HS331 Schedule 4 and 8 Drugs Procedure

Legend

1. Purpose and Scope

The purpose of the Schedule 4 and 8 Drugs Procedure is to ensure that drugs of addiction, which are used at UNSW for analysis, research and teaching activities, are regulated in a manner consistent with legislative requirements in order to eliminate or control potential health, safety and security risks. This procedure applies to all UNSW analysis, research and teaching activities that involve the use of drugs of addiction (which are designated as Schedule 8 drugs by the NSW Department of Health) and of Schedule 4 drugs.
This procedure details University practice in relation to the regulation of Schedule 8 drugs including: authorisation; information, training and supervision; storage; disposal; record-keeping; security and reporting. It also outlines the requirements for Pentobarbitone sodium and disposal of Schedule 4 drugs.

2. Definitions

**Authorised Manager** – The person who has written authority from the Pharmaceutical Services Branch of NSW Health to possess and use S8 drugs for analysis, research and teaching activities at UNSW.

**Approved Person** – A competent person who has been approved by the Authorised Manager to possess, use or store S8 drugs for the purposes of analysis, research and teaching and who is acting under their supervision.

**Competent Person** – is defined in NSW Work Health and Safety Regulation 2011 as “a person who has acquired through training, qualifications or experience, the knowledge and skills” to carry out a specified task.

**S8 Drugs Custodian** – A person who has been approved by the Authorised Manager to manage the drugs store and register in accordance with this procedure.

**PSB** – [Pharmaceutical Services Department](#) of NSW Department of Health.

**Schedule 8 (S8)** – Drugs of Addiction, as per the schedule maintained by the PSB. The PSB web site must be consulted for the current list of scheduled drugs.

**Schedule 4 (S4)** – Prescribed Restricted Substances as per the schedule maintained by the PSB. The PSB web site must be consulted for the current list of scheduled 4 substances.

**UNSW Contact Officer** – the Manager, Health and Safety (HS) Unit

3. Procedure

Possession and use of S8 drugs is prohibited without written authority from the PSB. At UNSW (normally) the authorized person is the Head of the School or Centre. This person then grants approval to researchers and S8 drug custodians via an approval process outlined below.

3.1 **Request Authority**

Heads of School and Centre Directors must notify the UNSW Contact Officer if their School/Centre is proposing to undertake analysis, research or teaching involving S8 drugs.

The Contact Officer will notify the Deputy Vice-Chancellor (Research) who is responsible for official correspondence with the PSB in relation to requesting authority for S8 drugs. DVC Research will make the request to the PSB for the Head of School or Centre to be added to UNSW’s List of Authorised persons Managers.

The PSB will write back to UNSW confirming the Head of School or Centre has been added to the list of Authorised persons.

DVC Researcher, with the assistance of the contact officer, is responsible to ensure that this list is kept current.

3.2 **Authorised Manager to grant approval to competent workers**

A manager with authority from the PSB (i.e. an Authorised Manager) may approve, in writing, competent persons acting under their supervision to possess...
and use S8 drugs for analysis, research and teaching. Such approval must be in writing and local records maintained of all Approved Persons. Form HS331-1 ‘Schedule 8 Drugs Approved Persons Application form’ should be used for this purpose.

3.3 **Maintain Register of Approved Persons**

The School / Centre must maintain a current register of all workers to whom approval, as outlined in step 3.2, is granted. Form HS331-2 ‘Schedule 8 Drugs Approved Persons Register’ should be used to maintain this information.

3.4 **Provide Information, Training and Supervision**

Following receipt of a letter of authority from the PSB the UNSW Contact Officer will provide each Authorised Manager with information relating to the conditions of the authority for S8 drugs and pertinent sections of the Poisons & Therapeutics Goods Regulation.

Authorised Managers must ensure that Approved Persons working with S8 drugs under their authority receive information and training in this Procedure and the legislative requirements for control of S8 drugs. The UNSW Contact Officer may be contacted regarding training options.

All staff and students working with animals are required to attend the Animal Ethics Training course which includes S8 drugs training. In addition separate S8 Drugs only training sessions will be available for stores custodians or others who are not required to attend animal ethics training.

Authorised Managers are responsible for the ongoing supervision of Approved Persons working with S8 drugs under their authority and for compliance with requirements for control of Schedule 8 drugs.

3.5 **Purchasing and Receipt of S8 Drugs**

The Approved Person who is ordering the S8 drug must highlight on the purchasing requisition form (or equivalent) the following wording:

**S8 DRUG - MUST BE COLLECTED BY AN APPROVED PERSON**

The wording must be highly visible in bold and capitals to assist the staff receiving the package (e.g. stores staff or reception). The stores/reception staff is then required to contact the approved person requesting the substance and let them know the substance has arrived and must be collected. The material must be stored in a secure location until pick up. If the named ‘Approved Person’ on the purchasing form cannot be contacted then the associated Authorised Manager can provide the contact details for an alternative ‘Approved Person’. Each laboratory ordering S8 drugs will supply the store/reception staff with two approved persons who can collect the drugs.

3.6 **Secure Storage of S8 Drugs**

Authorised Managers must ensure that S8 drugs are stored apart from all other goods (other than cash or documents) in a separate room, safe, cupboard or other receptacle securely attached to a part of the premises and kept securely locked when not in immediate use. The Head of School / Centre will nominate a competent person to act as S8 Drugs Custodian and this will be indicated in the application form as outlined in section 3.2. This person will be noted on the Approved Persons register as outlined in step 3.3, and their name written on the bound S8 drugs register.
Access to the S8 Drug Store must be tightly controlled by the Authorised Manager. This may involve keeping the number of keys to an S8 drugs store to an absolute minimum. Keys should be numbered and only issued to an approved person as nominated by the Authorised Manager. Confidential records of such access should be maintained. Other similar control measures should be implemented for combination locks to safes etc.

3.6.1 After Hours Emergency

A limited supply of S8 drugs for use in an emergency can be made available. In such cases authorization is obtained from the S8 Drugs Custodian. Approved Person, who is required to administer an S8 drug in an after-hours emergency animal welfare situation, is permitted to have the S8 drug in their possession in a bag in either a room or a vehicle which is kept locked when not occupied by the person.

3.7 Maintain a Drugs Register

Authorised Managers must ensure that a drugs register specifically for S8 drugs is kept at the place where the drugs are stored or used. Responsibility for maintaining the drugs register rests with the S8 Drugs Custodian. The name of the person responsible for maintaining the drugs register must be recorded on the drugs register.

3.7.1 Format of Drugs Register

The drugs register must be a bound book with consecutively numbered pages and space for the particulars required to be entered. A separate page must be used for each drug and for each form and strength of the drug.

Approved drug register books may be purchased from a drugs supplier (or Salmat). The format of an example drugs register is indicated below:

Table 1: Drugs register entry

<table>
<thead>
<tr>
<th>Date</th>
<th>Name and address of person or company to whom dispensed, sold, supplied, or from whom obtained</th>
<th>Out</th>
<th>Balance</th>
<th>Dispenser’s original dispensing number or letter</th>
<th>Name of Authority</th>
<th>Signature of dispenser or administrator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drug used</td>
<td>Date</td>
<td>Original volume received from supplier</td>
<td>Amount used/withdrawn from original</td>
<td>Amount remaining</td>
<td>For laboratory work, use this space to record the purpose for which the drug was used e.g. ethics approval no.</td>
<td>Name of Authorized Manager</td>
</tr>
</tbody>
</table>

3.7.2 Data Entry in Drugs Register

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

- made on the day on which a person receives, administers or uses an S8 drug;
- written indelibly in English;
- legible, complete and in sufficient detail;
- dated and signed by the person by whom it is made; and
- include no false or misleading information.

A mistake in any entry in a drugs register must be corrected by making a marginal note or footnote and by initialing and dating it. Alterations, obliterations or cancellations in a register are not permitted.

If it is not possible to record the exact volume of the drug then the weight of the S8 drug container and its contents can be used instead.
3.7.3 Recording Dilutions of S8 Drugs
If a quantity of S8 drug is removed from a stock solution and subsequently diluted to become a working solution then both entries need to be made on the S8 drugs register. A different page is used for each concentration. As an example:
50mls of Ketamine stock solution is listed on a page in the drugs register. 5mls of this is removed to be diluted thus the entry recorded in the register is that 5mls is removed and 45mls of this stock solution remains.
The 5mls is then diluted to 50mls. This becomes a 10% Ketamine Working Solution and should be recorded on a new page with a 50mls starting volume. Each removal is recorded in the usual manner. The working solution should be appropriately labeled and dated and stored in the S8 Drugs safe.

3.7.4 Retention of Records
Drugs registers must be kept for at least 2 years, running from the latest date on which:
- any entry was made in the register; or
- any S8 drug was received, administered or used.

3.7.5 Inspection of Drugs Register
Drugs registers must be made available for inspection on demand by the PSB, the Police or any authorised UNSW officer (e.g. the UNSW Contact Officer, Health and Safety Coordinator or Health and Safety Committee Representative).

3.8 Twice yearly inventory of S8 Drugs
The person responsible for maintaining a drugs store and register (i.e. Drugs Custodian) must:
- Make an accurate inventory of S8 drugs in March and September of each year (or as specified by the PSB);
- Use form HS331-3 to record this information
- Endorse the drugs register, immediately under the last entry for each S8 drug, with the quantity of each drug actually held and the date on which the inventory was made; and
- Sign each entry in the drug register.

There are two additional circumstances in which an inventory must be made:
- in the event of loss or destruction of a drugs register (see 3.12); and
- when a person assumes control for a period of one month or more over any S8 drugs store.

3.9 Arrange Disposal of S8 Drugs
Authorised Managers must ensure that S8 drugs are not willfully destroyed except under the direct personal supervision of a PSB officer or a police officer.

The disposal of S8 drugs should be arranged by contacting the Health and Safety Unit. The Poisons and Therapeutic Goods Regulation require that the Duty Pharmaceutical Advisor at PSB be contacted whenever S8 drugs are no longer required. The PSB will arrange a suitable time to collect the S8 drugs (or witness their destruction) and will make the required entry in the drugs register (see 3.7) as a record of the authorised destruction.

Concentration cut off points, below which an S8 drug is no longer considered harmful, have not been specified. Therefore any quantity and any concentration of S8 drugs must be collected for authorised disposal.

3.10 Requirements related to Schedule 4 Restricted Substances
The NSW Poisons and Therapeutic Goods Regulation 2008 in Appendix C: 19 (Persons authorised to possess and use substances) allows for “scientifically
qualified persons in charge of a laboratory or department, or a person acting under the direct personal supervision of such a person, to possess and use any Schedule 2, 3 or 4 substance that is required for the conduct of medical or scientific research or instruction or the conduct of quality control or analysis”.

3.10.1 Pentobarbitone sodium
An authorised person who uses pentobarbitone sodium (to the extent that it is an S4 Restricted Substance and not a S8 Drug of Addiction) for the destruction of animals must meet the requirements of Clause 65 of the Poisons and Therapeutic Goods Regulation 2008 specifically:

a) Pentobarbitone sodium must be kept separately from all other goods in a safe, cupboard or other receptacle:
   1. that is securely attached to a part of the premises, and
   2. that is kept securely locked except when in immediate use.

Storing Pentobarbitone sodium in the S8 Drugs safe will meet this requirement.

b) An authorised person must keep a separate register of all pentobarbitone sodium that is obtained or used by the authorised person.

Reserving a page in the S8 Drugs register with the Drug name recorded as Pentobarbitone sodium (S4) will meet this requirement rather than needing to keep a separate S4 Drugs Register.

c) On the day on which an approved person obtains or uses any pentobarbitone sodium, the approved person must enter in the register such of the following details as are relevant to the transaction:
   1. the quantity that was obtained or used;
   2. the name and address of the person from whom it was obtained;
   3. the number and species of animals for which it was used;
   4. the total quantity held by the authorised person after the entry is made.

Each entry must be dated and signed by the authorised person.

3.11 Disposal of S4 Drugs
Schedule 4 (Restricted Substances) must not be disposed of “in any place or any manner likely to constitute a risk to the public” (Clause 66 Poisons and Therapeutic Goods Regulation 2008).

At UNSW, disposal of such materials follows the same path as for any material which is to be incinerated. The two methods which can be used are:
1. Vials and ampoules of S4 substances can be disposed of in the sharps containers. Absorbent material can be used to provide soakage in the event that a spillage could occur. These containers are removed by UNSW’s biological waste contractor and are incinerated.
2. The S4 substances can follow the path of cytotoxic substances and can thus be collected in the cytotoxic waste bins. Cytotoxic waste is removed by UNSW’s biological waste contractor and is incinerated.

3.12 Security and Reporting of Loss/Theft
S8 drugs and associated records must be maintained in a secure manner (see 3.5 and 3.6). Any suspected loss or theft of S8 drugs, or loss or destruction of a drugs register must be reported immediately as described below.
3.12.1 Loss or Theft of an S8 Drug
Any suspected or actual loss or theft of an S8 drug must be reported to the UNSW Contact Officer by the Authorised Manager or their delegate. The UNSW Contact Officer will notify:
- UNSW Security for reporting to the Police; and
- The DVC (Research) for reporting to the PSB.

3.12.2 Loss or Destruction of a Drugs Register
Any suspected or actual loss or destruction of a drugs register must be reported to the UNSW Contact Officer by the Authorised Manager or their delegate. The UNSW Contact Officer must notify the DVC (Research) for the purpose of reporting to the PSB.

In event of loss or destruction of a drugs register an accurate inventory must be made of all S8 drugs held and the details entered into a new drugs register.

3.13 Monitor Compliance
The HS331-4 Schedule 8 Drugs Audit Checklist should be used as a compliance monitoring tool. It should be completed by the Authorised Manager (or delegate) (and not the S8 Drugs Custodian). The completed checklist should be forwarded to the Head of School/Centre Director or HS Committee for information and corrective action, as required.

4. Review & History
This procedure will be reviewed in accordance with the OHSMS Review Procedure.

5. Acknowledgements

5.1 Legal & Policy Framework
- Poisons & Therapeutic Goods Act 1966
- Poisons & Therapeutic Goods Regulation 2008
- Work Health and Safety Act 2011
- Work Health and Safety Regulation 2011
- NSW Health Pharmaceutical Services department – drugs schedules and procedures

Schedule 8 (S8) – Drugs of Addiction: This schedule is maintained by the PSB: (Publication number TG13). The PSB web site must be consulted for the current list of scheduled 8 drugs.

Schedule 4 (S4) – Prescribed Restricted Substances: This schedule is maintained by the PSB: (Publication number TG14). The PSB web site must be consulted for the current list of scheduled 4 substances.

5.2 Associated Documents
- HS331-1 Schedule 8 Drugs Approved Persons application form
- HS331-2,3 Schedule 8 Drugs Inventory (sheet 1) and Approved Persons register (sheet 2)
- HS331-4 Schedule 8 Drugs Audit Checklist

Appendix A: History

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<th>Version</th>
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<td>1/1/07</td>
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<td>New Document</td>
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<td>7/08/2012</td>
<td>a) Include S4 in title of procedure b) Add section 3.5: purchasing c) Add 3.6: Storage of S8 drugs to cater for emergency after hours animal welfare scenario d) Add 3.7.3: Explain how to manage S8 Drugs dilutions e) Add new section 3.10 and 3.10.1 related to S4 Restricted Substances and Pentobarbitone sodium f) Add 3.11: How to dispose of S4 restricted substances</td>
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<td>30 April 2014</td>
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