

Register for Medicines & Poisons

In conducting scientific research hazardous materials and processes may be employed. Society is rightly concerned about these, and has many control measures in place to reduce the risk associated with their use. These controls, in part, take the form of legislation, codes of practice and the like. The control of chemicals involves the Dangerous Goods, Hazardous Substances, and Medicines and Poisons Acts and regulations.

In simple terms, the -

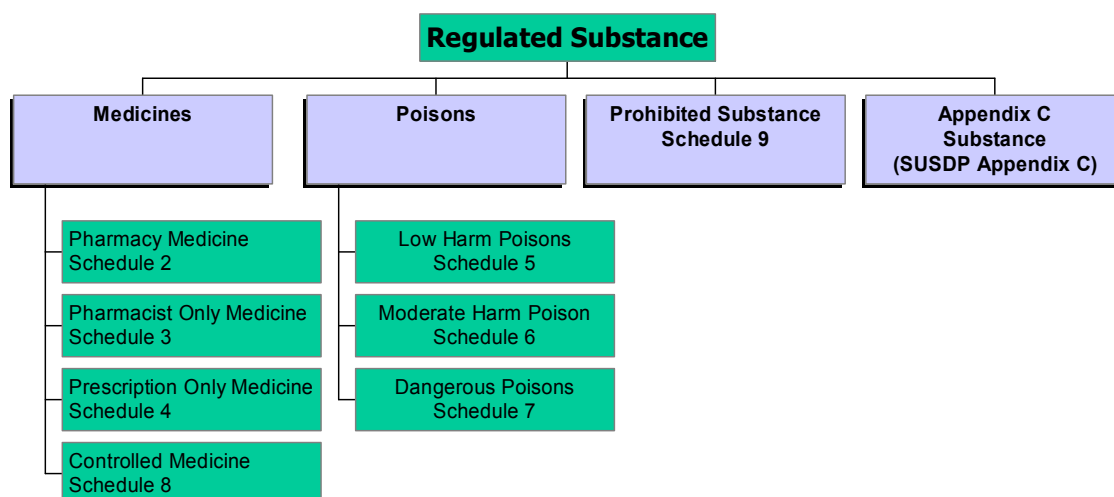
- Dangerous Goods requirements consider physiochemical properties of materials in storage and transport,
- Hazardous Substances (including carcinogens) requirements are concerned with health related issues of hazardous chemical use and control in the workplace. Hazardous substances are assigned according to certain criteria. (Material) Safety Data Sheets and labels indicate whether or not the material is considered a hazardous substance. Carcinogens should be stored in a locked cupboard. A separate [register](#) (similar to those for poisons) should be considered.
- Medicine (drug) and Poisons requirements are concerned with the labelling, supply and consumer access to poisonous chemicals, whether for human consumption or industrial processes. Medicines and Poisons are assigned into a Schedule according to their hazardous nature and degree of control required. The Schedules are determined by the National Drugs and Poisons Schedule Committee and are published in the Poisons Standard (incorporating the Standard for Uniform Scheduling of Drugs and Poisons (SUSDP)). The Schedules are -

| Schedule | Regulated Substance title | Property of Poison | Availability |
|----------|----------------------------|--|---|
| 1 | - | (Not currently in use) | |
| 2 | Pharmacy Medicine | Drugs (medicinal poisons for therapeutic use) | Pharmacy retail |
| 3 | Pharmacist Only Medicine | Drugs of higher potency | Restricted pharmacy retail |
| 4 | Prescription only Medicine | Prescription drugs | Medical/dental/veterinary prescription At ANU this should be under the control of a veterinarian or medical officer. |
| 5 | Low Harm Poison | Domestic poisons | General retail |
| 6 | Moderate Harm Poison | Industrial and Agricultural poisons | Restricted retail |
| 7 | Dangerous Poison | Special poisons | Restricted wholesale |
| 8 | Controlled Medicine | Drugs of Addiction | Restricted medical/dental/vet prescription At ANU, also contact the OHS Branch for advice |
| 9 | Prohibited Substance | Prohibited substances or Appendix C substances | Restricted wholesale At ANU, also contact the OHS Branch for advice |

The Schedule number for a chemical can be found in its Material Safety Data Sheet, or on the label (eg. S4). Some general exemption for certain materials exist and these can be found in Appendix A, B and G of the [Poison Standard 2008](#).

The [Medicines, Poisons and Therapeutic Goods Legislation](#) requires, in part, that regulated substances are used by authorized (licensed) persons and that a register is maintained.

Medicines and Poisons



The ANU is a 'Recognised Research Institution' under the Act [s20 (5)(b)].

Authorisation –

A summary of the legislation application to the ANU can be found [here](#). Further advice is available from the OHS Branch or ACT Health

Certain health related occupations (eg. Doctors, Veterinary surgeons etc) have other authorisations as set out in the Regulations.

An authorised (licensed) person/group may be permitted to 'deal with' the regulated substance, which may include (as stated in the licence) -

- Manufacture
- Obtain
- Possess
- Administer
- Discard
- Issues a purchase order

As a Licence Holder (or an authorised person), you will need to consider any dealings (uses of the substance) and restrictions, registers and reporting any losses. A Licence Holder is usually the Research Group Leader, and must have knowledge, experience and training related to the dealing. A Research School could be a licence holder for some regulated substances and these would be explored with the relevant authority on a case-by-case basis.

A licence can be no longer than 3 years and is not transferable.

Application forms are available for –

- [Controlled Medicines Research and Education Program Licence](#)
- [Dangerous Poisons Research and Education Program Licence](#)
- [Prohibited Substances Research and Education Program Licence](#)

A summary of the legislation application to the ANU can be found [here](#). Further advice is available from the OHS Branch or ACT Health

Written and approved **Risk Assessments** are required for regulated substances at ANU to indicate authorisation by the Area/institution.

A list of Authorised persons (eg. those able to order these scheduled poisons) should be kept by Area management.

Purchase of regulated substances –

A [written (including electronic form) and signed] Purchase order is the only method to purchase Regulated Substances – No credit cards, phone orders, walk-ins etc. The issuer's authority (licence number) is required to obtain the material.

Registers –

A regulated substance register is in addition to the chemical inventory type register maintained for hazardous substances and dangerous goods. The register must have -

- An individual page related to a single form and strength of the controlled medicine, dangerous poison, prohibited substance or appendix C substance.
- Entry to be signed. For controlled Medicines a witness is required, who must also sign
- Prescribed register storage location: on premises
- Keep for 2-years after last entry

A [regulated substance register](#) is available. A [controlled medicine register](#) (requiring a witness) is also available.

All registers and stock should be regularly maintained and inspected.

Storage –

The expectation and requirements are that the substances will be stored under the correct environmental conditions, especially temperature.

From a security aspect, controlled medicines, prohibited substances, appendix C substances, must be stored in a –

- Medicines cabinet, safe or strong room or vault, meeting [Schedule 5](#) of the Regulations.
- Securely locked when not in immediate use.
- Personal custody of the key or a secret combination code.

Disposal of –

An ACT Medicines and Poisons Inspector must witness the disposal of Controlled Medicines, Prohibited Substances.

The disposal of a Dangerous Poison is to be witnessed by the Hazardous Waste Safety Officer (as long as they are not supervised by, or the supervisor of, the person doing the disposal, in which case the head technical office or other safety officer may be substituted as the witness).