

Controlled Substances – Management of Regulated Chemicals

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1. Purpose

The intent of this procedure is to ensure a systematic approach is applied when selecting, procuring and managing regulated chemicals, to prevent or minimise potential health and safety risks.

The University must ensure that risks related to the sale, supply, possession and use of controlled substances are suitably managed and controlled. This includes:

- ensuring health and safety management is a key criterion in the selection of controlled substances;
- identifying hazards and mitigating risk at the procurement stage to ensure safe systems of work with controlled substances;
- ensuring appropriate storage and safe use of controlled substances;
- providing adequate information, instruction, training and supervision; and
- consulting with other duty holders who have a legislative duty in relation to the controlled substances.

2. Definitions

Controlled precursor – is a substance declared by the regulations to be a controlled precursor for the purposes of the *Controlled Substances Act 1984*.

Drug – is a poison designed for human or animal therapeutic use.

End User Statement/ Declaration – is a declaration that must be signed by the end user of the controlled substance and provided to the manufacturer/ supplier and/or regulatory body when purchasing a controlled substance (refer to Appendix 2: Example End User Statement).

Manufacture, of a controlled substance – means to undertake any process by which the substance is extracted, produced or refined or to take part in the process of manufacturer of the substance.

Other person - a person, organisation, their employees or representatives that are NOT engaged to carry out work on behalf of the University.

Possession, of a controlled substance – includes having control over the disposition of the substance or having joint possession of the substance.

Re-sold or re-supply, of a controlled substance – is the selling or supply to a person, organisation, their employees or representatives that are NOT engaged to carry out work on behalf of the University. [N.B. It is acceptable to transfer controlled substances between Schools/Portfolios/Units within the University.]

Restricted or prohibited carcinogen – means a substance listed under Schedule 10 of the *Work Health and Safety Regulations 2012* and present in a concentration of 0.1% or more.

Scheduled Drugs & Poisons – means pharmaceuticals and poisons that require licensing under the *Controlled Substances Act 1984*.

Scheduled medicine – means a medicine that contains a substance included in a schedule of the Uniform Poisons Standard.

Sell, a controlled substance – means sell, barter or exchange, offer or agree to sell, barter or exchange or expose for sale, barter or exchange the substance.

Supply, of a controlled substance – means provide or distribute or offer to provide or distribute the substance.

3. Scope

A wide range of regulated chemicals are handled and used at the University of South Australia, including:

- prohibited and restricted carcinogens;
- scheduled poisons;
- scheduled medicines, and;
- precursor chemicals.

These substances can cause harm if not used safely and managed appropriately. The relevant legislative instruments include controls over the manufacture, sale, supply, possession and use of some of these substances. The University is committed to ensuring all personnel are provided with a healthy and safe workplace and study environment and comply with their legislative requirements.

4. Roles and Responsibilities

The University, as a 'Person Conducting a Business or Undertaking' (PCBU) has 'Research Instruction, Training or Analysis' Permits for campuses, as required, which allows the University to manufacture, supply, possess and use Schedule 2, 3, 4 and 7 controlled substances and specified restricted carcinogens at these locations.

Staff who use controlled substances have a responsibility to:

Ensure there is an authorisation/permit for the controlled substances and the conditions of any permit for the controlled substance are met including:

- signing an End User Statement/ Declaration for controlled substances when requested by the manufacturer/supplier;
- ensuring the controlled substances must not be re-sold or supplied to any other person;
- storing the controlled substances in suitable containers, appropriately labelled, and when not in use, stored in a locked receptacle or enclosure;
- restricting access to the controlled substances to only authorised persons;
- when transporting controlled substances to a field trip location, complete a risk assessment detailing the safe transport and security of the substances including ensuring the substances are stored in a locked receptacle in their immediate possession or if the receptacle cannot be in their immediate possession, secured out of sight and in a locked facility (e.g. locked vehicle or cupboard);
- maintaining records indicating the quantity of each scheduled poison manufactured, produced, received, used or destroyed on the Controlled Substances Usage Log; and
- reporting any theft or loss of controlled substances to the University Chemical Safety Officer (chemsafety@unisa.edu.au) in accordance with the requirements of the SA Health 'Suspected Theft or Loss of Drugs or Substances from Licence or Permit Holders' policy.

Higher Degree Research (HDR) Students who use controlled substances have a responsibility to:

Ensure there is an authorisation/permit for the controlled substances and the conditions of any permit for the controlled substance are met including:

- not signing an End User Statement/ Declaration for controlled substances when requested by the manufacturer/supplier [N.B. Supervisors must sign the End User Statement];
- ensuring the controlled substances must not be re-sold or supplied to any other person;
- storing the controlled substances in suitable containers, appropriately labelled, and when not in use, stored in a locked receptacle or enclosure;
- restricting access to the controlled substances to only authorised persons;
- maintaining records indicating the quantity of each scheduled poison manufactured, produced, received, used or destroyed on the Controlled Substances Usage Log; and
- reporting any theft or loss of controlled substances to the University Chemical Safety Officer (chemsafety@unisa.edu.au) in accordance with the requirements of the SA Health 'Suspected Theft or Loss of Drugs or Substances from Licence or Permit Holders' policy.

Research Supervisors and Teaching Staff have a responsibility to:

Be aware of any work under their control being undertaken with controlled substances and they must:

- if obtaining or using any substances classified as Schedule 8 or 9, obtain an individual permit from SA Health, send a copy of the permit to chemsafety@unisa.edu.au and ensure all the conditions of the permit are met;
- sign an End User Statement/ Declaration for controlled substances being used by HDR students under their supervision, when requested by the manufacturer/supplier;
- ensure there is an authorisation/permit for the controlled substances and the conditions of any permit for the controlled substance are met for the use of controlled substances in undergraduate teaching;
- when transporting controlled substances to a field trip location, complete a risk assessment detailing the safe transport and security of the substances including ensuring the substances are stored in a locked receptacle in their immediate possession or if the receptacle cannot be in their immediate possession, secured out of sight and in a locked facility (e.g. locked vehicle or cupboard);
- ensure End User Statements relating to the sale of section 17B precursor chemicals are kept for at least 5 years after the date of sale and are available at any time for inspection by an authorised officer;
- contact the University Chemical Safety Officer (chemsafety@unisa.edu.au) for assistance with an application for authorisation to use, handle or store a restricted carcinogen;
- review controlled substance holdings and, where individual permits are held, submit amendments and renewals to the relevant governing body before licence expiry; and
- ensure all staff and HDR students under their responsibility are instructed in the management of controlled substances in accordance with this procedure.

Stores and Finance Staff that manage the procurement or receipt of delivery of controlled substances have a responsibility to:

- liaise with the University Chemical Safety Officer (chemsafety@unisa.edu.au) to maintain access to current site-based controlled substances licences and permits;
- liaise with individual permit holders to maintain access to current Schedule 8 or 9 controlled substances licences;
- provide controlled substances licences and permits to manufacturers and suppliers, as required;

- ensure an End User Statement/ Declaration for controlled substances when requested by the manufacturer/ supplier are signed by the staff member responsible for the precursor chemical [N.B. students must not sign an End User Statement for precursor chemicals]; and
- restrict access to the controlled substances, whilst under their control, to only authorised persons.

Executive Deans, Deans, Directors and General Managers have a responsibility to:

- ensure the requirements of this procedure are understood and implemented in their area of responsibility; and
- ensure the local area liaise with the University Chemical Safety Officer (chemsafety@unisa.edu.au) to maintain access to current site-based controlled substances licences and permits and individual permits held within their area of responsibility.

The University Chemical Safety Officer has a responsibility to:

Oversee the authorisation/permits for controlled substances including:

- liaising with regulatory bodies to maintain site-based controlled substances licences and permits;
- assisting research and academic staff to obtain and maintain individual permits, as required;
- maintain a list and copy of site-based and individual controlled substances licences and permits;
- liaising with Stores and Finance staff to maintain access to current site-based controlled substances licences and permits;
- regularly reviewing the controlled substance holdings and Controlled Substances Usage Logs; and
- reporting any theft or loss of controlled substances to SA Health in accordance with the requirements of the SA Health 'Suspected Theft or Loss of Drugs or Substances from Licence or Permit Holders' policy.

5. Procedure

There is a national classification system that manages how controlled substances, such as medicines and chemicals, are made available to the public. Medicines and chemicals are classified in schedules according to the level of control over their availability needed to protect public health and safety. Some of these controlled substances may be subject to abuse, diversion or conversion to other substances for misuse. Such outcomes result in risks to public health, and the regulators and the University have a duty to monitor and prevent or minimise such action. The controls under the Controlled Substances legislation include:

- only specified health practitioners are able to prescribe and supply prescription medicines such as antibiotics, strong pain killers and birth control pills;
- medical practitioners, nurse practitioners, veterinarians and dentists must hold an authority to prescribe or supply drugs of dependence (strong pain killers such as morphine) in specified circumstances;
- only people who hold a licence or permit may make, sell, supply or use some controlled substances;
- there are labelling, packaging and storage requirements to help ensure safe use;
- the sale of some dangerous poisons is restricted; and
- only people who have appropriate training can apply pesticides for fee or reward (for example, when working in a pest control business).

Controlled substances legislative requirements are designed to prevent unauthorised access and use of regulated chemicals. The use of regulated chemicals is restricted within the University. Licence and permit holders are empowered by their licence or permit to possess certain controlled substances. The purpose of authorisations and conditions placed on the licence and permit holders is to control work activities and the use of substances that are high risk, and to apply risk-based information to manage the risk to health and safety.

Only staff and students given permission to access individual laboratories and workshops are allowed access to the controlled substances in those workspaces. Any person who is not authorised to use chemicals in a

laboratory or workshop must be supervised (or not authorised to enter) where controlled substances are not locked in receptacles. The University Chemical Safety Officer must be contacted where there are reasonable grounds to suspect the occurrence of:

- a theft or loss of a controlled substance; or
- a quantity of a controlled substance cannot be reasonably accounted for.

5.1 Scheduled Drugs and Poisons

The *Controlled Substances Act 1984* prohibits any person from manufacture, sell or supply a scheduled drug or poison unless holding a licence and/or meeting the access and use requirements listed in the table below.

To specifically identify which Schedule a substance belongs to, refer to Section 2 of the SDS for that substance under 'Poisons schedule'. A controlled substance can also be identified by 'signal words' on the label.

Schedule	Signal Words	Access and use requirements	Licence type
Schedule 2 (S2)	Pharmacy Medicine	Substances, the safe use of which may require advice from a pharmacist and which should be available from a pharmacy or, where a pharmacy service is not available, from a licensed person.	UniSA (site) licence
Schedule 3 (S3)	Pharmacist Only Medicine	Substances, the safe use of which require professional advice but which should be available to the public from a pharmacist without a prescription.	UniSA (site) licence
Schedule 4 (S4)	Prescription Only Medicine, or Prescription Animal Remedy	Substances, the use or supply of which should be by or on the order of persons permitted by State legislation to prescribe and should be available from a pharmacist on prescription.	UniSA (site) licence
Schedule 5 (S5)	Caution	Substances with a low potential for causing harm, the extent of which can be reduced through the use of appropriate packaging with simple warnings and safety directions on the label.	None required
Schedule 6 (S6)	Poison	Substances with a moderate potential for causing harm, the extent of which can be reduced through the use of distinctive packaging with strong warnings and safety directions on the label.	None required
Schedule 7 (S7)	Dangerous Poison	Substances with a high potential for causing harm at low levels of exposure and which require special precautions during manufacture, handling or use. These poisons should be available only to specialised or authorised users who have the skills necessary to handle them safely. Special regulations restricting their availability, possession, storage or use may apply.	UniSA (site) licence
Schedule 8 (S8)	Controlled Drug (Drugs of dependence)	Substances which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce	Individual licence required

		abuse, misuse and physical or psychological dependence.	
Schedule 9 (S9)	Prohibited Substance	Substances which may be abused or misused, the manufacture, possession, sale or use of which should be prohibited by law except when required for medical or scientific research, or for analytical, teaching or training purposes with approval of Commonwealth and/or State or Territory Health Authorities.	Individual licence required

5.2 Regulation 25 Poisons

The *Controlled Substances Act 1984* prohibits any person possessing the following poisons (listed under regulation 25 of the *Controlled Substances (Poisons) Regulations 2011*) unless holding a licence for this purpose:

Acrolein	DDT	Mirex
Arsenic	Fluroacteamide	Sodium fluoroacetate (1080)
Chloropicrin	Fluoroacetic acid	Strychnine
Cyanides	Hydrocyanic acid	Thallium
Cyanogen	Methyl bromide	

5.3 Controlled Precursors

The *Controlled Substances Act 1984* prohibits any person from manufacture, sell or supply a controlled precursor (listed under the *Controlled Substances (Poisons) Regulations 2011*) unless holding a licence or end user statement and/or meeting the access and use requirements listed below:

Section	Access and use requirements	Licence type
17A Precursors	Cannot be sold or possessed without a permit. These chemicals are listed in Schedule B of the <i>Controlled Substances (Poisons) Regulations 2011</i> .	Individual licence required
17B Precursors	Can only be sold to account holders, photographic identification must be provided, and an End User Statement must be completed. These chemicals are listed in Schedule BA of the <i>Controlled Substances (Poisons) Regulations 2011</i> .	End User Statement
17C Precursors	Photographic identification may be required, and an End User Statement must be completed. These chemicals are listed in Schedule C of the <i>Controlled Substances (Poisons) Regulations 2011</i> .	End User Statement
Precursor Equipment	Although the sale of this equipment is not subject to regulation, possession without reasonable excuse by the purchaser may constitute an offence.	None required

5.4 Restricted or Prohibited Carcinogens

Carcinogens are chemicals which are directly involved in causing cancer in humans. Restricted and Prohibited Carcinogens are specifically listed in Schedule 10 of the *Work Health and Safety Regulations 2012*. The use of Prohibited Carcinogens within the University will not be authorised. Use of any Restricted Carcinogens requires approval by the University Chemical Advisory Safety Committee and a SafeWork SA licence.

Prohibited carcinogen [CAS number]
2-Acetylaminofluorene [53-96-3]
Aflatoxins
4-Aminodiphenyl [92-67-1]
Benzidine [92-87-5] and its salts (including benzidine dihydrochloride [531-85-1])
bis(Chloromethyl) ether [542-88-1]
Chloromethyl methyl ether [107-30-2] (technical grade which contains bis(chloromethyl) ether)
4-Dimethylaminoazobenzene [60-11-7] (Dimethyl Yellow)
2-Naphthylamine [91-59-8] and its salts
4-Nitrodiphenyl [92-93-3]
Restricted carcinogen [CAS number]
Acrylonitrile [107-13-1]
Benzene [71-43-2]
Cyclophosphamide [50-18-0]
3,3'-Dichlorobenzidine [91-94-1] and its salts (including 3,3'-Dichlorobenzidine dihydrochloride [612-83-9])
Diethyl sulfate [64-67-5]
Dimethyl sulfate [77-78-1]
Ethylene dibromide [106-93-4]
4,4'-Methylene bis(2-chloroaniline) [101-14-4] MOCA
3-Propiolactone [57-57-8] (Betapropiolactone)
o-Toluidine [95-53-4] and o-Toluidine hydrochloride [636-21-5]
Vinyl chloride monomer [75-01-4]

5.5 Chemicals of Security Concern

96 chemicals are identified as being chemicals of security concern because of their potential to be used by terrorists to make bombs or toxic weapons. In particular, there are 15 chemicals that are assessed as being particularly high-risk and are covered by the National Code of Practice for Chemicals of Security Concern. Although the code specifically applies to the 15 chemicals, if you handle, manage or store any of the 96 chemicals of security concern, you should adopt the code in relation to these chemicals.

Chemical	Concentration
Ammonium perchlorate	(a) in a water-based solution containing 10% or higher of ammonium perchlorate; or (b) in a form other than a water based solution, at a concentration of 65% or higher.
Hydrogen peroxide	(a) in a water-based solution at any concentration; or (b) in a form other than a water-based solution, at a concentration of 15% or higher.

Nitric acid	at a concentration of 30% or higher
Nitromethane	at a concentration of 10% or higher
Potassium chlorate	(a) in a water-based solution containing 10% or higher of potassium chlorate; or (b) in a form other than a water-based solution, at a concentration of 65% or higher.
Potassium nitrate	(a) in a water-based solution containing 10% or higher of potassium nitrate; or (b) in a form other than a water-based solution, at a concentration of 65% or higher.
Potassium perchlorate	(a) in a water-based solution containing 10% or higher potassium perchlorate; or (b) in a form other than a water-based solution, at a concentration of 65% or higher.
Sodium azide	at a concentration of 95% or higher.
Sodium chlorate	(a) in a water-based solution containing 10% or higher sodium chlorate; or (b) in a form other than a water-based solution, at a concentration of 65% or higher.
Sodium perchlorate	(a) in a water-based solution containing 10% or higher sodium perchlorate; or (b) in a form other than a water-based solution, at a concentration of 65% or higher.
Sodium nitrate	(a) in a water-based solution containing 10% or higher sodium nitrate; or (b) in a form other than a water-based solution, at a concentration of 65% or higher.
Toxic chemicals	
Aluminium phosphide	at any concentration.
Chlorine (gas only)	at any concentration.
Potassium cyanide	at any concentration.
Sodium cyanide	at any concentration.

6. Useful links and Documents

- [UniSA Safety & Wellbeing website](#)
- [Safe Management of Chemicals Procedure](#)
- [The Poisons Standard \(SUSMP\)](#)
- [Code of Practice for the Storage and Transport of Drugs of Dependence](#)
- [SA Health 'Suspected Theft or Loss of Drugs or Substances from Licence or Permit Holders' policy](#)
- [National Code of Practice for Chemicals of Security Concern](#)
- [WHS12 Chemical Process Risk Assessment and Control](#)
- [WHS15 Chemical Hazards Application](#)
- [Controlled Substances Usage Log](#)

Name of compound:..... Page No:.....

Storage location: Building: Rm No:.....

Fridge⁺/ Freezer⁺ / Cupboard⁺/ Drawer⁺.....

⁺ Delete as appropriate. [N.B. must be locked at all times]



University of
South Australia

CONTROLLED SUBSTANCES USAGE LOG

Chief investigator: _____ Permit No.: _____

Name of compound: _____

Date	User's name	Experiment / procedure name	Amount of drug received (g/mg/ml)*	Amount of drug used (g/mg/ml)*	Balance of drug (g/mg/ml)*	User's signature

Name of compound:.....

Page No:.....

Storage location: Building:

Rm No:.....

Fridge+ / Freezer+ / Cupboard+ / Drawer+ Chief Investigator:

+ Delete as appropriate. [N.B. must be locked at all times]

Date	User's name	Experiment / procedure name	Amount of drug received (g/mg/ml)*	Amount of drug used (g/mg/ml)*	Balance of drug (g/mg/ml)*	User's signature

COMPLETE WHEN BOTTLE FINISHED/DESTROYED OR USE OF DRUG IS NO LONGER REQUIRED.

Date Completed/ Destroyed	Comments	Signature	Witness

