

Management of Applications for Controlled Drugs and Substances Dealer's Licences

Table of Contents:

1. PURPOSE
2. SCOPE
3. COMMUNICATING WITH THE OCS
4. BEFORE FILING AN APPLICATION
5. FILING AN APPLICATION
6. PROCESSING AN APPLICATION
7. UNSOLICITED INFORMATION
8. TABLE A – SERVICE STANDARDS FOR PROCESSING CONTROLLED DRUGS AND SUBSTANCES DEALER'S LICENCE APPLICATIONS
9. APPENDIX A – PRE-APPLICATION CHECK LIST

1.0 PURPOSE

The purpose of this policy is to outline the manner in which the Office of Controlled Substances (the OCS) manages applications for Controlled Drugs and Substances Dealer's Licences submitted in accordance with the Controlled Drugs and Substances Act (CDSA), and the following Regulations:

- Narcotic Control Regulations (NCR);
- Benzodiazepines and Other Targeted Substances Regulations (BOTSR);
- Part G of the Food and Drug Regulations (FDR); and,
- Part J of the FDR.

This policy also outlines the responsibilities and expectations of applicants before and throughout the processing of an application.

2.0 SCOPE

This policy applies to the following types of applications:

- Application for a Controlled Drugs and Substances Dealer's Licence;
- Application for Amendment of a Controlled Drugs and Substances Dealer's Licence;
- Application for Changes Affecting Personnel in Charge; and
- Application for Renewal of a Controlled Drugs and Substances Dealer's Licence

3.0 COMMUNICATING WITH THE OCS

All information dealing with applications identified in the **SCOPE** section is to be sent via email to hc.cds-sdc.sc@canada.ca. The OCS communicates with applicants through generic email accounts for receiving and processing applications. Applicants may contact the Authorization Division general phone number 613-954-4760 and be redirected to the appropriate administrative section, if there is a need to speak with an OCS representative.

NOTES:

1. Generic email accounts are monitored daily on working days, and emails are assigned to the appropriate Officer.
2. An automatic acknowledgment reply is generated for all emails received.
3. Emails which are sent directly to an OCS employee, including CC'ed and BCC'ed, will be deleted without return notification. If an applicant knows the name of the OCS representative who is already working on their application, the OCS representative's name should be identified in the body of any email being sent via the generic email account.
4. The OCS may adapt its first in first out approach to the prioritization of applications, on a case-by-case basis.

4.0 BEFORE FILING AN APPLICATION

It is important to be aware of the following information before filing an application:

- It is the applicant's responsibility to be familiar with the legislative and regulatory requirements which govern controlled drugs and substances, as identified in the **PURPOSE** section of this policy. Access to the most current version of these documents is available through the Department of Justice website, <http://laws-lois.justice.gc.ca/eng/acts/>, and <http://laws-lois.justice.gc.ca/eng/regulations/>.
- The application forms listed in the **SCOPE** section above, except the Application for Renewal, are available on the Health Canada website, Controlled Substances, Application Forms, <https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/controlled-substances.html>.
- It is also the applicant's responsibility to be familiar with the requirements set out in the Directive on Physical Security Requirements for Controlled Substances and Drugs Containing Cannabis, <https://www.canada.ca/en/health-canada/services/drugs-medication/cannabis/laws-regulations/regulations-support-cannabis-act/directive-physical-security-requirements.html>. All licensed dealers are required to have a secure environ for the storage of controlled drugs and substances, in accordance with the requirements of the Security Directive. Note that the OCS provides fillable security templates for each security level. The template that corresponds with the requested security level(s) must be completed and submitted with an application.
- It is also the applicant's responsibility to confirm that all the controlled substances intended to be included on the licence, which are **not explicitly listed** in the CDSA and its regulations, are indeed controlled substances. A copy of an email of this confirmation from hc.status-demandestatut.sc@canada.ca is required.
- A Dealer's Licence is required for each physical location where activities are conducted with controlled substances. The OCS supports the renewal of dealer's licences through advance notification to every licensed dealer with a reminder of the upcoming expiry of their licence. Approximately three months before expiry, the OCS sends out the dealer's licences renewal package, including the application form to be completed and submitted. Failure to renew a Dealer's Licence before the expiry date will mean that upon expiry of the licence, the facility will no longer be able to legally conduct activities with, or possess, controlled substances, and appropriate administrative compliance actions may be taken.

Important Tip:

When filing an application for a Dealer's Licence, or an Amendment to the physical security, it is important to use the Security Directive and the security templates provided by the OCS to evaluate and determine the minimum level of security required to have in place relative to the controlled substance holdings to be managed.

5.0 FILING AN APPLICATION

Application forms are provided in electronic PDF fillable format through the Health Canada website and are intended to be completed in the same electronic format. The OCS cannot commit to the service standards outlined in this policy for applications which are completed and submitted in hand written form, or for applications that are not submitted electronically using the most recent version of the application form.

Correctly completed application packages provide benefits to both the applicant and the OCS, some of which include:

- Ensures clearly legible information, reducing the likelihood of errors in data entry;
- Ensures adherence to standard submission content; and
- Enables efficient application processing and faster response times.

All information and data submitted in support of a Dealer's Licence remains the property of Health Canada.

Important Tip:

Use and submit the Pre-Application Check List (Appendix A) with the application to ensure that all required signatures are included, and all required supporting documentation identified in the application form is provided. Failure to include all required documents with the application may result in the application being returned at INTAKE during the process.

6.0 PROCESSING AN APPLICATION

In general, applications are processed through five stages, as illustrated below: INTAKE, REVIEW, SECURITY INSPECTION (if applicable), DECISION, and OUT-TAKE. All applications are processed on a first-in first-out basis.



Management of Applications for Controlled Drugs and Substances Dealer's Licence

The OCS targets to meet these service standards for the processing of the following types of applications:

- New applications – within 270 calendar days
- Renewals – within 90 calendar days
- Amendments – within 45 calendar days
- Changes in Designated Personnel – within 45 calendar days

* **NOTE:** the service standard for Amendments does not apply to applications that require on-site inspections or that are subject to administrative measures due to the applicant's non-compliance history.

Changes of ownership that result in new certificates of incorporation require the submission of a new Controlled Drugs and Substances Dealer's Licence application. The OCS will issue a new licence number following the review of the new application. This type of change cannot be submitted via an Amendment application. However, a new licence application submitted for this reason will not require the 270 calendar days to process, so long as there are no changes to the information listed on the current licence. In these cases, the OCS will target to issue a new licence within 45 calendar days of receipt, if it is determined that a security inspection is not required. The OCS will work with the applicant to determine the preferred licence issuance date to ensure that regulated activities at the site are not impacted. The OCS does not allow the cross-referencing of information between files.

Refer to Section 8.0 Table A – Service Standards for processing Controlled Drugs and Substances Dealer's Licence Applications, for further details regarding service standards.

Important Tip:

It is important that the applicant respond as quickly and as thoroughly as possible to requests for additional information throughout the processing of the application. Response due dates will be identified in every request. The OCS will consider applicant extension requests supported by valid rationales.

Please note that the service standards outlined in this policy are dependent on any additional information submitted with timeliness by the applicant. Failure to respond by the due date may result in the refusal of the application.

If applicable, and to minimize the impact on business operations, applicants should contact the OCS as early as possible to discuss any business restructuring decisions (e.g. merger, acquisition, relocation, etc.) to help plan the transition to a new licence.

6.1 INTAKE

All applications are subject to an initial screening to determine that the application form has been completed and that all required supporting documentation has been provided. An in-depth review of the information is not performed during INTAKE.

The OCS targets to complete INTAKE within seven (7) calendar days of receipt of any type of application.

Incomplete application forms or failure to include all the required supporting documentation with the application will result in the application not being processed. The OCS will inform the applicant that the application is incomplete and the reasons why.

Applications that have successfully passed INTAKE will proceed to REVIEW. The OCS will notify applicants via email when their applications have entered REVIEW.

6.2 REVIEW

Applications at REVIEW are subject to a thorough review to verify the content of the information provided. The OCS targets to complete REVIEW within:

- two hundred forty-nine (249) calendar days of a New Application successfully completing INTAKE;
- sixty-nine (69) calendar days of a Renewal Application successfully completing INTAKE;
- twenty-four (24) calendar days of a Change in Personnel Application successfully completing INTAKE; and
- twenty-four (24) calendar days of an Amendment Application successfully completing INTAKE.

Where information deficiencies or questions are identified, the OCS will send a *Request for Additional Information* to the applicant via e-mail to identify the issues to be addressed.

During REVIEW every effort will be made by the OCS to consolidate identified information deficiencies into as few additional information requests as possible.

It is the responsibility of the applicant to provide the requested information by the response due date. Where a request is made to the applicant for additional information, and the applicant does not respond by the due date, or does not provide a complete response, the OCS may refuse the application. Once refused, a new application may be required to be submitted should the applicant still wish to obtain a licence.

NOTE: The OCS will only place an application on hold whenever an applicant is building secure environs following the issuance of a *Begin Construction Notice*. In determining the time taken to process the application, the OCS will not count the elapsed time between the date when the *Begin Construction Notice* is issued and the date the applicant informs the OCS that construction is completed.

6.2.1 Review of security proposal

The OCS will issue a *Begin Construction Notice* once the security portion of the application has been reviewed and is deemed satisfactory. Upon confirmation by the applicant that the construction has been completed, the OCS will notify the Health Canada, Regulatory Operations and Enforcement Branch (ROEB) and request a security inspection to confirm that the security measures are in compliance with the Security Directive, and to determine the applicant's level of readiness to conduct regulated activities (i.e. the required security measures and internal controls are in place and in compliance with the relevant regulatory requirements). The application will then proceed to SECURITY INSPECTION.

NOTE: the decision regarding when to commence building a storage area is a business decision which is solely up to the applicant, since it is the applicant who bears the risk should the application not meet the requirements for the desired level in the Security Directive.

6.3 SECURITY INSPECTION

The ROEB will contact applicants directly to schedule inspections following notification from the OCS that the construction is complete. The OCS does not provide specific timelines or dates as to when the ROEB will be in contact or when inspections will be conducted.

Both REVIEW and SECURITY INSPECTION (if applicable) must be completed prior to moving on to DECISION.

6.4 DECISION

During DECISION, applications and decision documents undergo final review.

The OCS targets to issue a decision within seven (7) calendar days following the completion of REVIEW and SECURITY INSPECTION (if applicable).

Decisions respecting applications include:

- approval and issuance of an amended, renewed or new Dealer's Licence;
- refusal to issue, an amended, renewed or new Dealer's Licence;
- approval of designated personnel (ICP, QPIC, A/QPIC); or

- refusal of designated personnel.

6.4.1 Approval

Where the decision is to approve an amended, renewed or new Dealer's Licence, the application will proceed to OUT-TAKE.

6.4.2 Refusal:

Where the decision is to refuse to issue, a new, amended or renewed Dealer's Licence, the OCS will send an *Intent to Refuse Notification* to the applicant via e-mail together with the reasons for the proposed refusal. The *Intent to Refuse Notification* will give the applicant an opportunity to be heard in respect of the proposed refusal.

Where an *Intent to Refuse Notification* has been sent to an applicant, it is the responsibility of the applicant to respond to the OCS within ten (10) calendar days of the issuance of the Notification, stating whether or not a hearing in respect of the proposed refusal is desired.

Where a hearing in respect of the proposed refusal is desired by the applicant, the OCS will contact the applicant to arrange a mutually acceptable mechanism e.g. in person, by telecom or webinar, date, time and location for the hearing.

Where the applicant does not reply to the *Intent to Refuse Notification* within the ten (10) calendar days set out in the *Notification*, the OCS will proceed with the issuance of the refusal. Once refused, a new application must be submitted should the applicant still wish to obtain a licence.

6.5 OUT-TAKE

During OUT-TAKE appropriate documents are prepared for communication of the decision.

The OCS targets to complete OUT-TAKE within seven (7) calendar days.

The final decision is sent to the applicant via email, and original licences are sent by mail.

Copies of all correspondence and documentation gathered in support of the application are maintained by the OCS for a period of five (5) years, in accordance with Library and Archives Canada, record retention and disposition frame work.

7.0 UNSOLICITED INFORMATION

Applicants may submit, at any time during the processing of an application, unsolicited information pertaining to any aspect of the submitted application. The OCS reserves the right to accept or not accept the unsolicited information based on the status of the application review. If the information is relevant, it will be added to the application package and processed. If the information is irrelevant, it will be shredded. Before shredding, the applicant will be informed whether the unsolicited information is being accepted or not accepted, together with the reasons why.

Whenever updated information is being submitted, it is the responsibility of the applicant to clearly identify the:

- relevant application to which the new information pertains;
- specific section of the application form to which the updated information applies; and,
- specific information which was originally submitted and how the updated information is to change the original information (e.g. replacement, modification, addition, deletion).

8.0 TABLE A - SERVICE STANDARDS FOR PROCESSING CONTROLLED DRUGS AND SUBSTANCES DEALER'S LICENCE APPLICATIONS

Application Type	Application Process Stages					Regulatory Decision Outcome	Overall Service Standard Calendar Days
	INTAKE	REVIEW	SECURITY INSPECTION	DECISION	OUT-TAKE		
Application for a Controlled Drugs and Substances Dealer's Licence	7 Calendar Days	249 Calendar Days (these two stages are completed in parallel)		7 Calendar Days	7 Calendar Days	Approval – Licence Issued Refusal – Licence not Issued	270
Application for Amendment of a Controlled Drugs and Substances Dealer's Licence	7 Calendar Days	24 Calendar Days	N/A*	7 Calendar Days	7 Calendar Days	Approval – Licence Issued Refusal – Licence not Issued	45
Application for Changes Affecting Personnel in Charge	7 Calendar Days	24 Calendar Days	N/A	7 Calendar Days	7 Calendar Days	Approval – Changes Accepted Refusal – Changes Not Accepted	45
Application for Renewal of a Controlled Drugs and Substances Dealer's Licence	7 Calendar Days	69 Calendar Days	N/A	7 Calendar Days	7 Calendar Days	Approval – Licence Issued Refusal – Licence not Issued	90

* The service standard for Amendment applications does not apply to applications that require on-site security inspections.

Pre-Application Check List

Prior to submitting an Application for a Controlled Drugs and Substances Dealer's Licence, an Application for Amendment of a Controlled Drugs and Substances Dealer's Licence, or an Application for Changes Affecting Personnel in Charge, the supporting documentation listed below, along with the required signatures, must be included in the application.

NOTE: Submit the complete Pre-Application Check List with the application.

Corporate Applicants

- Proof of corporate name (e.g. a photocopy of a certificate of incorporation or patent letter).
- Any document, filed with the province in which the premises to which the licence would apply are located, that states its corporate name or any other name registered with the province, under which the applicant intends to carry out the activities specified in its dealer's licence or intends to identify itself.

Physical Security

- A detailed physical security proposal, including a completed security template, floor plan or scale diagram and pictures, including details on how the proposal will meet all of the listed requirements of the *Directive on Physical Security Requirements for Controlled Substances and Drugs Containing Cannabis* for the security level intended to be obtained for the site.

Qualified Personnel

- Copy of Curriculum Vitae, if applicable
- Copy of degree, if applicable
- Copy of course transcript, if applicable
- Copy of Canadian equivalency, if applicable

Confirmation of Controlled Substance

- Copy of an email from hc.status-demandedestatut.sc@canada.ca confirming that all the substances intended to be included on the licence, that are **not explicitly listed** in the CDSA or its regulations, are indeed controlled substances.

Production of Pharmaceutical Products

- For each controlled drug product manufactured/packaged by/for the applicant:
 - A copy of the Notice of Compliance, if applicable
 - A copy of the Drug Identification Number (DIN) Form, if applicable
 - One sample label (or copy) for each package format of all the pharmaceutical products to be marketed

Management of Applications for Controlled Drugs and Substances Dealer's Licence

- When adding package size(s), provide one sample label (or copy) for each format to be added

Record Keeping

- A detailed description of the method which is planned to be used to ensure proper record keeping of the controlled substances transactions under the requested licence, demonstrating compliance with the applicable regulations set out in the **PURPOSE** section of this policy.
- A copy of the Standard Operating Procedure for the record keeping method and samples of the proposed record keeping template, if available.

Declarations for Designated Personnel

- A criminal record check certificate, issued by the RCMP or a local police service within the last 12 months.
- If an individual resided in another country in any of the previous 10 years, a criminal record check certificate issued within the last 12 months by a police force in that country stating the person has not been convicted, as an adult, in the previous 10 years, of an offence that if committed in Canada would have constituted a designated drug offence.
- Declaration signatures for each of designated person
 - Individual In-Charge of the Premises (ICP)
 - Qualified Person In-Charge (QPIC)
 - Alternate Qualified Person(s) In-Charge (A/QPIC)