	

SECTION 4: Attestation by responsible person

I hereby attest that all of the information submitted in support of the application is correct and complete, to the best of my knowledge and that any imported cannabis is for medical or scientific purposes only. I attest that the shipment of this product will not contravene the laws of the country or countries of transshipment, if applicable.	
Name of responsible person	
Signature	
Date	

Appendix E: Application for Permit to Export Cannabis for Medical or Scientific Purposes

This form should be used to apply for a permit to export cannabis for medical or scientific purposes under the *Cannabis Regulations*. Email the completed form to HC.import-export-cannabis-importation-exportation.SC@canada.ca. The subject of the email and the file name should indicate **Export Permit Application Form and the LIC #**.

SECTION 1: Licence holder information	
Name of licence holder	
Mailing address	
Licence number	

SECTION 2: Transit details	
Name of importer	
Country of import	
Address details	
Port of exit from Canada	
Address of customs office, sufferance warehouse or bonded warehouse to which shipment is to be delivered, if applicable	
Each mode of transportation used	
Any country of transit or transshipment, if applicable	

SECTION 3: Shipment details

Anticipated shipment date, if known	
Description of cannabis product form (e.g., extract/oil, seeds, plants) and description of the packaging if applicable	
Intended use of cannabis including a detailed description of what the exported product will be used for. <i>This information may be provided as an annex to this application.</i>	
Brand name, if applicable	
Quantity of cannabis	
The percentage of THC w/w and CBD w/w of the cannabis, except in the case of cannabis plants and cannabis plant seeds	

SECTION 4: Competent authority authorization

Attach the import permit from the competent authority in the country of import

SECTION 5: Attestation by responsible person

I hereby attest that all of the information submitted in support of the application is correct and complete, to the best of my knowledge and that any exported cannabis is for medical or scientific purposes only.

Name of responsible person	
Signature	
Date	

Appendix F: Cannabis Shipment Detail Notification Form

This form should be used to notify Health Canada within 15 days after the release of a shipment of cannabis in Canada or the export of a shipment of cannabis for medical or scientific purposes under the *Cannabis Regulations*. Email the completed form to HC.import-export-cannabis-importation-exportation.SC@canada.ca. The subject line of the email and the file name should indicate **Import/Export Notification of Shipment, the permit number and the LIC #**.

SECTION 1: Import/export shipment details	
Name of licence holder	
Licence number	
Permit type	<input type="checkbox"/> Import permit <input type="checkbox"/> Export permit
Import or export permit number	
Date shipment released/exported	
Description of the cannabis	
Intended use of the cannabis	
Brand name, if applicable	
Quantity of cannabis	
The percentage of THC w/w and CBD w/w of the cannabis, except in the case of cannabis plants and cannabis plant seeds	

SECTION 2: Attestation by responsible person

I hereby attest that all of the information submitted in support of the form is correct and complete, to the best of my knowledge.

Name of responsible person	
Signature	
Date	

Appendix G: Notice of Cessation of Cannabis Activities Form

This form should be used to notify Health Canada of a licence holder’s intent to cease all cannabis activities authorized by a licence. As required by the *Cannabis Regulations*, notification is required 30 calendar days before the activities cease. The completed form should be emailed to HC.licensing-cannabis-licences.SC@canada.ca. The subject line and the file name should indicate **Notice of Cessation of Cannabis Activities and the LIC #**.

SECTION 1: Administrative information	
<input type="checkbox"/> New notice of cessation of activities <input type="checkbox"/> Update to previously submitted information about cessation of activities (To update previously submitted information, outline the updates in the appropriate section of this form).	
Name of licence holder:	Licence number:
SECTION 2: Required information	
Date on which activities are expected to cease:	
Responsible person	
Describe how any cannabis remaining at the site will be disposed of:	
Total quantity of cannabis remaining on site as of date of cessation	_____
Will any cannabis remaining on site be sold or distributed, in whole or in part?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes:

	Name and address of the person to whom it will be sold or distributed: _____ Quantity to be sold or distributed: _____
Will any cannabis be destroyed in whole or in part?	<input type="checkbox"/> Yes <input type="checkbox"/> No If yes: Date when the destruction is to take place: _____ Location where destruction will take place: _____ Quantity to be destroyed: _____
Other information	
Address where the licence holder's records, reports, electronic data and other documents that are required to be retained under the <i>Cannabis Act</i> will be retained after activities have ceased	
Person from whom Health Canada may obtain further information after activities have ceased	
Name	
Address	
Telephone Facsimile if applicable	
Email	

SECTION 3: Attestation by responsible person

I hereby attest that all of the information provided in this report is correct and complete, to the best of my knowledge.

Full name of responsible person	
Signature of responsible person	
Date	

Appendix H: Annual Reporting Form: Reporting Information Related to Promotions

Information reported should only include information for the previous calendar year (January 1-December 31), with the format based on the attached forms below. Once completed, the forms should be emailed to hc.ctls-bi-sscdl-ie.sc@canada.ca no later than March 31. The subject line should contain the heading “Promotions Reporting” and include the affiliated licence number or numbers. Licence holders are encouraged to submit nil reports if no promotional spending occurred to demonstrate compliance with the reporting requirements. This will limit any follow-up Health Canada may need to undertake in order to confirm this aspect.

SECTION 1: Licence holder information	
Name of parent company (if applicable)	
Name of licence holder(s)	
Licence number(s)	
Brand name (i.e., brand element, if reporting by brand)	

SECTION 2: Cannabis		
	Promotions Directed to Consumers	Promotions Not Directed to Consumers
Total Amount Spent (\$)		

Description of the types of promotional activities	Expand the field as necessary.	Expand the field as necessary.
--	--------------------------------	--------------------------------

SECTION 3: Cannabis accessories		
	Promotions Directed to Consumers	Promotions Not Directed to Consumers
Total Amount Spent (\$)		
Description of the types of promotional Activities and materials	Expand the field as necessary.	Expand the field as necessary.

SECTION 4: Services related to cannabis		
	Promotions Directed to Consumers	Promotions Not Directed to Consumers
Total Amount		

Spent (\$)		
Description of the types of promotional activities	Expand the field as necessary.	Expand the field as necessary.

SECTION 5: Expenditures by province – cannabis, cannabis accessories and services related to cannabis	
	Expenditures (\$CAD)
National Spending	
Alberta	
British Columbia	
Manitoba	
New Brunswick	
Newfoundland and Labrador	
Northwest Territories	
Nova Scotia	
Nunavut	
Ontario	

Prince Edward Island	
Quebec	
Saskatchewan	
Yukon	
Total	

Please note that under section 236(c) of the *Cannabis Regulations*, all licence holders are obliged to retain “a sample or copy of any promotional materials for at least two years after the last day on which the promotion in question takes place,” and that copies of the promotional material can be requested by Health Canada under s. 43 of the *Cannabis Act*.

SECTION 6: Attestation by responsible person

I hereby attest that all of the information submitted in support of the report is correct and complete, to the best of my knowledge.

Name of responsible person	
Signature	
Date	

Appendix I: Application to Amend a Licence to Add Sale of Classes of Cannabis

Important Information:

By submitting this application, **processing** licence holders are applying to have their licence amended. If an amendment is issued, the licence holder will be authorized to sell cannabis products that are **(1) dried cannabis and/or fresh cannabis, (2) cannabis topicals, and/or (3) cannabis extracts and/or edible cannabis** to provincially and territorially authorized retailers and/or holders of a licence for sale for medical purposes.

If you are interested in selling cannabis products to clients for medical purposes, you must apply for a licence for sale for medical purposes through the Cannabis Tracking and Licensing System (CTLS).

An inspection by Health Canada may be required prior to approval of a request to amend a licence.

A licensed processor must notify Health Canada of any new cannabis products that they intend to sell (except for cannabis plants or cannabis plant seeds) at least 60 days before making that new product available for sale (as is required by section 244 of the *Cannabis Regulations*).

Based on the class(es) of cannabis being requested, submit documentation for the following number of representative lots/batches of cannabis products (i.e. packaged and labelled for sale to a consumer at the retail level):

Class(es) of Cannabis Requested	Number of Representative Lots/Batches Required	Class(es) of Cannabis Authorized to Sell
Dried cannabis and/or fresh cannabis	2 lots of dried cannabis or 2 lots of fresh cannabis	Dried cannabis and fresh cannabis
Cannabis topical	2 lots of cannabis topical	Cannabis topical
Cannabis extract and/or edible cannabis	2 lots of cannabis extract or 2 lots of edible cannabis	Cannabis topical, cannabis extract and edible cannabis
Dried cannabis and/or fresh cannabis and cannabis topical	2 lots of dried cannabis or 2 lots of fresh cannabis and 2 lots of cannabis topical	Dried cannabis, fresh cannabis and cannabis topical
Dried cannabis and/or fresh cannabis and cannabis extract and/or edible cannabis	2 lots of dried cannabis or 2 lots of fresh cannabis and 2 lots of cannabis extract or 2 lots of edible cannabis	Dried cannabis, fresh cannabis, cannabis topical, cannabis extract and edible cannabis
Dried cannabis and/or fresh cannabis and cannabis topical and cannabis extract and/or edible cannabis	2 lots of dried cannabis or 2 lots of fresh cannabis and 2 lots of cannabis extract or 2 lots of edible cannabis	Dried cannabis, fresh cannabis, cannabis topical, cannabis extract and edible cannabis
Cannabis topical and cannabis extract and/or edible cannabis	2 lots of cannabis extract or 2 lots of edible cannabis	Cannabis topical, cannabis extract and edible cannabis

Instructions:

1. Complete all sections (A, B, C **and** D) of the attached form.
2. Email the completed form and documentation as attachments to HC.licensing-cannabis-licences.SC@canada.ca with subject line “**Application to Amend Licence to Sell Cannabis Classes for LIC-XXXXXXXX-20XX**”.

Note: If you have an existing amendment in progress in CTLS, do not withdraw the existing amendment application and re-submit with new information as it may delay the processing of your application and may result in your application being moved to the bottom of the queue. Please do not submit this application in CTLS.

SECTION A: LICENCE HOLDER INFORMATION

Name of Licence Holder:

LIC Number:


SECTION B: GENERAL INFORMATION

An amendment to the licence is sought to authorize the licence holder to sell the following class(es) of cannabis:

- Dried Cannabis and/or Fresh Cannabis
- Cannabis Topicals
- Cannabis Extracts and/or Edible Cannabis

Specify the cannabis product form(s) (e.g., capsules, pre-rolls, lotions, baked goods):

SECTION C: APPLICATION REQUIREMENTS (DOCUMENTATION)

 Licence holders are expected to meet **all** applicable regulatory requirements including but not limited to packaging, labelling and good production practices. Please provide the following documents to demonstrate your compliance with the *Cannabis Regulations*:

- Evidence and justification that the lots/batches of cannabis products (i.e., packaged and labelled for sale to a consumer at the retail level) are representative of full-scale production runs at the site (e.g., packaging records, photos, etc.).
Note: Please refer to the table in the “Important Information” section for the number of representative lots/batches that documentation must be submitted for.
- Documentation (e.g., lot or batch approval standard operating procedure(s), completed release form(s), etc.) indicating that the Quality Assurance Person (QAP) has ensured the quality of the cannabis prior to the approval and release of the representative lots/batches.
- Certificate(s) of Analysis results for the representative lots/batches.
- The analytical testing specifications that the lots/batches have been assessed against. This should include the name of the selected publication(s) referred to in Schedule B of the *Food and Drugs Act* and the tolerance limits.



The information you provide must accurately reflect your site. In the case that an inspection is required and the Health Canada Inspector finds the cannabis product(s), SOPs and/or documentation to be significantly different than what was provided and reviewed for this application, the inspection may be terminated and your application may be refused. In such a case, you will be required to submit a new amendment application. This will add a minimum of 6-8 weeks to the processing of your application.

SECTION D: ATTESTATION

I, the undersigned, attest that in relation to at least two representative lots or batches of cannabis products that contain cannabis of a class in respect of which this amendment is sought:

- The site continues to meet all applicable physical security requirements under Part 4 of the *Cannabis Regulations*.
- All Standard Operating Procedures (SOPs) are designed to ensure that production, packaging, labelling, distributing, storing, sampling and testing of cannabis are conducted in accordance with the requirements of Part 5 and Part 6 of the *Cannabis Regulations* (section 80). In addition, SOPs have been established and implemented and will be available for inspection.
- The sanitation program has been updated to include processes associated with any new cannabis products (section 87).
- Validated methods were used to conduct the required analytical testing on a representative sample of the two representative lots or batches (section 92).
- All applicable testing has been completed as per Part 5 and Part 6 of the *Cannabis Regulations*. A minimum of two lots/batches of product is packaged and labelled for sale to a consumer at the retail level in an amount representative of full-scale production runs at the site.
- The analytical test results for the two lots/batches will be available at the site for inspection.
- The Quality Assurance Person will ensure that all cannabis is approved prior to being made available for sale (section 88).
- The immediate container(s) meets the requirements of a child resistant package under subsections C.01.001 (2) to (4) of the *Food and Drug Regulations* (paragraph 108(e)).
- The product label(s) meets all applicable labelling requirements under Part 7 of the *Cannabis Regulations*.
- All applicable record keeping requirements under Part 11 of the *Cannabis Regulations* will continue to be met.
- The products are not intended to be used in the area of the human eye and on damaged or broken skin or to penetrate the skin barrier other than by absorption.
- For cannabis **topicals**, the products must meet the requirements of Part 6 (e.g., must not contain or have on it anything that may cause injury to the health of the user when the cannabis product is used as intended or in a reasonably foreseeable way).
- For cannabis **extracts**, the products meet the requirements of Part 6 (e.g., products are not represented for use, directly or indirectly, on external body surfaces including hair and nails).
- For **edible cannabis**, the products meet the requirements of Part 6 (e.g., does not contain any ingredients other than

food and food additives that are compliant with subsection 102(5), does not contain meat products, poultry products or fish unless compliant with subsection 102(3), does not have a poisonous or harmful substance in it or on it and is not adulterated and does not contain caffeine or ethyl alcohol unless in accordance with the regulations).

- I am aware that the above attestations are not an exhaustive list of the requirements for conducting activities with cannabis.
- All information provided in this document is accurate.

Responsible Person Name (Printed):

Responsible Person Name (Signature):

Date:

Appendix J: Application for Approval of a Change to the Site Plan

Important Information:

Licence holders are asked to use this form when applying for the approval of the following change(s) to the site plan for their licensed site, as per section 33 of the *Cannabis Regulations*.

Changes to site	Examples
Adding a grow or operations area within an approved site	<ul style="list-style-type: none">• adding a new indoor or outdoor cultivation area within an approved site perimeter• adding a new operations area within an existing approved building
Modifying an approved grow or operations area	<ul style="list-style-type: none">• dividing an operations area into separate areas• converting an approved grow area into an operations area
Modifying an approved storage area	<ul style="list-style-type: none">• adding a new door to an approved storage area• modifying the physical security features of the area that surrounds an approved and existing storage area (section 67)
Modifying an approved building in a manner that does not affect the site perimeter	<ul style="list-style-type: none">• adding a new exterior door on an existing building when the site perimeter is not the building envelope• adding an expansion to an approved building

This form **does not** apply to the following site changes:

- Adding or modifying the approved site perimeter
- Adding a new building or modifying an approved building in a manner that affects the site perimeter
- Adding a new storage area within an approved building

Licence holders should continue to use “Appendix B: Cannabis Licence Attestation Form” found in the *Cannabis Licence Management Guide* for these types of changes.

Site plan changes that are submitted for approval must be built and ready for operation before the application is submitted. **Please note that activities with cannabis, or in some cases new activities with cannabis cannot be conducted within the areas until approval is granted by Health Canada.**

Health Canada may request that the licence holder submit additional information in support of this amendment application.

NOTE: Only some of the regulatory requirements will be assessed at the time of application, however compliance may be verified at any time by Health Canada. Refer to the *Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes*, the *Physical Security Measures for Cannabis* and the *Good Production Practices Guide for Cannabis* for more information on how to meet the applicable requirements of the *Cannabis Regulations*.

Instructions:

1. Complete sections **A**, **B**, and **C** of this form.
2. Complete section **D** of the attached form if you are a **standard cultivation, standard processing** and/or **sale for medical purposes** licence holder.
3. Complete section **E** of the attached form if you are a **micro cultivation, nursery** and/or **micro processing** licence holder.
4. Create an amendment application in the Cannabis Tracking and Licensing System (CTLS).
5. Upload this completed form along with the site plan (refer to section C of this form for details) under the “Record Keeping Description” section in the CTLS.

SECTION A: LICENCE HOLDER INFORMATION	
Name of Licence Holder:	LIC Number:

SECTION B: DESCRIPTION OF CHANGE
<p>An application for approval of a change to the site plan under section 33 of the <i>Cannabis Regulations</i> is sought for:</p> <p><input type="checkbox"/> Addition of a new grow or operations area</p> <p><input type="checkbox"/> Modification of an approved grow or operations area</p> <p><input type="checkbox"/> Modification of an approved storage area</p> <p><input type="checkbox"/> Modification of an approved building in a manner that does not affect the site perimeter</p> <p>Please provide a detailed description of the proposed changes in the space provided below.</p> <ul style="list-style-type: none"> • In the case where you are adding a new grow or operations area, please provide the following: <ul style="list-style-type: none"> ○ Details of the name and location of the new area(s) ○ Activities that will be conducted in the new area(s) • In the case where you are modifying an approved grow, operations and/or storage area or building,

please provide the following:

- Details of the name and location of the modified area(s)
- Description of how the area(s) have been modified including the impact to the physical security requirements
- Activities that will be conducted in the modified area(s)



Each outdoor area (if applicable) and indoor area (building or part of building) including rooms affected by the change, must be named and this name must be provided. The names used to identify each area must match all other information submitted (e.g., on the site plan and within the “Site Details” section of the CTLS).

If insufficient space, attach a separate sheet signed and dated by the responsible person.

SECTION C: APPLICATION REQUIREMENTS

Please provide the following document(s) to demonstrate your compliance with the *Cannabis Regulations*:

- Updated site plan (including applicable floor plans) with all changes highlighted and security measures identified.

In the case where you are modifying an approved building or adding a new or modifying an approved outdoor cultivation area, please ensure the following is included in your site plan:

- The perimeter of the site must be clearly identified.
- The footprint of any building(s) must be clearly identified.
- The location of any outdoor cultivation area(s) must be clearly identified (indicate the latitude and longitude coordinates for all corners of any outdoor areas).
- The locations of, and area covered by, the security devices and visual monitoring devices for the site perimeter and any outdoor cultivation area as applicable.
- All security devices must be clearly identifiable and uniquely labelled.
- In the case of micro cultivation and nursery licences, the respective surface areas on the site plan to demonstrate how the site meets the surface area threshold must be delineated.

In the case where you are adding a new or modifying an approved grow or operations area or modifying an approved storage area, please ensure the following is included in your site plan, including applicable floor plans:

- Clear delineation of rooms where operations, grow and storage activities, as applicable, take place.
- Clear identification of storage area(s) and the area(s) it is located within that meet the requirements of section 67 of the *Cannabis Regulations* as applicable.
- The locations of an area covered by the security devices and visual monitoring devices as they relate to any operations area (including grow areas) and storage areas, as applicable.
- All security devices must be clearly identifiable and uniquely labelled.
- Cannabis flow between the rooms must be identified.
- In the case of micro cultivation and nursery licences, the respective surface areas on the floor plans to demonstrate how the site meets the surface area threshold must be delineated.

SECTION D: ATTESTATION FOR STANDARD CULTIVATION, STANDARD PROCESSING AND SALE FOR MEDICAL PURPOSES LICENCE HOLDERS

I, the undersigned, attest that in relation to the proposed site plan changes of which this amendment is sought:

- The site continues to meet all applicable physical security requirements under Part 4 of the *Cannabis Regulations*, including but not limited to:
 - For operations areas, including grow areas, and storage areas, restricted access, physical barriers, visual monitoring, visual monitoring devices and the intrusion detection system(s), including monitoring and response, are sufficient to meet the requirements of sections 68 to 73 of the *Cannabis Regulations*.
 - If applicable, all storage areas continue to be located **within an area** that meets the requirements of section 67 of the *Cannabis Regulations* and a record is maintained of every individual entering or exiting the area (subsection 68(2)).
- Authorized activities with cannabis are only being conducted in operations areas, including grow areas, and storage areas that are approved by Health Canada as described in application(s) to Health Canada and through the CTLS.
- The organizational security plan has been updated to reflect the proposed site plan changes and a notification has been submitted to Health Canada.
- The good production practices in place for the proposed site plan changes continue to meet all applicable requirements under Part 5 of the *Cannabis Regulations*.
- The proposed changes to the site plan have been built and are ready for operation.
- The proposed changes to the site plan do not affect the site perimeter.
- All applicable record keeping requirements under Part 11 of the *Cannabis Regulations* will continue to be met.
- I am aware that the above attestations are not an exhaustive list of the requirements for conducting activities with cannabis.
- All information provided in support of this application is correct and complete to the best of my knowledge.

Responsible Person Name (Printed):

Responsible Person Name (Signature):

Date:

SECTION E: ATTESTATION FOR MICRO CULTIVATION, NURSERY, AND MICRO PROCESSING LICENCE HOLDERS

I, the undersigned, attest that in relation to the proposed site plan changes of which this amendment is sought:

- The site continues to meet all applicable physical security requirements under Part 4 of the *Cannabis Regulations* including but not limited to:
 - The site is designed in a manner and is surrounded by a physical barrier that prevents unauthorized access.
 - If applicable, the storage area(s) are surrounded by a physical barrier that prevents unauthorized access and access to each area is restricted to individuals whose presence in the area is required by their duties.
- Authorized activities with cannabis are only being conducted in operations areas, including grow areas, and storage areas that are approved by Health Canada as described in application(s) to Health Canada and through the CTLS.
- The organizational security plan has been updated to reflect the proposed site plan changes and a notification has been submitted to Health Canada.
- The good production practices in place for the proposed site plan changes continue to meet all applicable requirements under Part 5 of the *Cannabis Regulations*.
- The proposed changes to the site plan have been built and are ready for operation.
- The proposed changes to the site plan do not affect the site perimeter.
- All applicable record keeping requirements under Part 11 of the *Cannabis Regulations* will continue to be met.
- I am aware that the above attestations are not an exhaustive list of the requirements for conducting activities with cannabis.
- All information provided in support of this application is correct and complete to the best of my knowledge.

Responsible Person Name (Printed):

Responsible Person Name (Signature):

Date: