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Guidance Document

DESTRUCTION OF NARCOTICS, CONTROLLED AND RESTRICTED DRUGS AND TARGETED SUBSTANCES BY LICENSED DEALERS (CS-GD-020)

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Health Canada is responsible for helping Canadians maintain and improve their health. It ensures that high-quality health services are accessible, and works to reduce health risks.

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Document d'orientation - Destruction de stupéfiants, de drogues contrôlées et d'usage restreint et de substances ciblées par des distributeurs autorisés (CS-GD-020)

Foreword

Guidance documents are meant to provide assistance to regulated parties on how to comply with governing statutes and regulations. Guidance documents also provide assistance to departmental staff involved in administering legislation, regulations and/or policies in a manner that is fair and consistent.

Guidance documents are administrative instruments that do not have the force of law and are thus not intended to substitute for, supersede or limit the requirements set out under prevailing legislation. In the case of any discrepancy between this document and the actual text of prevailing legislation, the legislative text will prevail.

It is equally important to note that Health Canada reserves the right to request information or material, or define conditions not specifically described in this document in order to allow the Department to verify compliance with relevant regulations and/or adequately mitigate the risk of diversion of controlled substances to the illegal market.

Any questions of interpretation concerning this guidance document should be directed to the Controlled Substances Program Destructions Team by email at destructions@hc-sc.gc.ca.

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1.0 Introduction

The Controlled Drugs and Substances Act (CDSA) provides for the control of substances that can alter mental processes and that may produce harm to health and to society when diverted or misused. Except as authorized under its related regulations or via an exemption issued under section 56 of the CDSA, most activities involving substances regulated under the CDSA, such as possession, import, export, trafficking, production, etc., are prohibited.

Controlled substances are regulated and grouped into [Schedules I to V](#) to the CDSA.

At the present time, there are several sets of regulations made under the CDSA that set out the circumstances under which activities with controlled substances are permitted. Three regulations are relevant to this guidance document:

- [Narcotic Control Regulations](#) (NCR)
- [Food and Drug Regulations](#) (FDR-Parts G & J)
- [Benzodiazepines and Other Targeted Substances Regulations](#) (BOTSR)

1.1 Context

This document is intended to provide guidance to licensed dealers on the recommended procedures for the application, witnessing, transportation and acceptable methods of destruction of:

- Narcotics;
- Controlled and Restricted drugs; and
- Targeted substances.

Collectively, the above terms will be referenced as ‘*controlled substances*’ throughout the document.

This document does not apply to the destruction of post-consumer returns as defined in [Guidance Document: Handling and destruction of post-consumer returns containing controlled substances \(CS-GD-021\)](#), or controlled substances subject to a voluntary forfeiture.

1.2 Objectives

This guidance will:

- Set out guidelines for licensed dealers to destroy unserviceable drug products containing a controlled substance; and

- Set out record-keeping requirements related to destruction activities.

1.3 Scope and application

This document applies to:

- Licensed dealers intending to destroy controlled substances in their possession.

2.0 Roles and Responsibilities of Licensed Dealers

2.1 Environmental Legislation & Health Hazards

Despite having received an authorization from the Controlled Substances Program (CSP), it is still the responsibility of the licensed dealer to ensure that the destruction is not in contravention of any environmental legislation and will not present any health and safety hazard.

2.2 Records

Licensed dealers are to maintain, on the premises described in their Controlled Drugs and Substances (CDS) licence, accurate records (refer to Section 3.4) of all inventories pertaining to controlled substances and provide the CSP with the complete application forms (refer to Section 3.2) for destruction. Records must be made available to inspectors upon request during an inspection and provide traceability of the inventory.

2.3 Security – Storage and Transportation

The Senior Person in Charge (SPIC), Qualified Person in Charge (QPIC) or an Alternate QPIC (A/QPIC) is responsible for ensuring that adequate measures are in effect for the secure storage of unused, unserviceable or expired controlled substances. Products that are awaiting destruction must be stored in the approved secure environ, such as a safe, vault etc., as indicated on the licensed dealer's CDS licence. The licensed dealer should have an appropriate system in place to ensure that the value of the controlled substances stored in their secure environ does not exceed the maximum street value permitted under their licence.

If the products need to be transported off the licensed dealer's site for destruction (i.e. an off-site destruction facility), the licensed dealer must maintain security over the products until the destruction has been completed and the products are no longer recoverable. The off-site destruction facility does not need to be a licensed site as the licensed dealer is still in possession of the products.

3.0 Destruction Overview

Destruction of controlled substances cannot take place until it has been authorized by the CSP. An application must be submitted to the CSP office once the destruction is scheduled (refer to Section 3.2). All information presented in the application, including the method of destruction, date, time, name of witnesses and list of products to be destroyed, must be correct and unaltered from the time the authorization was provided until the time of the actual destruction.

Licensed dealers must determine the total street value of the controlled substances for destruction as described in *Appendix B – Table 1 of the [Directive on Physical Security Requirements for Controlled Substances and Drugs Containing Cannabis](#)*. It is the licensed dealer's responsibility to ensure that all of the requirements are met when applying for each destruction.

3.1 Unwitnessed and Witnessed Destructions

3.1.1 Unwitnessed Destructions

If the total street value of the destruction is less than \$750,000, the licensed dealer may destroy the controlled substances without the presence of a CSP inspector after receiving authorization from the CSP.

3.1.2 Witnessed Destructions

If the total street value of the destruction is more than \$750,000, the licensed dealer must contact the CSP destructions team to schedule a witnessed destruction with the presence of CSP inspector(s) at least 25 business days in advance of the planned destruction date.

Depending on the total street value of the destruction, the use of an escort to ensure the security during transportation should be evaluated and discussed with the CSP office.

The licensed dealer is required to implement occupational health and safety measures that are necessary to reasonably ensure the safety of inspectors and other personnel during the witnessing of destruction. The Inspector(s) may contact the licensed dealer to confirm that safety measures are in place prior to scheduling a destruction date.

The CSP Inspector(s) will conduct product reconciliation at the licensed dealer's site, witness transportation of the products (if applicable) and witness the destruction of the products. Licensed dealers need to ensure that there is adequate time for the Inspector(s) to conduct their duties prior to destruction.

In situations where significant deficiencies are identified during reconciliation, the destruction may be halted and the licensed dealer may be required to submit a corrective action plan prior to the destruction taking place.

3.1.3 Unannounced Compliance Verification

All destruction applications with a street value of less than \$750,000 may be subject to compliance verification inspections to verify that the information listed in the application is accurate and that the requirements of the destruction process are met.

In situations where significant deficiencies are identified during compliance verification, the destruction may be halted and the licensed dealer may be required to submit a corrective action plan prior to receiving subsequent authorizations for destruction.

3.2 Application Requirements

Licensed dealers must contact the CSP destructions team and follow the process to submit an application for destruction. Licensed dealers must provide the requested information pertaining to controlled substances inventory included in a destruction shipment and the associated destruction process to the CSP office. This information provides auditable and traceable records on products destroyed for subsequent inspections.

Licensed dealers are required to submit a destruction application to the CSP office at least ten business days prior to the proposed date of destruction if the total street value of the destruction is below \$750,000. For destructions with a street value of \$750,000 and above, licensed dealers are required to contact the CSP destructions team at least 25 business days in advance to schedule a Witnessed Destruction of the controlled substances.

3.2.1 Application Template

All applications concerning the destruction of controlled substances will only be accepted using the national destruction application template. Contact the CSP destructions team at destructions@hc-sc.gc.ca to obtain further information on the application and service standards.

All applications must contain, at minimum, the following:

- Licensed dealer's name, address and active CDS licence number;
- Date of the application;
- A unique destruction identification number;
- The reason for destruction;

- The proposed date, time and location of destruction;
- A brief outline of the proposed method of destruction;
- The total street value and the total weight of all the substances to be destroyed;
- Name and qualification of the witnesses (refer to Section 3.3.1), including the province of registration for those registered as health professionals; and
- A signed attestation indicating that the proposed method of destruction conforms with all applicable federal, provincial and municipal environmental legislation and that all information submitted in support of the application is correct and complete to the best of the QPIC or A/QPIC's knowledge.

A complete reconciliation of the controlled substances for destruction must be conducted by the QPIC and/or A/QPIC and entered into the table of the destruction application. The table should contain the most accurate and up to date information of the products and consist of the following:

- Product name;
- Dosage form/bulk;
- Strength per unit of controlled substance and the unit of measurement (such as mg, mg/ml, percent);
- Total quantity for destruction (such as dosage units, volume, net weight, no. of packages, skid weight) broken down into the type of container, number of container and units per container;
- Name of controlled substance active ingredient, as listed on the CDS licence (such as lorazepam);
- Street value of controlled substance per unit (such as \$25,000/kg for lorazepam);
- Total quantity of controlled substance active ingredient weight in kg;
- Conversion factor (see below paragraph);
- Total weight of the substances to be destroyed (including the weight of packaging components); and
- Total street value.

In order to determine the quantity of a controlled substance in its base form, the following formula can be utilized to calculate the conversion factor, which is used when a product contains controlled substances in a salt derivative form.

$$\text{Conversion factor} = [\text{molecular weight of base}] / [\text{molecular weight of salt}]$$

The International Narcotics Control Board (INCB) also provides a list of common derivatives in the [Yellow List](#) and [Green List](#). These lists include tables that show conversion factors for drugs in their ester, ether and salt forms, calculated on the basis of the pure anhydrous drug content.

The street value of the substances to be destroyed is to be calculated as described by the [*Directive on Physical Security Requirements for Controlled Substances and Drugs Containing Cannabis*](#). It is the responsibility of the licensed dealer to contact the CSP destructions team to confirm the street value if a controlled substance is not on the list.

It is important to ensure that applications are correct and complete to the best of the QPIC or A/QPICs knowledge. Any application that requires amendments and/or further clarifications may take longer to be processed for approval by the CSP. If the application is inadequate, it will be sent back to the applicant and will not be processed until the inadequacies are addressed. Examples of this may include, but are not limited to, missing required fields, incorrect conversion factor use, or missing signatures.

3.2.2 Multiple Destruction Applications

Licensed dealers are allowed to submit a maximum of two unwitnessed destruction applications with the same proposed date of destruction. The following requirements have to be met for the applications to be accepted:

- Each destruction must have a unique destruction identification number;
- Each destruction must take place at a different time if the same witnesses are listed;
- Witness packets and relevant documents such as Certificate of Destruction must indicate destruction times as proposed; and
- Each destruction must be transported and destroyed separately, if it is destroyed off-site.

3.2.3 Changes to Authorized Destruction Application

The licensed dealer must provide an amended destruction application for any changes to an authorized destruction, specifying all the changes made to the initial application as well as an explanation for the changes. Such changes can include, but are not limited to, changes in witness and the date/time of destruction. However, any change to the list of controlled substances, including the quantity, being destroyed requires a new application to be submitted to the CSP office for review and any previous authorization is annulled.

If there are any **planned changes** to the original authorized destruction application, the CSP office must be notified via email a minimum of **one business day prior** to the date of destruction.

Should a destruction not occur on the authorized date of destruction due to **unforeseen circumstances** (e.g. incinerator malfunction, witnesses unavailable), the CSP office must be notified via email within **24 hours**. An amended and signed application with the new proposed date of destruction and all applicable changes must be submitted to the CSP office **at least one business day prior** to the new date of destruction.

3.3 Personnel Involved

The QPIC or A/QPIC of the licensed dealer compiles all drug products containing controlled substances for destruction. The QPIC or A/QPIC signs the application and submits it to the CSP office, requesting authorization to destroy the listed products.

3.3.1 Licensed Dealer Witnesses

At least two people are required to be present to witness the destruction. One of the witnesses must be the SPIC, QPIC, or an A/QPIC. There must also be one of the following people acting as a second witness during the destruction:

- A/QPIC;
- Person who holds a senior position at the licensed dealer (such as Manager of Controlled Substances Division, Vice President, etc.).

No other person shall be present at the destruction unless they are required for one or more of the following reasons:

- Required to physically handle the drugs;
- Required to operate the equipment used to destroy the drugs;
- They are the person undertaking the destruction (which can be one of the qualified witnesses);
- To act as a witness; or
- They are a CSP inspector.

The licensed dealer may have more than two witnesses present if it is necessary for security or operational reasons and their presence does not reduce drug security. Witnesses cannot leave the destruction site until all controlled substances are destroyed or unrecoverable.

In the circumstance when the destruction takes place off the licensed dealer's site, the licensed dealer in possession of the controlled substances is responsible for meeting all witness requirements. This includes the qualified personnel maintaining security during transportation, and witnessing the destruction of the controlled substances.

3.4 Record Keeping Requirements

Within 24 hours of completing the destruction, the two witnesses and the person undertaking the destruction must sign and date a witness document containing the following:

- The name and title of the witnesses;
- The date, time, location and method of the destruction;

- The unique destruction identification number; and
- A statement indicating that the witness attests to witnessing the destruction of all the listed drugs in the application.

A copy of all documents relevant to the destruction must be forwarded to the CSP office within 15 business days of the destruction date. The witnesses and person undertaking the destruction must sign the application form. The original records must be retained on the licensed dealer's premises for at least two years in an auditable format.

Licensed dealers that are specialized in waste destruction are responsible to maintain accurate records of all controlled substances received from other licensed dealers for destruction by performing a 100% inventory reconciliation both upon receipt of the materials and immediately prior to their destruction.

4.0 Method of Destruction

The method of destruction must alter or denature the controlled substances to such an extent that consumption has been rendered impossible or improbable. Licensed dealers should be aware that the method of destruction may vary from substance to substance depending on its chemical or physical properties. It is the responsibility of the licensed dealer to ensure that all controlled substances are adequately destroyed by the proposed method of destruction.

Incineration is the preferred method of destruction for all unserviceable controlled substances; however, other methods of destruction may be considered for the instances listed under section 4.2. Licensed dealers are encouraged to consult the respective controlled substance monographs when determining appropriate methods of destruction.

Licensed dealers must carry out destructions in compliance with all applicable federal, provincial, and municipal environmental legislation or bylaws.

4.1 Incineration

The incinerator must:

- Retain all drugs on, or above, any grate contained therein until they are destroyed;
- Only have one opening, excluding the chimney. Should there be more than one such opening, then all openings must be under the constant vision of the witnesses unless the openings are locked in such a manner that drugs cannot be removed without the witnesses' knowledge; and
- Reach a temperature of at least 400 °C during the destruction cycle.

4.2 Denaturation

Chemical destruction (denaturation) can be used in instances where:

- Incineration will not meet federal, provincial or municipal environmental laws;
- Incineration may result in a health hazard to either those destroying the drugs or to the general public;
- The type of material being destroyed may damage an incinerator or is incompatible with incineration; or
- There is no incinerator available in the vicinity of the licensed dealer.

A description of the method of destruction, that includes but is not limited to, the quantity of denaturing agent to be used, the period of time the mixture will be stirred/settled and what will be done with the resulting chemical waste components (i.e. incinerated as pharmaceutical waste) should be included in the application.

The following are examples of denaturing methods:

- Mixing the products with strong acids such as hydrochloric acid, nitric acid, sulfuric acid, or strong base such as concentrated sodium hydroxide and disposing of waste products in accordance with environmental regulations; or
- Mixing the products with radioactive or halogenated waste and disposing of waste products in accordance with environmental regulations; or
- Mixing the products with a combination of denaturing agents and incinerating the waste.

5.0 Loss or Theft

Any loss or theft must be reported to Health Canada. Please refer to the [Guidance Document: Reporting Loss or Theft of Controlled Substances and Precursors \(CS-GD-005\)](#).

Annex A: Definitions

The following definitions are provided for reference:

controlled drug	means a drug set out in the Schedule to Part G of the FDR and includes a preparation ¹ ;
destruction	means to alter or denature a controlled substance to such an extent that its consumption is rendered impossible or improbable;
inspector	means any person properly designated as an inspector under section 30 of the CDSA;
licensed dealer	means the holder of a dealer's licence issued under the NCR, the FDR – Part G and J, or the BOTSR;
narcotic	means any substance set out in the Schedule to the NCR or anything that contains any substance set out in that Schedule ² ;
post-consumer return	means unused or expired drug substance or drug products containing a narcotic, targeted substance or controlled drug that are returned by an individual consumer to a retail pharmacy for destruction purposes but do not include drug products returned to a hospital pharmacy from patient wards;
practitioner	means a person who is registered and entitled under the laws of a province to practise in that province the profession of medicine, dentistry or veterinary medicine, and includes any other person or class of persons prescribed as a practitioner ³ ;

¹ See G.01.001(1) of Part G-FDR.

² See Interpretation section of the NCR.

³ See Section 2.(1) of the CDSA.

restricted drug	means a controlled substance that is set out in the Schedule to Part J of the FDR, or a product or compound that contains the substance
targeted substance	means a controlled substance that is included in Schedule 1 to the BOTSR or a product or compound that contains a controlled substance that is included in Schedule 1 to the BOTSR;
unserviceable stock	means drug product containing a narcotic, targeted substance or controlled drug that is unused, expired and/or that cannot be dispensed.