Managing drugs of dependence by licence and permit holders

This guidance document has been prepared by the Victorian Department of Health and Human Services (the Department) for organisations that hold Victorian licences or permits to obtain scheduled substances.
Many points in this document relate to Victorian Drugs and Poisons legislative requirements (and in those cases, the corresponding sections of legislation are underlined).
However, the vast majority of points in this document are guidance, and are not necessarily required by Drugs and Poisons legislation. The guidance is designed to prevent scheduled substances from being stolen or from being intentionally removed for illicit purposes.

Contents

All sections specifically relevant to internal auditors may be found in “boxed sections” of text in this document

Substances that carry a higher risk for illicit use

The guidance may be applied to all scheduled substances that may be obtained using a licence or permit. A full list of scheduled substances, including those in Schedules 4, 8 and 9 may be found in the Australian Standard for Uniform Scheduling of Medicines and Poisons (SUSMP).
However, the focus of the guidance is on those substances that carry a higher risk for illicit use, and which may subsequently cause significant harm in people when misused. Such substances include those listed in Schedule 11 of the current Drugs, Poisons and Controlled Substance Act 1981 (the DPCS Act) as being *drugs of dependence*. The substances also include any other substances that may be misused.

Substances that carry a higher risk for illicit use include:

- All substances listed in Schedule 9, including (but not limited to):
  - Cannabis and tetrahydrocannabinols
  - Heroin,
  - MDMA (N, α - dimethyl-3,4-(methylenedioxy)phenylethylamine)

- All substances listed in Schedule 8, including (but not limited to):
  - Alprazolam
  - Amphetamines
  - Buprenorphine
  - Codeine
  - Cocaine
  - Fentanyl
  - Ketamine
  - Methadone
  - Methylphenidate
  - Morphine
  - Oxycodone
  - Pethidine

- Some substances listed in Schedule 4 of the SUSMP, and also listed in Schedule 11 of the DPCS Act, including (but not limited to):
  Barbiturates, including:
  - Pentobarbitone (Lethabarb®)
  - Phenobarbitone

  Benzodiazepines, including:
  - Clonazepam
  - Diazepam
  - Midazolam
  - Nitrazepam
  - Oxazepam
  - Temazepam
  - as well as any other substances that are structurally related to benzodiazepines, such as zolazepam (within Zoletil®)
  - Piperidine derivatives
  - Phentermine
  - Anabolic steroids, including testosterone
  - Pseudoephedrine

- Other Schedule 4 substances that have a history of being misused, but which are *not* listed in Schedule 11 of the DPCS Act, including (but are not limited to):
  - Clonidine
  - Codeine combined with paracetamol
  - Pregabalin
  - Propofol
  - Quetiapine
  - Sildenafil
  - Tiletamine (within Zoletil®)
  - Xylazine
  - Zolpidem

This is not a complete list of substances that carry a higher risk for illicit use.
Also bear in mind that any substance that is closely related to, is a derivative of, or is a synthetic analogue of such a substance would also carry similar risks, and so should be treated the same way.

For the purposes of this guidance document, all of these substances will be referred to as *drugs of dependence*.

Many licences and permits list individual drugs of dependence that may be obtained using the licence or permit; while some licences or permits (which carry greater risks) may list all Schedule 4 substances or all Schedule 8 substances.
If a drug of dependence is listed on a licence/permit but it is determined by the licence/permit holder that the substance is actually no longer required (and there is no reason for it to be used in the foreseeable future), then the licence/permit holder should contact the Department to request that it be removed from the licence/permit. This would remove the unnecessary risk that the particular drug of dependence may be ordered by a corrupt staff member and then intentionally removed for illicit purposes.

Due diligence on persons proposed to have access to drugs of dependence

Organisations intending on conducting operations involving drugs of dependence should carry out due diligence on any person that it intends on becoming an "authorised person" to gain access to any storage facility holding a drug of dependence and/or be in possession of such a substance. (For more information about types of storage facilities, refer to the section below, entitled "Storage facilities").
(Note that not every "authorised person" needs to be formally listed as a "responsible person" on a licence/permit. It is only necessary to list one person as a responsible person on a licence/permit (although more than one may be listed if desired)).

A licence/permit holder should not allow a person access to any drugs of dependence if that person:
- Has committed a drug related crime;
- Has a drug dependency, or has used illegal or prescription drugs recreationally;
- Does not have the knowledge or practical skills necessary for the safe, secure and responsible handling of the substances.

A licence/permit holder may conduct due diligence on a staff member it intends to allow access to drugs of dependence by:

- A review of the person's national police record to ensure that the person has not been found guilty of a drug related crime.

- A review of the person's work history. The person should have accumulated many hours of practical work experience in safely, securely and responsibly handling similarly higher risk substances.

- A review of the person's education and skills. The person should have had education and training to equip him/her with the knowledge and practical skills necessary for the safe, secure and responsible handling of drugs of dependence (as well as any other dangerous substances that he/she may be handling).
  Formal qualifications that include chemistry or health sciences would certainly be helpful, but may not be absolutely required.
  While some qualifications may confirm a person's understanding of matters such as theoretical chemistry, they may not confirm that the person is competent in the safe, secure and responsible handling of dangerous substances in a practical setting.
  Similarly, just because a person holds a formal qualification, it would not mean that there is no need for the person to undergo a police record check.

- Requesting that a person undergo physiological testing (such as blood, urine or saliva testing) to determine whether or not the person may be using drugs illicitly. While the Department has suggested that a licence/permit holder may consider such drug testing, such testing is entirely optional to gain information about a person, and the Department does not endorse any specific test to be carried out.

- A review of any other information that the licence/permit holder may have in relation to the person. The more relevant information that an organisation knows about a person working for it, the better. While the Department does not endorse an organisation gaining access to a person's private and confidential information without the person's consent, an organisation should use judgment on whether or not it has sufficient information about a person to be able to adequately determine whether or not the person is suitable and competent enough to have access to drugs of dependence.

There may be situations where it is quite clear that a person would be unsuitable to access drugs of dependence - for example, if a person had an illicit drug dependency.
However, there may be other situations where there are no clear indicators that a person is unsuitable, but there may be uncertainty, and reason to express doubt or caution regarding a person's suitability. In such a situation, it is possible that the person may be able to carry out his/her work under the direct supervision of second person that may monitor the first person's activities. In such a scenario, it would be important that the organisation ensures that the first person cannot gain access to the storage facility holding drugs of dependence by him/herself. It would also be important that the second person remains as independent as possible from the first person.

Number of people accessing drugs of dependence and internal auditors

There are risks associated with allowing a large number of people access to a facility used to store drugs of dependence.
While there may be legitimate reasons for needing large numbers of people to access to a storage facility, such large numbers can sometimes make accountability of drugs difficult. It can also provide opportunities for corrupt persons to falsify records and divert drugs.
An organisation should closely examine any proposal for a person to gain access to drugs of dependence. This is particularly important when a large numbers of people are being considered.

Similarly, there are also risks associated with allowing only a very small number of people access, or allowing only one single person access to a facility used to store drugs of dependence without their activities being scrutinised by others.

Therefore, there should be authorised persons within an organisation that regularly, and randomly review and scrutinise the usage of drugs of dependence (internal "auditors"), regardless of the number of people granted access.
Any internal auditor should be someone that does not regularly work in the area that he/she audits, and can remain as independent as possible from those that are being reviewed.
The auditor should review access management, transaction records, as well as current holding balances of drugs of dependence (see relevant sections further below, indicated within a boxed boarder).

Ordering drugs of dependence

Only authorised persons should be permitted to order drugs of dependence to be supplied to an organisation that holds a licence or permit.
Permit holders in particular should have policies in place so that a single authorised person cannot order a drug of dependence without the order being reviewed and scrutinised by a second authorised person.
The order should be accompanied with justification for the type and quantity of the drug of dependence to be used in the permit holder's activities (which may be research or industrial use of substances).
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.

The authorised person that receives and checks any drug of dependence delivery to the organisation should check that the delivery container has not been tampered with prior to receipt. If there is any reason to believe that the container has been tampered with, the contents may be measured / weighed to confirm that the correct quantity has been received. If there is any indication that the received quantity is less than that which was ordered, it should be investigated without delay (see the further guidance below, regarding discrepancies within the section entitled "Usage and accountability records").

Storage facilities, general security and substance quantity limitations

All Schedule 4, 8 and 9 substances must be stored in a facility which is locked to prevent access by unauthorised persons (stipulated by Sub-regulations 73(2), 73(3) and 74(4) of the Drugs, Poisons and Controlled Substances Regulations 2017). It is expected that such a storage facility would be affixed to the premises when locked to prevent unauthorised access.

Schedule 8 and 9 substances must be stored in a facility that complies with Sub-regulation 74(2).
Most organisations comply with this Sub-regulation by storing the substances in a compliant safe or vault.
The walls of a compliant facility would be at least 10mm in thickness (Refer to Sub-regulation 74(2)(a)).
In addition to Schedule 8 and 9 substances, it is permissible to also store Schedule 4 drugs of dependence in such a facility, but no other items may be stored in such a facility (stipulated by Sub-regulation 74(5)).

Schedule 4 substances must be stored in a facility that is locked to prevent access by unauthorised persons (and is affixed to the premises when locked); however this doesn't necessary need to be a safe or a vault.
Storing any other item that is not a scheduled substance in the same facility (which is used to store a Schedule 4 substance) would be questioned, because Sub-regulation 73(3)(a) stipulates that the facility may *only* be opened to access the scheduled substances (or "poisons") stored inside it.

Additionally, for permit holders only, the quantity of any Schedule 8 or 9 substance being stored should never exceed the maximum holding quantity stated on the permit.
An internal auditor should regularly and randomly verify this.

Managing access to storage facilities

There are many methods by which different storage facilities holding scheduled substances may be accessed (including via a key, a swipe card, a code and other methods).

The access method should be inaccessible to unauthorised persons at all times.
Any efforts to store substances securely in a robust storage facility would almost seem pointless if unauthorised persons can easily get hold of a key (or swipe-card etc) to gain access to the storage facility.
Therefore, it may be deemed appropriate that authorised persons should carry their key (or swipe-card etc) at all times when they are on the research premises, and should ensure it is completely inaccessible to unauthorised persons after hours.
If keys (or swipe-cards etc) are to be kept on the research premises over-night, it may be advisable to secure them within a key-safe which is accessible only via an access code.

Where access codes are used (to access a key safe or to directly access a facility holding scheduled substances), it may be deemed appropriate that such codes are changed regularly, and always after an authorised staff member ceases employment.

An optional, useful access process would be one which automatically and electronically records occasions of access, and links the access with an individual authorised person. Such an electronic system may link access with individual persons via individually issued swipe-cards or individual access codes.

It may be useful for an internal auditor to examine such access records (if available) if he/she is reviewing persons that may have had access to a quantity of drug of dependence that may be unaccounted for.

This may be useful where large quantities of drugs of dependence are being stored and/or when large numbers of persons have been granted authorisation to access the facility.

However, if any electronic access system is being considered for a facility used to store Schedule 8 or 9 substances, it is very important to ensure that the locking mechanism of any such system does not compromise the strength of the storage facility. Such electronic systems often use weaker magnetic locking mechanisms that may be easily forced open, instead of a manual locking mechanism that uses a stronger, movable bolt. A facility used to store Schedule 8 and 9 substances should not be easily forced open (refer to Sub-Regulation 74(2)).

Usage accountability, records and investigating discrepancies

Whenever any scheduled substance is removed from its storage facility, the substances should be under the direct supervision of an authorised staff member.

- For permit holders: It should remain under the direct supervision of an authorised staff member until it is consumed through usage, destroyed compliantly or returned to the storage facility.
- For licence holders: It should remain under the direct supervision of an authorised staff member until it is supplied to a customer, destroyed compliantly or returned to the storage facility.

If it is necessary for the authorised person to temporarily stop directly supervising a substance, the person should either place the substance back into compliant locked storage, or request that a second authorised person directly supervise the substance while the first is absent. The first person should ensure that the correct quantity of substance is accounted for when he/she returns.

When permit holders use substances and when licence holders supply substances, authorised persons must make compliant records for accountability purposes, which document each transaction (in compliance with Sub-regulation 108(1)).
A transaction would occur whenever an amount of a substance is taken and supplied (by a licence holder), or used for a specific purpose (by a permit holder).
Such transaction records would include:

- The date of the transaction
- The quantity of the substance involved in the transaction
- The details of the substance

  Sometimes a 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.

  The details of the substance would include:
  - The name of the substance
  - The form of the substance (eg: tablets, liquid, powder etc)
  - The strength of the substance
- The name of the person carrying out the transaction

If a permit holder were to use a substance 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 of drugs of dependence should be documented for individual transactions.
Permit holders should take a practical approach towards this requirement in circumstances where minute quantities of substances are used repeatedly in thousands of identical transactions. The requirement is in place so to account for quantities of substances that could be intentionally removed for illicit purposes.

An internal auditor for a permit holder should have an idea of what quantity of a drug of dependence would be reasonably expected to be used for each recorded purpose. The auditor should investigate circumstances where amounts recorded for specific usages is noticeably more than what would be reasonably expected to be used for the purpose.

In addition to all of the above recording requirements, if a Schedule 8 or Schedule 9 substance is being used, there are further legislated requirements.
Transaction records of any Schedule 8 or Schedule 9 substance must:

- Be made in a way so that the records cannot be altered, obliterated, deleted or removed without detection (required by Sub-regulation 109(6)).

  Most organisations comply with this requirement by making such records in a *register* (a book) which has consecutively numbered pages, and that has bound pages (ie: pages are joined together, so that the only way a page could be removed is by ripping it out, and it would be obvious that the page has been ripped out).

  It is possible to comply with Sub-regulation 109(6) by making specialised electronic records, however most electronic records do not comply with Sub-regulation 109(6). For an electronic record to comply with this Regulation, after any transaction record has been made, it must be completely impossible to subsequently change or delete this transaction record. Any amendment may only be made by making an entirely new transaction record (and by maintaining all previous records).
- Include the quantity of substance remaining after each transaction (or a "running balance") (required by Sub-regulation 109(1)(b)).

This quantity balance must always be measured (ie: 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. It may be easier to physically count large quantities of stock by placing bulk stock of full packs into a single tamper-evident, seal container; Then, providing that the tamper-evident seal is always intact, this bulk quantity may be simply added to non-bulk stock that is more manually counted out.
It is also useful to mark a recorded balance (with a tick or some indicator) to confirm that the balance was measured and was correct.
If there is a discrepancy between the measured balance, and what the balance should be based on calculations, the matter should be investigated without delay.

While the above two requirements are only legislated for Schedule 8 or Schedule 9 substances, many organisations have an internal policy to apply them to Schedule 4 drugs of dependence for additional controls. Certainly, in situations where there may be uncertainty, and reason to express doubt or caution regarding a person's suitability to access Schedule 4 drugs of dependence, it is highly recommended that their transaction records comply with the above two requirements.

An internal auditor should regularly and randomly review records to detect discrepancies of any drugs of dependence in the following ways:

- Where a running balance is maintained, an auditor should:
  - Verify that the current holding quantity matches the current balance documented in the records; and
  - Review records to detect recorded balances which do not arithmetically reconcile with previous balances and amounts recorded as being used.
- Even if a running balance is not maintained for Schedule 4 substances, it is possible for an auditor to detect discrepancies by obtaining separate records of stock that has been delivered to the organisation (ie: an invoice from the organisation's supplier) from a particular date, measuring the quantity of that stock that is currently being stored, and reviewing the transaction records since the stock was delivered to ensure that the records can at least account for the difference between the quantity delivered and the current holding quantity.
- Similarly, orders placed for Schedule 8 and 9 substances should be reconciled by an auditor to ensure that they correspond to matching quantities of those substances being entered into Schedule 8 and 9 records.

If a discrepancy is detected (either by an authorised staff member or an internal auditor), it should be investigated without delay.
Often, there is an acceptable explanation for a discrepancy, in which case the explanation should be documented in the transaction records.
Acceptable explanations may include that:

- The amount of stock delivered to a permit holder was actually slightly more than the amount that was recorded as being delivered (eg: because a manufacturer included an "overage" in a bottle of liquid);
- The amount of liquid in a stock bottle held by a permit holder changed over a long period of time due to water evaporation;
- A small amount of a substance was inadvertently lost while an authorised staff member was attempting to carry out his/her work (e.g.: a liquid or powder was spilt, a bottle was broken, or an amount of substance measured by a permit holder was slightly more/less than what was recorded as being taken).

Such explanations would be acceptable if they were infrequent. However, an internal auditor should be mindful that it's possible for such explanations to be used on frequent occasions to conceal drugs of dependence being intentionally removed for illicit purposes.

If a discrepancy indicates that a substance has gone missing, it has been investigated, and no acceptable explanation can be determined, then it must be reported to the Department (required by Regulation 152).
Where an acceptable explanation for a discrepancy has been found, the explanation should be recorded, but the matter need not be reported to the Department.
It would be expected that a reasonable investigation into a discrepancy should not take longer than seven days from the time that the discrepancy is detected. Therefore, unresolved discrepancies indicating loss should be reported to the Department within seven days from the date of initial detection.
Obviously, instances where substances have quite clearly been stolen should be reported to the Department immediately.
Reports can be made to the Department by via its website by going to:

- https://www2.health.vic.gov.au/dpcs

→ Then clicking on the section in red entitled "Access commonly used online forms"
→ Then, in the subsequent page that opens, click on the link entitled:
"Lost scheduled item notification form (for organisations to complete)"

Destruction

If a substance is no longer required, arrangements should be made to destroy the substance.
There are legislative requirements in place for the accountability of substances that are destroyed to reduce the likelihood of substances being intentionally removed for illicit purposes.

Many organisations choose to arrange destruction by sending substances away for that purpose. If they are willing to accept substances for destruction, it would be acceptable to send any substances to a pharmacist working in a pharmacy, or possibly to send the substances back to the original supplier of the substance.

Some organisations choose to destroy substances on their own premises. When destroying substances on premises, it should be ensured that the destruction process renders the substances non-recoverable and non-identifiable.
After rendering the substances non-recoverable and non-identifiable, the resulting waste material may be sent to a waste company that specialises in chemical and/or pharmaceutical material (but should not be placed in general waste).

If a research organisation would like to send material to a waste company without first rendering substances non-recoverable and non-identifiable, then:
- The research organisation should ensure that no Schedule 8 or 9 substances are sent this way (as there are no waste companies in Victoria that have lawful authority to be in the possession of substances that can be identified as Schedule 8 or 9 substances).
- If Schedule 4 substances are sent this way, the research organisation should check that the waste company holds a poisons permit to be in lawful of substances that can be identified as Schedule 4 substances.

Any organisation that chooses to destroy Schedule 8 or 9 substances on their premises must ensure that the destruction is carried out by two health practitioners that are any registered medical practitioner, pharmacist, dentist, veterinarian or nurse; however the two persons cannot include the combination of two nurses where one is not a nurse practitioner. (These requirements are outlined in Regulation 115).
As many research organisations do not have two such health practitioners on their premises, many organisations choose to send their Schedule 8 and 9 substances to pharmacists working in pharmacies that are willing to accept the substances for destruction.

When either destroying substances on the premises, or sending the substances away for destruction, the following details should be recorded (to comply with Sub-regulation 108(1)):
- The details of the substance, including:
  - Name of the substance
  - Form of the substance (eg: tablets, liquid, powder etc)
  - Strength of the substance
- Date of the transaction
- Quantity of the substance involved

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

If Schedule 8 or 9 substances are being destroyed on the premises, then (to comply with Regulation 115) also record:
- The method of destruction
- The place of destruction
- The name of the witness(es)

An internal auditor can review instances were large quantities of drugs of dependence have been arranged to be destroyed in the following ways:
- Where substances have been sent to a pharmacy for destruction, an internal auditor can request that the pharmacy provide its record of receiving the substances, and verify that the quantity received by the pharmacy matches that purported to have been sent to the pharmacy.
- Where Schedule 8 or 9 substances have been destroyed on the premises, an internal auditor could verify the destruction with the health practitioners purported to have witnessed the destruction.

Responsibility of individual licence and permit holders to be proactive

Further to the minimal requirements defined in Victorian Drugs, Poisons and Controlled Substances legislation, it is often difficult for the Department to provide individualised guidance to the unique situations of every single organisation so that the organisation may be able to prevent and detect theft or the intentional removal of substances for illicit purposes.

Sub-regulations 73(3) and 74(4) indicate that permit holders must take *all reasonable steps* to ensure that scheduled substances remain secured to prevent access by unauthorised persons at all times.

Depending on the level of risk associated with a permit holder's proposed activities, the phrase "all reasonable steps" may mean that the permit holder must take additional steps to ensure adequate security.

Just because a practical control is not necessitated by the minimal requirements of Drugs, Poisons and Controlled Substances legislation does not mean that the control should not be in place.

Permit holders should be proactive in carrying out their own due diligence and reviewing any proposed activities involving scheduled substances to eliminate, as much as possible, ways in which substances may be stolen or intentionally removed for illicit purposes.