UNIVERSITY of TASMANIA

Handling and Storage of Scheduled Substances Procedure

UNDER REVIEW

Related Policy	*Work Health and Safety Policy*
Responsible Officer	Executive Director – Human Resources
Approved by	Executive Director – Human Resources
Approved and commenced	April, 2018
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Responsible Organisational Unit	Work Health and Safety Unit – Human Resources

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1 Objective

The objective of this Procedure is to provide information to ensure the safe and appropriate storage and use of scheduled substances according to the Commonwealth's Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP).

The SUSMP includes medicines, drugs, chemicals and poisons that have restrictions in relation to public use and access. This can include implications for their purchase and use within the University.

The Tasmanian Poisons Act 1971 and subordinate Poisons Regulations 2008 adopts the SUSMP in Tasmania by reference. The relevant legislation in NSW adopts the SUSMP under the Poisons and Therapeutic Goods Act 1966 No. 31 (NSW) and the Poisons and Therapeutic Goods Regulation 2008 (NSW). The local poisons legislation describes the licence, permit or authorisation requirements of these substances and the legal provisions regarding their supply, labelling, storage, record keeping and disposal.

2 Scope

This procedure has been developed for use by all University workgroups as a primary reference when developing local procedures for the management of scheduled substances.

Note: this document does not detail the requirements of supply, prescription or administration of a scheduled substance by a practitioner in a clinical environment.

3 Procedure

3.1 Classification of Scheduled Poisons

The Poisons Standard is the legal title of the Standard of the Uniform Scheduling of Medicines and Poisons (SUSMP), it is also referred to as the Poisons List. Medicines, chemicals (including industrial use) and poisons are classified into schedules (see Table 1) which determines public access and different levels of regulatory control.

Different conditions apply to the purchase, storage, labelling and disposal of these substances depending on their schedule or classification in the Standard. The schedule and label description for each substance can be found in the Safety Data Sheet and on the label.

3.2 Table 1 List of Schedules

Schedule 1.	This Schedule is intentionally blank.
Schedule 2.	**Pharmacy Medicine** – Substances (medicinal poisons), 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. Requires a permit for industrial, educational, advisory or research (laboratory) purposes under the Poisons Regulations 2008 An application for permit is available from Pharmaceutical Services Branch (DHHS).
Schedule 3.	**Pharmacist Only Medicine** – Substances ('potent substances'), the safe use of which requires professional advice but which should be available to the public from a Pharmacist without a prescription. Requires a permit for industrial, educational, advisory or research (laboratory) purposes under the Poisons Regulations 2008 An application for permit is available from Pharmaceutical Services Branch (DHHS).
Schedule 4.	**Prescription Only Medicine**, or **Prescription Animal Remedy** – These are restricted substances, the use or supply of which should be by, or on the order of, persons permitted by State. Requires a permit for industrial, educational, advisory or research (laboratory) purposes under the Poisons Regulations 2008 An application for permit is available from Pharmaceutical Services Branch (DHHS). Certain Schedule 4 substances have more stringent restrictions on their storage and use.
Schedule 5.	**Caution** – Substances (domestic poisons) 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.
Schedule 6.	**Poison** – Substances (industrial or agricultural poisons) 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. Certain substances require an authority for buying, obtaining and using, see Poisons Regulations 2008, Reg. 66.
Schedule 7.	**Dangerous Poison**– Substances with a high potential for causing harm at low 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. A University-wide permit covers most S7 substances (included in Appendix J of the SUSMP) but some may need a specific permit. Check with the WHS Unit or Pharmaceutical Services Branch (DHHS) for further advice.

Schedule 8.	**Controlled Drug** – Substances (narcotic substances) which should be available for use but require restriction of manufacture, supply, distribution, possession and use to reduce abuse, misuse and physical or psychological dependence. Requires a written direction from the Vice Chancellor of the University under Section 48 of the Poisons Act 1971.
Schedule 9.	**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 Health Authorities. A licence is required under the Poisons Act 1971.
Schedule 10 (previously Appendix C).	**Substances of such danger to health as to warrant prohibition of sale, supply and use** - Substances which are prohibited for the purpose or purposes listed for each poison because of their known dangerous properties.

3.3 Risk Assessment

In the first instance every effort should be made to eliminate the use of hazardous chemicals. Investigation of alternative methods or the use of an alternate chemical is recommended. If an alternative is not possible then a risk assessment must be completed in consultation with the workers who could be exposed. The possession and use of highly dangerous S7 poisons, S8 narcotics and S9 prohibited substances is prescribed through regulation.

The risk assessment aims to identify the potential for exposure during the planned activity and detail the control measures proposed to manage the risk, including training and supervision requirements. Once agreed and approved, control measures must be adhered to as a condition of use.

Whenever assessing the risk associated with an activity or task, various risk factors must be considered including the:

- nature of the chemicals involved and other hazards;
- work environment;
- physical activities required to complete the task;
- psychological demands of the task; and
- individual workers involved in the activity.

A detailed risk assessment must be completed prior to the initial purchase of any scheduled substance and it must be signed off at the correct delegation level.

3.4 Induction and Training

Induction, information and training must be provided for all staff, students and volunteers using any scheduled substances. It must include the following:

- Labelling of containers of scheduled substances, information included on each part of the label and why the information is provided.
- How to locate and use a Safety Data Sheet (SDS) and the information contained in each part of the SDS.
- The nature of the hazards and properties of the substance to which users are, or may be, exposed including routes of entry into the body and potential health risks.
- Work practises to be followed when using, handling, storing, cleaning up and disposing of substances
- Measures used to control exposure to substances including the correct use and maintenance of these controls.
- Proper use, fitting and maintenance of the personal protective equipment (PPE) required for handling substances.
- Emergency procedures, including evacuation and special decontamination procedures.
- First aid and incident reporting procedures to be followed in the case of exposure, injury or illness.
- Reasons for air monitoring (if required), type of monitoring used and how to find out the results of monitoring.
- Reasons for health surveillance (if required) and the type of surveillance used.

3.5 Authorisation for Use

For further information regarding legal requirements for possession and use of any scheduled substance, or to obtain the correct application form, contact the Pharmaceutical Services Branch of the Tasmanian Department of Health and Human Services (DHHS).

Schedules 2 – 4: a permit is needed for the possession of any Schedule 2, 3 and 4 substances for industrial, educational, advisory and research purposes.

Schedule S4D (declared restricted substances) is more stringently regulated and requires a special permit (such as specific psychotropic substances).

Schedule 5 and 6: particular substances require licencing (refer to the Poisons Regulations (Tasmania) 2008, regulation 66 and the Agricultural and Veterinary Chemicals (Control of Use) Act 1995.

Schedule 7: an authorisation is needed for the possession and use of certain Schedule 7 substances included in Appendix J of the SUSMP.

Note: There is a University authorisation that can be used for the purchase of most S7 substances (contact the WHS Unit for information). However, an individual licence may be needed for specific restricted substances such as: arsenic, benzene, cyanides, fluoroacetamide, fluoroacetic acid, hydrocyanic acid, strychnine and thallium.

Schedule 8: the possession of Schedule 8 substances is prohibited without written direction from the Vice Chancellor. A suitably qualified person may apply for authorisation to possess the following substances for the purpose of research, analysis, or instruction:

Schedule 9: the possession of a Schedule 9 prohibited substance requires a licence under the Poisons Act 1971. Contact should be made with Pharmaceutical Services Branch within DHHS.

3.6 Purchasing

Chemical suppliers will require confirmation of authorisation for S 7, 8, 9 and S4D. Some suppliers may require authorisation for S2, S4 and S6 substances as well depending on packing and concentration. There is a general University authorisation for most S7 substances administered by the WHS Unit, but all other substances require a user only authorisation that must be obtained from Pharmaceutical Services Branch. See PSB's webpage for further information regarding authorisations. The WHS Unit must receive a copy of the authorisation by the PSB, by the person requesting it.

All purchases of scheduled substances need to be in line with the University Procurement Policy. The Scheduled Substance authorisation and associated Chemical Risk Assessment must be uploaded as part of the justification of 'Hazardous Material' in the PurchaseNow system.

Restricted Schedule 4 pharmaceuticals, highly dangerous Schedule 7 poisons or Schedule 8 or 9 controlled drugs that are delivered to the University must be stored in a secure location until pick up can be arranged. Once collected by the purchaser they must be immediately stored in the appropriate manner defined by their schedule. There must be a custody trail for audit purposes. While pentobarbitone when packed and labelled for injection is a schedule 4, it is considered good practice for this to be stored in a secure location at all times.

3.7 Storage

In the laboratory, storage of all poisons should be in accordance with standard laboratory storage requirements. In addition:

• A poison should be clearly labelled with the descriptive phrase (e.g. "Dangerous Poison") and schedule number.

• Containers that have held poisons must not be re-used.

• Schedule 5, 6 or 7 poisons cannot be repacked and must be kept in the manufacturer's original, unopened container. This applies particularly to livestock medicines and agricultural chemicals.

Further conditions apply to the storage of Schedule 4, 7, 8 and 9 poisons.

Schedule 4: All Supervisors must ensure that Schedule 4 drugs are stored in a secure storage area e.g. locked laboratory. If a freezer or refrigerator is used for the storage of these substances it must be secured in a room with restricted access controls.

Special requirements for Schedule 8 Controlled drugs and restricted S4 (S4D) substances: An authorised person who uses a Schedule 8 controlled drug or S4D must keep these substances separately from all other goods in a safe or locked secure cupboard which is securely attached to a part of the premises. If these substances are to be kept in a freezer or refrigerator, the freezer or refrigerator must be kept securely locked when not in immediate use and only used for that purpose

and comply with the storage minimum standard. See Appendix 2 for the minimum requirements for S8 storage enclosures in Tasmania.

3.8 Handling

When handling any scheduled substances all safety directions must be followed. All specific use of these materials must be covered in the activity risk assessment and signed by the relevant delegation.

There are specific legislative requirement for the handling of schedule 8, 9 and restricted S4 (S4D) which include a drug register, auditing of the register and the requirements to report any theft or loss.

3.8.1 Drug Register

An authorised person must keep a drug register for all Schedule 8, 9 drugs and restricted S4 (S4D) that is obtained and/or used. See Table 2 for an example of a register format. While there is no legal requirement to keep a register of pentobarbitone when it is packaged as an S4 substance, it is considered good practice to do so.
The drug register must have:

- pages that cannot be removed or replaced i.e. must be a fully bound book and not spiral bound);
- consecutively numbered pages;
- separate page in the register for each drug/substance, each form and strength of drug.

Date	Name and Address to whom drug dispensed used or received	In	Out	Balance	Original dispensing drug or letter	Authorised persons name	Authorised persons signature
Date drug received or used	Supplier or name of person using substance	Original volume	Amount take	Amount remaining	Laboratory – purpose for which substance is used	Printed	Signed

A Scheduled Drugs Register must be kept to record all use by authorised persons working with these substances. When a new substance is received or used the authorised person must enter in the register the:

- quantity that was received or used;
- name and address of the supplier;
- number and species of animals for which it was used;
- total quantity held by the authorised person after the entry is made;
- date and sign each entry.

The authorised person who receives, administers or uses an S8 drug is responsible for entering the details in the drugs register. Each entry must be:

- made on the date the authorised person receives or uses an S8 drug;
- written permanently and in English;

- legible, complete and in sufficient detail;
- dated and signed by the person by whom it is used;
- true and correct.

The balance recorded in the register should always coincide with the actual stock on hand. A mistake in any entry in a drug register must be corrected by making a marginal note or footnote and by initialling and dating it. If the cause of the discrepancy is identified and found to involve a minor error (e.g. arithmetic) or departure from procedures (e.g. omission of recent use), include a comment to that effect against the amending entry. Alterations, obliterations or cancellations in a register are not permitted and multiple errors must be drawn to the attention of the Head of Academic Unit or Executive Dean.

Opening and closing balances should be verified and signed when the drug register is completed and a new drug register is commenced. In addition balances should be checked and verified from page to page. Whenever possible balances carried forward to a new page or book should be verified by a second authorised person.

3.8.2 Note on Dilutions

If a quantity of substance such as an S8 drug is removed from a stock solution and subsequently diluted to become a working solution then both entries need to be made in the register. A different page is used for each concentration.

For example: 50.0 ml of Ketamine stock solution is listed on a page in the drugs register. If 5.0 ml of this is removed to be diluted thus the entry recorded in the register is that 5.0 ml is removed and 45.0 ml of this stock solution remains. The 5.0 ml is then diluted to 50.0 ml. This becomes a 10% of the original concentration Ketamine Working Solution and should be recorded on a new page with a 50 ml starting volume. Each removal is recorded in the usual manner. The working solution should be appropriately labelled and dated and stored in the S8 approved storage area.

Drugs registers must be kept for at least 2 years, from the last date on which any:

- entry was made in the register; or
- S8 drug was received, administered or used.

3.8.3 Drug Register Auditing

The person responsible for maintaining a drugs store and register must:

- make an accurate inventory of all S8 and S9 substances held each year;
- endorse the drugs register, immediately under the most recent entry for each S8 or S9 substance, with the quantity of each drug actually held and the date on which the inventory was made;
- sign each entry in the drug register.

When checking stock, physically count opened containers of drugs, do not open sealed packs but rather check that the seals are intact and, if they are sealed record the quantity as labelled. Measure the volume of drugs in liquid form only when removing the last of the contents. If there is reasonable discrepancy (e.g. up to 3%),

make a note of that fact against the entry. Up to that point estimate the volume by observation and note the entry as "estimated". A complete inventory of S8 and S9 substances must also be made if:

- there is loss or destruction of a register;
- a person assumes control for a period of one month or more over any drugs store.

Registers must be made available for inspection on demand by the DHHS Pharmaceutical Services Branch, the Police or any other authorised officer (e.g. a poisons inspector).

3.9 Reporting Theft and Loss

The following incidents must be reported immediately and without delay, to the Head of School and/or Dean and to the WHS Unit. These reports will then be reported to the Chief Pharmacist in the Department of Health and Human Services and to Tasmania Police for S8, S9 and S4D

The Tasmanian Poisons Regulations (2008) require authorised persons to report any:

- suspected or actual loss or theft of an S7 substance;
- suspected or actual loss or theft of an S8 drug;
- suspected or actual loss or theft of an S9 drug;
- suspected or actual loss or theft of an S4D drug 'declared restricted substance',
- suspected or actual loss or destruction of a drugs register.

3.10 Disposal

Most substances in S2, 3, 4 are to be of disposed as outlined in the University hazardous waste program.

Schedule 4D (declared restricted substances) must not be disposed of 'in any place or any manner likely to constitute a risk to the public'. Until removal, waste Schedule 4 drugs should be kept secure in a store or laboratory. Disposal can also be via the Pharmacy.

Schedule 6 substance that require a licence must be disposed of as described by the licence or on advice from the Environmental Protection Agency.

Schedule 7 substances disposal should be carried out in accordance with the method approved by the Environment Protection Authority.

Schedule 8 and Schedule 9 substances must not be wilfully destroyed except by persons authorised outlined under Regulation 34 of the Poisons Regulations 2008 (Tas) and under the conditions of the authorisation. The disposal of these substances is usually made on recommendation of the DHHS Pharmaceutical Services Branch.

4 Definitions and Acronyms

Term/Acronym	Definition
Organisational Unit	College, Faculty, School, Centre, University Institute, other University Entity, Division, Section or University Business Enterprise.
DHHS	Department of Health and Human Services
Manager/Supervisor	An individual who assumes responsibility for the health or welfare of any other person in a workplace by providing instruction, direction, assistance, advice or service, (which includes those with responsibility for students).
Officer	Members of Council, Heads of Colleges, Executive Deans, Heads of Academic Units, Heads of Divisions and Sections and Members of Boards having strategic management responsibility, are considered to be Officers under the Act.
Organisational Unit	College, School, Centre, University Institute, other University Entity, Division, Section or University Business Enterprise.
Scheduled substance	Identified as medicines, drugs and poisons that have restrictions in relation to public use and access and require a permit from the DHHS Pharmaceutical Services Branch to hold and use.
Worker	Refers to any staff member, student undertaking work experience, contractor, affiliate or volunteer

5 Responsibilities

Worker	To adhere to this procedure a worker must comply with all controls and requirements.
Manager/Supervisors	Ensure this procedure is implemented within their area of responsibility. This includes: • Ensure persons undertaking work with Scheduled Substances are adequately trained. • Provide suitable facilities and resources to ensure the effective implementation of this procedure.
Officers	Provide suitable facilities and resources to ensure the effective implementation of this procedure Approve the use of any Scheduled Substance Review and approval of persons responsible for the drug register and audit.

6 Supporting Documentation

- *Work Health and Safety Act 2012*
- *Work Health and Safety Regulations 2012*
- *Poisons Act 1971*
- *Therapeutic Goods Act 2001*
- *Poisons Regulations 2008*
- *Poisons (Declared Restricted Substances) Order 1990 (S4D List)*
- *Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons)*
- *Agricultural and Veterinary Chemicals (Control of Use) Act 1995*

7 Acknowledgements

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8 Versioning

Former Version(s)	Version 1 –*Handling and Storage of Scheduled Substances Procedure*; approved by Executive Director, Human Resources; April 2018