

# UNIVERSITY OF AUCKLAND

Faculty of Science  
Faculty of Medical and Health Sciences

## STANDARD OPERATING PROCEDURE

### Chemicals as Controlled Drugs

Version 2 – June 2013

#### Definitions

AWO	Animal Welfare Officer
CDO	Controlled Drug Officer
CMR	Controlled Medicines Register
Controlled Drugs Officer	A nominated, trained person responsible for the control of Controlled Drugs Safes
HCM	Hazards and Containment Manager
Shall	Mandatory action to ensure desired outcome
Should	Recommended action to assist with achieving desired outcome

#### 1.1. Requisition of Chemicals as Controlled Drugs from NZ wholesalers

- 1.1.1. Chemicals qualifying as Controlled Drugs shall only be ordered using a written direction (signed Purchase Order) from the HCM or AWO.

#### 1.2. Importation of Chemicals as Controlled Drugs from Overseas

- 1.2.1. Chemicals qualifying as Controlled Drugs shall only be ordered once a Permit to Import Controlled Drugs has been obtained from Medicines Control, Ministry of Health (for details, see Application for a Licence to Import/Export Controlled Drugs: Guidelines for Applicants). HCM or AWO must be informed of each Application for a Permit to Import Controlled Drugs. Purchase of the Controlled Drugs must still be countersigned the HCM or AWO.

#### 1.3. Use of Controlled Drugs by Researchers

- 1.3.1. Controlled Drugs must be stored in a safe that is bolted to the structure of the building. Controlled Drugs safes must be approved by the Medicines Control before use. This is to ensure compliance with the conditions of the Controlled Drugs License.
- 1.3.2. Each safe will be under the control of a Controlled Drugs Officer nominated on the information provided on the application for the Controlled Drug license. This person will be trained and be recorded as qualifying as a Controlled Drugs Officer.

- 1.3.3. **All withdrawals of controlled drugs and the entry into the Controlled Drug Register will be witnessed by the Controlled Drugs Officer** to ensure accuracy. The CDO will enter their initials to signify their witnessing.
- 1.3.4. The Controlled Drugs Officer may nominate one other person to provide cover for holidays and sick leave. Nominees must, however be trained and approved as Controlled Drugs Officers (see 1.4.1).
- 1.3.5. The back up CDO is treated as a Controlled Drugs Officer for all intents and purposes. The primary Controlled Drugs Officer still retains overall responsibility for Controlled Drugs.

#### **1.4. Training of Controlled Drugs Officers**

- 1.4.1. Controlled Drugs Officers (or nominated deputies) are trained and approved by the HCM or AWO. Medicines Officers training covers Controlled Drugs and will suffice.

#### **1.5. Controlled Register**

- 1.5.1. Class A, B, C1 and C7 controlled drugs must be recorded in a Controlled Drugs Register.
- 1.5.2. Each form and strength of Controlled Drug must have its own page. Replacement vials should be recorded as a new "in" on the same page, as long as they contain the same controlled drug in the same form and strength as the previous entries.
- 1.5.3. Entries in the Controlled Drug Register (CDR) shall be recorded as Tare Weight (ie total weight of chemical and its container) in grams, and shall be recorded to at least one decimal place.
- 1.5.4. Weights shall be recorded using a relatively accurate balance. Weight after withdrawal shall be recorded, and the difference in weights before and after removal will be recorded as the amount used.
- 1.5.5. Where the total weight of a container exceeds the capacity of the balance, the chemical shall be decanted into a smaller glass container from which withdrawals are made. This smaller container shall be indelibly labelled as to its contents. Records for the working container will be made on a separate page from the original container.
- 1.5.6. Replenishment of a working container shall be witnessed by the HCM.

#### **1.6. Register Maintenance**

- 1.6.1. Entries:
  - i) to be legible and indelible
  - ii) to be signed and dated (including Stock takes and Reconciliations)
  - iii) no alterations or obliterations
  - iv) corrections: place a bracket around mistakes and make the correction in an additional entry on the next line
- 1.6.2. Use of IN column

The IN column is to be used for purchases of new stock, replenishing working containers, increases in weight and stock takes.

### **1.7. Reconciliation and Stock take of Controlled Drugs Registers**

- 1.7.1. Stock in the controlled Drugs Safes shall be reconciled every 3 months by the Controlled Drugs Officer.
- 1.7.2. The purpose of the Reconciliation is to correct any miscalculations that may have been carried down in the Balance column. This gives a true Balance from which to Stock take. It is calculated from the last reconciliation (or beginning of register if new drug entry)
  - (1) add up total of IN
  - (2) add up total of OUT (usage)
  - (3) subtract OUT from IN and record in BALANCE column
- 1.7.3. On the same day as the calculated reconciliation, the stock on hand shall be weighed (Stock take) and recorded both in the IN column and the Balance column of the CMR. Stock take is a physical measuring of stock. All Controlled Drugs are recorded as Tare Weights. Enter the stock amount into both the IN column and the Balance column.
- 1.7.4. Reconciliation and Stock take are calculated and signed off in the CMR by the Controlled Drug Officer on the last day of every THIRD month (i.e. 28 March, 30 June, etc) or as close to this date as practicably possible (within a week before or after). Legislation requires that a reconciliation and stocktake are performed as at close of business on 30 June and 31 December each year. It is the responsibility of the Controlled Drug Officer to ensure that this is carried out on the due dates. Please note that as the University closes on 23 December this stocktake can either be carried out on that day, or on the day that the University reopens at the beginning of January.
- 1.7.5. The reconciled balance and stock take balance should agree. Where there is a discrepancy between balances, the reason should be searched for (e.g. in lab notebooks) and the reason recorded on a new line in the CMR. Discrepancies of more than 0.3 gram must be reported to the HCM immediately for investigation and resolution of the discrepancy.
- 1.7.6. **Stock take only is required (i.e. no Reconciliation) where there has been no chemical use in the period since the last stock take.**
- 1.7.7. An institutional audit will be performed every 6 months by the HCM.

### **1.8. Destruction of controlled drugs**

- 1.8.1. Destruction of Controlled Drugs shall be witnessed by HCM and signed by the CDO.
- 1.8.2. Destruction of Controlled Drugs is achieved by discharging to sewer of a very large volume of solvent so it is impossible to easily retrieve the drug. Where the compound is mixed with solvent it must be discharged into a minimum of 20 litres solvent.
- 1.8.3. All empty containers shall be weighed, washed out and then signed out of the research group CMR by a CDO and witnessed by HCM.

**Chemical Name** (only one kind and one strength per page):

**Gamma  
Butyrolactone**

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DATE	Name of person supplied ( Or form from which or into which controlled drug was made	USAGE and RECONCILIATION			SIGNATURE	INITIALS (CDO)
		IN	OUT	BALANCE		
30/04/2012	Stocktake	180g		180g		TL
10/05/2012	David Jenkins		2.5g	177.5g		TL
12/05/2012	David Jenkins		5g	172.5g		TL
30/06/2012	Register reconciliation	180g	7.5g	172.5g		TL
30/06/2012	Physical Stocktake			172.5g		
20/6/12	Balance carried forward	172.5g		172.5g		
2/07/2012	David Jenkins (calibration std)		1g	171.5g		TL
15/07/2012	David Jenkins		(5g)	(166.5g)		TL
15/07/2012	David Jenkins (4.5g taken not 5g)		4.5	167g		TL
30/09/2012	Register reconciliation	172.5g	5.5g	167g		TL
30/09/2012	Physical Stocktake			167.1g		TL
30/09/2012	Measuring error/water absorption	0.1g		167.1		TL
30/9/12	Balance carried forward	167.1		167.1		
23/12/2012	Stocktake	167.1g		167.1g		TL
6/1/13	To Register page 24					TL
	N.B:					
	<b>1. Where there is no use of chemical, reconciliation is not required</b>					
	<b>2. Explain any discrepancies between reconciled balance and stocktake on new line</b>					

These two figures  
should agree

Put brackets  
around mistakes  
and put corrected  
entry on new line

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		IN	OUT	BALANCE		
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