

Standard Operational Procedure SOP-EHS-005

Controlled Substance/Drug Acquisition, Handling, Storage and Disposal

1. Purpose

To establish a procedure for ensuring that all Controlled Substances are acquired, handled, and disposed of in a safe and secure manner and for ensuring that Concordia University is in compliance with Health Canada's Directive on *Physical Security Requirements for Controlled Substances*, specifically the *Conditions of a Section 56: Exemption to Use Controlled Substances for Scientific Purposes*.

2. Definitions

- 2.1. **Controlled Substance:** a Controlled Substance is any type of drug that the federal government has categorized as having a higher-than-average potential for abuse or addiction. Such drugs are divided into categories based on their potential for abuse or addiction. Controlled Substances range from illegal street drugs to prescription medications listed in the *Controlled Drugs & Substances Act (S.C. 1996, c. 19)*.
- 2.2. **Drug** includes any substance or mixture of substances manufactured, sold or represented for use in :
 - a) the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state, or its symptoms, in human beings or animals,
 - b) restoring, correcting or modifying organic functions in human beings or animals, or
 - c) disinfection in premises in which food is manufactured, prepared or kept;
- 2.3. **EHS Investigator:** Environmental Health and Safety (EHS) staff assigned to conducting an incident investigation.
- 2.4. **Exemption period:** the period of time for which the Scientific Exemption License for Controlled Substances is valid.
- 2.5. **Inspector:** officers from Health Canada's Health Products and Food Branch Inspectorate.
- 2.6. **Protocols:** the process(es) or experiment(s) documented in the *Application Form for an Exemption to Use a Controlled Substance for Scientific Purposes* that researchers submit in order to obtain the right to purchase Controlled Substances under a scientific exemption.
- 2.7. **Researcher:** as referred to in the Section 56 Exemption to use Controlled Substances for Scientific Purposes, includes any Concordia University Principal Investigator or Lab Manager who holds a Scientific Exemption License for Controlled Substances from Health Canada's National Compliance and Exemption Division.

Created by	Document No.	Version	Effective Date	Replaces	Page
Frederic Guilhem	EHS-SOP-005	1.0	Oct 2014	N/A	1 of 7

- 2.8. **Scientific Exemption License for Controlled Substances:** the type of license granted to researchers from Health Canada’s Establishment License Unit in order to use Controlled Substances for scientific purposes as specified in Section 56: Exemption to use Controlled Substances for Scientific Purposes.

3. Roles & Responsibilities

3.1. Researcher

- Submit a copy of their [Application Form for an Exemption to Use a Controlled Substance for Scientific Purposes](#) to EHS prior to sending it to Health Canada
- Ensure that a *Scientific Exemption License for Controlled Substances* is obtained from Health Canada’s Establishment License Unit prior to obtaining Controlled Substances;
- Submit a copy of their *Scientific Exemption License for Controlled Substances* and accompanying conditions form to EHS when received from Health Canada;
- Liaise with EHS and Health Canada regarding matters of compliance with Health Canada’s Directive on Physical Security Requirements for Controlled Substances;
- Provide all individuals (staff and students) who will work with Controlled Substances detailed information on the procedures for acquisition, storage, use and disposal of Controlled Substances applicable at Concordia and keep a written record of it;
- Provide EHS with proof of training provided to all individuals (staff and students) who will work with Controlled Substances;
- Maintain proper recordkeeping for the administration, use and disposal of all Controlled Substances;
- Permit entry to any Inspector or member of EHS, at any reasonable time, to ensure compliance with their *Scientific Exemption License for Controlled Substances*;
- Immediately report any missing inventory of Controlled Substances to Concordia Security (as per Security Policy VPS-20) and EHS; and
- Report any missing inventory of Controlled Substances to Health Canada within 10 days of its discovery.

These responsibilities can be delegated to Departments or Centers with designated individuals whose responsibilities include the management of Controlled Substances on behalf of department or center faculty or researchers.

3.2. EHS

- Maintain oversight on all Controlled Substances purchased, used, stored and disposed of at Concordia University;
- Liaises with the Deans for Certification Letters on behalf of researchers;
- Prepare and enforce standardized procedures regarding the procurement, import, dispensing, use, storage and disposal of Controlled Substances at Concordia University;
- Liaise with Health Canada’s Establishment License Unit with respect to the purchase, use, storage and disposal of Controlled Substances at Concordia University;

Created by	Document No.	Version	Effective Date	Replaces	Page
Frederic Guilhem	EHS-SOP-005	1.0	Oct 2014	N/A	2 of 7

- Ensure that Controlled Substances are purchased, used, stored and disposed of in accordance with Health Canada’s requirements and conditions for licensure; and
- Work with Health Canada to overcome any difficulties or concerns regarding compliance with conditions of licensure.

3.3. EHS Investigator

- Work with the researcher and Health Canada to ensure the safe use of Controlled Substances and compliance with Health Canada’s conditions for licensure; and
- Make recommendations for improvements in safety and security with regards to the purchase, use, handling and storage of Controlled Substances.

4. Procurement of Controlled Substances

- 4.1. Researchers must only procure Controlled Substances listed in their *Scientific Exemption License for Controlled Substances*.
- 4.2. All substances scheduled in the *Controlled Drugs and Substances Act* or in *Schedule D* of the *Food and Drug Act* require a section 56 exemption specific to that substance.
- 4.3. Researcher must not exceed the quantity of Controlled Substances indicated in their *Scientific Exemption License for Controlled Substances*.
- 4.4. Exemptions are only active for one year; exemption period begins on the day Health Canada issues the Exemption authorization letter and ends one year from that date. Controlled substances may not be purchased after the Exemption is expired, regardless of any 'unused' portion remaining on the Exemption license. If any Controlled Substances remain in stock when the Exemption is due to expire, the researcher must submit an 'Extension' application to use and possess those Controlled Substances.
- 4.5. All orders for Controlled Substances must be placed through Concordia’s Purchasing Department, which has copies of *Scientific Exemption licenses* and records of previous shipments to ensure that the total quantity allowed by the license is not exceeded.
- 4.6. Packages containing Controlled Substances are received by Distribution Services then handed to the designated receiving person from the destination laboratory. The package must be opened in the presence of distribution services to examine the contents and ensure that the items present match the items ordered and that the seals on bottles/containers are intact. The recipient then signs acknowledging receipt of the package.
- 4.7. The total quantity of Controlled Substances in a specific location shall not exceed the quantity indicated in the *Scientific Exemption License for Controlled Substances* as doing so could render the security measures insufficient.

Created by	Document No.	Version	Effective Date	Replaces	Page
Frederic Guilhem	EHS-SOP-005	1.0	Oct 2014	N/A	3 of 7

- 4.8. Researchers must only procure Controlled Substances from the supplier listed in their *Scientific Exemption License for Controlled Substances*.
- 4.9. Researchers must only use the Controlled Substances for those protocols listed in their *Scientific Exemption License for Controlled Substances* and for the purpose indicated in those protocols.
- 4.10. Controlled Substances cannot be shared with other researchers working on other projects.
- 4.11. In the event that a project is terminated before the end of the Exemption period, the researcher must inform EHS and Health Canada of the remaining inventory.
- 4.12. Researcher cannot give, transfer or dispose of any remaining quantity of Controlled Substances in inventory to other researchers without authorization from Health Canada.

5. Record Keeping

- 5.1. Researchers are required to maintain records (*i.e.* a log book) of all Controlled Substances that have been purchased, received, used and/or destroyed. The log book must track the quantities removed from each original container using lot numbers and dates.
- 5.2. Researchers must keep and retain for a period of five (5) years from the making of such record, the following information:
- kind and quantity of any Controlled Substance purchased or received;
 - date of reception;
 - name and address of the person from whom the Controlled Substance was received;
 - details of their use.
- 5.3. Records must be made available to EHS, inspectors and the Minister of Health upon request.

6. Security

- 6.1. Researchers must safeguard Controlled Substances in their possession from theft in a satisfactory manner. Any theft or loss must be reported to Concordia Security and EHS immediately, and within 10 days of its discovery to the National Compliance Section, Officer of Controlled Substances.
- 6.2. Security measures must meet the requirements set out in the conditions for Scientific Exemption License for Controlled Substances set forth by Health Canada. A list of criteria for different security levels is included in Section 8.
- 6.3. Researchers are required to store their inventory of Controlled Substances separately from the Controlled Substance inventory of other researchers.

Created by	Document No.	Version	Effective Date	Replaces	Page
Frederic Guilhem	EHS-SOP-005	1.0	Oct 2014	N/A	4 of 7

7. Destruction

- 7.1. Researchers are responsible for ensuring the destruction of any unused or expired Controlled Substances by the end of the Exemption period so that the inventory of controlled substances on hand is zero at the end of the Exemption Period.
- 7.2. The method of destruction must alter or denature the Controlled Substance in such a way as to make it non-recoverable and thus make its consumption improbable or impossible.
- 7.3. Researchers must fill out the Controlled Substance Destruction Form (EHS-FORM-075) with the required information and retain it for a period of five (5) years from the date of destruction.
- 7.4. The destruction must be witnessed by a member of EHS.
- 7.5. The usage logs associated with a batch of Controlled Substances obtained under a scientific exemption can be transferred to EHS for long-term archiving following their destruction. EHS will keep these records at their local office at either the Loyola or Sir George Williams campus.

8. Security Requirements by Level

Controlled Substances must be kept in a secure area, preferably a dedicated lockable drawer or cabinet, to prevent loss or theft. A document outlining the physical security requirements for Controlled Substances can be found on the Health Canada website at:

http://www.hc-sc.gc.ca/hc-ps/pubs/precurs/dealers-distrib/phys_securit_directive/index-eng.php

For Concordia University, security levels 1, 2, or 3 may apply, depending on the value of the Controlled Substance(s). This value must be calculated according to the Appendix B of the above document, in Table 1 prices to be utilized in determining the illicit value of Controlled Substances.

Value of Controlled Substance	Security Level required
Licensee Holdings \$2,501 to \$10,000	3
Licensee Holdings \$501 to \$2,500	2
Licensee Holdings \$0 to \$500	1

8.1. Security requirements for Level 1

The following are examples of the minimum requirements which the Bureau will accept for level 1 security.

- A cupboard, refrigerator, a drawer in a steel cabinet, or an equivalent may be used to contain Controlled Substances provided that they are located in locked rooms and fastened to the room's floor or wall. This storage unit must be secured with an approved padlock or equivalent locking mechanism.

Created by	Document No.	Version	Effective Date	Replaces	Page
Frederic Guilhem	EHS-SOP-005	1.0	Oct 2014	N/A	5 of 7

- The approved security device must be located in a room to which the public does not have access.
- Records of the issuing of combinations and keys, under the authorization of a departmental designate must be maintained and made available to federal inspectors upon request.

8.2. Security requirements for Level 2

The following are examples of the minimum requirements which the Bureau will accept for level 2 security.

- A steel cabinet, refrigerator or equivalent located in a locked room and fastened to a wall or floor so that it is immovable. The cabinet or refrigerator must be locked with an approved padlock.
- The approved security device must be located in a room to which the public does not have access.
- Records of the issuing of combinations and keys, under the authorization of a departmental designate must be maintained and made available to federal inspectors upon request.
- An alarm system will be required and must activate at minimum a local electric horn or bell when an unauthorized access is attempted.

8.3. Security requirements for Level 3

Health Canada may, at their discretion, require controls up to this level from academic institutions conducting scientific research. The requirements for this level are as follows:

- An alarm system will be required and must activate at minimum a local electric horn or bell when an unauthorized access is attempted.
- The Controlled Substances must be located in a locked vault or safe with requirements for each listed below.
- Records of the issuing of combinations and keys, under the authorization of a departmental designate must be maintained and made available to federal inspectors upon request.

8.3.1. Vault (Secure Environs)

- Wall/Floor/Ceiling
 - Constructed of 10 cm (4") cement block minimum or equivalent.
 - Structural floor to structural ceiling construction (i.e. -no false floors or ceilings).
 - Unsecured openings must have one dimension less than 15 cm (6") and must not exceed 619 cm² (96in²). Acceptable grill work for secured opening will consist of 3.5 mm (10 gauge) metal mesh screen or equivalent.
- Door
 - Solid core wooden door or hollow metal.
 - Locking device must penetrate the door frame at least 1.25 cm or be of a vertical throw type lock. Locking device cannot be on a master key system.
 - Metal frame grouted in the area of the strike plate. Wood frame blocked in the area of the strike plate complete with a high security strike.
 - One and one half pair butt hinges (3 hinges (no removable pins if out-swinging door)).
 - Windows in door not permitted.

Created by	Document No.	Version	Effective Date	Replaces	Page
Frederic Guilhem	EHS-SOP-005	1.0	Oct 2014	N/A	6 of 7

- Records of the issuing of combinations and keys, under the authorization of a departmental designate must be maintained and made available to federal inspectors upon request.

8.3.2. Safe

- A records safe may be used for this security level providing it is not rated lower than U.L.C. (Underwriters Laboratories of Canada) type “D” (350-1 new rating). The safe must be anchored to the floor.
- The safe must be located in a locked cupboard or room. No window should be located within 4.5 metres (15’) from the grade level or roof deck unless it is locked. There are no size restrictions on the windows. Windows are not permitted within 1 metre (3’) of the door. Windows fixed or openable with a lock must have a grill or screen of 3.5 mm (10 gauge) expanded metal mesh or equivalent installed in a manner that it is removable from the inside only. An acceptable alternative to the window requirements stated above is if the windows are polycarbonate glazed and mounted in a heavy duty frame.

9. Approved Locks for Drug Cabinets*

Manufacturer	Model	Shackle Diameter (mm)	Shackle Clearance (mm)
ABLOY	2071	11	25
AMERICAN	570 (with dead locking)	10	28
BEST	27B462 (with security sheath)	12	32
MASTER	15	11	25
MEDECO	50-600	10	25
PAPAIZ	CR60	10	35
VIRO	304/60 MM	10	35

- Any padlock not listed into that table must be approved by the Office of Controlled Substances. Contact EHS for assistance in obtaining the approval.

10. SOP Revision History

Version	Sections changed	Author	Date
1.0	New SOP	Frederic Guilhem	Oct. 2014

11. Signature

This SOP requires the following approvals:

Pietro Gasparini

Director

Environmental Health & Safety

Signature

Date

Created by	Document No.	Version	Effective Date	Replaces	Page
Frederic Guilhem	EHS-SOP-005	1.0	Oct 2014	N/A	7 of 7