

## Summary of Changes

August 30, 2019

Table: Changes to the Cannabis Licence Management Guide: Cultivation, Processing and Sale for Medical Purposes (August 30, 2019 version)

Management Guide Section	Change
<b>Title</b>	Change in title to reflect the removal of the analytical testing and research testing licences from this guide.
<b>1.0 Purpose</b>	Addition of note that the Guide provides information to holders of licences authorizing cultivation, processing and sale for medical purposes to reflect the fact that information on the analytical testing and research testing licences has been removed from this guide and will be henceforth the subject of a separate guidance document.
	Addition of an “Important” box to clarify that this guide is to be used for information purposes only until October 17, 2019.
<b>2.0 Background</b>	Removal of note that licences are issued by Health Canada ‘after applicants have demonstrated that they comply with the requirements in the Act and Regulations’ as Health Canada considers the entire application within the framework of the Act and Regulations, and not just an applicant’s ability to demonstrate their compliance.
	Addition of note that the CTLS can be used for amendment applications and licence renewal applications along with licence applications and security clearance applications.
<b>3.0 Scope</b>	Addition of note that this guide only applies to holders of a licence for cultivation, processing and sale for medical purposes and that it does not apply to holders of a hemp, analytical testing, research or cannabis drug licences.
	Removal of note that this guide provides guidance on notices of new cannabis products (also known as new product notifications) as this is no longer in the scope of this guide.
	Addition of note that information on new product notifications can be found in the new Notice of New Cannabis Product Guide.
	Addition of the guidance documents for physical security measures and good production practices in the list of the additional guides found on the Health Canada website.
	Changed the version of the CTLS which the guide is based on.
<b>4.0 Definitions and Abbreviations</b>	Addition of definition of cannabis extract, cannabis topical, edible cannabis, dried cannabis, fresh cannabis and cannabis plant.
	Addition of definition of ingredient.
	Addition of CBD, CBDA, THC and THCA in the list of abbreviations.
<b>4.3 Icons</b>	Changed colours of “Tip” boxes to align with all other Health Canada guidance documents and webpages.
<b>5.0 Licence Renewals and Changes</b>	Addition of note to refer to section 5.1 for information on licence renewals.
	Removal of “section 24” as a change requiring approval as it relates to a change in the head of laboratory. This is a change for holders of an analytical testing licence and is no longer in the scope of this guide. A new licence management guide specific to holders of a licence for analytical testing will be released in the future.
	Removal of note regarding how both changes requiring approval and notification must be submitted to Health Canada, and instead this information is provided in Table 1 for ease of reference.



	Addition of a note that for the purposes of this guide the application for of a new licence (cultivation, processing or sale for medical purposes) at an existing licensed site is also considered a change requiring approval.
	Changed description of Table 1 to state that it lists ‘some examples’ of the types of changes that may be made, to clarify that the table is not an exhaustive list.
	Table 1: Changed header of table to refer to section 5.3 for more information on changes requiring notification.
	Table 1: Addition of new column “Submission method” to indicate how each type of change should be submitted to Health Canada.
	Table 1: Removal of the change in the head of laboratory as an example of a personnel change, as this is a change for holders of an analytical testing licence which is no longer in the scope of this guide. A new licence management guide specific to holders of a licence for analytical testing will be released in the future.
	Table 1: Created a new row for a change to the responsible person as this change type requires a submission in the CTLS versus other changes in personnel which are to be submitted via email.
	Table 1: Provided greater clarity in what is considered a change to a site plan requiring physical security measures and examples.
	Table 1: Included examples for what a change to the organization security plan could entail.
<b>5.1 Licence renewals</b>	Table 1: Included further information on what a change to the conditions on a licence would entail.
	Provided additional information on how to apply for and submit an application for licence renewal in the CTLS.
	Addition of the additional information that Health Canada may request during the licence renewal process.
	In the “Important” box clarified the process for submitting licence change requests at the same time as a licence renewal.
	Addition that Health Canada will now verify that the licence holder has not been convicted of an offence under the <i>Safe Food for Canadians Act</i> as a part of the licence renewal.
	Removal of note that once Health Canada confirms that all requirements have been met, the renewed licence is issued. Subsection 62(7) of the <i>Cannabis Act</i> lists other reasons the Minister may refuse to renew a licence.
<b>5.2 Changes requiring approval by Health Canada</b>	Addition of a note to highlight that applications to amend a licence to add the sale of classes of cannabis is the only change requiring approval that must be submitted outside of the CTLS.
	Provided additional clarity on how to interpret the status reasons regarding the amendment application status as shown in the CTLS. Clarified that there are three categories in the CTLS which denote the status of an application and provided an explanation of what each means.
	Removal of note in the “Important” box that a change to cannabis licence attestation form must be uploaded for every amendment application. This form is no longer required for all amendments.
	Addition of new “Tip” box to clarify the process surrounding personnel changes requiring approval and their associated security clearance applications.
	Table 2: Removal of ‘amendment application required’ in the header of the table. This no longer reflects the contents of the table as certain changes indicated in the table do not require an amendment application to be submitted in CTLS .

	Table 2: Throughout the table added information on which form is required to be either uploaded into the CTLS or sent via email to Health Canada for each amendment type.
	Table 2: Throughout the table provided greater clarity for each amendment type for what information is required to be uploaded and in which area in the CTLS this information is to be uploaded.
	Table 2: Created a new row for a change to the name of a licence holder if the licence holder is an individual. This was done to help clarify what is required for a change in the licence holder for a corporation versus an individual.
	Table 2: Included a new requirement to submit the documentation associated with a legal name change when submitting a change to the name of the licence holder (when the licence holder is an individual).
	Table 2: Throughout the table included the addition of the applicable sections to refer to in the Cannabis Licensing Application Guide for further information on the details to be included with the application.
	Table 2: Included note that an application for a new cultivation, processing and sale for medical purposes licence at a licensed site is considered to be a change to an authorized activity at the site.
	Table 2: Included new requirement for the QAP to submit details of their qualifications with Part 6 of the <i>Cannabis Regulations</i> .
	Table 2: Split the row containing the requirements for a change to the site plan requiring physical security measures into 2 rows. This change was done to clarify the requirements for the specific types of changes that may be made to a site plan.
	Table 2: Provided additional information on the requirements for submission for a change to the conditions on a licence. This amendment type was changed to a 'change to amend the licence to add the sale of a new class of cannabis' to more accurately reflect the change request.
	In the "Important" box, added a note that the information submitted in the amendment application in the CTLS must also match the information provided on the Application for Approval of a Change to the Site Plan if applicable.
	Included a note that an amendment requesting a change to the site plan must be approved by Health Canada before activities with cannabis can be conducted in the proposed areas.
	In the "Tip" box changed the example given for what is not considered an amendment to better reflect the cannabis classes for the new amended regulations.
<b>5.3 Changes requiring notification to Health Canada</b>	Removal of the note regarding changes related to analytical testing and research licences to reflect the removal of the analytical testing and research testing licences from this guide.
	Table 3: Throughout the table added the reference to the appendix for each form which is required to be completed for the notification.
	Table 3: Addition of a note that individuals who have been identified to fill a role listed in section 50 of the <i>Cannabis Regulations</i> must hold a security clearance prior to occupying the position.
	Addition of a new "Tip" box to clarify the process surrounding personnel changes requiring approval and their associated security clearance applications.
<b>5.4 Multiple changes</b>	Addition of a note that any other applicable forms must be uploaded along with the Cannabis Attestation Form for multiple amendment requests.
<b>5.6 Requests for more information</b>	Removal of the specific circumstances for which Health Canada may refuse to issue, renew or amend a licence as these are outlined in the applicable provisions of the Act and regulations.

<b>and refusal to issue</b>	Changed the 30 day timeframe for which the licence holder has to respond after Health Canada sends a notice of intent to refuse to state that Health Canada will provide the timeframe within which to respond when the notice is sent to allow for greater flexibility.
<b>6.1 Applications for an import or export permit for medical or scientific purposes</b>	Table 5: Corrected the required details to include on the import and export application. The name and address of the importer and exporter was previously captured incorrectly.
<b>6.3 Refusal to issue an import or export permit</b>	Changed the 30 day timeframe for which a licence holder has to respond after Health Canada sends a notice of intent to refuse to state that Health Canada will provide the timeframe within which to respond when the notice is sent to allow for greater flexibility.
<b>7.4 Notice of new cannabis products</b>	Removal of content of the required submission details for a notice of new cannabis products to as this is no longer in the scope of this Guide. A new guide - Notice of New Cannabis Product Guide has been created.
<b>8.2 Revocation of a licence or permit</b>	Removal of the specific circumstances for which Health Canada may revoke a licence or permit as these are outlined in the applicable provisions of the Act.
<b>Appendix A: Summary of other notification and reporting requirements</b>	Included a reference to the new Notice of New Cannabis Product Guide for the form and manner by which to submit the notification.
	Addition that the organizational security plan must be submitted at Health Canada's request and within 5 days of making a change to the plan.
<b>Appendix B: Cannabis Licence Attestation Form</b>	Clarified that this form should only be used as a part of the licence amendment applications as referred to on this form.
	Clarified that this form should be uploaded in the Record Keeping Description section of the CTLS.
	Removal of the change to the head of laboratory as a type of change covered by this form. This role is now out of scope with the removal of the analytical testing and research testing licences from this guide.
	Clarified the types of changes to the site plan requiring physical security measures that are covered on this form. Included examples of what each type of change could entail.
	Included a new note that for all other changes to the site plan requiring physical security measures, a completed Appendix J form should be submitted.
	Included a new note that for an application to amend a licence to add the sale of a new class of cannabis, a completed Appendix K form should be submitted.
<b>Appendix C: Notification Attestation Form</b>	Removal of information on notifications related to analytical testing, research and cannabis drug licences as they are now out of scope with the removal of the analytical testing and research testing licences from this guide.
	Addition of new examples for what a change to the site plan that does not require physical security measures could entail.
<b>Appendix D: Application for a Permit to Import Cannabis for Medical or</b>	Addition of requirement to include licence number in the subject line of the email for a permit application.
	Changed the example of cannabis product given to account for the new classes of cannabis.

<b>Scientific Purposes</b>	
<b>Appendix E: Application for Permit to Export Cannabis for Medical or Scientific Purposes</b>	<p>Addition of requirement to include licence number in the subject line of the email for a permit application.</p> <p>Changed the example of cannabis product given to account for the new classes of cannabis.</p>
<b>Appendix F: Cannabis Shipment Detail Notification Form</b>	Addition of requirement to include licence number in the subject line of the email for a cannabis shipment detail notification form.
<b>Appendix G: Notice of Cessation of Cannabis Activities Form</b>	Addition of requirement to include licence number in the subject line of the email for a notice of cessation of cannabis activities form.
<b>Appendix I: Notice of a New Cannabis Product Form</b>	Removal of this form as this will now be captured under the new guide - Notice of New Cannabis Product Guide.
<b>Appendix I: Application to Amend a Licence to Add Sale of Classes of Cannabis</b>	<p>Addition of new form to be used for an application to amend a licence to add the sale of a new class of cannabis. This form was previously released to licence holders and has undergone some revisions since that release. In general the changes include the following:</p> <ul style="list-style-type: none"> <li>• Addition of note that new product notifications are not required for cannabis products that are cannabis plants or cannabis plant seeds.</li> <li>• Addition of the requirement to specify the cannabis product forms</li> <li>• Addition of new attestation which requires licence holders to attest that all applicable testing has been completed in accordance with Part 5 and Part 6 of the <i>Cannabis Regulations</i>.</li> <li>• Inclusion of a new example for how topical cannabis products must meet the requirements of Part 6 of the <i>Cannabis Regulations</i>.</li> </ul>
<b>Appendix J: Application for Approval of Change of the Site Plan</b>	Addition of a new form to be used for an application for approval of a change to the site plan requiring physical security measures as indicated on the form.