Frequently Asked Questions: Micro-Cultivation, Micro-Processing and Nursery Cannabis Licences

1. What are the critical fail points for applications?

Your application must meet the applicable requirements for the licence class or subclass in order to be approved. You can refer to the <u>Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes</u> for the information which is required in an application.

If an application is going to be refused, it is most likely to happen at the screening stage. The most common reason an application is refused is that the required information was either insufficient or not provided. Some specific examples or reasons for this include:

- The applicant does not understand the *Cannabis Act* and Regulations and is not able to demonstrate compliance with the licensing requirements;
- Poor quality applications which are disorganized or missing information, which makes it unworkable for Health Canada to assess compliance with the Regulations;
- Applications lack information on the flow of activities and materials used within the site as they relate to Good Production Practices; and
- The video evidence submitted does not contain the information required to allow Health Canada to understand how the facility will operate and conduct activities with cannabis.

Please use the guidance documents provided by Health Canada in the creation and submission of your application. Use the <u>Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes</u> to help identify the application requirements and the <u>Physical Security Measures Guide for Cannabis</u> and the <u>Good Production Practices Guide for Cannabis</u> for examples of principles and practices that you can use to demonstrate compliance.

Section 7.3.2 Refusals and Withdrawals of the <u>Cannabis Licensing Application Guide: Cultivation</u>, <u>Processing and Sale for Medical Purposes</u> lists many of the reasons why Health Canada may refuse to issue a licence.

2. Do I have to have all of my rooms built and ready for approval at the time of the initial licence application, or can I start small and ramp up my operation after I receive my licence? Is there a minimum start-up cost for a micro-licence?

Activities with cannabis can only occur in areas as submitted and approved by Health Canada. All areas that will be used to conduct activities with cannabis must be built and approved by Health Canada prior to their use.

The number of areas proposed for licensing in the initial application is a business decision and you may choose to request approval for only a small number of areas for the initial licence application and apply to add additional areas at a later date, after initial licensing. In this case, you would need to ensure that the number and type of areas submitted in the original application are sufficient to conduct the intended



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activities at the site (e.g., if storage of cannabis is occurring on site, a storage area must be part of the initial application).

It is difficult to provide a minimum or average start-up cost for micro-licence applicants, since these costs vary depending on the specifics of an applicant's business model and pre-existing infrastructure. Some applicants have found it cost effective to obtain their licence with a modest-sized site and to scale up through licence amendments and expansions. As noted above, you could do this as long as you do not exceed the thresholds for micro-cultivation or micro-processing permitted by the *Cannabis Regulations*.

You can request changes to the site plan, such as adding additional grow or operations areas to a licence, through a licence amendment application in the Cannabis Tracking and Licensing System (CTLS). You can find more information on the process of amending a licence in the Cannabis Licence Management Guide: Cultivation, Processing and Sale for Medical Purposes.

3. Can I scale up from a micro-class licence to a standard-class licence?

Yes, micro-class licence holders are able to apply to have their licence amended to become a standard-class licence. You would need to submit an amendment in the Cannabis Tracking and Licensing System (CTLS) as described in the *Licence Management Guide: Cultivation, Processing and Sale for Medical Purposes* to make this change. Table 2 of this guide: 'Changes requiring approval by Health Canada' provides the required information and instructions for an application for a change of this type (change to an authorized activity at a site). It is important to note that you would be required to submit all required information **and** receive approval from Health Canada **prior to** scaling up your activities under the standard class licence. The approval of your standard class licence would result in the cancellation of your micro-class licence.

You can refer to the <u>Cannabis Licensing Application Guide: Cultivation, Processing, and Sale for Medical Purposes</u> for any additional details that will be required to be submitted. In particular, you should refer to Table 11 for the new physical security requirements for a standard-class licence and Table 13 for the Good Production Practices requirements that must be demonstrated. You would have to re-evaluate the process and flow of activities in your facilities as a result of the scaling up of operations, and submit any changes to the existing approved space as required to Health Canada. It is important to note that standard-class licences are subject to different cost recovery fees, so please see the website on <u>cost recovery for the regulation of cannabis</u> for more information.

Initial applicants who have not received a licence and wish to change their micro-class licence application to a standard-class licence application while still in the application queue, will be asked with withdraw their application from the CTLS and resubmit with all the required supporting documentation as described in the <u>Cannabis Licensing Application Guide: Cultivation, Processing, and Sale for Medical Purposes</u>.

4. What has to be in place or present at the site to meet the site evidence requirement? For example, does it include equipment?

The site evidence requirement for an application for cultivation, processing or sale for medical purposes (with possession of cannabis) must demonstrate that the site is fully built and meets all the requirements of the *Cannabis Regulations* including physical security and Good Production Practices (GPP) requirements. This would generally include evidence of an operational and functional site (e.g. building equipped with all **permanent** fixtures such as security features, facility lighting, ventilation and air filtration system).

There is no requirement to submit any information on the cultivation and processing equipment (e.g., cultivation tables and lights, trimmers, scales, etc.) on site or have it present during the site evidence video walkthrough.

Please note that the requirement for the presence of an operational and functional site only applies to the areas you are seeking to include on your licence. For example, you may choose to only request a licence for a portion of a building, within the identified site perimeter. In this case you are only required to demonstrate compliance (physical security, GPP, etc.) for the areas you would like approved as part of the initial licence, not the entire building.

You should refer to the following sections in the <u>Cannabis Licensing Application Guide: Cultivation</u>, <u>Processing and Sale for Medical Purposes</u> for what you need to include in the site evidence package:

- Section 6.8 Physical security including organizational security plan
- Section 6.9 Good production practices
- Section 6.10 Record keeping and reporting
- Section 7.1.1 Submission of Site Evidence

Additionally, Health Canada provides guidance on the regulatory requirements for physical security measures and GPP, and examples of principles and practices that may be used to achieve compliance. You can access this guidance at the following links:

- The Physical Security Measures Guide: https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/laws-regulations/regulations-support-cannabis-act/guide-physical-security-measures.html
- The Good Production Practices Guide: https://www.canada.ca/en/health-canada/services/cannabis-regulations-licensed-producers/good-production-practices-guide/guidance-document.html

5. Do I have to provide a professional video for my site video evidence?

No. The requirements for the site evidence are found in the <u>Cannabis Licensing Application Guide:</u> <u>Cultivation, Processing and Sale for Medical Purposes</u>. All video and images must have sufficient resolution to clearly visualize the areas depicted, as well they should include a guided tour of all areas, highlighting the physical security and Good Production Practices features of the site. You do not have to use any special equipment in the production of this footage. In many cases, you can use a personal cellular device or camera. Just make sure you have good lighting so that the features the video is recording are clearly visible to the Health Canada reviewer.

6. I have a personal grow site and I now want to change that site into a commercial site. Can I do that?

A personal or designated grow site may be appropriate for a commercial cannabis site, however should you wish to conduct commercial cannabis activities as authorized under the *Cannabis Act and Regulations*, a licence application must be submitted through the Cannabis Tracking and Licensing System (CTLS). Please refer to the *Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes* for the application requirements to apply for a cultivation, processing or sale for medical purposes licence.

Activities under a personal or designated grow licence are permitted to be located at the same address as a commercial cannabis licence under the *Cannabis Act and Regulations*, provided the licence holder is the same as the holder of the personal or designated grow authorization and the licence holder is able to clearly demonstrate that they are in full compliance with the *Cannabis Act and Regulations*. This will mean keeping a clear distinction of the activities conducted under the commercial licence(s) and under the personal or designated production registration (e.g., separation of record keeping documents and ensuring that there is no movement of product between the commercial licence and the personal or designated production registration).

If the holder of the personal or designated production registration and the licence holder are different entities, the personal or designated production activities can be conducted at the same location provided they are conducted outside the site perimeter of the commercial site.

7. Are licence parks/campuses allowed (e.g., multiple sites in one building)

Under the *Cannabis Act* and Regulations there is no specific restriction on the number of licences permitted on a single parcel of land or within the same building, provided each licence is within a separate site. A site is defined in the Regulations as an area that is used exclusively by the holder and that consists of at least one building or one part of a building.

It is however, important to note that Health Canada will consider any licenced activities that occur in close proximity to the proposed application site in order to assess the risk to public health and public safety. If, in Health Canada's assessment, the colocation of licences creates an elevated risk to public health or public safety, Health Canada may require additional security measures to be put in place.

In addition, local municipal bylaws may impose restrictions on the number of, or location of licensed sites within their jurisdiction.

8. Can the approved personnel at my site also work at another licensed site? Can the approved personnel hold more than one position at my site?

The *Cannabis Regulations* do not require the exclusive use of personnel at each licensed site. This means that an individual may fulfill a role at multiples sites (e.g., Quality Assurance Person for two different licence holders), assuming they meet all the requirements of those positions. Please refer to Section 5.4 and Appendix A of the *Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes* for a summary of individuals to be identified, and their specific responsibilities depending on the type of licence.

Please note, that if an individual is working at multiple licensed sites, consideration must be given as to how they will be able to fulfill their duties at all sites, given the site locations, the individual's hours of work at each site and whether they are fulfilling the primary or alternate role of the position.

Additionally, the *Cannabis Regulations* do not prohibit one individual from occupying multiple key roles within the same site (e.g., Quality Assurance Person and Head of Security) provided that it can be demonstrated that the roles can be satisfied by one person while satisfying the objectives of protecting public health and public safety, and the qualifications are met, particularly in the case of a Quality Assurance Person.

9. How long does it take to process security clearances?

Health Canada works with the RCMP in processing all security clearance applications. You should ensure that all information, especially pertaining to past employment, education and travel history, and any past criminal convictions, is complete and correct at the time of application submission. As part of this application, a consent and certification form must also be uploaded with a signature by each security clearance applicant.

The time needed to complete security screening is variable as each case is unique. For many individuals, security screening can take a few months. For others, the security screening may be longer as additional consultations with law enforcement agencies may be required. In rare cases, it has taken over one year to complete.

Factors such as missing information, multiple addresses and/or employers over the past five years, or individuals who have lived abroad, could affect the time required to complete this process. The information revealed by the checks and/or the need to seek additional information from a security clearance applicant either in the form of written representations or otherwise, can also affect the overall amount of time required to complete this process. Please note that licences will not be issued until all required security clearances have been approved.

If Health Canada intends to refuse to grant a security clearance, the security clearance applicant will be notified in writing and given the opportunity to respond. You can find more information on security clearances on the website "Security clearances under the Cannabis Act and Regulations" and Appendices C and I of the Cannabis Licensing Application Guide: Cultivation, Processing and Sale for Medical Purposes.

10. If I intend to utilize the exception granted under subsection 10(2) – can I have my cannabis starting material on site before licensing and where do I buy this starting material?

The Cannabis Regulations, in subsection 10(1), sets out that a licence holder that is authorized to possess cannabis must only possess cannabis if that cannabis was obtained in accordance with the former Access to Cannabis for Medical Purposes Regulations (ACMPR), the former Industrial Hemp Regulations (IHR), the Industrial Hemp Regulations (IHR), the Cannabis Regulations or a provincially or territorially authorized retailer (subsection 62(1) of the Cannabis Act).

Subsection 10(2) of the *Cannabis Regulations* provides an exception to this requirement which permits the holder of a licence for cultivation (micro, standard or nursery) to legally possess cannabis plants and cannabis seeds that were not obtained in accordance with the sources described in subsection 10(1) of the *Cannabis Regulations* if they submitted the required declaration to the Minister as part of their licence application.

Health Canada would assess whether the following three tests have been met by a cultivation licence applicant who wished to bring in cannabis plants and/or cannabis seeds under subsection 10(2) at the time of licensure:

- 1. The applicant has obtained all required security clearances associated with the application, and has provided all required financial information establishing that they are not associated with organized crime or other illegal activities that pose an unacceptable risk to public health or public safety.
- 2. As part of their application, they have declared the number of cannabis seeds and/or cannabis plants they will have at the time of licensing.
- 3. All future cannabis produced under the licence, regardless of its original source, must meet all quality-control and testing requirements.

The declaration must indicate the quantity of cannabis plants and/or cannabis seeds that will be in your possession on the effective date of your licence. This declaration must also be signed and dated by the responsible person.

The number of cannabis plants and cannabis seeds brought in under a 10(2) declaration must match the number of cannabis plants and cannabis seeds on the declaration. Any extra cannabis plants and cannabis seeds would not be considered to be lawfully possessed by you, the licence holder, unless their possession is otherwise authorized.

Once licensed, you as a cultivator will only be able to obtain additional cannabis seeds or cannabis plants from the following legal sources:

- Other cannabis licence holders, including licensed nurseries;
- Your own plant breeding program to produce new varieties;
- Under some circumstances, from licensed cannabis researchers; and
- By applying for an import permit for starting materials if it is for medical or scientific purposes.

There is no opportunity to bring in more cannabis plants and cannabis seeds under a new or supplemental 10(2) declaration once a licence is granted.

Health Canada does not provide any recommendations for sources of cannabis plants and cannabis seeds that would be subject to a 10(2) declaration, and provides no recommendations on taking possession or transporting the cannabis plants and cannabis seeds prior to licensing.