Detailed list of changes: August 1 ,2019

Table: Changes to the Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes (August 1, 2019 version)

Application Guide Section	Change
Title	Change in title to reflect the removal of the analytical testing and research testing licences from this guide.
1.0 Purpose	Addition of note that the Guide provides the requirements for 'certain' licences only, to reflect the removal of the analytical testing and research testing licences from this guide.
	Addition of an "Important" box to clarify that this guide is to be used for information purposes only until October 17, 2019.
3.0 Scope	Removal of analytical testing and research licences as a licence type within scope of this guide.
	Addition of analytical testing and research licences in the list of activities not covered in this guide.
	Addition of hyperlinks where applicable.
	Changed the version of the CTLS which the guide is based on.
	Changed note on the cost recovery information as it is now available on the Health Canada website.
4.0 Definitions and Abbreviations	Addition of definition for cannabis extract, cannabis topical, edible cannabis, dried cannabis, fresh cannabis and cannabis plant.
	Addition of definition for ingredient.
	Provided greater clarity in the 'site organizational chart' definition.
	Changed colours of Information and "Tip" boxes to align with all other Health Canada guidance documents and webpages.
5.0 Application Requirements	Provided greater clarity to Figure 1 by stating that each box references a section in this Guide.
5.1 Knowledge Areas	Table 1: Addition of the Canada Consumer Product Safety Act and Tobacco and Vaping Products Act as acts which the applicant are responsible for complying with.
	Table 1: Merged the Canada Revenue Agency row with the Other federal Acts and Regulations row as the *Excise Act, 2001* is covered under federal Acts and regulations.
	Table 1: Removal of the information regarding the requirement for some research licences to have additional approvals as this is not in the scope of this guide.
	Table 1: Removed 'and regulations' as regulations are a type of law and legislation.
5.2 Determine the type of licence to apply for	Figure 3: Addition of note that research licences and analytical testing licences are out of the scope of this guide.
	Figure 3: Changed <200m^2 to ≤ 200m^2 with respect to the threshold limits for micro-cultivators and changed <600kg to ≤600kg with respect to the threshold limits for micro-processors for greater accuracy.
	In "Important" box provided a new example of which application combinations the CTLS would not allow to be submitted at the same time to provide greater clarity.
	Referenced the Cannabis Licensing Application Guide: Research for applicants who wish to conduct research and development activities outside of their authorized licence activities.

5.4 Associated individuals create accounts in the CTLS	Table 3: Removed reference to analytical testing and research licences, and associated personnel.
	Table 3: Changed 'Licence holder (where holder is an individual)' to 'Licence holder (where applicant is an individual)', to provide greater accuracy as the individual will not be a licence holder at this stage.
5.5 Create a corporate profile for organizations	Changed 'corporation' to 'organization' for a more accurate description.
	Table 4: Changed 'The Account ID' to 'The Corporation ID' for a more accurate description.
	Table 4: Changed the required details to include for the Organizational chart to better align with the definition of Corporate Organizational Chart. Changed the requirement to 'Corporate organization chart' for consistency.
	Table 4: Removed content regarding who Health Canada considers an officer as it is unnecessary as all officers of the corporation are required to submit a security clearance.
	Table 4: Provided a reference to the Health Canada webpage with more information on security clearances under the *Cannabis Act and Regulations.*
	Table 4: Provided further clarity on who is required to hold a security clearance with the addition that individuals who exercise or are in a position to exercise direct control are required to hold a security clearance.
	Addition to "Tip" box regarding changes to the corporate profile.
6.0 Application Requirements: Creating an Application	Reordered the text to provide greater clarity that licences may be issued once applicable requirements as outlined in this guide are met.
	Removal of reference to analytical testing and research licences in list of licence classes covered by this guide.
	Addition of the classes of licences not addressed in this guide.
	Provided clarification in the "important box" that the guide establishes the application requirements for a cultivation, processing and/or sale for medical purposes licence application only.
	Table 5: Removed reference to analytical testing and research licences as outside the scope of this guide.
	Provided further clarification on which new areas in the CTLS are opened when sale with possession is selected by the applicant.
6.3 Licence Class and Subclass	Added in new CTLS requirement for processors to identify the classes of cannabis they intend to conduct activities with, to reflect change implemented in release 2 of the CTLS to provide greater information for statistical purposes.
	Removal of "Information" box related to analytical testing and research licences as outside the scope of this guide.
	Addition of reference to the Cannabis Licensing Application Guide: Research in "Tip" box.
6.4 Site Details	Removed example of analytical testing licence requirements as it outside the scope of this guide. Included a new example related to sale for medical purposes.
	Changed "Important" box to remove the reference to research licences. Included a new note that if an applicant wishes to conduct activities at two separate locations, then separate applications will be required, as licences are site specific.
	Table 6: Renamed table as it applies to all licence types covered by this guide.
	Table 6: To increase clarity with respect to both the site survey and aerial view included the addition of 'accurately depict the site at point of submission'.
	Table 6: Changed the name of room activities to reflect the change in CTLS for release 2.0.

	Table 6: Provided further clarification on which new areas in the CTLS are opened when sale with possession is selected by the applicant.
	Addition of new "Important" box to highlight the prohibition for processors to conduct cannabis activities in the same building where food that is to be sold is produced, packaged and labelled.
	Removal of Table 7 and 8 as analytical testing and research licences are outside the scope of this guide.
6.5 Site Personnel	In "Tip" box removed the note to submit qualifications for head of laboratory as this is outside scope of guide.
	In "Important" box removed 'for cultivations, process and sale for medical purposes licences' as it applies to all licence types covered by guide.
	Table 7: Removed reference to site personnel requirements associated with analytical testing and research licences.
	Table 7: Addition of new "Important" box to highlight the requirement to have a individual with a security clearance be present at the site when activities with cannabis are being conducted.
	Table 7: Updated QAP qualifications to include new requirements under new amended regulations.
	Table 7: Addition of new "Important" box for processors conducting activities with cannabis extracts or edible cannabis to highlight applicable requirements for the QAP under new amended regulations.
	Table 7: Addition of new "Important" box for processors conducting activities with edible cannabis, highlighting the requirement to retain an individual with the required training, experience and technical knowledge related to edible cannabis in the event their QAP does not possess the training, experience and technical knowledge required.
6.6 Site Ownership	Removal of reference to analytical testing and research licences as this is out of scope of this guide.
6.7 Notices to local authorities	Removal of reference to analytical testing and research licences as this is out of scope of this guide.
6.8 Physical Security	Clarification on how the organizational requirements apply to all licence classes, and highlighting the differences in physical security requirements.
	Renamed Table 10 as it applies to all licence types covered by this guide.
	Table 10: Clarified that the they physical security attestation (9) is not required by a sale for medical purposes without possession licences.
	Table 11: Clarified that the floor plan should include the 'cannabis flow between rooms'.
	Table 11: In the 'Additional Information' section clarified that the visual monitoring devices and intrusion detection devices are to be installed and operating.
	Table 11: In the 'Access Log' section provided clarity on what information should be recorded.
	Table 11: In the 'Monitoring and Response' section added the requirement to include the procedure in place for responding to intrusion detection alarms, and the information to record when an occurrence is detected.
	Table 12: Clarified that the floor plan should include the 'cannabis flow between rooms'.
	Removed Table 15 as it is now out of scope of this guide.

6.9 Good production practices	Removal of reference to analytical testing and research licences from "Information" box as they are out of scope of this guide.
	Table 13: Separated the good production practices requirements to highlight which regulation they pertain to.
	Table 13: Included the new requirement for the good production practices to apply to both cannabis and 'anything to be used as an ingredient' where applicable.
	Table 13: Provided greater detail on the requirements associated with the filtration or ventilation system.
	Table 13: Provided clarity on the supply of water requirements.
	Table 13: Included the new requirement to submit a description of cleaning effectiveness verification.
	Table 13: Addition of new requirements related to the lighting, hand cleaning, sanitizing stations, and lavatories.
	Table 13: Included the 'former *Industrial Hemp Regulations and the Industrial Hemp Regulation*' as a starting material source.
	Table 13: Included the new requirement for processing applicants to submit the signed completed Appendix J form: Good Production Practices Attestation.
	Table 13: Addition of new "Important" box to highlight the prohibition for processors to conduct cannabis activities in the same building where food that is to be sold is produced, packaged and labelled.
6.10 Record Keeping (and Reporting)	Table 14: Removal of note that the record keeping attestation applies only to cultivation, processing and sale for medical purposes licences. This is no longer necessary as it applies to all licence types covered by the scope of this guide.
	Table 14: Removed copy of government issued identification requirement as this is no longer in the scope of this guide.
	Table 14: Removal of note that the key investor reports applies only to cultivation, processing and sale for medical purposes licences. This is no longer necessary as it applies to all licence types covered by the scope of this guide.
7.1 Submitting the application	Addition of new declarations and attestations which are now a part of the CTLS application for processing applicants.
	Addition of note that an application cannot be changed after submission by an pplicant, but the corporate profile can continue to be changed after submission.
7.2.1 Application screening	Provided greater clarity on the service standard for the screening process to include that it is a 30 business day nonbinding service standard.
	Removed the note that the inspection team will schedule a pre licence inspection with the applicant.
7.2.4 Issuance of a licence	In "Tip" box further clarified that the graduated licensing approach allows Health Canada to verify the quality of the cannabis to be sold.
7.3.1 Receivinga nd responding to a request for more information	Changed 'Health Canada asks the applicant to clarify information' to 'Health Canada may require the applicant to submit additional information' to more accurately represent the process.
	Changed the time an applicant has to respond to a request for more information from 5 business days to 10 business days.
	Included further information in the types of information that may need to be submitted in response to a request for more information. This may include visual evidence.

7.3.2 Refusals and withdrawals	Included the new licence refusal circumstance.
	Changed the timeframe in which an application has to respond after Health Canada sends a notice of intent to refuse. Health Canada will provide the timeframe within which to respond when the notice is sent.
Appendix A	Changed name of table to 'Key Individuals at the Site' to more accurately reflect the individuals captured in this table.
	Addition of new requirements for QAP to have training, experience and technical knowledge related to Part 6, and the new requirement for approving a preventive control plan if conducting activities with edible cannabis or cannabis extracts.
	Removal of the Head of Laboratory as this role is not in scope of this guide.
Appendix B	Removal of references to analytical testing and research licences as they are not in scope of this guide.
	Added that the table provides examples of activities only as it is not a comprehensive list of activities.
Appendix E	Update to references to the applicable record keeping regulations to reflect the changes as a result of the new amended regulations.
	Addition of new attestations stating that all information in the document is accurate and that the responsible person has read and understands all requirements highlighted on the form.
Appendix G	Removed references to defacto control.
Appendix H	Renamed appendix.
	Edited appendix to provide greater clarity on what constitutes direct control.
Appendix F	Edited table to more accurately reflect the application status in the CTLS.
Appendix J	New appendix: Good Production Practices Attestation to address the new GPP requirements specific to processors only.