Management of Applications for Class B Precursor Dealer Registration

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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 Class B Precursor Dealer's Registrations submitted in accordance with the *Controlled Drugs and Substances Act*, and the *Precursor Control Regulations*.

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

2.0 SCOPE

This policy applies to the following types of applications:

- Application for a Class B Precursor Dealer's Registration
- Application for Amendment of a Class B Precursor Dealer's Registration
- Application for Renewal of a Class B Precursor Dealer's Registration

3.0 COMMUNICATING WITH THE OCS

All information dealing with applications identified in the **SCOPE** section is to be sent via e-mail to hc.precursors-precurseurs.sc@canada.ca. The OCS communicates with applicants through generic e-mail 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 e-mail accounts are monitored daily on working days, and e-mails are assigned to the appropriate Officer.
- 2. An automatic acknowledgment reply is generated for all e-mails received.
- 3. E-mails 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 e-mail being sent via the generic e-mail 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 filling an application:

- It is the applicant's responsibility to be familiar with the Legislative and Regulatory requirements which govern Class B Precursors, 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/regulations/.
- The application forms listed in the SCOPE section above, except the Application for Renewal, are available on the Health Canada website, Precursor Chemicals, Licences, Permits, Registrations and Exemptions, https://www.canada.ca/en/health-canada/services/health-concerns/controlled-substances-precursor-chemicals/precursor-chemicals/licenses-permits-registration-exemptions.html.
- Registered dealers must take precautions to ensure the safety and security of the
 precursors at the site as well as to protect the registration certificate or export
 permit from loss or theft. For more details on what is required, refer to <u>Guidance</u>
 <u>Document for the Precursor Control Regulations Application For Class B</u>
 <u>Precursor Registration</u> and <u>Guidance Document for the Precursor Control</u>
 <u>Regulations Requirements and Responsibilities of Registered Dealers of Class</u>
 B Precursors.
- Multiple physical locations can be registered under a single Registration. A Class B Precursor Dealer's Registration Certificate is issued to the applicant's head office address in Canada, and additional sites where the applicant intends to conduct regulated activities pertaining to Class B precursors may be added to this Registration. The OCS supports the renewal of dealer's registrations through advance notification to every registered dealer with a reminder of the upcoming expiry of their registration. Approximately three months before expiry, the OCS sends out the dealer's registrations renewal package, including the application form to be completed and submitted. Failure to renew a Dealer's Registration before the expiry date will mean that upon expiry of the registration, the facility will no longer be able to legally conduct regulated activities with, Class B precursors, and appropriate administrative compliance actions may be taken.

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:

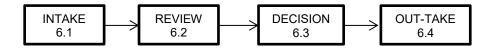
• Ensures clearly legible information, reducing the likelihood of errors in data entry;

- Ensures adherence to standard submission content; and
- Enables efficient application processing and faster response times.

All information and data submitted in support of a registration remains the property of Health Canada.

6.0 PROCESSING AN APPLICATION

In general, applications are processed through four stages, INTAKE, REVIEW, DECISION, OUT-TAKE, as illustrated below. All applications are processed on a first-in first-out basis.



The OCS targets the processing of the following types of applications through these process stages within the following service standard time frames:

- New applications within 90 calendar days
- Renewals within 60 calendar days
- Amendments within 30 calendar days
- Changes in Designated Personnel within 30 calendar days

Changes of ownership that result in new Certifications of Incorporation require the submission of a new Class B Precursor Dealer's Registration application. The OCS will issue a new registration number following the review of the new application. This type of change cannot be submitted via an Amendment application. A new registration application submitted for this reason will not require 90 calendar days to process, as long as there are no changes to the information listed on the current registration. In these cases, the OCS will strive to issue a new registration within 30 calendar days of receipt. The OCS will work with the applicant to determine the preferred registration issuance date to ensure 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 Class B Precursor Dealer Registration Applications, for further details regarding service standards.

Important Tip:

It is important for the applicant to 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 response due date may result in the refusal of the application.

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

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 provided is not performed during INTAKE.

The OCS targets to complete INTAKE within five (5) 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 e-mail 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:

- 75 calendar days of a New Application successfully completing INTAKE;
- 45 calendar days of a Renewal Application successfully completing INTAKE;
- 15 calendar days of a Change in Designated Personnel Application successfully completing INTAKE; and

 15 calendar days of an Amendment Application successfully completing the 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 registration.

6.3 DECISION

During DECISION, applications and decision documents undergo final review.

The OCS targets to issue a decision within five (5) calendar days following the completion of REVIEW.

Decisions respecting applications include:

- approval and issuance of an amended, renewed or new Dealer's Registration;
- refusal to issue, amend or renew a Dealer's Registration;
- approval of designated personnel (SPIC); or
- refusal of designated personnel.

6.4.1 Approval

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

6.4.2 Refusal

Where the decision is to refuse to issue a new, amended or renewed Class B Precursor Dealer's Registration, the OCS will send an *Intent to Refuse Notification* to the applicant via e-mail which sets out the reasons for the proposed refusal. The *Intent to Refuse Notification* will give the applicant or the Registered Dealer 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 registration.

6.5 OUT-TAKE

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

The OCS targets to complete OUT-TAKE within five (5) calendar days.

Final decision is sent to the applicant via e-mail, and original registration certificates 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:

- o relevant application that the new information pertains to;
- specific section of the application form to which the updated information applies;
 and.

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 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 CLASS B PRECURSOR DEALER'S REGISTRATION APPLICATIONS

Application Type	Application Process Stages				Regulatory Decision Outcome	Overall Service
	INTAKE	REVIEW	DECISION	OUT-TAKE	Guiconie	Standard Calendar Days
Application for a Class B Precursor Dealer's Registration	5 Calendar Days	75 Calendar Days	5 Calendar Days	5 Calendar Days	Approval – Registration Issued Refusal – Registration not Issued	90
Application for Amendment of a Class B Precursor Dealer's Registration	5 Calendar Days	15 Calendar Days	5 Calendar Days	5 Calendar Days	Approval – Registration Issued Refusal – Registration not Issued	30
Application for Changes Affecting Designated Personnel in Charge	5 Calendar Days	15 Calendar Days	5 Calendar Days	5 Calendar Days	Approval — Changes Accepted Refusal – Changes Not Accepted	30
Application for Renewal of a Class B Precursor Dealer's Registration	5 Calendar Days	45 Calendar Days	5 Calendar Days	5 Calendar Days	Approval – Registration Issued Refusal – Registration not Issued	60