HIGH RISK SCHEDULED DRUGS AND POISONS PROCEDURE

SCOPE

This procedure relates to all activities involving the use of high-risk drugs and poisons under the management and control of Monash University in Australia and applies to affected staff, students, contractors and visitors.

PROCEDURE STATEMENT

This procedure sets out the requirements for the purchase, access, use and destruction of high risk scheduled drugs and poisons (S8/S9/S4D).

1. Abbreviations

DHHS	Department of Health and Human Services
OH&S	Monash Occupational Health & Safety
PCP	Poisons Control Plan
NPC	National Police Check
SARAH	Safety and Risk Analysis Hub
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons

2. Risk Management

A documented risk assessment must be completed in SARAH for all activities involving use of S8/S9/S4D poisons in accordance with the Risk Management Procedure.

3. Scheduling Descriptors

The table below summarises the relevant Schedules for this procedure:

Scheduled Poison descriptor	Primary label requirement	Description	Examples
Schedule 4 (S4), may include Drugs of Dependence (S4D)	Prescription Only Medicine OR Prescription Animal Remedy.	These are restricted substances which may include drugs of dependence known to be subject to misuse and trafficking.	Benzodiazepines, Midazolam, Lethabarb, Clonazepam, Diazepam, Duromine® and anabolic steroids.
Schedule 8 (S8)	Controlled Drug.	Controlled Drug – Substances that have a high risk for abuse, misuse and physical or psychological dependence	Cocaine, Pethidine, fentanyl, morphine (MS-Contin®, Kapanol®), oxycodone (Oxycontin®, Endone®), methadone (Physeptone®) and buprenorphine. Ketamine, GHB
Schedule 9 (S9)	Prohibited Substance.	Prohibited Substance – Substances that have a very high risk for abuse and misuse	Heroin, MDMA, , LSD, Mescaline

4. Permit to Obtain a Scheduled Poison or Drug

4.1 Organisational Unit must ensure that they have a current and compliant permit before purchasing and commencing any work involving S8/S9/S4D poisons as identified by the Chemical Pre-Purchase Checklist. Application for a new permit or amendment of an existing permit can be made online on the DHHS Website. The responses provided on the online application form will constitute the area's Poisons Control Plan (PCP).

4.2 The area must keep a copy of the completed permit application form.

4.3 The permit is only valid for:

- Specific locations stated on the permit;
- Specified schedules or individual poisons;
- Any specified quantity limits.

4.4 For general guidance on requirements for purchase, storage and handling of S8/S9/S4D poisons, refer to the Purchase and Storage of Scheduled Poisons poster.

5. Due Diligence

5.1 Organisational Units must:

- Undertake "due diligence" on all workers proposed to have access to S8/S9/S4D poisons;
- Establish a process whereby work involving S8/S9/S4D poisons is monitored by a local Committee (e.g. Local OHS Committee or a similar local area Committee)
- Develop a documented procedure which equips the person with knowledge and practical skills necessary for the safe, secure and responsible handling of S8/S9/S4D poisons;
- Provide competency-based training to verify the level of understanding of the local procedure.

5.2 Due diligence on Responsible and Authorised Persons:

5.2.1 All Responsible and Authorised Persons must:

- Have a current NPC conducted and;
- Sign a Statutory Declaration form acknowledging under "matter declared" that they:
- Had not committed a drug related crime in the last 36 months;
- Did not have a drug dependency in the last 36 months;
- Had not used illegal or prescription drugs recreationally in the last 36 months.
- Have acquired relevant tertiary qualification, sufficient knowledge and training to enable them to have access to S8/S9/S4D poisons.

5.3 Relevant Manager/Supervisor or their delegate must inform all Responsible and Authorised Persons of the need to conduct a NPC in accordance with the University's Employment Checks Procedure.

5.4 Responsible and Authorised Persons must provide their HR Business Partner with a copy of the NPC for verification. The HR Business Partner will notify the relevant Manager/Supervisors or their delegate of the outcome of the NPC. The local area is not required to store the NPC record.

5.5 A record of the outcome of the NPC and the completed statutory declaration form must be kept locally in accordance with the Data Protection and Privacy Procedure.

5.6 The following is also recommended:

- Past employment reference checks;
- Review of work history to ensure that they have accumulated sufficient hours of practical work experience in safe handling of similar substances;

5.7 Some areas (e.g. manufacturing) may consider conducting physiological screening (e.g. blood, urine, saliva testing) to rule out any illicit drug use.

5.8 Due diligence on Approved Persons:

5.8.1 Where it is not practical for an area to conduct NPC on all workers who may be required to handle S8/S9/S4D poisons (e.g. students) those workers must sign a statutory declaration form as per 5.2.1.

5.8.2 Approved Persons must not have direct access to the storage facilities where stock quantities of S8/S9/S4D poisons are stored.

5.8.3 Approved Persons must work under direct supervision of an Authorised Person until such time when they are deemed to have gained sufficient knowledge and practical skills necessary for the safe, secure and responsible handling S8/S9/S4D poisons.

6. Acquisition

Only Authorised Persons are allowed to purchase and receive S8/S9/S4D poisons.

6.1 Ordering (Organisational Unit)

6.1.1 The Authorised Person responsible for purchasing must ensure a valid permit exists for the poison being ordered as per Section 4.

6.1.2 The order must be reviewed and scrutinised by a second Authorised Person. The second Authorised Person that reviews the order should not regularly work in the same area as the first person, and the second person should remain as independent as possible from the first.

6.1.3 To ensure that the order is checked and released by the nominated local approval chain for poisons, where the Commodity has not been pre-assigned, when placing a purchase request for S8/S9/S4D poisons in Coupa, an appropriate Commodity type must be selected as follows: Laboratory > Laboratory Supplies > Drugs & Pharmaceuticals > Schedule "X" Drug.

6.1.4 The following information is to be included in the "Special Delivery Instructions" section of the purchase request:

- Permit Number;
- Instruction for S8/S9/S4D poison to be placed in a compliant storage facility immediately upon arrival and that it may only be collected or received by an Authorised Person from the Organisational Unit that placed the order;
- Names and contact numbers of Authorised Persons responsible for ordering and collection.

6.2 Receiving of Goods (Stores/Organisational Unit)

6.2.1 All Stores or areas that receive S8/S9/S4D poisons must have an appropriate storage facility that complies with Section 10 in a secure location.

6.2.2 Upon receiving a S8/S9/S4D poison, the Stores or area must:

- Inspect the goods and verify that the package was delivered intact; and
- Document the following:
  - Date received/released;
  - Time received/released;
  - Quantity received; and
  - Condition of packaging (Intact or Compromised).

6.2.3 If there is any reason to believe that the container has been tampered with or that it arrived damaged, the Stores or area must notify the Supplier and the area's Authorised Person.

6.3 Collection of Goods (Organisational Unit)

6.3.1 Only an Authorised Person from the area must receive or collect the S8/S9/S4D poison and check that the:

- Delivery has been received intact;
- Delivery container has not been tampered with; and
- Quantity matches the purchase order and the invoice.

6.3.2 The Authorised Person must store the S8/S9/S4D poison in a compliant storage facility as per Section 10.

6.3.3 Where the packaging or the container has been received damaged or there is any reason to believe that the container has been tampered with, the contents must be measured/weighed to confirm the quantity received. If there is any indication that the received quantity is less than what was ordered, it should be investigated without delay.

6.3.4 If the discrepancy cannot be reasonably explained, the Authorised Person must notify the Responsible Person who will notify the DHHS.

7. Labelling – Additional Requirements

7.1 The primary packaging and the immediate container must be labelled in accordance with the requirements listed in the SUSMP. Additional information must be included on the label:

- Name of the Authorised Person who received the container;
- Details of the requestor (if different to the Authorised Person receiving the poison);
- Date received.

7.2 Chemwatch can be used to generate labels for any aliquoted containers that are not for immediate use. Refer to the Labelling of Decanted Chemicals - OHS Information Sheet for information on compliant labels.

8. Transactions

8.1 All transactions must be individually recorded. These transaction records must include:

- The date of the transaction;
- The quantity of the substance involved in the transaction;
- The name of the substance;
- The form of the substance (e.g. tablets, liquid, powder etc);
- The strength of the substance;
- The name of the person carrying out the transaction;
- The quantity of substance remaining after each transaction (This quantity balance must always be measured (i.e. the quantity must be weighed or counted). The balance should not simply be calculated based on what the previous recorded balance was and what the amount used was);
- A dedicated page must be used for each poison.

8.2 If a poison is being used for multiple, different purposes at different times, it would not be sufficient to record a single daily transaction to encompass all such varied usages throughout a day. Individual records should be documented for individual transactions.

8.3 Sometimes a single dedicated page may contain multiple transactions of the same substance. In such a case, the details of the substance may only need to be recorded once on the page.

8.4 Transaction records of S8/S9/S4D poisons must:

- Be made in a way so that the records cannot be altered, obliterated, deleted or removed without detection;
- Be made in bound books;
- Contain consecutive page numbers;
- Users are not permitted to remove pages.

8.5 Transaction records may be kept electronically. Electronic transaction records must be completely impossible to subsequently change or delete.

8.6 Any amendment may only be made by making an entirely new transaction record while maintaining all previous records. A reason for the amendment must be recorded.

9. Register of High-Risk Poisons

9.1 All areas that store S8/S9/S4D poisons must maintain a register of their poisons in Chemwatch in accordance with Using Chemicals Procedure. The register must comply with the requirements of the Chemwatch Procedure.

9.2 To maintain confidentiality, the record in Chemwatch may be made hidden by the Local Administrator and only be visible to specific persons as required.

10. Storage

10.1 No other substances are to be stored in the same storage facility where S8/S9/S4D poisons are stored.

10.2 The quantity of any scheduled substance being stored should never exceed the maximum holding quantity stated on the permit.

10.3 The storage facility must be inaccessible to unauthorised persons at all times and must remain locked and unable to be easily removed from the premises when not being accessed e.g. locked cabinet or a refrigerator.

10.4 In addition, the storage facility for S8 and S9 poisons must be:

- Constructed of mild steel plate of 10 mm thickness; and
- Constructed with continuous welding of all edges; and
- Be fitted with a door constructed of mild steel plate of 10 mm thickness swung on hinges welded to the door and body of the cabinet, the door being flush fitting with a clearance around the door of not more than 1.5 mm; and

- Fitted with a fixed locking bar, welded to the inside face of the door near the hinge edge, which engages in a rebate when the door is closed; and
- Fitted with a 6-lever lock securely affixed to the rear face of the door; and
- Securely attached to a wall or floor in such a manner that it will resist attack by hand tools for 30 minutes or power tools for 5 minutes.

10.5 A locked box that is not affixed to premises does not meet the requirements of a compliant storage facility.

11. Handling

11.1 A S8/S9/S4D poison must only be dispensed to an Approved Person by an Authorised Person for an approved activity. Such activity must be verified by the Authorised Person at the time of dispensing.

11.2 Dispensing of the poisons must be recorded as a transaction by the Authorised Person.

11.3 Any remaining S8/S9/S4D poison must be returned to the storage facility and the balance weighed and recorded in accordance with Section 8.

11.4 If a S8/S9/S4D poison is not used up within the planned time period, it must be returned to the Authorised Person to be logged back into the storage facility or placed in the laboratory compliant storage facility (as per Section 10) or compliantly destroyed in accordance with Section 16.

11.5 Whenever any S8/S9/S4D poison is removed from its storage facility, the poison should be under the direct supervision of an Authorised Person or Approved Person until it is consumed through usage, destroyed compliantly or returned to the storage facility.

11.6 If it is necessary for the Authorised Person or Approved Person to temporarily stop directly supervising a S8/S9/S4D poison, the poison must be placed back into the storage facility, or be supervised by a second Authorised Person or Approved Person. The first Authorised or Approved Person must ensure that the correct quantity of poison is accounted for when they return.

12. Animal Ethics Exemption

12.1 An Authorised Person may dispense a S8/S9/S4D poison overnight if a research experiment involves an animal that may require euthanasia or appropriate treatments.

12.2 If a S8/S9/S4D poison is supplied to an Approved Person it must be returned as soon as possible and accounted for by the Authorised Person back into an appropriate S8/S9/S4D storage facility.

13. Laboratory Storage Requirement

Where a S8/S9/S4D poison is dispensed by an Authorised Person to be used over multiple days, the area must have a compliant laboratory storage facility available until it can be returned to the original storage facility or compliantly destroyed in accordance with Section 16.

14. Synthesis of Drugs and Poisons

All compounds that are able to be synthesised in a single synthesis to a S8/S9/S4D poison are to be controlled as if the poison was a S8/S9/S4D poison (e.g. codeine methyl ether and oripavine).

15. Compliance Monitoring

15.1 Organisational Units obtaining S8/S9/S4D poisons must monitor the activities involving use of poisons via a local Committee.

15.2 An independent internal auditor must regularly and randomly audit all relevant transaction records to detect discrepancies of any S8/S9/S4D poisons use.

15.3 If a discrepancy is detected, it should be investigated without delay (no longer than 7days) in consultation with the relevant Authorised and Approved Persons involved.

15.4 If there is an acceptable explanation for a discrepancy, the reason must be documented in the transaction records.

15.5 If the investigation indicates that a substance has gone missing without a reasonable explanation or was stolen, the Responsible Person must notify DHHS immediately via Lost Scheduled Items Notification Form.

16. Destruction of Poisons

16.1 If a S8/S9/S4D poison has not been consumed through the research activity, and it is no longer required, arrangements should be made to destroy the poison.

16.2 Out of “use by date” poisons must be destroyed.

16.3 Recording Substances for Destruction

16.3.1 When either destroying S8/S9/S4D poisons on premises, or sending the substances away for destruction, the following details should be recorded:

- The details of the substance, including;
- Name of the substance;
- Form of the substance (e.g. tablets, liquid, powder etc);
- Strength of the substance;
- Date of the transaction; and
- Quantity of the substance involved.

16.3.2 If substances are being sent away for destruction, then also record:

- The name of the place where the unwanted substance is being sent to;
- The address of where the unwanted substance is being sent to.

16.3.3 If S8/S9/S4D poisons are being destroyed on the premises, then also record:

- The method of destruction;
- The place of destruction; and
- The name of the witness(es).

16.4 Pharmacy Destruction (Off Site)

16.4.1 If they are willing to accept substances for destruction, it would be acceptable to send any S8/S9/S4D poisons to a pharmacist working in a pharmacy, or send the substances back to the original supplier.

16.5 Chemical Contractor Destruction (Off Site)

16.5.1 For S4D poisons, ensure that the waste company holds a permit to handle Schedule 4 poisons.

16.5.2 S8 and S9 poisons are not permitted to be sent to a waste company for destruction.

16.6 Destruction on Site

16.6.1 Any area that chooses to destroy Schedule 8 or 9 substances on their premises must ensure that the destruction is carried out by two practitioners who are either registered medical practitioners, pharmacists, dentists, veterinarians or nurses; however, the two persons cannot include the combination of two nurses where one is not a nurse practitioner.

16.6.2 When destroying substances on premises, the destruction process must render the substances non-recoverable and non-identifiable.

16.6.3 After rendering the substances non-recoverable and non-identifiable, the resulting waste material may be sent for disposal to a Monash approved chemical waste contractor (but should not be placed in general waste).

17. Transfer

17.1 Research permits do not allow poisons to be supplied to other areas unless sent for destruction.

17.2 An Authorised or Approved Person can transfer S8/S9/S4D poisons to other locations for an approved activity as long as the poison remains in their possession at all times. A transaction record of such transfer must be maintained.

17.3 S8/S9/S4D poisons must be transported in a locked, tamper proof, metal container of sound structural integrity.

17.4 The poison must not be left at another location overnight unless that location is listed on the permit of the permit holder undertaking the transfer and a compliant storage facility is available at that location.

17.5 At the end of the activity, the poison must be used up, compliantly destroyed or returned to its primary storage location.

18. Training

18.1 Areas must develop and implement a competency based local training program for handling high risk poisons.

18.2 Records of such training must be maintained using the Local Training Record template or in myDevelopment.

19. Responsibility for Implementation

A comprehensive list of OHS responsibilities is provided in the Roles, Responsibilities and Committees Procedure. A summary of the specific responsibilities relevant to this procedure are provided below.

19.1 Heads of Academic/Administrative Units must ensure:

- A safe system of work is implemented with the use of high-risk poisons;
- That all users of poisons adhere to their PCP through a monitoring process;
- That a current Permit is maintained;
- That a suitable Responsible Person/s is/are appointed; and
- That a system is established to support due diligence requirements in accordance with section 6.

19.2 Managers and Supervisors are responsible for ensuring:

- That all workers handling S8/S9/S4D poisons are either Authorised Persons or Approved Persons.
- That local procedures are developed to support the use of S8/S9/S4D poisons.
- That all persons handling poisons have been adequately trained and are competent in the use of S8/S9/S4D poisons.
- That access to storage facilities where S8/S9/S4D poisons are stored is only available to Authorised Persons.
- Any individuals that require physiological testing are notified.

19.3 Local Committee/Safety Officers are responsible for:

- Overseeing and monitoring implementation of the requirements for the management of S8/S9/S4D poisons.
- Reporting the status of poisons control planning and performance to the Senior Management of the Organisational Unit.

19.4 Responsible Person:

- Have a regular involvement, and/or regularly oversee the handling of products associated with the permit;
- Periodically review the local procedures to ensure they are being carried out in compliance with Drugs and Poisons legislation and with conditions of the permit;
- Be the contact point for DHHS to answer any questions relating to the permit and the PCP.

19.5 Authorised Person:

- Responsibilities of an Authorised Person are described in the relevant sections of this procedure.

19.6 Approved Person:

- Responsibilities of an Approved Person are described in the relevant sections of this procedure.

20. Tools

The following tools are associated with this procedure:

- Chemical Pre-Purchase Checklist

21. Records

For OHS Records document retention please refer to:

- Monash University OHS Records Management Procedure

DEFINITIONS

A comprehensive list of definitions is provided in the Definitions tool. Definitions specific to this procedure are provided below.

Key word	Definition
Approved Person	A worker who has been deemed competent by an Authorised Person to have the necessary skills and knowledge required for the safe and responsible handling of poisons.
Authorised Person	A staff member authorised by the permit holder to gain access to a storage facility holding a drug of dependence and can work with or be in possession of such a substance.
High Risk Drugs and Poisons	Include all the drugs and poisons that are listed in the SUSMP under Schedule 8 (S8), Schedule 9 (S9) as well as substances that are Schedule 4 (S4) that are also drugs of dependence. These are listed in Schedule 11 of the Act and are known to be the subject of misuse and trafficking. The S4 drugs that are also drugs of dependence will be referred to in this procedure as S4D.
Independent internal auditor	Is nominated by the permit holder and is independent of the persons dispensing or recording the transactions for the area that is being audited.
Permit	A permit issued by the Department of Health and Human Services (DHHS) to Purchase or Otherwise Obtain Poisons or Controlled Substances for Industrial, Educational or Research Purposes.
Permit Holder	A physical person or a Monash University Business Unit named on the Poisons Control Plan and the permit.
Poison	A poison is any substance which is listed in the Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP). A drug, poison or controlled substance can also be a hazardous substance and/or a dangerous good. For the purpose of this procedure, high risk drugs, poisons and controlled substances will be referred to as poisons.
Responsible Person:	A person listed on the permit who had been delegated responsibility by the permit holder to deal with the DHHS on all matters relating to scheduled drugs and poisons. ● A Responsible Person would typically be: – A Medical Practitioner, Veterinarian, Pharmacist or; – Have an equivalent qualification that included significant studies in chemistry and/or human health or; – Have at least five years of experience and training in the handling and recording of scheduled substances, similar to those listed on the permit.
Storage facility:	Compliant storage facility for the specific schedules must meet the requirements detailed in Section 10.
Transaction:	The removal, transfer or return of a poison to or between premises. A transaction would occur whenever an amount of a poison is taken from its storage by an Authorised Person and supplied to an Approved Person, or is used for a specific purpose by an Approved Person.

GOVERNANCE

Parent policy	OHS&W Policy
Supporting procedures	**Monash University OHS documents** • Chemwatch Procedure • Employment Checks Procedure • Local OHS Training records proforma • Purchase and Storage of Scheduled Poisons poster • Risk Management Procedure • Roles, Responsibilities and Committees Procedure • Using Chemicals Procedure
Supporting schedules	N/A
Associated procedures	**Australian and International Standards** • ISO 45001:2018 Occupational Health and Safety Management Systems • Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) **DHHS Documents** • Managing drugs of dependence by licence and permit holders July 2019
Related Legislation	• Occupational Health and Safety Act 2004 (Vic) • Drugs, Poisons and Controlled Substances Act (1981) • Drugs, Poisons and Controlled Substances Regulations (2017)
Category	Operational
Approval	Chief Operating Officer & Senior Vice-President 5 April 2022
Endorsement	Monash University OHS Committee 15 March 2022
Procedure owner	Health, Safety and Wellbeing Manager
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Review date	5 April 2025
Version	3.0
Content enquiries	ohshelpline@monash.edu

DOCUMENT HISTORY

Version	Date Approved	Changes made to document
1	September 2017	High Risk Scheduled Drugs and Poisons Procedure (S8/9/11), v1
2	December 2020	1. Amended the title. 2. Aligned terminology and definitions with those used by DHHS. 3. Replaced reference to S11 with S4D in line with DHHS terminology. 4. Updated the list of definitions. 5. Added risk management requirement including the use of Chemical Pre-Purchase checklist. 6. Expanded on requirements for areas to obtain appropriate permit. 7. Clarified that information provided in the DHHS Permit application form is now the PCP. 8. Added a section on Due Diligence in line with DHHS guidance. 9. Added requirement to complete Statutory Declaration for Authorised and Approved Persons.

		10. Added record keeping requirements relating to NPC and Statutory Declarations. 11. Clarified the requirements for the acquisition process. 12. Removed section “Processing of Orders (Stores). 13. Outlined purchasing requirements using Coupa. 14. Added the requirement to keep a register of scheduled poisons in Chemwatch. 15. Aligned storage and handling requirements with DHHS guidance. 16. Broadened the Expanded Overnight Storage requirements to Laboratory Storage requirements for greater flexibility. 17. Clarified and expanded requirements for Compliance Monitoring to be undertaken by an independent internal auditor. 18. Reordered Destruction on Site section to improve flow. 19. Revised Transfer requirements in line with DHHS advice. 20. Added the requirement to keep training records locally. 21. Updated the Responsibility for Implementation section to include additional requirements for Management, Local Committees and Safety Officers. 22. Removed overlapping procedural requirements for some roles. 23. Updated and checked hyperlinks. 24. Added a link to the Department of Justice Statutory Declaration form. 25. Added Tools section. 26. Removed the requirement for S9 to only be supplied by Responsible Medical practitioner. 27. Changes to wording to improve clarity. 28. Updated logos in header.
2.1	July 2021	1. Updated certification logo in footer to ISO 45001 2. Updated the Standard to ISO 45001 under “Associated procedures” in the Governance table 3. Updated OHS Policy under ‘Parent Policy’ to OHS&W Policy
3.0	April 2022	1. Updated 5.3-5.5 to align with the revised HR Employment Checks Procedure for the process of obtaining, verifying and storing NPCs. 2. Updated title of Procedure owner in Governance table.