



# CYTOTOXIC DRUGS AND RELATED WASTE – RISK MANAGEMENT

JULY 2017

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# ACKNOWLEDGEMENTS

This guide was prepared by the cytotoxic drugs working party and first published in 2008. It provides a practical health and safety standard for the health care industry in workplaces where cytotoxic drugs and related waste are handled.

Members of the working party represented a range of stakeholders and health care practitioners who are dedicated to improving health and safety in the health care industry. Without their participation, this project would not have been possible. Members of the original working party were:

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In 2016, this guide was updated for the requirements of current Work Health and Safety Regulation 2011 (WHS Regulation) by Dr Bhoopathy Sankaran and Dr Vivian Fung of SafeWork NSW and was circulated to members of the 2008 cytotoxic drugs working party. Their generous feedback in updating this guide is greatly appreciated.

We also thank the Ministry of Health (Workplace Relations Unit) for providing comments on the revised Guide and especially Angie Stanojevic – Senior Policy Advisor; Dr Ian Cheng – Occupational Physician, Royal North Shore Hospital and Leslie Gibbs – Professional Officer, NSW Nurses and Midwives' Association, Australian Nursing and Midwifery Federation, NSW Branch.

The following publications provided invaluable reference during the preparation of this guide:

- *Handling cytotoxic drugs in the workplace*, January 2003, WorkSafe Victoria
- *Guide for handling cytotoxic (anti neoplastic) drugs and related waste*, 2005, Queensland Department of Industrial Relations
- *Guidelines for handling cytotoxic drugs and related waste in health care establishments*, 2nd edition, 1995, WorkCover NSW.

This guide is neither definitive nor 'set in concrete'. Practices change over time and comments on how this document can be improved are welcome. Please contact SafeWork NSW.

Vivienne Freeman and the Royal North Shore Hospital are gratefully acknowledged for the provision of the forms and instructions relating to the *Cytotoxic drug precautions alert* in Appendix 11 and *Your continuous infusion device pump and Chemotherapy spill at home* in Appendix 12.

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# 1. INTRODUCTION

## 1.1 PURPOSE

This guide provides practical advice to PCBUs and workers on how to prevent or minimise the risks to health associated with handling cytotoxic drugs and related waste within health care establishments, community settings and veterinary practices. It will assist in the development and implementation of safe systems of work that are consistent with the requirements of NSW work, health and safety laws.

The use of cytotoxic drugs includes their preparation, administration, handling, storage, movement, disposal, and spills management.

## 1.2 SCOPE

This guide applies primarily to the clinical handling of cytotoxic drugs and related waste in health care settings, including:

- hospital settings
- pharmacies - hospital and community
- analytical pathology and research laboratories
- doctors' surgeries and medical practice rooms
- domiciliary ambulatory clinics
- patients' homes
- nursing homes, hostels and other residential care settings
- veterinary clinics
- ambulance vehicles
- pharmacy and pathology courier services
- waste collection and disposal facilities
- laundry facilities and Non-Emergency Patient Transport (NEPT)
- funeral homes
- mortuaries.

## 1.3 WHAT ARE CYTOTOXIC DRUGS?

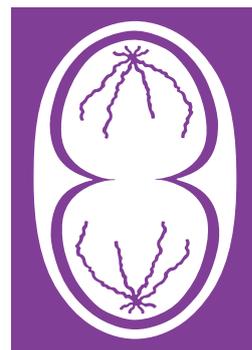
Cytotoxic drugs work by causing the death of certain type of cells and are used to treat conditions such as cancer, rheumatoid arthritis, multiple sclerosis, some ophthalmic conditions. Not all drugs prescribed for cancer are cytotoxic.

Cytotoxic drugs are known to be highly toxic to non-target cells, mainly through their action on cell reproduction. Some have been shown to cause second cancers in cancer patients. Some have also been shown to be mutagenic (causing changes to DNA) or teratogenic (causing birth defects) in various experimental systems.

Cytotoxic drugs are increasingly being used in a variety of health care and community settings, laboratories and veterinary practices for the treatment of cancer and other medical conditions, such as rheumatoid arthritis, multiple sclerosis and autoimmune disorders e.g. psoriasis and systemic lupus erythromatosis.

Generally, cytotoxic materials are identified by a purple symbol that depicts a cell in late telophase.

**Cytotoxic drug**



With the implementation of Globally Harmonised System of Classification and Labelling (GHS), under WHS Regulation, a new GHS hazard pictogram was introduced to communicate health hazards of workplace chemicals. The pictogram below should appear on labels of cytotoxic drugs supplied to workplaces from 1 January 2017.



Workplace exposure to cytotoxic drugs and related waste may occur where control measures fail or are not in place. Exposure may occur through skin contact, skin absorption, inhalation of aerosols and drug particles, ingestion and sharps injuries. Exposure may occur when:

- preparing drugs
- administering drugs
- transporting drugs
- handling patient waste
- transporting and disposing of waste
- cleaning spills
- contact with equipment/surfaces in areas where cytotoxic drugs may be used or administered
- contact with cytotoxic contaminated linen.

Those most likely to be involved in these activities include:

- nurses and medical officers
- pharmacists
- laboratory staff
- cleaning, maintenance and waste disposal staff
- laundry workers
- carers
- veterinary staff
- ambulance officers and drivers.

## 1.4 POTENTIAL ADVERSE HEALTH EFFECTS

Where control measures are inadequate, adverse health effects may result from workplace exposure.

Health effects that have been attributed to those who prepare and administer cytotoxic drugs include:

- alterations to normal blood cell count
- foetal loss and possible malformations in offspring
- fertility changes
- abdominal pain, hair loss, nasal sores and vomiting
- liver damage
- contact dermatitis, a local toxic reaction or an allergic reaction that may result from direct contact with the skin or mucous membranes.

These effects have not been reported where a high standard of risk control is in place.

Current statistics indicate that one-in-two Australian men and one-in-three Australian women have a life-long risk of developing cancer. However, there is little scientific evidence to suggest that working with cytotoxic drugs actually increases the risk of developing cancer. In the absence of such data, a strategy of prudent avoidance is recommended.

Little is known about the long term effects from workplace exposure to cytotoxic drugs. There are no workplace exposure limits set for cytotoxic drugs. Medical opinion suggests that even low-level exposure to cytotoxic drugs should be avoided. Research shows that the implementation of suitable safety precautions and risk control measures minimises the incidence of adverse health effects.

Application of the procedures outlined in this guide should give pregnant women and those that are planning parenthood substantial confidence that risks have been minimised. If involved in the preparation or administration of cytotoxic drugs, those who are pregnant, breast-feeding or planning parenthood should be informed of the reproductive risks and the possible effects on foetal development.

Those who normally prepare or administer cytotoxic drugs may elect not to do so and, in such cases, appropriate and suitable alternative duties must be provided.

## 1.5 RISK CONTROL

Due to the concentrations and quantities used, the most significant risk of workplace exposure to cytotoxic drugs is during their manufacture and preparation. A significant risk also occurs when handling cytotoxic drugs and related wastes. To protect the health of workers, the first priority is to eliminate or minimise the risks to health.

Risk control may be implemented by:

- planning and designing of workplace set-up to minimise exposure to cytotoxic drugs
- using control measures and specialised equipment, such as cytotoxic drug safety cabinets
- establishing written policies and protocols to ensure the safe handling of cytotoxic drugs
- implementing stringent handling procedures for both drugs and waste materials
- training and educating workers
- wearing personal protective equipment
- integrating a health monitoring program that:
  - includes the assessment and counselling of prospective workers before they commence any work involving cytotoxic drugs and related waste
  - ensures worker confidentiality

It is paramount that patients and carers are appropriately educated before treatment so that they understand and appreciate the health and safety requirements for themselves and others.

## 2. LEGISLATIVE REQUIREMENTS

There are a number of work health and safety requirements that are relevant when using and handling cytotoxic drugs and related waste. See Appendix 2.

### 2.1 WORK HEALTH AND SAFETY ACT 2011

In NSW, there is a legal obligation to provide a healthy and safe workplace. Under the *Work Health and Safety Act 2011* (WHS Act), a Person Conducting a Business or Undertaking (PCBU) must ensure, so far as is reasonably practicable, the health and safety of workers and provide and maintain a work environment without the risks to their health and safety. Self-employed persons, workers, and manufacturers, importers and suppliers of plant, equipment and chemicals also have obligations for workplace health and safety under WHS Act.

A person who designs, manufactures or supplies any plant or chemicals for use by people at work must provide, so far as is reasonably practicable, adequate information about the plant or chemicals to the persons to whom it is supplied to ensure its safe use.

The Work Health and Safety Regulation 2011 (WHS Regulation) makes specific provisions for hazardous chemicals including dangerous goods. So far as is reasonably practicable information must be provided to ensure it is safe and without risks to health when properly used, even when a chemical is not classified as a hazardous chemical or dangerous goods (see below). Product information, including adverse effects, is often provided with packaged drugs and provides an additional source of information about their risks and safe use.

### 2.2 WORK HEALTH AND SAFETY REGULATION 2011

Work involving the handling and transport of cytotoxic drugs falls within the scope of the WHS Regulation, specifically Chapter 3, General Risk and Workplace Management and Chapter 7 Hazardous Chemicals.

A limited number of chemicals are exempt from the WHS Regulation, including therapeutic goods that are brought into the workplace for personal use. However, exemption does not apply when the chemicals are used for a work-related activity.

#### 2.2.1 Managing risks

Even when a chemical including a cytotoxic drug, is not classified as a hazardous chemical by the manufacturer or importer, the PCBU must still comply with Chapter 3 of the WHS Regulation with respect to that chemical and the PCBU must ensure that each chemical does not pose a health or safety risk to those at work.

In other words:

- any hazards associated with the cytotoxic drug must be identified
- any risks must be assessed in consultation with workers
- risks must be eliminated or controlled in consultation with workers
- training must be provided
- information and supervision must be provided
- first-aid and emergency procedures must be developed.

Key safe use information is provided on labels, and more detailed workplace, health and safety information is provided in safety data sheets. The safety data sheet and the label are the main information sources for most workplace risk assessments. Other sources of information include, product information sheets, research papers, Medical Information Management System (MIMS) and technical reports.

## 2.2.2 Hazardous chemicals

Chapter 7 of the WHS Regulation aims to protect people against risks to their health and safety when hazardous chemicals are used at work.

For a chemical used at a workplace to be classified as a hazardous chemical, it must:

- meet the criteria set out in the Safe Work Australia publication, *Classification of hazardous chemicals under the WHS Regulations*; or
- be listed in the *Hazardous Chemicals Information System of Safe Work Australia*

Most cytotoxic drugs will be classifiable as hazardous chemicals in accordance with the *Classification of hazardous chemicals under the WHS Regulations hazardous chemicals*. The Safe Work Australia Code of Practice for *Managing the risks of hazardous chemicals* in the workplace provides practical guidance on complying with the WHS Regulation.

Cyclophosphamide is a carcinogenic chemical requiring authorisation under Clause 384 of the WHS Regulation and its use must be authorised by SafeWork NSW in accordance with Clause 383 and authorisation must be obtained to use, handle or store. Schedule 10 of WHS Regulation contains a list of prohibited carcinogens (Table 10.1) and a list of restricted carcinogens (Table 10.2). For information on authorisation see *Guide for applicants for authorisation to use, handle or store prohibited or restricted carcinogens* and the application form *Application for the authorisation to use, handle or store prohibited and restricted carcinogens*.

Where/when cytotoxic drugs are classified as hazardous chemicals, any waste they generate is also likely to be classified as a hazardous chemical and the WHS Regulation applies.

The NSW Environment Protection Authority (NSW EPA) regulates the transport of cytotoxic waste, particularly bulk transports. See Chapter 10 on waste management for further information.

## 2.2.3 Duties of manufacturers, importers and suppliers of hazardous chemicals

In addition to the general duties of the WHS Act, the WHS Regulation requires manufacturers and importers who supply hazardous chemicals to workplaces to provide certain information about their product.

They are required to:

- determine whether a chemical is a hazardous chemical
- prepare and provide specific information in the form of safety data sheets and labels to PCBUs who use their chemicals.

Suppliers (excluding retailers) are required to:

- provide PCBUs with a copy of the manufacturer's or importer's safety data sheets
- ensure that containers of hazardous chemicals are correctly labelled with safety information.

When hospital departments supply cytotoxic drugs to other hospitals, or to other facilities or services, they are considered to be suppliers.

## 2.2.4 Labelling

In a workplace, how a cytotoxic drug is to be used, determines the appropriate label that is required. The NSW Poisons and Therapeutic Goods Regulation 2008 requires a supplier to ensure that the packaging and labelling of a Scheduled medicine or poison complies with the *Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)*. However, the labelling requirements of this standard do not apply to a poison that is:

- packed and sold solely for dispensary, health care facility/services, laboratory or manufacturing purposes
- labelled in accordance with the Safe Work Australia Code of Practice for the Labelling of workplace hazardous chemicals 2015.

Cytotoxic drugs that are packed and sold solely for workplace uses such as dispensary, industrial, laboratory or manufacturing purposes must be labelled in accordance with the requirements of the WHS Regulation.

Under the WHS Regulation, suppliers and PCBUs have specific responsibilities for labelling cytotoxic drugs that are hazardous chemicals. In NSW, the supplier must ensure hazardous chemicals are appropriately labelled (see Clause 338).

A PCBU must ensure that a container that holds a hazardous chemical used at work, including one supplied to or manufactured within the PCBU's workplace or transferred or decanted from its original container at the workplace, is appropriately labelled (see clauses 335 and 342).

The label must:

- clearly identify the hazardous chemical
- provide basic health and safety information about the chemical, including any relevant hazard and precautionary statements.

For specific practical guidance and advice on labelling requirements, refer to the:

- *Code of practice for labelling of workplace hazardous chemicals 2015*, Safe Work Australia
- *Code of practice for managing the risks of hazardous chemicals in the workplace 2012*, Safe Work Australia
- *Factsheet for understanding safety data sheets for hazardous chemicals*, Safe Work Australia
- *Factsheet for understanding hazardous chemical labels*, Safe Work Australia
- *Standard for the uniform scheduling of medicines and poisons (SUSMP) 2011*.

Table 1: Workplace labelling for hazardous chemicals

Label items	All containers	Containers too small to attach full label	Containers having chemicals decanted or transferred	Containers holding hazardous waste chemicals
Product Identifier: IUPAC name or CAS name or technical name	Yes	Yes	Yes	Yes (specify the nature of the waste as closely as possible)
United Nations number, class and subsidiary risk (where required by ADG Code and NSW EPA)	No	No	No	Yes (where required by ADG Code and NSW EPA)
Ingredients and formulation	Yes	No	No	No
Identity and proportion of each chemical ingredient	Yes	No	No	No
Name and Australian address and business telephone number of the manufacturer or importer	Yes	Yes	No	Yes
Hazard pictogram(s)	Yes	Yes or hazard statement	Yes or hazard statement	Yes
Hazard statement(s)	Yes	Yes or hazard pictogram	Yes or hazard pictogram	Yes
Signal word	Yes	No	No	No
Precautionary statement(s)	Yes	No	No	No
First aid and emergency procedure details	Yes when not included in the hazard statement or precautionary statement	No	No	No
Any other information that is reasonably practicable to include	Yes	Yes	No	No
Expiry date (if applicable)	Yes	No	No	No

## 2.2.5 Safety Data Sheets

The Safety Data Sheet (SDS) is a document that describes the chemical and physical properties of the hazardous chemicals and provides advice on the safe handling and use of the hazardous chemicals. The safety data sheet is a recognised source of information in the workplace and underpins the overall risk management program to control exposure to hazardous and dangerous chemicals.

Legal obligations in relation to safety data sheets are specified in the WHS Regulation. Manufacturers are required to classify chemicals and prepare safety data sheets. Importers must ensure that the manufacturer's responsibilities are met.

Suppliers are required to provide safety data sheets for those chemicals classified as hazardous chemicals if they supply to workplaces. If a supplier fails to provide an adequate safety data sheet, other sources of information should be used to obtain information and to assist in the risk management process.

PCBUs must ensure that safety data sheets and other sources of information are accessible to workers who may be exposed to the chemicals.

For more specific guidance and advice on safety data sheets, refer to the:

- *Code of practice for the preparation of safety data sheets for hazardous chemicals 2011*, Safe Work Australia.
- *Code of practice for managing the risks of hazardous chemicals in the workplace 2012*, Safe Work Australia.

## 2.2.6 Duty of supplier supplying carcinogenic chemicals

A person who supplies a restricted carcinogenic chemical (Cyclophosphamide) for use at work must keep a record containing:

- the name of the person to whom the carcinogenic chemical has been supplied
- the name and quantity of the carcinogenic chemical supplied.

The record must be retained for at least five years.

## 2.2.7 Summary of duties of PCBUs who use hazardous chemicals

PCBUs must use information provided by manufacturers, importers or suppliers to identify the hazardous chemicals used in the workplace, assess the risk to health, and control any risk to health associated with their use, in consultation with workers.

In summary, the WHS Regulation requires PCBUs to:

- obtain a copy of the manufacturer's or importer's safety data sheet and ensure that it is accessible to workers
- ensure all containers of hazardous chemicals are labelled according to legislation
- set-up a hazardous chemical register (see Appendix 5)
- assess workers' risk to health from exposure to hazardous chemicals
- eliminate or control the risk associated with the use of hazardous chemicals
- provide workers with information, instruction and training
- consult with workers on the above.

SafeWork NSW is the competent authority on dangerous goods in NSW. However, the NSW Environment Protection Authority (EPA) is responsible for regulating the transport of dangerous goods in NSW.

Cytotoxic drugs that are classified as dangerous goods and are being transported must comply with the *Australian Code for the Transport of Dangerous Goods by Road and Rail* (the ADG Code) and NSW EPA's requirements.

## 2.2.8 Plant and equipment

Chapter 5 Plant and structures of the WHS Regulation outlines specific obligations with respect to plant, as well as the general obligation to ensure workplace health and safety. Plant includes any machinery, equipment or appliance. With respect to cytotoxic drugs and related waste, plant may include cytotoxic drug safety cabinets, trolleys for carrying cytotoxic drugs administration equipment, drug delivery services, washing machines and laundry equipment, and needles and syringes.

PCBUs, self-employed persons, designers, manufacturers, suppliers and installers of plant also have obligations under Chapter 5 Plant and structures. Obligations include:

- installing, erecting and commissioning plant
- using plant
- maintaining and repairing plant
- keeping records
- providing information.

## 2.3 OTHER NSW LEGISLATION AND STANDARDS

Other legislation and standards covering the handling and storage of cytotoxic drugs and related waste that need to be considered when implementing safe systems of work include:

- drugs and poisons legislation administered by NSW Health:
  - *Poisons and Therapeutic Goods Act 1966 No 31.*
  - Poisons and Therapeutic Goods Regulation 2008.
  - *Standard for the Uniform Scheduling of Medicines and Poisons*, Therapeutic Goods Administration.
- waste management legislation administered by NSW Environment Protection Authority:
  - *Protection of the Environment Operations Act 1997.*
  - Protection of the Environment Operations (Waste) Regulation 2014.
  - *Environmental guidelines – assessment, classification and management of liquid*

*and non-liquid wastes*, NSW Environment Protection Authority.

- Waste classification guidelines, NSW Environment Protection Authority.
- transport of dangerous goods legislation administered by NSW Environment Protection Authority *Dangerous Goods (Road and Rail Transport) Act 2008.*
- Dangerous Goods (Road and Rail Transport) Regulation 2014.
- Road and Rail (Dangerous Goods) (Road) Regulation 1998.
- *Australian code for the transport of dangerous goods by road and rail (ADG Code) 7.4 edition 2016*, National Transport Commission.
- The Professional Standards of The Society of Hospital Pharmacist of Australia (SHPA) *Standards of practice for the safe handling of cytotoxic drugs in pharmacy departments, 2005 and Standards of practice for the transportation of cytotoxic drugs from pharmacy departments, 2007* endorsed by the SHPA.
- policy directives issued by the NSW Health such as the *Waste management guidelines for healthcare facilities.*

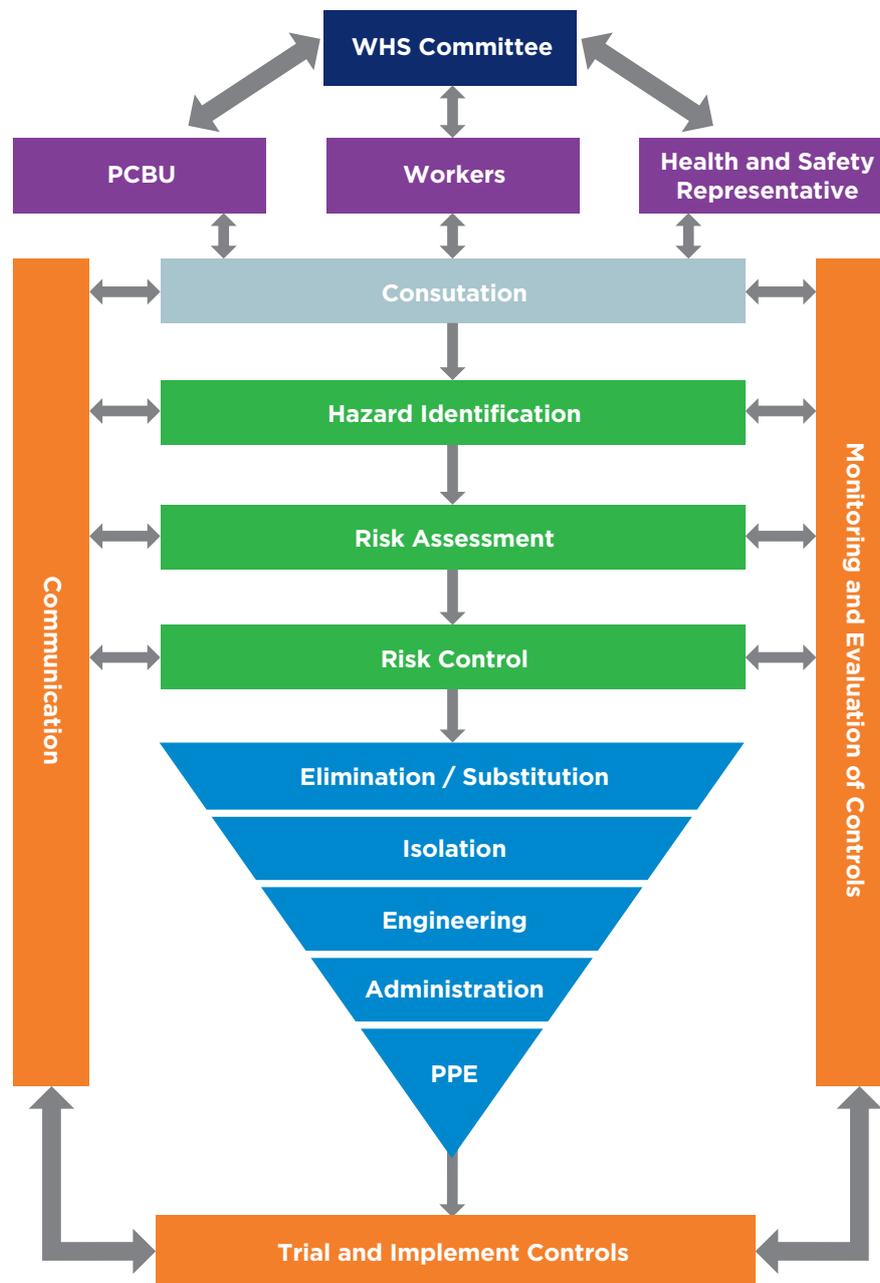
Various agencies and institutional policies and policy directives assist in interpreting legislation. For further information, see Appendix 2.

## 2.4 INTEGRATING HEALTH AND SAFETY INTO THE WORKPLACE

Effective management of health and safety is essential to protecting the health of workers. A PCBU should ensure that all managers, contractors, supervisors and workers are aware of their workplace health and safety responsibilities. This should be done by collaborating, documenting responsibilities and ensuring that there are processes in place to hold persons accountable for work health and safety compliance with safe work practices and by providing training and supervision.

Systems and processes for the management of health and safety are integral to the day-to-day running of any business. Work health and safety should be managed systematically (see figure 1).

Figure 1: The risk management approach



Aspects that need to be considered in a risk management approach include consultation, hazard identification, risk assessment, risk control, and the implementation and review of controls.

## 2.5 THE RISK MANAGEMENT APPROACH

The aim of risk management approach is to eliminate or minimise the risk of illness or injury associated with work. The process is outlined in Chapter 3 of the WHS Regulation.

In general, risk management is a process by which a duty holder identifies all hazards and risks at the workplace and eliminates these risks to health and safety – so far as reasonably practicable. If it is not reasonably practicable to eliminate all risks, the duty holder must implement risk control measures and minimise the risks. The key steps in the risk management process are:

- hazard identification
- risk assessment
- risk control
- evaluation of control measures
- continuous improvement.

Effective management of health and safety also involves:

- consultation
- training
- documentation of activities
- regular review of the work, health and safety management system.

An overview for managing the risks associated with cytotoxic drugs and body waste is provided in Chapter 3 and Appendix 6, Risk assessment template.

## 2.6 CONSULTATION

The WHS Act places a duty to consult on each PCBU. This enables workers to contribute to making decisions that affect their health, safety and welfare at work. Adopting a planned, systematic approach to health and safety and applying risk management principles will help identify when to consult.

The WHS Act also requires PCBUs to consult with workers about consultative arrangements. These arrangements include:

- Health and Safety Committee comprised of PCBU and Worker Representatives
- Health and Safety Representatives (HSR) elected by workers
- other agreed arrangements
- a combination of the above.

Meaningful and effective consultation requires drawing on the knowledge, experience and ideas of workers and encouraging their participation and input in order to improve the systems the PCBU has in place for managing workplace health and safety.

Consultative arrangements should include a mechanism to ensure the views of workers from non-English speaking background are canvassed and considered. Enough time must be allowed for health and safety representative(s) to confer with workers and relay their ideas back to PCBUs.

PCBUs are required to consult with the relevant health and safety representatives when assessing and controlling risks arising from the handling of cytotoxic drugs. Consultation should take place as early as possible when planning to introduce new cytotoxic drugs into the workplace. A range of mechanisms can be used to facilitate consultation, including direct discussion, toolbox meetings, quality circles, health and safety committee meetings, quality reports, hazard inspections, special working parties or combination of these.

Consultation must occur:

- when identifying cytotoxic drugs and associated hazards
- during the risk assessment process
- when determining which control strategies should be applied to eliminate or minimise risks associated with the handling of cytotoxic drugs and cytotoxic contaminated body fluids/wastes
- when reviewing the effectiveness of control measures
- prior to changing premises, work environment, plant, systems of work or chemicals used for work, including safety data sheets.

Accurate and relevant safety information made available to workers and their health and safety representative(s) should include:

- work processes and procedures
- risks associated with exposure to cytotoxic drugs
- work health and safety policies and procedures, including risk assessments and control measures
- changes to premises, work environment, plant, systems of work or chemicals used for work, including safety data sheets (if available)
- records of incidents, illnesses or injuries (in a way that protects the confidentiality of personal information).

Volunteers also need to be considered as workers and consulted. The PCBU owe volunteers a duty of care to ensure they are not exposed to risks to their health and safety under the WHS Act and consultation is most valuable in assisting the PCBU to meet this duty of care.

Refer to the *Code of practice for Work health and safety consultation, co-operation and co-ordination 2011*, Safe Work Australia for detailed information, advice and legal obligations on consultation.

# 3. MANAGING RISKS TO HEALTH AND SAFETY

This Chapter outlines the risk management process that PCBUs should follow for identifying the hazard, assessing the risk, and controlling the risk. It leads PCBUs through the risk management process in a logical progression. When designing a risk management strategy, workers should be consulted at every stage of the risk management process, as per agreed consultation arrangements that reflect the WHS Act.

In managing the risks, if it is not reasonably practicable to eliminate the risk, then risks should be minimised so far as is reasonably practicable by substituting (wholly or partly) with the hazard that gives lesser risk or isolating the hazard from exposure to workers, providing specific engineering controls, using administrative controls to reduce exposure to workers and providing and ensuring the use of appropriate PPE.

Specific requirements under the WHS Regulation for the management of risk should be complied with when implementing the requirements. These include:

- a requirement not to exceed an exposure standard
- a duty to implement a specific control measure.

See Appendix 6 for an example of the type of content required in a written risk assessment for cytotoxic drugs.

## 3.1 IDENTIFY HAZARDS OF CYTOTOXIC DRUGS USED AND STORED AT THE WORKPLACE

Identify areas where cytotoxic drugs are used	Ways of achieving this include: <ul style="list-style-type: none"><li>• current building plan of health care facility</li><li>• hazardous chemicals register</li><li>• hazardous chemicals (cytotoxic drugs) register (Appendix 5)</li><li>• review workplace activity</li><li>• risk assessment reports</li></ul>
Identify types of cytotoxic drugs	Ways of achieving this include: <ul style="list-style-type: none"><li>• taking note of labelling warnings</li><li>• obtain copies of SDSs (see below)</li><li>• identify where risk assessments will be required and complete/review them</li><li>• noting additional information from sources/referencing – eg MIMS</li></ul>
Obtain information from manufacturers, importers or suppliers	Ways of achieving this include: <ul style="list-style-type: none"><li>• contacting the supplier</li><li>• obtaining a safety data sheet</li><li>• if a safety data sheet is not available, obtaining safety information about the relevant cytotoxic drug from the manufacturer or importer</li></ul>

Identify adverse effects	<p>Ways of achieving this include:</p> <ul style="list-style-type: none"> <li>• a safety data sheet</li> <li>• drug inserts on adverse health effects</li> <li>• medical information and data support from MIMS - <a href="http://www.mims.com.au">www.mims.com.au</a></li> <li>• scientific and medical literature</li> </ul>
Set up and maintain a hazardous chemicals register	<p>Ways of achieving this include:</p> <ul style="list-style-type: none"> <li>• having cytotoxic drugs in your hazardous chemicals register</li> <li>• list locations where the cytotoxic drugs are stored and the maximum amounts stored</li> <li>• checking the safety data sheet and label to identify cytotoxic drugs that are classified as hazardous chemicals - the safety data sheet will state whether the product is classified as hazardous</li> <li>• listing the product names of all cytotoxic drugs used at the workplace</li> <li>• refer to Appendix 5</li> </ul>
Consult with workers	<p>Ways of achieving this include:</p> <ul style="list-style-type: none"> <li>• work health and safety committees</li> <li>• work health and safety representatives</li> <li>• other agreed arrangements</li> <li>• direct consultation with workers</li> <li>• refer to section 2.6</li> </ul>

## 3.2 ASSESS THE RISKS

The risk assessment determines whether there is a risk to workers' health from using cytotoxic drugs. The risk assessment may be done for a work process and may cover more than one cytotoxic drug or it may look at an individual

drug if the mode of preparation or administration of drug differs. The following step-by-step process may be used to assist with the risk assessment process.

### Step 1: Decide who will carry out the risk assessment

Select a competent person or team comprising workers, health and safety representatives, supervisors/managers and work health and safety personnel

What to look for:

- appropriate skills, knowledge and experience to evaluate the risks
- a sound and practical understanding of work being undertaken at the workplace
- an understanding of health and safety legislation
- the ability to deal with the complexity of the assessment process and/or the work being assessed

## Step 2: Obtain and review information about cytotoxic drugs used

Determine the routes of exposure	This may include: <ul style="list-style-type: none"><li>• inhalation of aerosols, particulates and droplets</li><li>• skin or eye contact through splash of liquid</li><li>• ingestion through poor personal hygiene or splash of liquid</li><li>• injection resulting from injuries from sharps</li></ul>
Determine the form of the drug	This may include: <ul style="list-style-type: none"><li>• liquid</li><li>• powder</li><li>• tablet or capsule</li><li>• creams, ointments and lotions for topical application</li></ul>
Ascertain the potential harmful effects	This may include: <ul style="list-style-type: none"><li>• carcinogenic, mutagenic or teratogenic potential</li><li>• alterations to normal blood cell count</li><li>• foetal loss and possible malformations in offspring</li><li>• fertility changes</li><li>• abdominal pain, hair loss, nasal sores, vomiting</li><li>• liver damage</li><li>• contact dermatitis, local toxic or irritation to the skin</li></ul>
Consult the safety data sheet or other available information for each drug for details of the properties and hazard associated with the chemical	This may include: <ul style="list-style-type: none"><li>• health hazard information</li><li>• precautions for use</li><li>• safe handling information</li></ul>

## Step 4: Evaluate the risks

Determine whether or not an injury or illness is likely to occur as a result of any identified work activity or exposure to cytotoxic drugs and related waste. There are three possible outcomes:

**No likelihood of injury or illness.** It may be reasonable to make such a conclusion when:  
Risk assessment indicates a high degree of confidence that work practices are sound and that workers are protected.

- risks have been eliminated/minimised as far as is practicable
- work methods employ best practice controls
- drug packaging features in-built breakage prevention systems
- cytotoxic drugs are handled in an enclosed area such as a proper operational cleanroom with a laminar flow cytotoxic drug safety cabinet
- needleless drug administration systems or retractable needles are used

**OR**

**Likelihood of injury or illness is uncertain.** It may be reasonable to make such a conclusion where PCBUs are not sure if there is a risk to health. It may require PCBUs to do more evaluation of the workplace, such as:  
Risk assessment indicates whether work practices are adequate to protect workers.

- eliminate or minimise exposure as far as is practicable
- conducting wipe tests and atmospheric monitoring if valid and interpretable tests are available to determine whether there is any contamination – these tests must be individualised to each workplace according to the drug used

**OR**

#### Step 4: Evaluate the risks

Determine whether or not an injury or illness is likely to occur as a result of any identified work activity or exposure to cytotoxic drugs and related waste. There are three possible outcomes:

**Likelihood of injury or illness.**  
Risk assessment indicates that work practices need improvement.

It may be reasonable to make such a conclusion when:

- work methods do not employ effective control strategies
- drug preparation is not conducted within a proper operational cleanroom with a laminar flow cytotoxic drug safety cabinet
- drug administration does not employ needleless or other safety systems
- housekeeping is poor
- some activities involve skin contact
- appropriate personal protective equipment is not worn
- the workforce has not received appropriate training
- control measures are not maintained or serviced
- no spill management system exists
- there is poor compliance with the safety data sheet or other guidance material
- staff are not reporting incidents or symptoms of exposure

### 3.3 RECORD, REVIEW AND REVISE THE RISK ASSESSMENT

#### Record the risk assessment.

Always record the work done during the risk assessment and the outcomes of the assessment. This provides a measure of effectiveness of the risk controls and helps to identify areas of improvement.

What to include:

- name of the assessor(s)
- nature and level of consultation
- names of those consulted
- date of the assessment
- the workplace/unit
- the chemical for which the safety data sheet or equivalent information has been reviewed
- the controls in place to prevent a risk to health
- a summary of the process
- hazard information on the chemicals
- the degree of exposure or nature of risk identified
- why/how decisions about the risk were made
- any information that assisted in reaching a conclusion
- conclusions and recommendations
- signatures of people involved in the risk assessment

#### Review and revise the risk assessment.

The risk assessment should be reviewed and revised as necessary and at least every five years.

Ways of achieving this include:

- scheduling regular reviews once in every five years to ensure that the assessment is valid and still applies
- establishing the circumstances that would trigger a review or revision such as:
  - an incident or near miss resulting from the failure of the control measures used
  - symptoms reported which may be related to the substance used
  - a change in the product used (including its form)
  - introduction of a new work process/plant or changes to an existing process/plant
  - increase in the hours worked or frequency and duration of exposure
  - increase in the quantities used
  - availability of new information about the health hazards of the chemicals
- ensuring that management, supervisors, health and safety representatives and purchasing officers feed-back the outcome of the review into the assessment process
- recording the date of the review or revision of the assessment, including the outcome, any action required to be taken, by whom and by when

### 3.4 CONTROL THE RISK

The WHS Regulation sets out a hierarchy of control (or ranking of controls) to manage workplace risks. The PCBU's primary duty is to **eliminate** any risk to health arising from the use of a hazardous chemical. Where elimination of risk is not practicable, PCBUs must minimise the risk using other control measures.

### 3.5 HIERARCHY OF CONTROL

An effective risk control uses a range of strategies from different levels of the hierarchy of control. The hierarchy takes the following order – elimination of the risk, substitution, isolation, engineering controls, administrative controls and personal protective equipment.

### 3.5.1 Eliminate the risk

PCBUs must first consider whether the risk can be eliminated – this is the most effective way of protecting the health of workers.

<b>Eliminate the risk</b>	Ways of achieving this include: <ul style="list-style-type: none"><li>• purchasing cytotoxic drugs in ready-to-use concentrations to eliminate pharmacy preparation</li><li>• establishing supply arrangements with a company or health care institution that specialises in the preparation of cytotoxic drugs</li></ul>
<b>Substitution</b> – using a less hazardous chemical or a chemical in a less hazardous form	Ways of achieving this include: <ul style="list-style-type: none"><li>• purchasing single-dose preparations</li><li>• purchasing cytotoxic drugs in a liquid form, rather than a powder form</li><li>• using a less hazardous cytotoxic drug to achieve the desired therapeutic benefit</li><li>• incorporating handling techniques that minimise aerosol generation</li><li>• purchasing drugs in vials not ampoules</li><li>• purchase drugs in plastic vials, or vials reinforced with plastic casings</li></ul>
<b>Isolation</b> – separating people from the substance by distance or barriers to prevent or minimise exposure	Ways of achieving this include: <ul style="list-style-type: none"><li>• adopting closed-system operations</li><li>• conducting drug preparation work in a properly designed and secure cleanroom</li><li>• placing dispensed drugs in an impermeable packaging for delivery to administration areas</li><li>• designating a cytotoxic drug administration area, which permits entry only to authorised people</li></ul>
<b>Engineering controls</b> – plant or processes that minimise the generation of chemicals, suppress or contain chemicals, or limit the area of contamination in the event of spills and leaks	Ways of achieving this include: <ul style="list-style-type: none"><li>• installing ventilation and air-filtering systems, such as laminar flow cytotoxic drug safety cabinets</li><li>• using wide-bore needles to transfer liquids from containers or vials in the pharmacy</li><li>• using needleless injection sets for drug administration</li><li>• incorporating secure storage facilities</li><li>• designing workplace layout</li><li>• installing adequate lighting</li></ul>

**Administrative controls** – safer ways of doing a job, which helps to minimise worker exposure to cytotoxic drugs and related waste. The effective use of administrative controls relies on the full cooperation of workers, and therefore consultation is important during their development. Adequate supervision and training is paramount if work practices are to play an effective part in reducing worker exposure to cytotoxic drugs and related waste.

Ways of achieving this include:

- allocating responsibilities for health and safety
- minimising the number of workers who work with cytotoxic drugs
- cleaning work areas regularly
- keeping containers of cytotoxic drugs secure
- incorporating handling techniques that minimise aerosol generation
- prohibiting eating, drinking and smoking in work areas
- developing and implementing standard operating procedures (safe working procedures) for all work activities
- providing appropriate information, education and training to workers and carers
- using cytotoxic signs and labels to clearly identify all cytotoxic drugs
- storing cytotoxic drugs in specific, clearly identified areas
- storing cytotoxic waste in specific, clearly identified areas, separate from other waste
- developing emergency procedures to deal with spills

**Personal protective equipment** – something worn that provides a barrier between the person and the hazard.

This may include

- impermeable coveralls and gowns
- head covering
- closed footwear
- overshoes
- gloves of appropriate material and thickness
- safety glasses
- respiratory protective devices – respiratory filters must be inspected and maintained regularly (see Appendix 9)

### 3.5.2 Personal protective equipment

Ensure that personal protective equipment is:

- properly selected for the individual and task
- readily available
- clean and functional
- correctly used when needed
- maintained by appropriately trained staff in keeping with relevant standards.

PCBUs must ensure that all workers know how to fit and use personal protective equipment.

Obtain information from the supplier of the cytotoxic drugs, suppliers of the personal protective equipment and published technical standards.

For further information, see Appendix 2 and Appendix 9.

### 3.6 MAKE THE WORKPLACE SAFER

PCBUs need to ensure that all control measures are properly used and maintained. PCBUs must not rely exclusively or primarily on administrative controls or personal protective equipment to control the risk. To be effective, these measures depend heavily on human behaviour. A workplace needs to be made safer rather than placing the onus on workers to work safely in a hazardous environment. A number of risk controls should be used in combination to effectively eliminate or minimise the risk.

### 3.7 DEVELOP A RISK CONTROL PLAN

One way of keeping track of proposed and implemented controls is to prepare a risk control plan.

#### Risk control plan

A risk control plan sets out the actions required to implement controls over time. It also provides a useful tool to effectively manage this process. The WHS Regulation requires the risk control plan to be developed in consultation with workers.

This may include:

- a history of health and safety activities for work involving cytotoxic drugs, including any current control measures and their effectiveness
- the immediate, interim and long-term control measures
- the priorities for putting controls in place
- the date controls are to be implemented
- the names of those responsible for overseeing the implementation
- the date of completion and 'sign off' by a management-nominated person
- the relevant policies and procedures for work involving cytotoxic drugs
- training
- consultation
- documentation of activities
- regular review of management systems
- provisions for those at special risk – eg pregnant women, disabled workers

### 3.8 MAINTAIN RISK CONTROLS

Control measures should be regularly maintained, reviewed and where necessary improved, extended or replaced.

#### Maintain control measures

Maintain risk control measures to ensure that they perform as originally intended and continue to provide adequate risk control.

This may include:

- auditing compliance with safe work practices
- inspections
- equipment testing
- preventive maintenance
- checking and replacing of cabinet filters
- checking and replacing PPE
- review of worker competencies
- review health monitoring results
- periodic environmental monitoring
- incident investigation

### 3.9 REVIEW CONTROL MEASURES

Controls should also be reviewed if indicated by an evaluation of data on risk assessments, near misses, incidents, injuries or a report of work-related ill health.

<b>Review control measures</b> This can be done in conjunction with a review of the risk assessment to ensure currency, relevance and effectiveness of risk control measures. Criteria for triggering a review of risk control measures are the same as for review of risk assessments.	This may include: <ul style="list-style-type: none"><li>• comparison with standards and guidelines, especially if these have been updated or reviewed</li><li>• compare with advances in technology and knowledge in the field</li><li>• consultation with workers</li><li>• conduct health and/or environmental monitoring</li><li>• review of incidents</li></ul>
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## 4. PERSONNEL MANAGEMENT

### 4.1 GENERAL

An important aspect of the risk management program is to protect the health of workers and manage the systems of work. Personnel management involves worker health monitoring and counselling, reporting of work health and safety matters and record keeping.

PCBUs have a duty to provide supervision to workers who handle cytotoxic drugs and related waste. In the case of unplanned exposure to cytotoxic drugs (for example spills or sharps injuries) provision of health monitoring must be considered.

### 4.2 WHAT IS HEALTH MONITORING?

The WHS Regulation requires PCBUs to provide health monitoring of workers when a significant risk to health is identified when using hazardous chemicals in the workplace. Health monitoring is the monitoring and counselling of individuals to identify changes to health status due to workplace exposure to a chemical. Health monitoring may include biological monitoring, which is the measurement and evaluation of a chemical, or its metabolites, in the body tissue, fluids or exhaled air of an exposed person.

PCBUs have a responsibility to ensure that they remain aware of and apply current developments for monitoring the health of workers involved in the handling of cytotoxic drugs.

### 4.3 BIOLOGICAL MONITORING

Many methods have been used to investigate potential health effects of exposure to cytotoxic drugs. These methods have given results that are often inconclusive and difficult to interpret. The ideal test should meet several requirements – it should be sensitive, specific, quantitative, rapid, reproducible and inexpensive. Importantly, the procedures for taking a sample should be non-invasive and should not cause unnecessary duress or anxiety to the individual.

### 4.4 WHAT TYPE OF HEALTH MONITORING SHOULD BE PROVIDED?

PCBUs should implement a health monitoring program for cytotoxic drugs when there is significant risk identified for workers health. Clause 368 of the WHS Regulation requires PCBUs to provide health monitoring for the workers carrying out ongoing work at a workplace using, handling, generating or storing hazardous chemicals, and there is a significant risk to the worker's health because of exposure to a hazardous chemical and valid techniques are available to detect the effect on the worker's health, or a valid way of determining biological exposure to the hazardous chemical is available. In practical terms, all cytotoxic drugs are hazardous chemicals.

In NSW, cyclophosphamide is a cytotoxic drug that is also a restricted carcinogenic chemical under the WHS Regulation. The type of health monitoring to be undertaken for cyclophosphamide is not specified in the Regulation but Safe Work Australia provides guidance documents for registered medical practitioners undertaking or supervising the health monitoring (for workers exposed to hazardous chemicals, lead and asbestos).

The need for biological monitoring to detect exposure to a scheduled carcinogenic chemical, or tests to detect health effects caused by exposure should be carefully considered when the risk assessment is carried out. In particular, information must be obtained about health monitoring that can detect the early signs of hazardous exposure or disease.

Health monitoring must continue throughout the period of use of a scheduled carcinogenic chemical.

The health monitoring program must meet the needs of workers by providing security of personal information, care, freedom of selecting a medical practitioner of the worker's choice, elimination of sex bias, and privacy.

It should be based on the following factors:

Factors in implementing a health monitoring program	Considerations
<p>1. A medical practitioner is appointed to oversee the program. Appointment means that the PCBU has a formal arrangement with a medical practitioner. All workers must be made aware of this arrangement.</p>	<ul style="list-style-type: none"> <li>• the medical practitioner may be an occupational physician, oncologist, haematologist or local general practitioner</li> <li>• the medical practitioner should have the necessary knowledge and skills to provide health monitoring</li> <li>• information for performing health monitoring are provided by the SWA <i>Health monitoring for exposure to hazardous chemicals – Guide for medical practitioners</i> (2013)</li> </ul>
<p>2. Guidance is provided to the appointed medical practitioner.</p>	<ul style="list-style-type: none"> <li>• guidance is outlined in Appendix 7</li> <li>• general guidance is provided in the SWA <i>Health monitoring for exposure to hazardous chemicals – Guide for medical practitioners</i> (2013)</li> </ul>
<p>3. The health monitoring program is an integrated part of the risk management program.</p>	<ul style="list-style-type: none"> <li>• Work health and safety representatives must be involved in the development and management of the program</li> <li>• the PCBU must ensure that the appointed medical practitioner is provided with access to the workplace and information required</li> <li>• the PCBU should involve the appointed medical practitioner in managing risk strategies of the workplace, such as health and safety committee meetings (a guidance for PCBU is provided by the SWA <i>Health Monitoring for Exposure to Hazardous Chemicals – Guide for persons conducting a business or undertaking</i> (2013))</li> <li>• history of incidents and health and safety performance</li> </ul>
<p>4. Prospective workers are counselled and provided information about the risks of working with cytotoxic drugs.</p>	<p>The counselling should include:</p> <ul style="list-style-type: none"> <li>• health and safety information from SDSs</li> <li>• the nature of work to be undertaken</li> <li>• potential risks to health</li> <li>• reproductive risks</li> <li>• how exposure may occur</li> <li>• availability of tests for biological monitoring</li> <li>• the control measures in place</li> </ul>
<p>5. Baseline health monitoring is conducted by the appointed medical practitioner before a worker commences work with cytotoxic drugs.</p>	<p>Baseline health monitoring, as outlined in Appendix 7, provides:</p> <ul style="list-style-type: none"> <li>• collection of demographic data</li> <li>• occupational history</li> <li>• medical history</li> <li>• physical examination</li> <li>• investigation, if appropriate</li> <li>• health advice and counselling</li> <li>• a report to the PCBU and prospective worker</li> </ul>

Factors in implementing a health monitoring program	Considerations
6. Health monitoring is conducted during the period that the worker works with cytotoxic drugs.	<p>Health monitoring conducted during the period the worker works with cytotoxic drugs, as outlined in Appendix 7, provides:</p> <ul style="list-style-type: none"> <li>• data for inclusion in health records, such as health advice and counselling</li> <li>• medical review after a spill or sharps injury</li> <li>• review of control measures – eg needleless injection sets should be in place to eliminate the potential for sharps injuries</li> </ul>
7. Medical advice and counselling is available to workers at any time during their employment.	<p>Workers may arrange a consultation with the appointed medical practitioner at any time.  Guidance is provided to workers in the SWA <i>Health Monitoring for Exposure to Hazardous Chemicals – Guide for persons conducting a business or undertaking</i> (2013)</p>
8. Workers are provided with freedom of choice and have the right not to work with cytotoxic drugs.	<p>Appropriate and suitable alternative duties should be provided to workers who choose not to, or are unable to, work with cytotoxic drugs.</p>
9. The results of health monitoring are provided to the worker to whom the results relate.	<p>The results should be available as soon as reasonably possible.</p>
10. Workers' medical records are confidential.	<p>Where any form of health monitoring is undertaken, confidentiality of a worker's medical records must be ensured. Access to a worker's medical records can be obtained only with the written consent of the worker.</p>
11. Health monitoring is offered on termination of employment where cytotoxic drugs were used.	<p>Health monitoring on termination of employment, as outlined in Appendix 7, provides:</p> <ul style="list-style-type: none"> <li>• data collection</li> <li>• final medical examination</li> </ul> <p>On the termination of the worker's employment each worker must receive, a written statement that includes the following:</p> <ol style="list-style-type: none"> <li>a. the name of the restricted or prohibited carcinogenic chemicals involved</li> <li>b. the period of exposure or potential exposure</li> <li>c. details of how and where records of the exposure or potential exposure can be obtained</li> <li>d. a recommendation on the advisability of having periodic health assessments and details of the types of health tests that are relevant in the circumstances</li> </ol>

Factors in implementing a health monitoring program	Considerations
12. Biological monitoring issues.	<p>When choosing tests the following requirements should be considered:</p> <ul style="list-style-type: none"> <li>• specificity</li> <li>• sensitivity</li> <li>• availability</li> <li>• rapidity</li> <li>• reproducibility</li> <li>• cost</li> </ul> <p>Consult with workers on appropriate biological monitoring, if available, to be carried out.</p> <p>Obtain informed consent from workers to do tests.</p>
13. Consultation.	<p>PCBUs need to consult with workers including those of non-English speaking backgrounds about consultative arrangements.</p> <p>Consultation should occur:</p> <ul style="list-style-type: none"> <li>• when identifying cytotoxic drugs and associated hazards</li> <li>• during the risk assessment process</li> <li>• when determining which control strategies should be applied to eliminate or minimise risks associated with the handling of cytotoxic drugs</li> <li>• when reviewing the effectiveness of control measures</li> <li>• prior to changing premises, work environment, plant, systems of work or substances used for work, including safety data sheets</li> <li>• where appropriate, when workers circumstances changes – eg pregnant women and immuno-compromised individuals</li> </ul> <p>Accurate and relevant safety information must be made available to workers and others.</p>

Risk control is the key to protecting the health of workers that takes into account the following:

- focus on elimination, or minimisation of risks to health
- strive for best practice controls
- ensure that control measures are maintained and working as designed
- remember that health monitoring is no substitute for a safe workplace.

## 4.5 PLANNING PARENTHOOD, PREGNANCY AND LACTATION

Workers who are pregnant, breast-feeding or planning parenthood and are involved in the preparation or administration of cytotoxic drugs and handling of cytotoxic contaminated wastes should be informed of the reproductive risks and possible effects on foetal development.

Personnel required to perform these duties may elect not to do these duties. In such cases, appropriate and suitable alternative duties must be provided.

## 4.6 EMERGENCY PROCEDURES

Planning for emergencies is an essential part of risk management. Systems should therefore be in place to manage sharps injuries, spills and personal contamination. Any incident should be reported so that the cause can be investigated and determined, and follow-up action taken if required.

## 4.7 REPORTING AND KEEPING RECORDS

The PCBU must keep the following records:

- the name of any worker exposed to a restricted or prohibited carcinogens (cyclophosphamide), including:
  - their date of birth
  - their address while employed by the PCBU
  - this record must be kept for at least 30 years from the date of the last record
- a register of all hazardous chemicals (including cytotoxic drugs) that are used in the workplace, along with the current safety data sheet for each chemical listed
- a copy of each notification to SafeWork NSW of an intention to carry out work that involves the use of a carcinogenic chemical (this record must be kept for at least 30 years after the date on which the notification is given)
- risk assessment reports
- health monitoring records (this record must be kept for at least 30 years)
- training records, including any training on hazardous chemicals
- individual worker records – medical records are to be kept confidential
- details about drug preparation equipment, such as cytotoxic drug safety cabinets
- details about spills, sharps injuries and contamination.

Currently, cyclophosphamide is the only cytotoxic drug that is listed in Schedule 10 of the WHS Regulation as a restricted carcinogen.

On the termination of a worker's employment, the PCBU must provide a worker who has been, or is likely to have been, exposed to a restricted or prohibited carcinogenic chemical with a written statement that includes the following:

- the name of the prohibited or restricted carcinogen to which the worker may have been exposed during the engagement
- the period of exposure or potential exposure
- details of how and where records of the exposure or potential exposure can be obtained
- a recommendation as to the advisability of having periodic health assessments and details of the types of health tests that are relevant in the circumstances.

The worker should keep copies of their records.

## 5. INFORMATION, INSTRUCTION AND TRAINING

PCBUs have a duty to provide information, instruction and training to workers who handle cytotoxic drugs and related waste.

Training should be undertaken:

- at induction
- prior to commencement of duties where cytotoxic drugs and or related waste are involved
- when new equipment or chemical substance is introduced or procedures change
- on an ongoing basis with two yearly review.

PCBUs should ensure that only workers who have received appropriate training, and have attained the required level of proficiency, handle cytotoxic drugs and related waste.

### 5.1 WHO SHOULD BE TRAINED?

The risk assessment results should be used to identify workers and carers who require specific training.

Two levels of training are recommended, depending on the level of contact to cytotoxic drugs and related waste. These levels and workers/carers potentially affected include:

Level 1 training should be given to workers, who regularly handle cytotoxic drugs and are at high risk, including:

- pharmacy personnel
- nursing and medical personnel
- laboratory staff
- veterinary surgeons and veterinary nurses.

Level 2 training should be given to workers or carers who have limited contact with cytotoxic drugs and are at low risk, including:

- supervisors and managers
- maintenance personnel
- stores personnel
- cleaners and laundry workers
- on-site waste transporters
- couriers and porters
- waste handlers

- carers
- allied health staff and ward persons
- ambulance and paramedical officers
- non-emergency patient transport officers.

Advice on the use of cytotoxic drugs should also be provided to volunteers and contractors.

### 5.2 IDENTIFY WHAT INFORMATION AND TRAINING IS NEEDED

The training needed should reflect the level of risk of exposure, as well as the anticipated exposure.

Consideration should be given to the use of training competencies that may exist for cytotoxic drugs and the NSW Cancer Institute and other health industry association training courses. Any written training competencies on cytotoxic drugs that are available for specialist professions should be reviewed regularly.

Training and information in relation to cytotoxic drugs and related waste should cover:

- workplace hazards of exposure to cytotoxic drugs and waste
- legislative requirements for health and safety
- legislative requirements for waste management
- the risk management process
- control measures and work practices to be adopted when handling cytotoxic drugs and related waste
- maintenance of equipment
- correct selection, use, cleaning and disposal of personal protective equipment
- procedures to be adopted in the event of accident, injury or spill, including reporting and recording
- access to first aid resources
- storage, transport, treatment and disposal of cytotoxic waste
- health monitoring and reporting
- any written standard operating procedures.

## 5.3 EVALUATE THE TRAINING PROGRAM

The training program should be evaluated to:

- assess its effectiveness by monitoring how work is being performed to determine whether control measures are used
- validate competencies over time by checking that people remain competent to carry out their job – this will determine how often the training should be given or repeated
- ensure the modules and topics required in the training are applicable to the work being carried out – this should be done:
  - each time there is a change of equipment, chemical or in work practices and/or a control measure, or
  - at least every two years.

Oncology and haematology specialists should review any written competencies regularly. Training program should be reviewed to ensure its adequacy after any incidents and accidents.

## 5.4 KEEP TRAINING RECORDS

PCBUs must keep records of workers training for at least five years, in accordance with *Code of practice for managing risks of hazardous chemicals in the workplace* (2012) after the date the record was created. Training records should include:

- date of the session
- topics dealt with during the session
- name of the person who conducted the session
- names of the workers (and their signatures) who attended the session
- course evaluations
- competencies assessed.

## 6. PREPARING AND DISPENSING CYTOTOXIC DRUGS

Pharmacy personnel may be involved in preparing and dispensing cytotoxic drugs. In health care settings, drug preparation work poses the greatest risk of workplace exposure to personnel.

Exposure may occur through:

- skin, eye or mucous membrane contact with cytotoxic materials
- spills
- inhalation of aerosols and powders
- sharps injuries.

To facilitate the safe preparation of cytotoxic drugs, consideration should be given to:

- workplace design, set-up and maintenance according to Australian Standards
- use of clean rooms
- cytotoxic drug safety cabinets
- other specialised equipment.

Education and training is crucial in ensuring that control measures and safe work practices are developed, understood, implemented and maintained.

### 6.1 CONTROL MEASURES

The standards of practice in Australia in relation to cytotoxic drugs in pharmacy departments are outlined in:

- *Standards of practice for the safe handling of cytotoxic drugs in pharmacy departments* (2005), The Society of Hospital Pharmacists of Australia (SHPA).
- *Standards of practice for the transportation of cytotoxic drugs from pharmacy departments* (2007), The Society of Hospital Pharmacists of Australia (SHPA).
- *Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer* (2007), The Society of Hospital Pharmacists of Australia (SHPA).

Key risk controls include:

- reviewing health and safety information about cytotoxic drugs before making a decision to purchase them
- purchasing cytotoxic drugs in the safest form available (for example – purchase cytotoxic drugs in a ready-to-use form, such as pre-filled syringes)
- outsourcing cytotoxic drug preparation work to a licensed manufacturer that specialises in this type of work
- using facilities that meet recommended technical and safety standards
- designing and laying out work area according to recommended standards
- adopting closed system operations
- providing workers with information and training.

These control options should be considered a priority. A purchasing policy may help build these control measures into the health and safety management system of the drug preparation facility.

### 6.2 ALTERNATIVE SUPPLY ARRANGEMENTS

Health care establishments that are unable to provide the facilities, equipment and training as specified in this guide should not undertake to provide cytotoxic drug service.

Alternative arrangements could include:

- purchasing and supplying prepared cytotoxic drugs in a single-dose delivery unit from a commercial source – it is not safe for local pharmacies and community workers to reconstitute cytotoxic drugs if adequate risk control measures are not in place
- establishing supply arrangements with a health care institution that has the required facilities, equipment and trained personnel to provide prepared cytotoxic drug doses.

## 6.3 SETTING UP A CYTOTOXIC DRUG PREPARATION FACILITY

### 6.3.1 Drug preparation facilities

Cytotoxic drugs should be prepared in a purpose-designed cleanroom suite that comprises:

- a cytotoxic cleanroom, which houses a cytotoxic drug safety cabinet or pharmaceutical isolator for drug preparation
- access only through an anteroom and pass-through hatch – a secondary barrier to prevent cytotoxic drugs contamination of the outside environment should be provided by high efficiency particulate air (HEPA) filters, which supply filtered-air to the cleanroom and the anteroom.

Where/when people are working in isolation:

- arrangements should be in place (for example – duress alarm)
- access should be controlled.

The following technical standards describe suitable risk controls for facilities and installation of those facilities are recommended:

- AS 1807.1-22 – 2000 *Cleanrooms, workstations, safety, cabinets and pharmaceutical isolators – Methods of test.*

Standards for the provision of drug containment and aseptic manipulation include:

- a separate dedicated cytotoxic drug safety cabinet installed with a carbon filter that complies with AS 2567-2002 *Laminar flow cytotoxic drug safety cabinets*. Installation and use of cytotoxic laminar flow drug safety cabinets should be in accordance with the specifications of AS 2639-1994 *Laminar flow cytotoxic drug safety cabinets – installation and use*, or
- use of a pharmaceutical isolator that complies with AS 4273-1999 and AS 4273-1999/Amdt1-2000 *Guidelines for the design, installation and use of pharmaceutical isolators*.

### 6.3.2 Work organisation layout and design

Attention to ergonomic design principles, equipment layout and work practices will minimise operator error. Factors to consider in work layout and design include:

- the level of concentration and visual control required
- precision of movements needed
- design of equipment and availability of adjustable furniture, such as chairs, stools and foot rests
- storage requirements
- potential noise sources.

Other considerations in designing and setting-up a cleanroom and anteroom include:

- access for cleaning
- seam-free, smooth and durable work surfaces and furniture
- recessed lights
- the number of surfaces and shelves to minimise particle shedding or the accumulation of particulate matter
- accessible emergency shower outside the anteroom
- an effective airlock between the cytotoxic suite and external environment
- equipment dedicated to the cytotoxic cleanroom
- the anteroom provides:
  - the only access to the cleanroom
  - access to only one cleanroom
  - facilities for donning personal protective equipment and checking that it fits correctly
- the pass-through hatch has:
  - no direct access to the external environment unless an appropriate chemical or HEPA filter is used to control emissions
  - interlocking doors and is supplied with appropriate chemical or HEPA filtered air
- means of communication between the cleanroom and other areas
- a manometer to monitor the pressure differential within the cytotoxic suite and record daily the differential pressure readings
- a manometer alarm in case of inadequate pressure differentials
- a spill switch that reverses the airflow, minimising contamination to the external environment.

### 6.3.3 Drug storage

Cytotoxic drugs in storage must be identifiable by all workers. It is recommended that a dedicated, clearly-marked storage area, including refrigeration, be available for cytotoxic drugs in pharmacy departments and storage areas. Use of a dedicated facility offers quick and efficient containment and management of a spill. A dedicated facility should also be designed to limit the chance of breakage, and limit the extent of contamination if breakage occurs.

Generally, the quantity of cytotoxic drugs stored in pharmacy departments, wards, clinics and satellite pharmacies should generally be restricted to those required for short-term use.

Areas where cytotoxic drugs are stored must have a current Safety Data Sheet for each drug. Storage areas should be secured and access limited to authorised personnel.

A dedicated area should be provided for the unpacking of cytotoxic drugs. Cytotoxic drugs should be handled with care when unpacking. Badly damaged packages should be safely contained and returned to the manufacturer or supplier with suitable warning labels.

In the drug preparation area, only a worker wearing the same personal protective equipment as is used in preparation and with the appropriate respirator, should open damaged packages. Contents should be examined for damage or leakage to determine whether they are safe for repackaging or must be disposed of as cytotoxic contaminated waste. Institutional investigation and reporting should be followed when badly damaged packages are received and subsequent repackaging occurs.

Those involved in the receipt, distribution and storage of cytotoxic drugs must receive appropriate instruction and training on the hazards, risks of exposure and control measures.

Other agencies such as NSW Health and the NSW EPA also have requirements for drug storage and cytotoxic drug contaminated waste removal that must be complied with.

## 6.4 DRUG PREPARATION EQUIPMENT

Equipment used for preparing drugs should incorporate a closed system where possible and should also minimise the potential for preparing drugs under pressure. Specific control methods include:

- using Luer-lock syringes and fittings to keep connections together
- using Luer-slip syringes only if Luer-lock connections are incompatible, such as intrathecal needles
- using syringe-to-syringe connectors when transferring solutions from one syringe to another
- using wide-bore needles to reconstitute and draw-up cytotoxic drugs
- using filter needles only when the cytotoxic drug has been removed from a glass ampoule or if particulate matter is visible (for example – if coring of vial rubber has occurred)
- using air-venting devices to equalise pressures and to prevent the passage of powder aerosols and liquids
- not priming intravenous (IV) lines in the cytotoxic drug safety cabinets.

## 6.5 STANDARD OPERATING PROCEDURES FOR PREPARING CYTOTOXIC DRUGS

Specific handling techniques and procedures that incorporate equipment designed to minimise the risk of exposure should be used.

All preparations must be undertaken in cytotoxic drug safety cabinets as specified in AS2567-2002 *Laminar flow cytotoxic drug safety cabinets* and AS4273-1999 *Guidelines for the design, installation and use of pharmaceutical isolators*.

### 6.5.1 Parenteral preparations

Standard operating procedures should be documented and stress the need to:

- avoid using cytotoxic drugs supplied in glass ampoules – if glass ampoules must be used, open with an ampoule breaker or a low-linting swab

- contain excess drug solutions and air when priming
- use techniques that avoid the generation of pressure differentials.

### 6.5.2 Non-parenteral preparations (extemporaneous)

Tablets, capsules and topical creams should be prepared under the same conditions as parenteral cytotoxic drugs. Additional standard operating procedures include:

- using purpose-dedicated equipment
- making mixtures by dispersing tablets in water inside a laminar flow cytotoxic drugs safety cabinet
- not crushing tablets in an open mortar
- not counting tablets or capsules by machine
- cleaning equipment immediately after use with a strong alkaline detergent with pH>10.

## 6.6 LABELLING

- Appropriate warning labels should be placed on cytotoxic drug containers (including syringes and intravenous bags).
- Cytotoxic drugs should be labelled with the name of the cytotoxic drug, the dose, expiry date and the name of fluid in which it is reconstituted
- Containers that carry cytotoxic drugs should identify the contents as cytotoxic drugs
- Intrathecal cytotoxic drugs should be labelled 'for intrathecal use only'
- Vinca alkaloids should be labelled **'for intravenous use only – fatal if given by other routes'**
- Oral medications should be labelled 'do not cut or crush'.
- Topical cytotoxic medication should be labelled 'wear Latex/polyvinyl gloves and use spatula to apply'
- Cytotoxic drugs that are vesicants should have an extravasation-warning label
- Additional labelling should be used if so required by as the workplace.

## 6.7 PERSONAL PROTECTIVE EQUIPMENT

Together with other control measures, the following personal protective equipment should be provided to those who prepare cytotoxic drugs:

- impermeable coverall or gown
- head covering
- closed footwear and overshoes
- protective gloves – long enough to cover elasticised cuff of gown or coverall
- protective eyewear
- respiratory protective mask (class P2 – refer to Appendix 9).

## 6.8 PACKAGING AND TRANSPORTING CYTOTOXIC DRUGS

Cytotoxic drugs should be packaged and transported so as to provide adequate physical and chemical protection for the drugs and protection to handlers in the event of a spill.

Transport of cytotoxic drugs by a commercial transporter or by others in large quantities, may be regulated by dangerous goods legislation and incur additional packaging and transport requirements. Contact the NSW Environment Protection Authority (EPA) for further information on transport of dangerous goods.

### 6.8.1 Drug packaging

- Keep in a labelled, sealed, leak-proof container, with outer bags heat-sealed
- Ensure the container offers protection from light
- Protect the drugs from breakage in transit
- Contain leakage if breakage occurs
- Provide tablet containers with childproof lids
- Tablet containers should be labelled 'do not cut or crush'
- Containers should be appropriately labelled (for example – intrathecal, oral or topical) for the specified use
- Safe handling instructions should accompany the package.

## 6.8.2 Drug transport inside and outside the hospital

Containers used for transporting the cytotoxic drugs must be:

- hard walled, robust containers capable of withstanding shock
- made from moulded foam or some other suitable packaging material that is capable of withstanding shock equivalent to a one-metre drop onto a concrete surface
- securely closed and labelled with cytotoxic warnings.

Drugs for intrathecal use should be transported separately. All intrathecal products, including syringes and outer wraps of packages, should be appropriately labelled.

When transported, drug containers should be placed in the boot of the vehicle.

Spill kits should accompany cytotoxic drug packages in transit. Those receiving cytotoxic drug packages should be aware of emergency spill procedures and know how to handle cytotoxic drugs. Handling instructions should accompany drugs in transit.

For additional information on the transport of cytotoxic drugs, refer to the SHPA *Standards of practice for the transportation of cytotoxic drugs from pharmacy departments*.

## 6.9 MAINTAINING CONTROLS

Equipment used to prepare cytotoxic drugs and air-handling facilities should be maintained under a planned maintenance schedule. Defective equipment must not be used.

### 6.9.1 Performance testing and inspection of facilities and equipment

Cytotoxic drug safety cabinets and secondary and tertiary barriers should be assessed and certified by a suitably qualified person as specified in AS 2639-1994 *Laminar flow cytotoxic drug safety cabinets - installation and use*.

If access to plant is required for the purpose of maintenance, cleaning or repair, the plant must be stopped and one or more of the following measures used so as to control risks to health and safety:

- lockout or isolation devices
- danger tags
- permit-to-work systems.

If it is not practicable to stop the plant, fittings that allow controlled movement of the plant must be implemented and safe systems of work employed.

### 6.9.2 Equipment maintenance

An equipment maintenance schedule should include:

- inspection of cytotoxic drug safety cabinets, isolators and the suitable filters (as required by the Australian Standards)
  - at regular intervals, and at least every 12 months
  - after relocation and after mechanical or electrical maintenance
- test records and a summary of results in a place accessible to workers
- identification of faulty cabinets (for example - attach a lock-out tag and do not use until fixed)
- repair of faulty cabinet, and recertification prior to use
- routine performing and recording of microbial and air-particle testing.

### 6.9.3 Cleaning drug preparation facilities

Standard operating procedures should be documented and emphasise the need to:

- clean daily
- use a dedicated mop and bucket
- treat all equipment as potentially contaminated
- use personal protective equipment.

## 6.10 SUMMARY OF CONTROL MEASURES

The following information will ensure all the options have been considered when implementing control measures.

Controls covered in this chapter	Completed
Key risk controls	<input type="checkbox"/>
Setting up a cytotoxic drug preparation facility	<input type="checkbox"/>
Using specially designed and dedicated equipment	<input type="checkbox"/>
Standard operating procedures	<input type="checkbox"/>
Personal protective equipment	<input type="checkbox"/>
Labelling, packaging and transporting	<input type="checkbox"/>
Equipment maintenance controls	<input type="checkbox"/>

Control measures referred to elsewhere in these guidelines	
Chapter 3	Risk Management
Chapter 4	Personnel Management
Chapter 5	Information, Instruction and Training
Chapter 9	Spill Management
Chapter 10	Waste Management
Appendix 9	Personal Protective Equipment

## 7. ADMINISTERING CYTOTOXIC DRUGS

Nursing and medical personnel may be involved in administering parenteral, oral and topical cytotoxic drugs. Exposure while administering drugs may occur through:

- handling cytotoxic drugs
- spills
- splashes to the skin, mucosa or eyes
- inhalation of airborne contaminants (which can be generated by the expulsion of air from a drug-filled syringe)
- sharps injuries.

To ensure that cytotoxic drugs are safely administered, workplace design, use of specially designed equipment, safe work practices and personal protective equipment are essential. It is crucial to ensure that control measures and safe work practices are developed, understood, implemented, maintained and periodically reviewed. This must be supported by education, training and supervision.

### 7.1 KEY RISK CONTROL MEASURES

The following risk controls should be considered a priority:

- do not undertake a drug administration service unless control measures can be provided
- use the safest administration techniques available (for example – needleless systems)
- use closed drug administration devices where possible
- drugs intended for administration should be appropriately packaged, labelled and ready to use
- cytotoxic medications should be identified by using a specific cytotoxic medical chart, or by using a cytotoxic label attached to a standard medical chart
- use pre-diluted cytotoxic drugs where possible

- provide secure and labelled storage of waste and sharps containers to minimise exposure to cytotoxic waste
- provide training and education about side effects of cytotoxic drugs
- use personal protective equipment.

A policy to build these control measures into the health and safety management system of the service/ward/clinic is highly recommended.

### 7.2 SETTING UP A DRUG ADMINISTRATION AREA

When setting-up a designated drug administration area in a health care facility:

- allocate an area that restricts access to unauthorised personnel
- allow sufficient room for movement to ensure for safe drug administration
- provide storage for cytotoxic waste and sharps containers
- provide storage for cytotoxic waste ready for disposal
- establish a system for obtaining and keeping health and safety information such as safety data sheets in a place accessible to workers
- provide washable chairs and other furnishings
- provide liquid resistant mattress covers
- install warning signs that prohibit eating, drinking and application of cosmetics
- provide hand-washing facilities
- provide facilities for storage and disposal of personal protective equipment.

Ideally, a patient care area should have a safety shower and appropriate hygienic liquid resistant flooring (instead of carpet).

When administering cytotoxic drugs in a home setting, comply with these instructions as closely as possible (refer to Chapter 10).

## 7.3 CYTOTOXIC DRUG ADMINISTRATION

### 7.3.1 Equipment

To minimise risks, the following equipment is recommended:

- needleless administration systems
- closed administration devices
- luer-lock syringes
- portable lined trolleys to store equipment
- disposable injection trays to contain and carry syringes
- disposable gauze squares around the injection site
- plastic-backed absorbent sheets or pads under the injection site
- purple plastic, rigid-walled, wide-necked, sharps disposal containers that are readily accessible
- personal protective equipment
- a spill kit.

Particular care should be taken when using complex administration lines to ensure that all necessary connections are made and the system remains closed.

### 7.3.2 Parenteral administration

Standard operating procedures should be documented and emphasise the need to:

- follow recommendations from the suppliers and the pharmacy for administration procedures
- cross-check chemotherapy with the pharmacist, doctor or nurse
- involve the patient and encourage them to alert administration staff to any problems
- maintain close supervision of the patient
- use lines with compatible solutions
- connect all drug administration bags and bottles at waist level
- wear appropriate personal protective equipment at all times

- avoid contact with fluid from body cavities following administration (for example – after intrapleural, intravascular or intraperitoneal administrations)
- use cytotoxic labels to identify all intravenous solution flasks, syringes and pump cartridges
- manage extravasation incidents promptly
- dispose of empty intravenous bags and flasks (with the administration set attached) into a sealable bag before placing them into a multi-use cytotoxic waste bin
- discard gloves after use into cytotoxic waste bin
- wash hands following administration and disposal of cytotoxic drugs and related waste
- appropriately seal and return the unused cytotoxic drugs to the pharmacy, or to the source of referral.

Prior to administration calculate the body surface area (or other parameters), then calculate the required dose.

During drug administration, **DO NOT:**

- recap needles
- cut down intravenous infusion sets or contaminated needles
- expel air from a syringe (it contaminates the air)
- expel fluid from a syringe (it contaminates the area).

### 7.3.3 Topical agents

Topical agents may be in the form of ointments, lotions or eye drops.

Additional control measures when using topical agents include:

- avoiding unnecessary contact with the topical agent
- minimising contact with a patient's clothing
- applying ointments as a film and lotions with a disposable spatula
- educating a patient on how to apply medication
- disposing of all contaminated equipment as cytotoxic waste
- wearing appropriate personal protective equipment at all times.

### 7.3.4 Oral administration

Oral agents are generally given as tablets and capsules.

Additional control measures when using oral agents include:

- using a non-touch technique when transferring tablets or capsules from their container into a disposable medication cup, to avoid direct handling
- not crushing or breaking tablets or capsules for any reason (for example – oral, nasogastric or PEG feed) outside the pharmacy’s cytotoxic drug preparation area
- isolating and discarding damaged tablets or capsules as cytotoxic waste and notifying pharmacy
- contacting the pharmacy if it is necessary to produce a cytotoxic drug mixture
- discarding contaminated medication cups as cytotoxic waste
- wearing appropriate personal protective equipment.

## 7.4 SUMMARY OF CONTROL MEASURES

The following information will ensure all the options have been considered when implementing control measures.

Controls covered in this chapter	Completed
Key risk controls	<input type="checkbox"/>
Setting up a drug administration area	<input type="checkbox"/>
Using specially designed and dedicated equipment	<input type="checkbox"/>
Standard operating procedures	<input type="checkbox"/>

Control measures referred to elsewhere in these guidelines	
Chapter 3	Managing risks to health and safety
Chapter 4	Personnel Management
Chapter 5	Information, Instruction and Training
Chapter 9	Spill Management
Chapter 10	Waste Management
Appendix 9	Personal Protective Equipment

## 8. MANAGING CYTOTOXIC CONTAMINATED BODY WASTES

After cytotoxic drugs have been administered, nursing and medical, pathology staff and others may care for patients. Ambulance officers, ward persons and non-emergency patient transport officers too, may be involved in caring for and transporting patients after they have received cytotoxic drug treatment.

Cytotoxic drugs are primarily eliminated from the patient by renal and hepatic excretion. All body substances may be contaminated with the unchanged drug or with active drug metabolites.

Exposure to cytotoxic waste may occur through:

- removing or inserting catheters
- handling vomitus, saliva, blood, excreta, or fluid drained from body cavities
- handling bedpans, urinals, emptying urinary catheter bags, colostomy or urostomy bags, or vomitus bowls, wet nappies and incontinence pads and wet dressing materials
- handling bed linen or clothing soiled with a patient's waste or potentially contaminated with the drug or active drug metabolites
- cleaning spills
- tracheal suctioning.

The period during which body substances may be contaminated with cytotoxic drugs will differ for individual drugs and patients (refer to Appendix 10). However, Cancer Institute NSW recommends a standardised period of seven days.

Workplace design and set-up, use of appropriate equipment and resources, safe work practices and personal protective equipment are required to ensure that the risks associated with handling patients are adequately controlled. To ensure that safe work practices are developed, understood, implemented, maintained, and periodically reviewed, education, training and supervision are crucial.

### 8.1 KEY RISK CONTROL MEASURES

The following key risk controls should be considered a priority:

- review the history of a patient's treatment before undertaking care
- design and set-up of the workplace
- use appropriate equipment and resources
- review health and safety information about administration of the drug.

To build these control measures into the health and safety management system of the patient care centre, a standard operating procedure should be developed and maintained.

### 8.2 ASSESSMENT OF BODY WASTE CONTAMINATION

To assist in determining whether body waste is potentially contaminated, the patient care sheet should include:

- the name of the drugs
- the route of administration
- the time the drugs were administered
- how the drugs were administered
- the dosage
- the duration of exposure.

### 8.3 PROCEDURES

#### 8.3.1 The patient care area

When designing and setting-up a patient care area, ensure:

- sufficient room to move
- ensure the patient and carer are involved
- hand-washing facilities are provided
- appropriate hygienic and liquid-resistant flooring is used, instead of carpet
- a purple cytotoxic waste disposal bin is available

- purple laundry bag is provided for those having or who have just had chemotherapy
- an area to store PPE.

### 8.3.2 Patient care equipment

To minimise the risk of exposure, the following equipment is recommended:

- a spill kit
- appropriate cleaning detergent
- container for spills (if access to a waste outlet is not available)
- approved cytotoxic waste container for sharps and other wastes
- closed and heated pan washers or sanitisers
- scales to weigh urine
- appropriate personal protective equipment
- toilets with lids on
- hand wash facilities.

### 8.3.3 Standard operating procedures

Standard operating procedures should be adopted which emphasise the need to:

- avoid skin contact with a patient's body substances
- use closed systems where possible to prevent generating aerosols when handling a patient's vomitus, blood, excreta or fluid drained from their body cavities
- contain and clean-up spills immediately
- use urine hats to avoid sprays and aerosols
- dispose of waste such as urine, faeces and vomitus into hot pan flusher/toilet with lids on
- the contents of colostomy or urostomy bags, incontinence aids disposable nappies and heavily exudating dressing materials bagged into purple cytotoxic waste bin
- bag cytotoxic contaminated linen in purple linen bags
- take precautions when handling body waste during drug excretion (all staff and carers should be informed)
- use indwelling catheters for incontinent patients

- label all specimens sent to the laboratory as 'contaminated with cytotoxics'
- wear PPE when handling body waste or cytotoxic contaminated equipment
- wash hands thoroughly – before and after handling cytotoxic drugs.

### 8.3.4 Personal protective equipment

When handling anything potentially contaminated with a cytotoxic drug or active drug metabolites, the following personal protective equipment is recommended:

- gown
- closed footwear
- protective gloves
- protective eyewear (where there is a risk of splash to the eye)
- respirator (P2 type).

## 8.4 TRANSPORTING PATIENTS

### 8.4.1 Within an establishment

When relocating a patient to another area within a hospital or treating centre, the following control measures should be implemented:

- constant supervision by medical or nursing staff (if drug administration is in progress)
- immediate access to emergency assistance in the event of a spill (if drug administration is in progress)
- immediate access to a spill kit
- those at the patient's new destination must be made aware of cytotoxic procedures and the patient's cytotoxic status.

### 8.4.2 By ambulance

When transporting a patient by ambulance, the control measures outlined in this chapter should be implemented and followed. The ambulance service should be made aware that the patient is undergoing cytotoxic drug treatment.

## 8.5 LAUNDERING

### 8.5.1 Personal protective equipment

Special precautions are required for the laundering of non-disposable, personal protective equipment that may be contaminated with cytotoxic drugs. The requirements of the manufacturer or supplier of the equipment should be followed. Attention should also be given to prevent contamination of other materials being laundered. Cytotoxic contaminated laundry should not be pre-sorted, as there is a risk of exposure through dermal and inhalation.

Systems should be established to:

- protect laundry personnel from exposure to residues of a cytotoxic drug
- prevent contamination of other materials being laundered
- ensure personal protective equipment is decontaminated prior to sterilisation or reuse.

When handling contaminated linen, the following personal protective equipment should be used:

- gown
- protective gloves
- eye protection
- respirator (P2 type).

### 8.5.2 Linen

Linen that is contaminated with cytotoxic drugs or related waste should be discarded or placed in the alginate bag and sent for laundering. Bed mattresses should be cleaned appropriately.

HealthShare NSW, in accordance with the International Society of Oncology Pharmacy Practitioners (ISOPP), recommends the following when laundering cytotoxic contaminated linen:

- It is acceptable industry practice to launder cytotoxic contaminated linen if there is a safe process by which this can be done
- The primary principle is to carry out the laundry process (from collection through to wash) without actually handling the contaminated linen

- Cytotoxic contaminated linen should be stored separately to regular linen to avoid cross- contamination including at the hospital prior to collection, during transport and at the Linen Service prior to washing
- Cytotoxic contaminated linen should be placed in bags as per the sequence below:
  - Firstly in a purple Alginate/dissolvable bag so it can be washed without handling which is then placed in
  - a purple plastic bag (impermeable layer) to contain any leakage through the alginate/dissolvable bag and it is then placed in
  - a purple normal fabric linen bag to protect the plastic bag from damage
- Cytotoxic contaminated linen should be washed separately and without handling (such as – no sorting, wash in dissolvable bags)
- Cytotoxic contaminated linen is to be washed twice without handling between the first and second cycle. The first cycle should be cold wash and the second cycle as per normal temperature
- Once the second wash cycle is complete the linen is no longer considered contaminated and can be handled as per normal
- The outer fabric linen bag should be washed in the same cycle as the cytotoxic contaminated linen and the plastic bag disposed as cytotoxic waste

## 8.6 SUMMARY OF CONTROL MEASURES

The following information may be used to help ensure all the options have been considered when implementing control measures.

Controls covered in this chapter	Completed
Key risk controls	<input type="checkbox"/>
Before accepting a patient	<input type="checkbox"/>
Setting-up a patient care facility	<input type="checkbox"/>
Using suitable equipment	<input type="checkbox"/>
Standard operating procedures	<input type="checkbox"/>
Personal protective equipment	<input type="checkbox"/>
Transporting patients	<input type="checkbox"/>
Laundering	<input type="checkbox"/>

Control measures referred to elsewhere in these guidelines	
Chapter 3	Risk Management
Chapter 4	Personnel Management
Chapter 5	Information, Instruction and Training
Chapter 9	Spill Management
Chapter 10	Waste Management
Appendix 9	Personal Protective Equipment

## 9. SPILL MANAGEMENT

Spills of cytotoxic drugs and related waste must be dealt with immediately as they present a high risk of exposure. Spills may occur wherever cytotoxic drugs and related waste are handled, stored, transported or disposed. People in the immediate vicinity of a spill should be alerted immediately and told to stay clear. Ancillary workers should assist only in the containment of a spill, while alerting trained personnel.

### 9.1 SOURCES OF SPILLS

A risk assessment should identify all areas where there is a risk of a cytotoxic spill.

Spills may involve:

- cytotoxic drugs in all forms – liquid, powder, broken tablets, tablets or creams etc,
- drugs spilt (or leaking) during preparation, storage or transport of packaged drugs
- drugs spilt during administration
- drugs spilt during the transport of a patient undergoing drug therapy in situ
- cytotoxic contaminated body substances
- cytotoxic contaminated waste

Spills may result in the contamination of floors, work surfaces, equipment, bedding and clothing.

### 9.2 SPILL MANAGEMENT STRATEGY

The PCBU should establish a spill management strategy with the assistance of those involved in preparing, administering, transporting and managing cytotoxic drugs. Safe work practices for spill management should be developed, understood, implemented, maintained and periodically reviewed by all those who handle cytotoxic drugs and those who may be involved in managing spills.

A standard operating procedure for handling spills should be developed and should be part of any general standard operating procedures for preparing and administering cytotoxic drugs.

### 9.3 TRAINING

Training in spill containment and decontamination procedures must be provided to all those who are likely to be involved in spill management.

### 9.4 SPILL KIT CONTENTS

The risk assessment should be used to determine the contents appropriate to the situation in which the cytotoxic spill kit will be used. Appropriate locations for storing a spill kit should be selected and sign-posted. A spill kit must be reviewed routinely to ensure supplies are adequate and its contents have not deteriorated.

A spill kit should include:

- instructions on how to use (for example – standard operating procedures for the management of a cytotoxic spill)
- signs to identify and isolate the spill area
- personal protective equipment (for example – P2 respirator mask, 2 pairs of gloves, gown/apron)
- adequate quantities of absorbent materials (for example – swabs, absorbent towels, spill pillow, chemical absorbent pads, protective mats (bluey or ‘chemo mat’))
- a small scoop to collect any glass fragments
- two purple plastic waste bags, clearly identified as cytotoxic
- incident report forms.

Water can be used for cleaning, rinsing or dampening a spill. Appropriate detergent should be used as appropriate.

## 9.5 SPILL CONTAINMENT

### 9.5.1 In health care settings

The following procedures are recommended for spill containment, but may be modified for local requirements:

- Alert all those in the immediate vicinity that a cytotoxic spill has occurred and tell them to stay clearly away from spills
- Open the cytotoxic spill kit – display signs, restrict access and call for assistance if required
- Don a particulate (P2) respirator, then appropriate personal protective equipment
- For liquid spills, wait a few seconds for aerosols to settle, then cover the spill using available absorbent material, taking care not to generate any splashes (aerosols) – for large spills, a spill pillow to absorb the liquid may be used
- If the spill involves a powder, place an absorbent mat over the powder and ensure minimal dust production – carefully wet the mat so that the powder dissolves and is absorbed by the mat
- Gather absorbed material and collect and contain any broken glass
- Discard collected waste into a cytotoxic plastic waste bag or cytotoxic sharps waste container (for example – for broken glass)
- Wash with water once the area has been rinsed and wiped with absorbent material. Detergent may be applied as a final step, washing from area of least contamination
- Dry the affected area with absorbent towels or other suitable materials
- Discard the contaminated cleaning waste into the cytotoxic plastic waste bag
- Discard outer gloves into the cytotoxic plastic waste bag. Seal the bag and place it inside a second cytotoxic plastic waste bag
- Discard and seal contaminated personal protective equipment and inner gloves into the outer bag
- Place cytotoxic plastic waste bag in a cytotoxic waste disposal bin
- Wash hands with soap and water

- Complete an incident report as per local requirements
- Ensure that the cytotoxic spill kit is replenished and maintained.

### 9.5.2 In community care settings

A patient who is treated at home or in a community care setting should be provided with a cytotoxic spill kit, with easy-to-understand instructions. These may be based on the procedures outlined above for health care settings. The kit should include a list of contents and information on the replacement and disposal of used items.

### 9.5.3 On carpets

The use of carpet is not recommended in a cytotoxic drug administration area. Where carpeted areas are in use, the above procedures should be followed with regard to personal protective equipment and the disposal of contaminated waste.

Initially, to absorb as much fluid as possible, use absorbent pads, granules or powder, then clean with detergent and water, minimising the seepage into unaffected areas of the carpet. If necessary, clean the carpet with a commercial machine, or have it dry cleaned. Decontamination of carpet cleaning machines is not considered necessary due to the dilution effect.

### 9.5.4 Within a cytotoxic drug safety cabinet or cleanroom

Training on spill containment and decontamination must be provided to those who handle cytotoxic drugs in safety cabinets and cleanrooms. Cleaning methods are set out in Appendix C of AS 2639-1994 *Laminar flow cytotoxic drug safety cabinets – installation and use*.

Within a cleanroom, everyone must wear personal protective equipment.

## 9.6 CONTAMINATION

### 9.6.1 Clothing and personal protective equipment

- Immediately remove outer gloves, gown and any contaminated clothing
- Place disposable personal protective equipment in the cytotoxic waste bin
- Contaminated clothing should be bagged separately, machine washed separately and line dried
- Remove and dispose of inner gloves.

### 9.6.2 Penetrating injuries, skin and other body contact

- Wash the affected skin with soap and clean thoroughly with copious amounts of tepid water and do not scrub or create friction in the area of concern
- Do not administer anaesthetic drops or ointments
- Report to supervisor immediately
- Seek immediate medical advice and further medical attention as necessary
- Refer to extravasation policy where appropriate
- Document incidents.

### 9.6.3 Mucosal exposure

- Immediately flush the affected area (for example – eye) with an isotonic saline solution for at least 15 minutes – continuous irrigation may be facilitated with an intravenous infusion set connected to an intravenous normal saline
- Report to supervisor immediately
- Seek immediate medical advice and further medical attention as necessary
- Document incidents.

## 9.7 REPORTING PROCEDURES

PCBUs must have a system in place to report a spill or contamination as soon as practicable. A supervisor should be notified immediately and should be trained in appropriate procedures. The supervisor or workplace health and safety officer must record the type of incident in an incident register and outline the procedures taken to manage the spill. Incidents should be recorded and investigated in accordance with organisational incident reporting procedures. If a worker is contaminated, a medical review with the appointed medical practitioner must be arranged as outlined in the *Health monitoring for exposure to hazardous chemicals – Guide for persons conducting a business or undertaking*, Safe Work Australia.

### 9.7.1 Notification of incidents

It is a legal requirement of persons conducting a business or undertaking (PCBU) of a workplace to notify SafeWork NSW of any cytotoxic drugs spills that may impose significant risk to workers' health.

For further information on notification requirements, refer to *The notifying and recording an incident or injury*, SafeWork NSW.

## 9.8 SUMMARY OF CONTROL MEASURES

The following information will ensure all the options have been considered when implementing control measures.

<b>Controls covered in this chapter</b>	<b>Completed</b>
Setting-up a spill management strategy	<input type="checkbox"/>
Managing spills	<input type="checkbox"/>
Standard operating procedures	<input type="checkbox"/>
Personal protective equipment	<input type="checkbox"/>
Reporting procedures	<input type="checkbox"/>

<b>Control measures referred to elsewhere in these guidelines</b>	
Chapter 3	Risk Management
Chapter 4	Personnel Management
Chapter 5	Information, Instruction and Training
Chapter 9	Spill Management
Chapter 10	Waste Management
Appendix 7	Guidelines for Medical Practitioners in Health Monitoring for Cytotoxic Drugs
Appendix 8	Record Keeping
Appendix 9	Personal Protective Equipment

# 10. WASTE MANAGEMENT

This chapter outlines a waste management strategy that involves identifying, segregating and containing waste and transporting, storing and disposing of waste.

Cytotoxic contaminated waste is a hazard and workers must be protected from the risk of exposure through the entire waste management process, from generation to destruction.

A waste management strategy should include the key elements of identifying, segregating and containing waste and transporting, storing and disposing of waste and contaminated personal protective equipment. The strategy should define safe systems of work such as standard operating procedures and spill management and include training and information for all those involved in the handling and transporting of contaminated waste.

As cytotoxic waste is hazardous to human health and the environment, it is a regulated waste and is subject to the requirements of the *Protection of the Environment Operations Act 1997* (POEO Act) and the *Protection of the Environment Operations (Waste) Regulation 2014* (Waste Regulation). These requirements cover the generation, storage and transportation of waste that is pre-classified as hazardous waste, restricted solid waste, special waste (cytotoxic waste is pre classified as special waste) and liquid waste.

The NSW Health publication *Waste management guidelines for health care facilities* provides advice on the packaging, labelling, handling and segregating of cytotoxic waste in health care facilities. In dealing with cytotoxic waste, other related waste derived from clinical settings such as clinical waste and pharmaceutical waste should also be considered as cytotoxic waste is often associated with such wastes.

For more information on NSW EPA requirements, see specific information regarding clinical and related waste which is available on the EPA website.

## 10.1 WHAT IS CYTOTOXIC WASTE?

Cytotoxic waste includes any residual cytotoxic drug following a patient's treatment and the materials or equipment associated with the preparation, transport or administration of the drug therapy. It includes:

- cytotoxic pharmaceuticals past their recommended shelf life, unused or remaining drugs in all forms, contaminated stock, and cytotoxic drugs returned from a patient
- contaminated waste from preparation processes
- sharps and syringes, ampoules and vials
- intravenous infusion sets and containers
- empty cytotoxic drug bottles
- cotton wool from bottles containing cytotoxic drug
- used HEPA or chemical filters and other disposable contaminated equipment
- contaminated personal protective equipment (for example – gloves, disposable gowns, shoe covers, respirators)
- swabs, cloths, mats and other materials used to clean cytotoxic contaminated equipment or to contain spills
- contaminated body substance receptacles (for example – disposable vomit bags)
- dressings, bandages, nappies, incontinence aids and ostomy bags
- heavily soiled and contaminated bedding that is determined to be disposed
- contaminated specimens from the laboratory.

Cytotoxic waste is defined in the POEO Act and NSW EPA *Waste Classification Guidelines – Part 1: Classifying Waste (Nov 2014)* – *Cytotoxic waste means 'any substance contaminated with any residues or preparations that contain materials that are toxic to cells principally through action on cell reproduction.'*

For waste purposes it is not necessary to assess and classify cytotoxic waste. It is already pre-classified as special waste in the POEO Act.

Cytotoxic waste should be managed separately from other types of special waste and from other wastes generated in a clinical setting that are not assessed and/or classified as hazardous waste. Effective separation and segregation of the different waste streams in a clinical setting is essential for compliance with the legal requirements of the POEO Act and for protecting the health and safety of workers and the environment. Information relating to the management of cytotoxic waste in a clinical setting is found in the NSW Health publication *Waste management guidelines for health care facilities*.

## 10.2 RISK MANAGEMENT

PCBUs should develop and periodically review a comprehensive strategy to safely manage and dispose of cytotoxic waste. The strategy should be developed after a comprehensive audit of all sections of the organisation that generate or handle cytotoxic waste. Other waste-handling requirements for individual premises may be included in a comprehensive waste management strategy.

To assist with the development of policies and procedures regarding waste management, contact NSW Health.

An organisation's policy for the disposal of wastes will depend on its location, size, service mix, existing infrastructure and whether incinerator treatment facilities are available. Cytotoxic wastes may not be disposed of at landfill in NSW. Cytotoxic wastes must be treated by thermal destruction or by a chemical process that removes their cytotoxic and other hazardous characteristics.

To streamline work activities and provide consistent safe practices for all those involved in waste management, procedures should be uniform from one organisation to the next.

Key elements of a waste management strategy include:

- designating a person with suitable experience and training to be responsible for ensuring an efficient waste disposal system
- a clear chain of responsibility and involvement of all levels in policy development and implementation
- compliance with legal requirements

- policies and systems to avoid and minimise waste at the point of generation
- extensive consultation with all those who may be exposed, including those generating the waste, waste handlers and waste disposal workers
- appropriate control measures
- monitoring and reviewing the strategy regularly.

### 10.2.1 Control measures

To minimise the risk of exposure to cytotoxic waste, control measures may include:

- elimination, substitution or isolation of identified high risk activities
- engineering or automated methods to minimise the amount of handling
- safe systems of work for identified waste management activities - segregation, packaging, storage, transport, administration and disposal
- identification of cytotoxic waste through designated labelling and use of purple bags and containers
- managing cytotoxic waste generated by outpatients and domiciliary services under the direction of the referring health care facility
- training of supervisors, workers and all those who may be exposed to contaminated waste
- maintaining records and tracking cytotoxic waste in accordance with the requirements of the POEO Act and Waste Regulation
- a transport and disposal flowchart covering internal and external activities from waste generation to treatment and destruction
- appropriate personal protective equipment for identified waste management activities.

## 10.3 IDENTIFICATION, CONTAINMENT AND SEGREGATION

The NSW Health publication *Waste management guidelines for health care facilities* outlines packaging, labelling and the segregation of waste including clinical, pharmaceutical and cytotoxic waste generated from clinical settings.

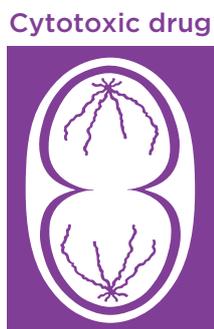
Further information on the management of cytotoxic waste can be found in AS/NZ 3816:1998 *Management of clinical and related waste* and HB 202-2000 (R2017) *A management system for clinical and related wastes – guide to application of AS/NZ 3816-1998, Management of clinical and related wastes*.

### 10.3.1 Labelling requirements

To minimise the risk of exposure to cytotoxic materials and to ensure the safe and correct disposal of cytotoxic waste, the identification of contaminated waste is essential.

All cytotoxic waste should be placed into compliant bags or containers that are appropriately identified. AS/NZ 3816:1998 *Management of clinical and related wastes* and the NSW Health publication *Waste management guidelines for health care facilities*, specify the following colours and symbol for cytotoxic waste:

- containers and bags must be purple
- the container must have a white label with symbol of a cell in late telophase as below:



- the correct labelling words: 'CYTOTOXIC WASTE'
- packaging for transport off-site must be approved and labelled in accordance with the ADG Code (refer to Section 10.8 of this guide).

With the implementation of Globally Harmonised System of Classification and Labelling (GHS), under WHS Regulation, a new GHS hazard pictogram was introduced to communicate health hazards of workplace chemicals. This pictogram must appear on labels of cytotoxic drugs supplied to workplaces from 1 January 2017.



Storage areas should be appropriately sign-posted to distinguish cytotoxic waste from general or infectious waste, particularly if different waste management contractors are used.

Hazardous waste products must be identified and correctly classified, so far as is reasonably practicable. The label on a container of hazardous waste must include the words 'CYTOTOXIC WASTE' clearly displayed and where possible a product identifier and appropriate hazard pictogram(s) and hazard statements under the GHS to indicate a chronic health hazard, acute toxicity and environmental hazards respectively.

See section 6.6 of this guide for further details on labelling requirements for cytotoxic drugs and related waste.

### 10.3.2 Containment

The requirements for containing or packaging contaminated waste are outlined in AS/NZ 3816:1998 *Management of clinical and related wastes* and the NSW Health publication *Waste management guidelines for health care facilities*.

All plastic bags or other non-rigid receptacles containing cytotoxic contaminated waste must be placed in a rigid-walled container (of the appropriate colour and labelling) before transport to a collection or storage area or to a treatment facility that is licensed to receive this type of waste. A labelled wheelie bin may be used for storage. It should be locked before being transported from the clinical area to the containment area.

The storage of sharps should be undertaken according to AS/NZ 3816:1998 *Management of clinical and related wastes* and AS 4031-1992 *Non-reuseable containers for the collection of sharp medical items used in health care areas*, and the NSW Health publication *Waste management guidelines for health care facilities*.

The NSW EPA also has specific requirements with regard to the transport of sharps.

Sharps waste in this guide means 'any waste resulting from medical, nursing, dental, veterinary, pharmaceutical, skin penetration or other related clinical activity and that contains instruments or devices:

- that have sharp points or edges capable of cutting, piercing or penetrating the skin (for example – needles, syringes with needles or surgical instruments)

- that are designed for such a purpose
- that have the potential to cause injury or infection.

*This does not include any such waste that has been treated by a method approved in writing by the Secretary, NSW Ministry of Health’.*

All cytotoxic contaminated sharps must be placed into a rigid-walled, puncture-resistant container that meets the requirements of AS 4031-1992 *Non-reusable containers for the collection of sharp medical items used in health care areas*. Sharps containers should be labelled ‘CYTOTOXIC SHARPS’. Once the sharps container has been sealed and secured, it can be placed directly into a secondary container for transportation.

Packaging for transport off-site must be approved and labelled in accordance with the ADG Code (refer to Section 10.8 of this guide).

### 10.3.3 Segregation

Cytotoxic waste should be segregated from other waste by the development and implementation of appropriate control measures. These measures may include:

- consultation with those who generate cytotoxic waste and those responsible for the provision of support services
- efficient waste disposal
- segregating waste at the point of generation
- appropriate signage at all collection and storage areas

- separating cytotoxic waste from general and clinical waste during internal transport and storage
- ensuring that non-rigid receptacles are placed in a rigid-walled container such as a wheelie bin (of the appropriate colour and labelling) for transport to a collection area
- containers and bins secured with mobile or fixed stands.

Further information on the segregation of cytotoxic waste and related waste is outlined in the NSW Health publication *Waste management guidelines for health care facilities, AS/NZ 3816-1998 Management of clinical and related wastes* and HB 202-2000 (R2017) *A management system for clinical and related wastes – guide to application of AS/NZ 3816:1998, Management of clinical and related wastes*.

## 10.4 LICENCES FOR THE GENERATION AND STORAGE OF CYTOTOXIC WASTE

Under the POEO Act and Protection of the Environment Operations Amendment (Scheduled Activities and Waste) Regulation 2008, premises that generate or store clinical and related waste including cytotoxic waste (pre-classified as special waste) are no longer required to hold an environment protection licence to operate.

Activities	Generation of cytotoxic waste	On-site storage of cytotoxic waste
Local authorities Pharmacies Veterinary surgeons Nursing homes Funeral homes	Exempt	Exempt
Dental surgeries Doctors surgeries Hospitals Pathology laboratories	Exempt	Exempt

## 10.5 REQUIREMENTS FOR HANDLING OR STORAGE OF CYTOTOXIC WASTE

Although hospitals and clinics are exempt from licensing under the POEO Act, cytotoxic waste still needs to be handled in accordance with the requirements that were formerly in section 4.6.2 of the previous *Waste Guidelines (EPA 1997)*. These requirements are included in Clause 43 of the Protection of the Environment Operations (Waste) Regulation 2005. The waste must be packaged in accordance with the NSW Health publication *NSW Health: Waste Management Guidelines for Health Care Facilities*.

Environment protection standards that need to be complied with include:

- storing the waste in an environmentally safe manner
- not storing the waste or have it come into contact with any incompatible waste.

The Waste Regulation also provides for exempting certain waste from tracking requirements. Movement of cytotoxic waste solely within NSW is exempt from tracking – see the NSW EPA website for details.

However, the transport of clinical and related waste including cytotoxic waste interstate needs to be tracked pursuant to Schedule 1 of the Protection of the Environment Operations (Waste) Regulation 2014. Part three of the Waste Regulation sets out the waste-tracking and record-keeping requirements for waste that must be tracked.

NSW EPA has developed an internet-based waste tracking system (online waste tracking) as an alternative to paper-based waste tracking. Further information is available on the NSW EPA website.

## 10.6 INTERNAL MOVEMENT OF CYTOTOXIC WASTE

Internal movement of cytotoxic drugs and related waste is the movement of containerised cytotoxic waste from the point of generation to the designated storage, collection or treatment point.

To minimise exposure, the following control measures are recommended when moving cytotoxic waste within a medical facility:

- do not overfill cytotoxic waste containers

- locate cytotoxic waste collection bins as close as practicable to the site of generation and to transport corridors
- use dedicated, rigid-walled, puncture-resistant containers (for example – wheelie bins, handcarts and trolleys) to move cytotoxic waste around the facility
- ensure such equipment (for example – purple wheelie bins, handcarts and trolleys) is appropriately labelled and kept clean in accordance with infection control and other relevant standards
- schedule frequent waste collection rounds – movement should be planned to avoid peak activity times (for example – visiting hours, meal times and change of shifts)
- lock cytotoxic contaminated waste bins that are full prior to moving to a secure location for storage until removed from site
- avoid movement of cytotoxic waste through public areas or general staff thoroughfares
- ensure that waste disposal and linen chutes are not used for moving cytotoxic waste
- develop a cytotoxic spill management plan for spills occurring during transport
- where required, keep a record of waste movements.

## 10.7 WASTE STORAGE

Cytotoxic waste should be transported to a dedicated, secure storage area to await collection for disposal and treatment. Bins should be sealed or otherwise secured prior to waste collection and not re-opened while on-site.

The storage area should be:

- dedicated to the storage of cytotoxic waste, well secured and with adequate lighting and ventilation
- clearly separated from other waste streams if situated within a main waste storage area
- appropriately identified and sign-posted according to legislative requirements
- located away from stormwater drains and other sensitive areas
- easy to clean, decontaminate and maintain to acceptable hygiene standards
- secure from unauthorised access.

## 10.8 OFF-SITE TRANSPORT

Cytotoxic drugs and related waste are often transported off-site from the generating premises to an appropriately licensed storage, treatment or disposal facility. Contracts with waste transporters and waste disposal sub-contractors must be documented and specify waste transport and disposal requirements under the POEO Act and Waste Regulation (NSW EPA) and must be consistent with other relevant regulations. PCBUs should also ensure that transport, packaging, labelling, documentation and the like comply with state transport regulations, the provisions of environmental protection legislation and local council by-laws. Appropriate licenses must also be held.

Those involved with transporting and handling cytotoxic waste must be protected from the risk of exposure to the waste. Control measures to eliminate or minimise the risk of exposure should be included in waste disposal contracts.

Control measures should include:

- use of personal protective equipment
- transport in a rigid-walled, puncture-resistant container with a secure lid – reusable bins are to undergo regular inspection to ensure they are in good condition and not split, cracked or otherwise damaged
- safe systems of work when collecting waste from storage areas, loading waste onto transport vehicles, securing contaminated loads and unloading at the treatment facility
- appropriate information (for example – any special transport requirements)
- use of labelling, signage and vehicle placards to identify contaminated waste
- development of emergency procedures in case of a spill or vehicle accident
- training of drivers and waste-handling workers
- use of designated transport vehicles for clinical or cytotoxic waste which should:
  - be used solely for that purpose
  - have a system for securing containers to prevent movement during transport
  - be designed to protect the driver and the public from the risk of exposure during transport and in the event of an accident
  - be safe to load, unload and clean.

For transport purposes, the waste generator must classify cytotoxic waste in accordance with the Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code), taking account of the potentially different properties of drug waste and patient waste. Cytotoxic waste may be classified as a Division 6.1 toxic substance or a Division 6.2 infectious substance.

If cytotoxic waste is classified as a dangerous good, it must be packaged, labelled, documented, handled and transported in accordance with the *Australian Code for the Transport of Dangerous Goods by Road and Rail* (ADG Code).

Air transport of cytotoxic waste must be in accordance with the International Air Transport Association (IATA) Dangerous Goods Regulations. Contact the Civil Aviation Safety Authority (CASA) or the airlines for specific advice.

### 10.8.1 Licences to transport

In NSW, cytotoxic waste is pre-classified as special waste and a licensed transporter must be used, subject to certain exceptions. The transporter of cytotoxic waste or a combined load of hazardous waste, restricted solid waste, liquid waste, clinical and related waste (including cytotoxic waste) or friable asbestos waste which involves loads of over 200 kg needs an environment protection licence to operate.

Required documentation must accompany each load of waste.

### 10.8.2 Vehicle signage

Licensed vehicles that are used to transport any volume of cytotoxic waste are subject to special requirements with regard to displaying information, as outlined in the ADG code. If the transporter is likely to convey both the cytotoxic (Division 6.1 toxic) and the clinical (Division 6.2 infectious) waste, the vehicle must display both the Division 6.1 and Division 6.2 dangerous goods label.

### 10.8.3 Other requirements for cytotoxic waste transportation

If the waste is transported from the premises, the consignor must provide the transporter with any required documentation and must accurately identify the waste.

Both the waste generator and the transporter have obligations and a general duty of care under work health and safety legislation.

Where waste transported from a premise is over 200 kg in quantity per load, the waste must be transported by a licensed transporter.

The Waste Regulation provides for exempting certain waste from tracking requirements. Movement of cytotoxic waste solely within NSW is exempt from tracking – see the NSW EPA website for details. However, when cytotoxic waste is transported outside of NSW, it must be tracked.

## 10.9 WASTE DISPOSAL AND TREATMENT

Waste treatment facilities receiving and treating hazardous waste, restricted solid waste, special waste including cytotoxic waste and liquid waste are required to hold environment protection licences under the POEO Act. A waste disposal facility that provides thermal treatment of any quantity of clinical and related waste must hold an environment protection licence.

### 10.9.1 Thermal destruction

Waste treatment must render the cytotoxic waste non-infectious and unrecognisable and must also meet NSW EPA requirements to protect the environment. Currently, thermal destruction treatment (1100° Celsius or higher) is the only acceptable technology for treating cytotoxic waste. If the waste consists of a mixture of cytotoxic and other waste, it should be incinerated at the temperature recommended for cytotoxic waste. All incinerators or other processes used for the thermal destruction or treatment of cytotoxic waste must be licensed by the NSW EPA and must satisfy the conditions of the environment protection licence.

### 10.9.2 Stockpiling cytotoxic waste

Stockpiling cytotoxic waste may be an alternative for an isolated area that has no access to a licensed incineration facility. The waste may be stockpiled and stored in a dedicated area until there is sufficient quantity to make it economical to transport the waste to licensed facility. Waste storage requirements as outlined in 10.7 Waste storage should be followed.

### 10.9.3 Record-keeping requirements

Record-keeping requirements relating to occupiers of waste facilities are outlined in Part 3 of the Protection of the Environment Operations (Waste) Regulation 2014. The generator, transporter and facility receiving the waste must keep records and the tracking documentation for four years and provide any reports to the NSW EPA as may be required.

## 10.10 SUMMARY OF CONTROL MEASURES

The following information will ensure all the options have been considered when implementing control measures.

<b>Controls covered in this chapter</b>	<b>Completed</b>
Setting-up a waste management strategy	<input type="checkbox"/>
Identifying, segregating and containing waste	<input type="checkbox"/>
Waste transport	<input type="checkbox"/>
Waste storage	<input type="checkbox"/>
Waste treatment and disposal	<input type="checkbox"/>
Personal protective equipment	<input type="checkbox"/>

<b>Control measures referred to elsewhere in these guidelines</b>	
Chapter 3	Risk Management
Chapter 4	Personnel Management
Chapter 5	Information, Instruction and Training
Chapter 9	Spill Management

# 11. CARING PATIENTS IN COMMUNITY SETTINGS

## 11.1 DOCTOR'S SURGERY AND AMBULATORY CARE FACILITIES

Patients may receive cytotoxic drug therapy in a doctor's surgery or ambulatory care facilities. Nursing, medical staff and carers such as family and friends may care for patients in these situations.

### 11.1.1 Managing risks

Health care establishments unable to provide facilities, equipment or a level of care as outlined in these guidelines should not undertake to care for patients receiving cytotoxic drug therapy.

If facilities are not available, patients should be transferred to a hospital or centre that has the required facilities, equipment and trained personnel.

See chapter 3 for a detailed outline of developing a risk management strategy.

### 11.1.2 Personnel management

All workers in a community setting who handle cytotoxic drugs and related waste should have a risk management program available to them. See chapter 4 for details.

Information should be provided to health care workers and carers who are pregnant or breastfeeding regarding precautions when dealing with cytotoxic drugs and related contaminated body wastes.

Workers who are pregnant, breast-feeding or planning parenthood and are involved in the preparation or administration of cytotoxic drugs or exposure to cytotoxic waste should be informed of the reproductive risks and possible effects on foetal development.

Those required to perform these duties may elect not to do so and appropriate and suitable alternative duties must be provided.

### 11.1.3 Information, instruction and training

PCBUs in a community setting have a duty to provide information, instruction and training to those who handle cytotoxic drugs and related waste.

See chapter 5 for further information.

### 11.1.4 Preparing and dispensing cytotoxic drugs

Pharmacy personnel may be involved in preparing and dispensing cytotoxic drugs. In community settings, drug preparation work should not be undertaken as it poses the greatest risk of occupational exposure to personnel.

Health care establishments that are unable to provide facilities, equipment or training as specified in these guidelines should not undertake to provide a cytotoxic drug service.

Alternative arrangements could include:

- purchasing and supplying prepared cytotoxic drugs in a single-dose delivery unit from a commercial source. It is not safe for local pharmacies and community workers or carers who handle cytotoxic drugs to reconstitute them if adequate risk control measures are not in place
- establishing supply arrangements with a health care facility that has the required facilities, equipment and trained personnel to provide prepared cytotoxic drug doses.

See chapter 6 for further information.

### 11.1.5 Administering cytotoxic drugs

Nursing and medical personnel and carers may be involved in administering cytotoxic drugs in community settings. Exposure while administering drugs may occur through:

- handling
- spills
- splashes to the skin or eyes
- inhalation of airborne contaminants that can be generated by the expulsion of air from a drug-filled syringe
- sharps injuries.

See chapter 7 for further information.

### 11.1.6 Managing cytotoxic contaminated body waste

See chapter 8 for information on managing and disposing of cytotoxic contaminated body waste.

See chapter 10 for information on developing a waste management strategy.

### 11.1.7 Spill management

Spills of cytotoxic drugs and related waste must be dealt with immediately as they present a high risk of exposure to workers.

See chapter 9 for information on developing a spills management strategy, training workers, maintaining spill kits and developing standard operating procedures for spills in health care settings.

## 11.2 CARING FOR PATIENTS AT HOME

The information in this section relates primarily to carers (such as – a patient’s family and friends). However, it is also relevant to residential care facility staff, community health care workers and general practitioners.

Some patients receive their cytotoxic drug therapy at home or in residential care facilities. However, the majority receive their therapy in some form of health care facility. Regardless of where cytotoxic drug therapies are administered, cytotoxic safety precautions, especially those related to handling contaminated body waste are an ongoing concern in a patient’s residence.

### 11.2.1 Role of the treating facility

Written information must be provided to residential care facility staff, community health care workers, general practitioners and where applicable, ambulance officers. Information must include:

- what cytotoxic drugs are administered
- the special care requirements
- the timeframes for excretion of the cytotoxic drugs in the patient’s body waste following administration of a dose (refer to Appendix 10)
- the safety precautions for those who are pregnant or breast feeding if dealing with cytotoxic drugs and related contaminated body waste.

### 11.2.2 Setting up a patient care area

The following facilities should be available in the home:

- hand-washing facilities
- laundry facilities
- access to a sewered toilet (although this may not be available in all rural areas)
- appropriate waste disposal (for example – cytotoxic waste bins).

A patient care area should be setup in a non-carpeted area of the home.

### 11.2.3 Drug transport

Containers used for transporting prepared cytotoxic drugs must be:

- hard-walled and robust
- made from moulded foam or another suitable packaging material that is capable of withstanding a shock that is equivalent to a drop of one metre onto a concrete surface
- securely closed and labelled with cytotoxic warnings
- when transported outside the facility, containers should be placed in the boot of the vehicle, not in the cabin space.

### 11.2.4 Maintaining controls

Standard operating procedures should be documented and should emphasise the need to:

- clean daily
- use a dedicated mop and bucket
- treat all equipment as potentially contaminated
- use personal protective equipment.

### 11.2.5 Equipment

The hospital or community health service should provide the patient and carer with written health and safety information. The information should include:

- instructions for dealing with a spill or leakage from administration sites and sets (Appendix 11)
- contents of a spill kit
- details about appropriate personal protective equipment
- specifications regarding approved containers for disposal of cytotoxic contaminated waste (see Chapter 12 for more details)
- details about impermeable mattresses and furniture protectors for incontinent patients.

### 11.2.6 Administering cytotoxic drug

The treating facility should provide the patient and carer with:

- appropriately packaged and labelled drugs
- information on how to store cytotoxic drugs at home
- information on the drugs being used and the side effects
- instructions on how to safely handle the drugs
- instructions on how to safely administer the drugs
- information on how to deal with accidental ingestion
- information on how to dispose of unwanted drugs.

### 11.2.7 Managing cytotoxic contaminated body waste

The treating facility should provide the patient, carer and relevant community workers with advice about:

- the routes of excretion and how long it takes to excrete the drug (see Appendix 10)
- disposing of cytotoxic contaminated body waste (such as – urine, faeces, vomitus, the contents of colostomy and urostomy bags and the like) into a household toilet by using a full flush and with the lid down
- cleaning a splash or spill of cytotoxic contaminated body waste while wearing two pairs of gloves. Clean-up contaminated waste, then wash affected area with water once the area has been rinsed and wiped with absorbent material and the detergent may be applied as a final step. With gloves still on, discard soiled cloths into a plastic bag, discard gloves into the bag, seal the bag and discard it into the household waste
- wash hands
- preventing the generation of aerosols when handling a patient's body waste by covering vomitus bowls or bed pan with lids
- avoiding skin contact with cytotoxic contaminated body wastes by wearing disposable gloves
- managing suspected personal contamination.

### 11.2.8 Waste management

Cytotoxic waste includes any residual cytotoxic drug that remains following a patient's treatment and any materials or equipment contaminated with cytotoxic drugs.

Cytotoxic waste generated in the home must be disposed of safely to reduce the risk of exposure to waste management workers. This waste may include dressings, nappies, incontinence aids, ostomy bags, catheters, catheter bags and the like. Community health care workers should remove these items following their visit. The waste should be disposed in a cytotoxic waste bin and taken back to the health care facility (in the boot of the vehicle) for disposal into a cytotoxic waste bin. Small amounts of waste generated by a patient or carer can be disposed of into a sealed plastic bag and then into the household rubbish.

The treating facility should inform the patient and carer about:

- what constitutes cytotoxic waste
- containing waste that is generated from drug administration (for example – in a dedicated container, such as a cytotoxic waste bin)
- keeping waste containers secure and appropriately labelled
- using and disposing of incontinence aids and disposable nappies.

### 11.2.9 Home laundering

The treating facility should inform the patient and patients carer about laundering contaminated linen. They should be told to:

- wear two pairs of disposable gloves
- wash contaminated items separately at the maximum cycle and in hot or cold water, then line dry
- once used, put the gloves into a plastic bag, then into the household garbage
- once laundered, contaminated linen can be reused.

### 11.2.10 Standard operating procedures

Standard operating procedures are safe work procedures. With the assistance of the treating facility, standard operating procedures should be developed. The procedures should emphasise the need to:

- advise carers, ambulance officers and hospital staff that the patient is undergoing cytotoxic drug treatment
- avoid skin contact with the patient's body substances
- prevent generation of aerosols when handling the patient's body waste
- dispose of waste, such as urine, faeces, vomitus, the contents of colostomy and urostomy bags, incontinence aids and disposable nappies as outlined in chapter 10
- contain waste generated from drug administration in a dedicated container
- keep waste containers secure and appropriately labelled
- clean-up spills immediately

- have written instructions on how to manage a spill in an ambulatory or home care situation
- have information on the contents of a spill kit contents
- provide precautionary information to carers who are pregnant or breast-feeding.

## 11.3 EMERGENCY PROCEDURES

Planning for emergencies is an essential part of risk management. Systems should be in place to manage sharps injuries, spills and personal contamination. Any incident should be reported so that the cause can be investigated and determined and follow-up action taken if required.

## 11.4 SUMMARY OF CONTROL MEASURES

The following information will ensure that all the options have been considered when implementing control measures.

Controls covered in this chapter	Completed
Key risk controls	<input type="checkbox"/>
Spills involving cytotoxic drugs	<input type="checkbox"/>
Laundering contaminated linen	<input type="checkbox"/>
Requirements for patient care at home or in community settings	<input type="checkbox"/>

Control measures referred to elsewhere in these guidelines	
Chapter 3	Risk Management
Chapter 4	Personnel Management
Chapter 5	Information, Instruction and Training
Chapter 6	Preparing and Dispensing Cytotoxic Drugs
Chapter 7	Administering Cytotoxic Drugs
Chapter 9	Spill Management
Chapter 10	Waste Management
Appendix 9	Personal Protective Equipment
Appendix 10	Guidelines for safe handling of cytotoxic contamination excreta
Appendix 11	Cytotoxic Drug Precautions Alert Proforma
Appendix 12	Cytotoxic Drug Home Spills Proforma

## 12. CYTOTOXIC DRUGS IN VETERINARY PRACTICES

Veterinarians, veterinary nurses, animal attendants and cleaners may be involved in handling cytotoxic drugs and related waste during the treatment and care of animals. The risk of exposure to cytotoxic drugs during their preparation and administration is much greater than during occasional contact, such as when carers handle pets or walk on grass where a treated animal may have relieved itself.

If facilities are not available, alternative arrangements should include transferring animals to a practice that has the required facilities, equipment and trained personnel.

Exposure may occur when:

- preparing drugs
- administering drugs
- caring for treated animals
- there are spills of cytotoxic drugs or animal waste
- the surface is contaminated

Exposure may occur through:

- skin contact with cytotoxic drugs or animal waste
- mucous membranes
- inhalation of aerosols
- sharps injuries.

Workplace design and the use of clean rooms, drug safety cabinets and other specially designed equipment should be in place to facilitate the safe handling of cytotoxic drugs and related waste. Education, training and supervision are crucial to ensure that control measures and safe work practices are developed, understood, implemented, maintained and periodically reviewed.

### 12.1 INFORMATION, INSTRUCTION AND TRAINING

PCBUs in veterinary practices have a duty to provide information, instruction and training to those who handle cytotoxic drugs and related waste.

PCBUs should also ensure that only workers who have received appropriate training and have attained the required level of proficiency to handle cytotoxic drugs and related waste.

Advice on the use of cytotoxic drugs should also be provided to carers, volunteers and others such as contractors who are not staff.

The necessary training should reflect the level of exposure as well as the anticipated exposure. The training program should be evaluated to assess its effectiveness. How tasks are undertaken should be monitored to determine whether control measures are appropriate and to validate competencies over time by checking that people remain competent to carry out their job.

PCBUs must keep records of training for at least five years after the date of creation of that record.

The treating facility should pass on instructions, information and training to community health care workers and carers about special precautions to be taken with cytotoxic drugs and the management of spills.

See chapter 5 for further information.

### 12.2 PERSONNEL MANAGEMENT

Those handling cytotoxic drugs in a veterinary practice include:

- veterinary surgeons and veterinary nurses
- laboratory staff
- patient transport personnel
- animal maintenance personnel
- cleaners
- cytotoxic drug couriers and porters
- waste handlers
- animal carers.

Workers who are pregnant, breast-feeding or planning parenthood and are involved in the preparation or administration of cytotoxic drugs or exposure to cytotoxic waste should be informed of the reproductive risks and possible effects on foetal development.

Those required to perform these duties may elect not to do so and appropriate and suitable alternative duties must be provided.

See chapter 4 for a detailed outline of personnel management.

## 12.3 MANAGING RISK

In work health and safety, the risk management process follows a logical progression involving identifying the hazard, assessing the risk and controlling the risk. The information should be used to design a risk management strategy. Workers should be consulted at every stage of the risk management process as required under the WHS Act.

The risk assessment determines whether there is a risk to workers' health from using cytotoxic drugs. The risk assessment may be done for a work process and may cover more than one cytotoxic drug. Appendix 6 provides an example of the type of content that may be required in a written risk assessment for cytotoxic drugs.

Once workplace risks are identified and assessed, appropriate control measures would need to be put in place.

The following risk management process should be undertaken:

- identify cytotoxic drugs used and stored at the workplace – useful information that may be added to a hazardous chemicals register is provided in Appendix 5
- assess the risks using the following process:

Step 1: decide who will carry out the risk assessment

Step 2: obtain and review information about cytotoxic drugs used

Step 3: evaluate the nature of the work involving cytotoxic drugs

Step 4: evaluate the risks

Step 5: record, review and revise the risk assessment

- control the risk.

See chapter 3 for a more detailed outline of developing a risk management strategy.

### 12.3.1 Good practice controls

Examples of 'good practice' controls:

- refer animals for cytotoxic drug treatment and care to a veterinary practice equipped to provide the service
- review health and safety information about cytotoxic drugs before making a decision to purchase them
- purchase cytotoxic drugs of appropriate dosage in a ready-to-use form to eliminate drug preparation work
- purchase cytotoxic drugs in the safest form available
- use a dedicated and isolated place for cytotoxic drug treatment within the veterinary facility
- ensure the primary clinician and nurse restrict personnel in the chemotherapy treatment areas to those who have had appropriate training
- ensure there are appropriate warning signs on doors and in treatment areas
- avoid hosing urine with a pressure hose so as not to create aerosolisation.

These control options should be considered a priority. A policy may assist to build these control measures into the health and safety management system of the practice.

## 12.4 DETERMINE WHAT IS NEEDED FOR A DRUG TREATMENT FACILITY

Determine what services will be offered. They may include:

- drug preparation
- drug administration
- animal care following treatment.

If facilities are not available, alternative arrangements should include transferring patients to a veterinary practice or hospital that has the required facilities, equipment and trained personnel to care for patients.

The use of carpets is not recommended in a cytotoxic drug administration area.

### 12.4.1 Information for veterinary staff

The veterinary practice should provide the following written information:

- the reasons for taking precautions when handling cytotoxic drugs and related waste
- precautions to take with interaction between the animal and staff particularly women who are pregnant or breast feeding
- how to store cytotoxic drugs
- equipment which may be needed for the animal's care
- route of excretion of drugs
- disposal of body waste
- the approximate duration that cytotoxic residues may be excreted after drug administration
- spills procedures for cleaning up
- laundering contaminated bedding
- emergency procedures for accidental exposure
- how to dispose of drugs no longer needed.

Training in the management of spills should be provided to those involved with cytotoxic drugs in the veterinary practice.

### 12.4.2 Emergency procedures

Planning for emergencies is an essential part of risk management. Systems should be in place to manage cytotoxic drug spills, sharps injuries and personal contamination. Any incident should be reported to management and considered so that the cause can be investigated and determined and follow-up action taken if required.

For further information on emergency procedures involving exposure to workers, see chapters 9 and 10 on spill management and waste management.

## 12.5 PREPARING AND DISPENSING CYTOTOXIC DRUGS

There is a significant risk of exposure during the preparation and administration of cytotoxic drugs. Exposure is more likely to occur to concentrated cytotoxic drugs.

Workplace design, use of clean rooms, drug safety cabinets and other specially-designed equipment should be in place to facilitate the safe handling of cytotoxic drugs. Where facilities do not have the recommended purpose-designed cleanroom suite, alternative arrangements should be made to obtain the cytotoxic drugs ready to use single dose form.

Consider the following precautions:

- set aside a dedicated space
- protective gloves
- respirator
- eye protection
- absorbent pad
- draft free area
- use chemotherapy products such as sealed systems for dispensing where available.

### 12.5.1 Labelling and packaging of cytotoxic drugs

Appropriate warning labels should be on all cytotoxic drug containers, including syringes, intravenous bags and the like.

The name of the cytotoxic drug, dose, expiry date and the name of the fluid in which it is reconstituted should be included on the label. All containers should identify the contents as cytotoxic drugs and oral medications should be labelled 'do not cut or crush'.

Cytotoxic drugs should be packaged as follows:

- kept in a labelled, sealed, leak-proof container with outer bags heat-sealed
- the container should provide protection from light where required
- the drugs should be protected against breakage in transit
- leakages should be contained and absorbed if breakage occurs
- tablet containers should have childproof lids
- tablet containers should be labelled 'do not crush'
- safe handling instructions should accompany the package
- packaged in a hard-walled, robust container capable of withstanding shock when in transit.

## 12.5.2 Drug storage

Cytotoxic drugs in storage must be identifiable by all staff. It is recommended that a dedicated clearly marked storage area, including refrigeration be available for cytotoxic drugs. The quantities of drugs stored should generally be restricted to those required for short-term use. Areas where cytotoxic drugs are stored must have a current safety data sheet for each drug in the area. Storage should be secured and access limited to authorised personnel. Unpacking of cytotoxic drugs should be carried out in this same dedicated storage area.

See chapter 6 for further information.

## 12.6 DRUG ADMINISTRATION

A dedicated and isolated place within the veterinary practice should be used for cytotoxic drug treatment. It should be a secure area that provides restricted access.

Specific operating procedures for a veterinary practice include:

- ensuring that parenteral or oral cytotoxic drugs are administered under the supervision of a registered veterinary practitioner
- using signs to identify animals receiving cytotoxic drug treatment

Key risk control measures include:

- not undertaking a drug administration service unless control measures can be provided
- using closed administration devices
- requiring drugs intended for administration to be appropriately packaged, labelled and ready for administration
- using diluted cytotoxic drugs where possible
- providing secured, labelled storage of waste and sharps containers to minimise exposure to cytotoxic waste
- training and education about the side effects of cytotoxic drugs
- using personal protective equipment.

See chapter 7 for further information.

## 12.7 CYTOTOXIC DRUG EXCRETION AND MANAGING ANIMAL WASTE

Significant exposure to cytotoxic drugs can occur from animal waste, especially when handled on a regular basis. Cytotoxic drugs are primarily eliminated from the animal by renal and hepatic excretion. All body substances may be contaminated with either the unchanged drug or active drug metabolites.

The period during which body substances may be contaminated with cytotoxic drugs will differ for individual drugs and animals. For animals, the approximate duration of excretion of cytotoxic drugs or their active metabolites is not readily available for many drugs. However, two drugs of particular concern are cisplatin and carboplatin where the majority of the active drug is also excreted in the urine. Appendix 10 deals with excretion rates in humans and it may provide a useful approximation for animals.

## 12.8 SPILL MANAGEMENT

A spill management strategy should include a spill kit. Spills of cytotoxic drugs and related waste may occur in any area where they are used or handled. Spills may result in the contamination of floors, work surfaces, equipment, bedding and clothing. Workers, carers and other animals may be affected. Procedures should be developed after considering the local work area and environment.

Identify all areas where there is a risk of a cytotoxic spill including all areas where cytotoxic drugs and related waste are handled, stored, transported or disposed.

Safe work policies and practices should be developed, understood, implemented and maintained by all those who handle cytotoxic drugs and those who may be involved in managing spills.

Training in spill containment and decontamination procedures must be provided to those who are likely to be involved in spill management.

Appropriate locations for storing the spill kit should be selected and sign-posted appropriately. The spill kits must be reviewed routinely to ensure the contents have not deteriorated. See section 9.4 for information on spill kit contents.

Water can be used for cleaning, rinsing or dampening a cytotoxic drug spill. Household detergent should also be made available for cleaning-up cytotoxic drug spills.

See chapter 9 for further information.

## 12.9 ANIMAL CARE

Particular attention should be given to preventing environmental contamination as contaminated excreta is not as easily contained in animals as it is for humans. Significant exposure to personnel can occur due to the continuous exposure to animal excreta during regular handling and cleaning of cages.

Care should be taken when handling contaminated materials such as bed linings and cages used for chemotherapy-treated animals because the active drug is excreted in significant quantities (for example – cisplatin in urine).

Pregnant and breast-feeding women should not be involved in cleaning the cages of animals undergoing chemotherapy treatment.

See chapter 8 for further information.

### 12.9.1 Setting-up an animal care area

When setting-up an animal care area, consider:

- allocating a secure area that identifies it is a restricted access area only for authorised personnel
- allowing sufficient room for personnel to move
- providing secure storage of waste
- setting-up a system for obtaining and keeping health and safety information, such as safety data sheets in a place accessible to workers.

### 12.9.2 Equipment

Where possible, equipment that should be provided includes:

- animal cages that are designed to contain and flush excreta directly into the sewerage system
- sealable, labelled bags to contain waste products
- a spill kit
- absorbent pads for cleaning.

### 12.9.3 Standard operating procedures

Standard operating procedures are safe working procedures. Standard operating procedures should be developed and should emphasise the need to:

- place a warning sign on animal cages stating that the animal is 'receiving cytotoxic drug therapy'
- use purpose-dedicated equipment
- clean equipment immediately after use with an appropriate cleaning detergent
- avoid skin contact with animal excreta and body fluids
- keep animal cages clean
- adopt cleaning techniques that contain waste
- prevent the generation of aerosols (such as – hose gently, do not use pressure hose)
- ensure that animals are immediately washed down if they become contaminated and avoid the generation of aerosols
- use labelled purple coloured bins for cytotoxic waste
- dispose of cytotoxic waste in cytotoxic waste bins.

### 12.9.4 Personal protective equipment

When caring for animals, use the following personal protective equipment:

- coverall or gown (preferably disposable)
- protective gloves
- protective eyewear
- rubber boots
- waterproof apron
- respirators.

This equipment is suitable to wear when cleaning cages contaminated with animal excreta from animals receiving cytotoxic drugs.

See Appendix 9 for further information.

## 12.10 CONTAMINATION OF WORKERS

### 12.10.1 Contamination of clothing and personal protective equipment

- Immediately remove outer gloves, gown and any contaminated clothing
- Place disposable personal protective equipment in the cytotoxic waste bin
- Contaminated clothing should be separately bagged and machine washed separately and line dried
- Remove and dispose of inner gloves.

### 12.10.2 Direct exposure of workers – penetrating injuries, skin and other body contact

- Wash the affected skin with soap and flush thoroughly with copious amounts of water
- Do not administer antiseptic or anaesthetic drops or ointments
- Report to supervisor immediately
- Seek immediate medical advice and further medical attention as necessary
- Document incidents.

### 12.10.3 Mucosal exposure of workers – eyes

- Immediately flood the affected eye with an isotonic saline solution for at least 15 minutes – continuous irrigation may be facilitated through use of an IV infusion set connected to IV normal saline
- Report to supervisor immediately
- Seek immediate medical advice and further medical attention as necessary
- Document incidents.

## 12.11 REPORTING PROCEDURES

PCBUs must have a system in place for workers to report any spill or worker contamination as soon as practicable. Supervisors should be notified immediately and the type of incident and the procedures taken to manage the spill should be recorded (possibly in a spill register).

In cases of spills involving cytotoxic drugs a medical review with a medical practitioner should be arranged. Consideration should be given to providing medical attention and conducting biological monitoring for exposure.

### 12.11.1 Notification of incidents involving cytotoxic drugs to SafeWork NSW

SafeWork NSW must be notified of any significant spill involving cytotoxic drugs that may pose significant risk to the worker's health. This is a legal requirement of the PCBU and/or occupier of a workplace.

For further information on notification requirements, refer to *The WHS Incident Notification: Fact Sheet, SafeWork NSW*.

### 12.11.2 Authorisation of cyclophosphamide use from SafeWork NSW

Cyclophosphamide is a restricted carcinogenic chemical under the WHS Regulation. Therefore, its use must be authorised by SafeWork NSW.

See *Work involving use of carcinogenic chemicals- guidelines for Authorisation for Work Involving use of carcinogenic chemicals – Guide for applicants for authorisation to use, handle or store prohibited or restricted carcinogens*.

## 12.12 MANAGING CYTOTOXIC CONTAMINATED WASTE

Cytotoxic waste includes any residual cytotoxic drug and active metabolites that remain following patient treatment and any materials or equipment contaminated with cytotoxic drugs.

Cytotoxic contaminated waste is a hazard and workers must be protected from the risk of exposure at all stages of the waste management process from generation to destruction. A waste

management strategy should include the key elements of identification, segregation and containment of waste, transport, storage and disposal of waste and personal protective equipment. The strategy should define safe systems of work such as standard operating procedures and spill management and include training and information for all those handling and transporting contaminated waste.

As cytotoxic waste is hazardous to human health and the environment, NSW Environment Protection Authority (NSW EPA) regulates this type of waste.

For more information on NSW EPA legislative requirements, waste containment, sharps containment and waste segregation, see chapter 10.

### 12.12.1 Waste identification – labelling requirements

Contaminated waste identification is essential to minimise the risk of exposure to cytotoxic materials and to ensure the safe and correct disposal of cytotoxic waste.

All cytotoxic waste should be placed into compliant bags or containers that are appropriately identified. AS/NZ 3816 *Management of clinical and related wastes* specifies the following colours and symbol coding for cytotoxic waste:

- containers and bags must be purple
- the container must have a white label with symbol of a cell in late telophase as below:

**Cytotoxic drug**



- the correct labelling words are 'CYTOTOXIC WASTE'
- packaging for transport off-site must be approved and labelled in accordance with the ADG Code (refer to Section 10.8 of this guide)

With the implementation of Globally Harmonised System of Classification and Labelling (GHS), under WHS Regulation, a new GHS hazard pictogram was introduced to communicate health hazards of workplace chemicals. This pictogram should appear on labels of cytotoxic drugs supplied to workplaces from 1 January 2017.



Storage areas should also have appropriate signage to identify cytotoxic waste from general or infectious waste, particularly if different waste management contractors are used.

Hazardous waste products must be identified and correctly classified so far as is reasonably practicable. The label on a container of hazardous waste must include the words 'CYTOTOXIC WASTE' clearly displayed and where possible a product identifier, the details of either the manufacturer or the importer and a hazard pictogram and hazard statement.

See section 2.2.4, 6.6 and 10.3.1 of this guide for further details on labelling requirements for cytotoxic drugs and related waste.

### 12.13 ANIMAL CARE AT HOME

Carers at home may be involved in administering cytotoxic drugs and caring for animals that receive cytotoxic drug therapy.

Compared to handling concentrated cytotoxic drugs, the risk of exposure is usually significantly lower during occasional contact, such as when carers handle pets undergoing chemotherapy, handle excreta or walk on grass where the animal may have relieved itself.

When pregnant women or young children are at home, additional care must be taken while administering the drugs or handling contaminated materials such as bedding and linen.

Contamination involving cytotoxic drugs is a concern and administration must not be carried out in the kitchen or bathroom.

Laundering of contaminated linen may be undertaken in some situations but suitable care must be taken when handling (see 12.13.6 for more details).

### 12.13.1 Role of treating facility

Owners and carers of animals that are receiving cytotoxic drug therapy should be provided with written information about the drugs and precautions to take during the time the drug may be excreted. They should also be told about the special requirements of the particular drug used.

The treating facility should:

- ensure that cytotoxic drugs are appropriately packaged and labelled
- provide written instruction to home carers
- provide advice on laundering contaminated linen at home.

### 12.13.2 Information for carers

Home carers should be told, in writing:

- the reasons for taking precautions when handling of cytotoxic drugs and related waste
- to avoid interaction between the animal and those in the home, particularly small children and women who are pregnant or breast-feeding
- how to store cytotoxic drugs at home
- about the equipment that may be needed for the animal's care
- the route of excretion of the drugs
- the approximate duration that cytotoxic residues may be excreted after drug administration
- about spills and procedures for cleaning-up
- how to dispose of contaminated clothing and bedding, and how to launder
- about emergency procedures for accidental exposure or accidental ingestion of cytotoxic drugs
- how to dispose of drugs that are no longer needed.

### 12.13.3 Equipment used in animal care

The following equipment is recommended:

- paper towelling
- household cleaning detergent
- a small shovel or implement to scoop-up faeces
- a clip-lock plastic bag
- waterproof gloves.

### 12.13.4 Written procedures

Written procedures should be developed with the assistance of the treating facility and should emphasise the need to:

- administer the drugs without breaking or crushing the tablet (as it generates dust and contamination)
- use protective gloves
- monitor and contain the urinating habits of the animal
- dilute excretions by gently hosing affected areas
- clean-up faeces by scooping with a small shovel and placing it in a clip-lock plastic bag, then dispose of it
- clean or discard soiled articles after use
- wash hands following any contact with cytotoxic drugs, animals receiving treatment or related waste products
- dispose of contaminated items such as gloves in the normal household waste system.

### 12.13.5 Spills

Spills of cytotoxic drugs and related waste must be dealt with immediately as they present a high risk of exposure. Spills may occur in all areas where cytotoxic drugs and related waste are handled, stored, transported and disposed. People in the immediate vicinity of a cytotoxic spill should be alerted immediately that a spill has occurred and requested to stay clear away from spills. Guidelines from the treating veterinary clinic should be followed.

### 12.13.6 Laundering

Dispose all the heavily contaminated linen and where possible, use disposable materials during the period of cytotoxic drug treatment.

Owners and carers should be told to:

- wear two pairs disposable gloves when handling contaminated linen
- wear gloves when emptying contaminated linen from a container into the washing machine
- wash contaminated linen separately at maximum cycle capacity, in hot or cold water, then line dry
- place gloves in a plastic bag and discard into household garbage.

Once laundered, linen can be reused.

## 12.14 SUMMARY OF CONTROL MEASURES

The following information may be used to help ensure all the options have been considered when implementing control measures.

Controls covered in this chapter	Completed
Managing risk	<input type="checkbox"/>
Good practice controls	<input type="checkbox"/>
Setting-up a drug treatment facility	<input type="checkbox"/>
Preparing, dispensing and administering cytotoxic drugs	<input type="checkbox"/>
Use of suitable equipment	<input type="checkbox"/>
Operating procedures	<input type="checkbox"/>
Personal protective equipment	<input type="checkbox"/>
Contamination	<input type="checkbox"/>
Managing cytotoxic contaminated waste	<input type="checkbox"/>
Animal care at home	<input type="checkbox"/>

Control measures referred to elsewhere in these guidelines	
Chapter 3	Managing Risk
Chapter 4	Personnel Management
Chapter 5	Information, Instruction and Training
Chapter 6	Preparing and Dispensing Cytotoxic Drugs
Chapter 7	Administering Cytotoxic Drugs
Chapter 9	Spill Management
Chapter 10	Waste Management
Chapter 11	Caring Patients in Community Settings

# APPENDIX 1 – GLOSSARY

## A

**absorption:** a route of exposure – see dermal absorption, mucosal.

**administration (of drugs):** the giving of cytotoxic drugs to a patient – common methods include parenteral, oral and topical administration.

**administrative control:** a type of control measure which involves minimising the risk through the use of procedures or instruction (for example – SOPs, labelling, training).

**ADG Code:** *Australian code for the transportation of dangerous goods by road and rail*, as published by the Commonwealth of Australia and amended from time to time.

**aerosol:** very fine droplets or particles that are homogeneously dispersed in air.

**ALARA:** ‘as low as reasonably achievable’.

**alginate bag:** bag made of artificial fibres spun from a constituent of kelp – the fibres become gelatinous when moist and so are biodegradable.

**allergic:** unduly sensitive to some substances

**ampoule:** small sealed bulb, usually of glass, typically designed to contain a single dose of a drug for injection.

**aseptic manipulation:** activity performed so as to exclude micro-organisms.

**aseptic suite:** work space free from micro-organisms in the working area.

**auto-immune disease:** alteration of the function of the immune system causing it to attack the body’s own cells.

## B

**biological monitoring:** measurement and evaluation of hazardous chemicals or their metabolites in the body tissue, fluids or exhaled air of a person.

**body substances:** includes urine, faeces, vomitus, bile, sweat, blood and fluid drained from body cavities.

## C

**carers:** Patient’s family members/friends/volunteers who are involved in providing care and support for the patient.

**carcinogen:** substance or physical agent with the potential to cause cancer in certain circumstances or to make cancer more likely to occur.

**catheter bag (urinary):** a urine-collecting bag connected to a tube inserted into the bladder.

**code of practice:** an approved industry code of practice is a practical guide to PCBUs and others who have obligations under the *Work Health and Safety Act 2011* (WHS Act) and the *Work Health Safety Regulation 2011* (WHS Regulation) with respect to work health, safety and welfare.

An approved industry code of practice is intended to be used in conjunction with the requirements of the WHS Act and the WHS Regulation but does not have the same legal force. An approved industry code of practice is advisory rather than mandatory. However, in legal proceedings under the WHS Act or WHS Regulation, failure to observe a relevant approved industry code of practice is admissible as evidence concerning an offence under the WHS Act or WHS Regulation.

**colostomy:** diversion of faeces away from a diseased or defective lower bowel through a surgically created opening in the skin of the abdominal wall.

**community care:** care of patients in a domestic or domiciliary situation.

**consultation:** discussion with workers regarding workplace health and safety issues.

**container:** anything in or by which substances are, or have been, wholly or partly encased, covered, enclosed, contained or packed (whether empty, partially full or completely full), but does not include a bulk container, namely:

- in the case of a container designed to hold gas – a container that has a capacity of more than 500 litres, or
- in the case of a container designed to hold either solids or liquids – a container that has either a net mass of more than 400 kilograms or a capacity of more than 450 litres.

**control measure:** a measure implemented to prevent or minimise the risk of injury from a particular hazard.

**cytogenic:** to do with the formation of cells.

**cytotoxic:** harmful to cells of the body, particularly those that reproduce rapidly.

**cytotoxic contaminated body waste:** Body fluid/substance that are contaminated with cytotoxic drugs following drug administration.

**cytotoxic drug:** drugs that cause the death of certain cells and that are used to treat conditions such as cancer, rheumatoid arthritis, multiple sclerosis, and some ophthalmic conditions.

**cytotoxic spill:** a spill of cytotoxic drugs or related wastes.

**cytotoxic waste:** waste contaminated with cytotoxic drug or metabolites – it includes any residual cytotoxic drug that remains following patient treatment and any materials or equipment potentially contaminated with cytotoxic drug.

## D

**dermatitis:** inflammation of the skin

**dermal absorption:** a route of exposure – taking in cytotoxic drug or related waste through the skin.

## E

**elimination:** a type of control measure in which the hazard is eliminated.

**engineering control:** a type of control measure which uses technological means to isolate or remove hazards.

**EPA:** Environment Protection Authority.

**equipment:** see plant.

**exposed:** a person is exposed to a hazardous chemical if they are in a situation where they absorb or are likely to absorb the substance by ingestion, inhalation or through the skin or mucous membrane – exposure may also occur as a result of percutaneous injuries.

**exposure standards:** exposure standards are the calculated airborne concentrations of individual chemical substances which, according to current knowledge, should neither impair the health of, nor cause undue discomfort to, nearly all workers – the exposure standards serve as guides only and the control measures selected must ensure that the applicable exposure standard is not exceeded.

**extravasation:** unplanned escape of a liquid from a vessel or tube into surrounding body tissues.

## F

**faeces:** waste from the intestines.

**foetal:** to do with a foetus.

**foetus:** developing baby in the womb (except for the very early stage, when it is called an embryo).

## G

**GHS:** Globally Harmonised System for Classification and Labelling of Chemicals.

## H

**hazard:** a hazard is the potential for a substance to adversely affect the health and safety of people in the workplace.

**hazardous chemical:** chemicals listed in the List of designated hazardous chemicals produced by Safe Work Australia (SWA), or a drug that meets the criteria for a hazardous chemical as set out in the *List of designated hazardous chemicals* by Safe Work Australia.

**note:** the list and the criteria are now part of the electronic database called the *Hazardous Chemicals Information List* (HCIL) administered by Safe Work Australia.

**hazardous chemicals register:** regularly maintained list of the product names of all hazardous chemicals used in a workplace accompanied by a safety data sheet, which is not older than five years for each chemical.

**hazard pictogram:** hazard pictogram means a graphical composition, including a symbol plus other graphical elements, that is assigned in the GHS to a hazard class or hazard category.

**hazard statement:** means a statement assigned to a hazard class or hazard category describing the nature of the hazards of a hazardous chemical including, if appropriate, the degree of hazard.

**HAZCHEM Code:** code reflects the initial emergency response recommended in a dangerous situation such as leakage, spillage or fire involving the dangerous good to which it relates. The emergency action codes which are specified in Appendix 4 of the ADG Code for cytotoxic drugs are 2PE – which means use a water fog (2), full body protection, including breathing apparatus (P) and consider evacuating the area in case of fire (E).

**health care facility:** includes hospitals, clinics, ambulatory care facilities and medical practices.

**health monitoring:** the monitoring of persons to identify changes (if any) in their health due to exposure to a hazardous chemical, and includes biological monitoring, but does not include the monitoring of atmospheric contaminants.

**HEPA [high efficiency particulate air] filter:** filter that is made to be at least 99.97 percent efficient in removing an aerosol of particles with a diameter of 0.3 micrometres when tested with a standardised procedure.

**hepatic excretion:** removal of a chemical from the blood by the liver – from the liver, the excreted chemical passes into the intestine and the faeces.

## I

**IMDG Code:** The International Maritime Dangerous Goods (IMDG) Code provides for the safe transportation of dangerous goods by vessel and marine pollution prevention – the code contains advice on terminology, emergency response, handling, labelling, markings, packaging, placarding, stowage and segregation.

**immune system:** system of cells and special proteins throughout the body that serves to resist and overcome infection, and attack foreign matter (for example – transplants) and abnormal cells (for example – early cancer).

**immuno-suppressive:** relating to a substance or procedure that lessens or prevents adequate response of the immune system.

**incipient:** beginning, in early stage.

**infusion:** therapeutic introduction of a fluid other than blood into a vein.

**ingestion:** a route of exposure – taking in cytotoxic drug or waste through the mouth.

**inhalation:** a route of exposure – breathing in cytotoxic drug or waste in aerosol or powder form.

**injection:** a sterile fluid preparation of a medicament to be used parenterally (such as – by injection, subcutaneously, intramuscularly, intravenously or intrathecally).

**in-situ:** in its original place.

**intraperitoneal:** administered by entering the peritoneum.

**intrapleural:** the cavity that lies between the two layers of the pleura, a thin membrane that surrounds the lungs and lines the internal surfaces of the chest cavity.

**intrathecal injection:** injection into the fluid-filled space that surrounds the spinal cord.

**[IV] intravenous infusion:** introduction of a liquid into a vein through a hollow needle or flexible tube over a period of time.

**intravesical infusion:** introduction of liquid through a hollow needle or tube into the urinary bladder.

**isolation:** a type of control measure that uses barriers to prevent exposure.

## L

**lyophilised cytotoxic drugs:** cytotoxic drugs preserved during manufacture by being rapidly frozen and dehydrated in a vacuum – they do not require refrigeration, although sterile distilled water needs to be added before use.

## M

**manufacturer:** an obligation holder under the WHS Act.

**metabolites:** what a substance changes into when acted upon by the normal chemical processes that go in a person's body.

**MIMS:** a medical publication and reference on drugs published by CMPMedica Australia.

**mucosal absorption:** a route of exposure – taking in cytotoxic drug or waste through mucus membranes (for example – in the mouth, eyes or nose).

**mutagen:** chemical with the potential to change DNA, the part of a body cell that controls its growth and multiplication – being a mutagen also gives a chemical the potential to cause cancer.

## O

**obligation:** a legal requirement to take specified action under the WHS Act or WHS Regulation.

**occupational exposure:** exposure to cytotoxic drugs during a work activity.

**oncology:** relating to cancer.

**oral:** a method of administration – usually in the form of tablets or capsules.

**ostomy:** a surgically created artificial opening, usually created through the abdominal wall to allow the discharge of bodily wastes.

## P

**parenteral:** administration of cytotoxic drug by methods other than through alimentary canal, such as intravenous, subcutaneous, intramuscular, intrapleural, intraperitoneal, intravesical.

**PCBU:** person conducting a business or undertaking.

**PEG:** percutaneous endoscopic gastrostomy.

**percutaneous injury:** a route of exposure – taking in cytotoxic drug or waste through a puncture of the skin.

**personal protective equipment:** clothing, equipment and chemicals designed to be worn by a worker to protect them from the risk of injury or illness.

**pH:** measure of how strongly acidic or basic a chemical is when dissolved in water – acids have a pH less than 7; bases have a pH greater than 7.

**place of work:** premises where persons work (under the WHS Act).

**plant:** includes machinery, equipment, appliances, pressure vessels, implement and tools; personal protective equipment; and any components, fittings, connections and accessories to plant.

**PPE:** abbreviation for personal protective equipment.

**premises:** under the WHS Act, includes any place, and in particular includes:

- any land, building or part of any building
- any vehicles, vessel or aircraft
- any installation on land, on the bed of any waters or floating on any waters
- any tent or movable structure.

**precautionary statement:** means a phrase prescribed by the GHS that describes recommended measures to be taken to prevent or minimise the adverse effects of exposure to a hazardous chemical or the improper handling of a hazardous chemical.

**preparation of drugs:** handling of cytotoxic drugs up to the stage of administration to a patient – includes manufacture, forming tablets and capsules, preparing a pre-measured single dose unit (for example – drawing liquid cytotoxic drug into a syringe from a vial), and crushing or dissolving tablets or emptying capsules to prepare part doses abbreviation for polyvinyl chloride.

**PVC:** a common type of plastic with good resistance to water, acids and alkalis.

## R

**renal excretion:** removal of a chemical from the blood by the kidneys – from the kidneys, the excreted chemical passes into the urine.

**reproducible test result:** extent to which multiple measurements of a characteristic by a particular test are likely to be in agreement.

**respirable:** aerosol whose particle size and density enables it to reach the alveoli of a person's lungs by traversing the body's narrowest air tubes.

**respirator:** respirator used as personal protective equipment.

**respiratory protective equipment:** equipment that is designed to prevent inhalation of contaminated air.

**risk:** a risk is the likelihood that a chemical or hazard will cause illness or injury in the conditions of its use – the risk to health and safety usually increases with the severity of the hazard, the amount of hazardous chemicals used and the duration and frequency of exposure.

**risk assessment:** evaluation of the probability that an adverse health effect may occur under the conditions that are likely to develop – a risk assessment of the use of a chemical will take account of its toxicity, the frequency and duration of exposure, control measures in use (engineering, administrative, or personal protective equipment) and their effectiveness, and conditions of use.

**risk control:** control of factors associated with an increase in the probability of a toxic effect occurring – there is an ordered priority for selection of the means to minimise the level of an occupational exposure; ranked from most desirable form of control to least desirable: elimination, substitution, isolation, engineering controls (for example – local exhaust ventilation), administrative controls, personal protective equipment).

**risk management:** analysis and judgment that uses the results of risk assessments to produce decisions about environmental actions to be initiated (such as – the giving of priorities to various risks, the delivery of risk-averting outcomes and the continuing audit of outcomes and trends).

## S

**safety data sheet (SDS):** means a document that describes the identity, properties (that is to say chemical and physical properties and health hazard and environmental hazard information), uses, precautions for use, safe handling procedures and safe disposal procedures of a hazardous chemical.

**self-employed person:** a person who works for gain or reward otherwise than under contract of employment or apprenticeship, whether or not employing others (WHS Act).

**sensitive test:** diagnostic or screening test that correctly indicates disease is present in a high proportion of persons tested that do have the disease.

**sharp:** article capable of piercing skin, such as a used needle or fragment of broken glass that has been in a health care setting.

**sharps:** pointed or cutting implements that are capable of inflicting a penetrating injury and include hypodermic, intravenous or other medical needles, Pasteur pipettes, scalpel blades, lancets, scissors, glass slides and broken glass such as vials, bottles and laboratory glass.

**SHPA:** Society of Hospital Pharmacists of Australia.

**SOP:** see standard operating procedure.

**special waste:** NSW EPA, no longer pre classifies, waste on the Poison list as hazardous waste. Under the waste classification guidelines special waste includes ‘clinical and related waste’. Clinical and related waste includes ‘pharmaceutical, drug or medicine waste’ meaning, ‘waste generated by activities carried out for business or other commercial purposes and that consists of pharmaceutical or other chemical substances’ specified in the Poisons List made under section 8 of the *Poisons and Therapeutic Goods Act 1966*.

**specific test:** diagnostic or screening test that correctly indicates disease is absent in a high proportion of persons tested that do not have the disease.

**standard operating procedure(s):** a set of instructions or steps to be followed to complete a job safely and in accordance with legal, operational and company or institutional requirements – SOPs should be written for any processes an individual or group performs.

**sterile:** free from living organisms.

**substitution:** a type of control measure that substitutes a hazardous chemical or process with a less hazardous one.

**supplier:** an obligation holder under the WHS Act.

**SUSMP:** means the Standard for the Uniform Scheduling of Medicines and Poisons, published by the National Drugs and Poisons Schedule Committee as amended from time to time.

**surveillance:** see health monitoring.

**systemic:** affecting a person’s inner organs.

## T

**telophase:** the last of four stages in the division of a single body cell into two identical cells.

**teratogen:** agent capable of causing harm to an embryo or foetus to produce birth defects.

**topical:** a method of administration.

**topical cytotoxic drugs:** cytotoxic drugs prepared in the form of a cream or ointment for direct application to the skin.

## U

**UN Number:** in relation to dangerous goods:

- the number assigned to the dangerous goods by the UN Committee of Experts on the Transport of Dangerous Goods
- the chemical identification serial number shown in the list of dangerous goods mentioned in the ADG Code (for example – cytotoxic drugs that meet the classification criteria of Class 6.1 are listed in the ADG Code as UN Number 2810 or UN Number 2811).

**urostomy:** diversion of urine away from a diseased or defective bladder through a surgically created opening in the skin of the abdominal wall.

**use (of cytotoxic drugs):** use includes administration, preparation, handling, storage, movement and disposal of cytotoxic drugs and related waste.

## V

**vesicants:** cytotoxic drugs that induce blistering.

**vial (phial):** small glass jar with a stopper that contains one or more doses of a drug for injection.

## W

**WHS committee:** a work health and safety committee or committees established by the PCBU and workers for the place of work or the PCBU's undertaking.

**WHS representative:** a work health and safety representative or representatives elected by the workers to represent them.

**work:** work as a worker or as a self-employed person WHS Act.

**worker:** an individual who works under a contract of employment or apprenticeship.

**workplace:** see place of work.

**work injury:**

- an injury to a person that requires first aid or medical treatment if the injury was caused by work, a workplace, a work activity or specified high risk plant
- the recurrence, aggravation, acceleration, exacerbation or deterioration of an existing injury in a person if first aid or medical treatment is required for the injury; and it was caused by work, a workplace, a work activity or specified high risk plant
- any serious bodily injury, if the injury was caused by work, a workplace, a work activity or specified high risk plant.

**workplace incident:** an incident resulting in a person suffering a work injury or a work-related injury or an incident resulting in a dangerous event.

## APPENDIX 2 – INFORMATION SOURCES

The following acts, regulations, standards, codes of practice and guidance notes apply to work involving handling of cytotoxic drugs and cytotoxic waste.

### NSW WORK HEALTH AND SAFETY LEGISLATION

#### Acts and regulations

- *Work Health and Safety Act 2011*
- Work Health and Safety Regulation 2011

### OTHER NSW LEGISLATION

#### Acts and Regulations

- *Poisons and Therapeutic Goods Act 1966 No 31*
- Poisons and Therapeutic Goods Regulation 2008
- *Standard for the Uniform Scheduling of Medicines and Poisons*, Therapeutic Goods Administration
- Waste management legislation administered by NSW Environment Protection Authority
  - *Protection of the Environment Operations Act 1997*
  - Protection of the Environment Operations (Waste) Regulation 2014
  - *Environmental guideline – assessment, classification and management of liquid and non-liquid wastes*, NSW Environment Protection Authority.
  - Waste classification guidelines, NSW Environment Protection Authority
  - Transport of dangerous goods legislation administered by , NSW Environment Protection Authority *Dangerous Goods (Road and Rail Transport) Act 2008*
  - Dangerous Goods (Road and Rail Transport) Regulation 2014
  - Road and Rail (Dangerous Goods)(Road) Regulation 1998

#### Guidance material

- POEO Act and Protection of the Environment Operations Amendment (Scheduled Activities and Waste) Regulation 2008
- *NSW Health: Waste Management Guidelines for Health Care Facilities*

### SAFE CYTOTOXIC DRUG PRACTICES IN OTHER AUSTRALIAN STATES/ TERRITORIES

- *Handling cytotoxic drugs in the workplace*, Victorian SafeWork Authority, January 2003
- *Guide for handling cytotoxic drugs and related waste*, Queensland Workplace Health and Safety, Department of Industrial Relations, 2005

### INDUSTRY CODES OF PRACTICE

- *Code of Practice for the management of clinical and related wastes*, Australian and New Zealand Clinical Waste Management Industry Group (anzcwmig), 4th edition

#### Codes of practice

- *Code of Practice for the Labelling of workplace hazardous chemicals 2015*, Safe Work Australia.
- *Code of practice for the Preparation of safety data sheets for hazardous chemicals*, Safe Work Australia, 2011.
- *Code of practice for Work health and safety consultation, co-operation and co-ordination 2011*, Safe Work Australia.
- *Code of Practice for Managing the risks of hazardous chemicals in the workplace 2012*, SafeWork Australia

## CODES OF PRACTICE

- *National code of practice for the labelling of workplace substances* [NOHSC:2012 (1994)]. Australian Safety and Compensation Council
- *National code of practice for the preparation of safety data sheets*, 2nd Edition, [NOHSC:2011 (2003)]. Australian Safety and Compensation Council
- *Standard for the uniform scheduling of drugs and poisons*. National Drugs and Poisons Schedule Committee, Department of Health and Aging, Australian Government
- *Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code)*. Federal Office of Road Safety, Federal Department of Transport and Communications, Australian Government Publishing Service, Canberra, 6th edition, 1 January 1998

## Guidance material

- *List of designated hazardous chemicals* in Hazardous chemicals Information System (HCIS) on [www.swa.gov.au](http://www.swa.gov.au) (previously available as *List of designated hazardous chemicals* [NOHSC: 10005 (1999)]) Australian Safety and Compensation Council
- *Approved criteria for classifying hazardous chemicals* in Hazardous chemicals Information System (HSIS) on [www.swa.gov.au](http://www.swa.gov.au) (previously available as *Approved criteria for classifying hazardous chemicals* 3rd Edition [NOHSC: 1008 (2004)]) *Safe Work Australia*
- *Classification of hazardous chemicals under the WHS Regulations*, Safe Work Australia
- *Adopted national exposure standards for atmospheric contaminants in the work environment* in Hazardous chemicals Information System (HCIS) on [www.swa.gov.au](http://www.swa.gov.au) (previously available as *Adopted national exposure standards for atmospheric contaminants in the work environment* [NOHSC: 1003 (1995)]) Australian Safety and Compensation Council

## GUIDANCE MATERIAL

- *Australian code for the transport of dangerous goods by road and rail (ADG Code) 7.4 edition 2016*, National Transport Commission. The Professional Standards of The Society of Hospital Pharmacist of Australia (SHPA) Standards of practice for the safe handling of cytotoxic drugs in pharmacy departments, 2005 and *Standards of practice for the transportation of cytotoxic drugs from pharmacy departments, 2007* endorsed by the SHPA
- *Standards of practice for the safe handling of cytotoxic drugs in pharmacy departments* (2005), The Society of Hospital Pharmacists of Australia (SHPA)
- *Standards of practice for the transportation of cytotoxic drugs from pharmacy departments* (2007), The Society of Hospital Pharmacists of Australia (SHPA).
- *Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer* (2007), The Society of Hospital Pharmacists of Australia (SHPA)
- *Factsheet for Understanding Safety Data Sheets for Hazardous Chemicals*, Safe Work Australia
- *Factsheet for Understanding Hazardous Chemical Labels*, Safe Work Australia
- *Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP) 2011*
- SWA Health monitoring for exposure to hazardous chemicals- Guide for medical practitioners (2013)
- SWA Health Monitoring for Exposure to Hazardous Chemicals – Guide for persons conducting a business or undertaking (2013).
- SWA Health Monitoring for Exposure to Hazardous Chemicals – Guide for persons conducting a business or undertaking (2013)

## AUSTRALIAN STANDARDS

- AS 1807.1-2000 Cleanrooms, workstations, safety cabinets and pharmaceutical isolators – Methods of test. Determination of air velocity and uniformity of air velocity in clean workstations, laminar flow safety cabinets and pharmaceutical isolators
- AS 2567-2002 *Laminar flow cytotoxic drug safety cabinets*
- AS 2639-1994 *Laminar flow cytotoxic drug safety cabinets – Installation and use*
- AS 4273-1999 and AS 4273-1999/Amdt1-2000 *Design, installation and use of pharmaceutical isolators.*
- AS 2567-2002 *Laminar flow cytotoxic drug safety cabinets*
- AS/NZ 3816:1998 *Management of clinical and related wastes*
- AS/NZ 4031-1992 *Non-reusable containers for the collection of sharp medical items used in health care areas*
- AS/NZS 4261:1994 *Reusable containers for the collection of sharp items used in human and animal medical applications.*
- HB 202-2000 (2017) *A management system for clinical and related wastes – Guide to application of AS/NZS 3816-1998, Management of clinical and related wastes.*
- AS/NZS 1715-2009 *Selection use and maintenance of respiratory protective equipment.*
- SA/SNZ HB 436:2013 (Guidelines to AS/NZS ISO 31000:2009) *Risk Management guidelines*

## TECHNICAL REPORTS

- Baker ES and Connor TH. (1996) *Monitoring occupational exposure to cancer chemotherapy drugs.* Review Article. American Journal of Health-System Pharmacists 53:2713-2723
- Cavallo D, Ursini CL, Perniconi B, Francesco AD, Giglio M, Rubino FM, Marinaccio A, Iavicoli S. (2005) *Evaluation of genotoxic effects induced by exposure to antineoplastic drugs in lymphocytes and exfoliated buccal cells of oncology nurses and pharmacy workers.* Mutat Res 587 (1-2):45-51
- Nygren O, Gustavsson B, Eriksson. (2005) *A test method for assessment of spill and leakage from drug preparations systems.* Ann Occup Hyg 49(8):711-8
- Sabatini L, Barbieri A, Tosi M, Violante FS. (2005) *A new high-performance liquid chromatography/electrospray ionization tandem mass spectrometric method for the simultaneous determination of cyclophosphamide, methotrexate and 5-fluorouracil as markers of surface contamination for occupational exposure monitoring.* J Mass Spectrom 40(5):669-74
- Sessink PJM and Bos RP. (1999) *Drugs hazardous to healthcare workers – Evaluation of methods for monitoring occupational exposure to cytostatic drugs.* Aids International Limited
- Spatari G, Fenga C, Minciullo PL, Di Pasquale G, Cacciola A, Ventura-Spagnolo E, Gangemi S. (2005) *Modification of interleukin-15 serum levels in workers exposed to chemotherapeutic agents.* Mediators Inflamm. 2005(1):60-2
- Turchi R, Sottani C, Ronachi A, Minoia C. (2002) *Biological monitoring of hospital personnel occupationally exposed to antineoplastic agents.* Toxicol Lett 134:57-64
- Turchi R, Sottani C, Schierl R, Minoia C. (2005) *Validation protocol and analytical quality in biological monitoring of occupational exposure to antineoplastic drugs.* Toxicol Lett Oct 20 (ahead of print)
- Ziegler E, Mason HJ, Baxter PJ. (2002) *Occupational exposure to cytotoxic drugs in two UK oncology wards.* Occup Environ Med 59:608-612

## APPENDIX 3 – COMMONLY USED CYTOTOXIC DRUGS

Development of second cancers as a consequence of cancer chemotherapy, or (more rarely reported) similar adverse impacts of cytotoxic drugs when used to treat non-cancerous conditions, specifically involves particular classes of drugs. These carcinogenic hazards are presented by those agents that cause cell death (such as – are cytotoxic) through damaging DNA, or processes involving cell replication.

In listing drugs that warrant attention in relation to these guidelines, it is prudent to specify all widely-used cytotoxic agents, as indicated by the mechanism of action just described, rather than just those agents that have been specifically shown to cause cancer.

Such a listing of drugs would once have included almost all agents used to treat cancer patients. Today, however, drugs used to treat cancer specifically include, for example, agents that affect protein-to-protein interactions ('signal transduction inhibitors') and antibodies to proteins expressed on the surface of some cancer cells. Agents such as these are not known to present the hazard associated with conventional cytotoxic drugs. Although such agents are reasonably called 'anticancer drugs', they are not necessarily included in this list because current evidence suggests a lack of hazard. An unmanageably long list may obscure attention being paid to drugs deemed to present a risk to staff.

All therapeutic drugs should be handled in accordance with good pharmacy practice and good nursing practice, and such practices should minimise exposure of staff. These guidelines provide for a measure of protection over and above that resulting from good practice. As indicated above, the hazard that is addressed in this way is not necessarily associated with all preparations used in the treatment of cancer patients. Conversely, however, the absence of a drug from the present listing does not necessarily indicate that it is innocuous. Particularly in relation to newly introduced drugs, information should be sought concerning their similarity or otherwise to agents listed below in order to determine whether these guidelines are reasonably applicable.

The following is a list of commonly used cytotoxic drugs\*:

<b>Drug</b>	<b>Trade names</b>	<b>Usual method of administration</b>
Altretamine	Hexalen	Oral
Amsacrine (AMSA)	Amsidyl	Infusion
L-Asparaginase	see Colaspase	Injection
Erwina Asparaginase	-	Injection
Azathioprine	Imuran Azamun Azahexal	Oral, injection, infusion
Bleomycin (BLEO)	Blenoxane Bleomycin sulfate	Injection
Busulfan (BUS)	Myleran	Oral, infusion
Capecitabine	Xeloda	Oral
Carboplatin (PP)	Carboplatin	Infusion
Carmustine (BCNU)	BiCNU	Infusion
Chlorambucil (CLB)	Leukeran	Oral
Cisplatin (DDP)	Cisplatin	Infusion
Cladribine (2-CDA)	Leustatin	Infusion
Colaspase (L-Asp)	Leunase	Injection
Cyclophosphamide (CTX)	Cycloblastin Endoxan-Asta	Oral, injection, infusion
Cytarabine Arabinoside (Ara-C)	Cytarabine	Injection, infusion
Dacarbazine (DTIC)	Dacarbazine D.T.I.C.	Infusion
Dactinomycin-D (ACT-D)	Cosmegen	Injection
Daunorubicin (DNR)	Daunorubicin	Injection
Daunorubicin liposomal	DaunoXome	Infusion
Docetaxel (TXT)	Taxotere	Infusion
Doxorubicin (ADR)	Adriamycin Doxorubicin	Infusion, injection
Doxorubicin HCl liposome (DOX-L)	Caelyx Doxil	Infusion
Epirubicin	Pharmorubicin	Injection
Estramustine	Estracyt	Oral
Etoposide Phosphate	Etopophos	Infusion
Etoposide (VP-16)	Etoposide Vepesid	Oral, infusion
Floxuridine FUDR	Fudr	Infusion
Fluorouracil (5-FU)	Efudix Fluoroplex Fluorouracil	Injection, infusion, topical

Drug	Trade names	Usual method of administration
Fludarabine (FAMP)	Fludara	Injection, infusion
Fotemustine	Muphoran	Infusion
Ganciclovir	Cymevene	Infusion
Gemcitabine (GEM)	Gemzar	Infusion
Hydroxyurea (HU)	Hydrea	Oral
Idarubicin (IDA)	Zavedos	Oral, injection, infusion
Ifosfamide (IFX)	Holoxan	Infusion
Irinotecan (CPT-11)	Camptosar	Infusion
Lomustine (CCNU)	CeeNU	Oral
Melphalan	Alkeran	Oral
Mercaptopurine (6MP)	Puri-nethol	Oral
Methotrexate (MTX)	Ledertrexate Methoblastin Methotrexate	Oral, injection, infusion
Mitozantrone (NOV)	Novantrone	Injection, infusion
Mitomycin-C (MITO)	Mitomycin C	Injection
Nitrogen mustard (HN2)	Mustine hydrochloride	Injection
Oxaliplatin	Eloxatin	Infusion
Paclitaxel (TAX)	Anzatax Taxol	Infusion
Procarbazine (PCZ)	Natulan	Oral
Raltritrexed	Tomudex	Injection
Streptozotocin (STN)	Zanosar	Infusion
Temozolomide	Temodal	Oral
Teniposide (VM-26)	Vumon	Infusion
Thioguanine (6-TG)	Lanvis	Oral
Thiotepa (TT)	Thiotepa	Injection, infusion
Topotecan (TOPO)	Hycamtin	Infusion
Tretinoin	Vesanoid	Oral
Valganciclovir	Valcyte	Oral

\*This list contains cytotoxic drugs currently used. However this listing is not exhaustive. When any new cytotoxic drug enters the workplace, it must be listed, and a risk assessment and a risk management plan must be developed.

The NIOSH Alert published by the Centre for Disease Control, US has provided an extensive list of cytotoxic drugs\*

\*Centre for Disease Control (2004). NIOSH Alert. Preventing Occupational Exposures to Antineoplastic and Other Hazardous Drugs in Health Care Settings. DHHS/NIOSH, Cincinnati, OH.

## APPENDIX 4 – SAFETY DATA SHEET (SDS)

Mandatory core information is listed in regular font, additional information is in italics.

**Note:** From 1 January 2017, all Safety Data Sheets must be GHS compliant and must be prepared as per the Safe Work Australia *Code of practice 2011 for the preparation of safety data sheets for hazardous chemicals*.

### SECTION 1 – IDENTIFICATION OF THE MATERIAL AND SUPPLIER

- Product (material) name
- Other names
- Recommended use
- Supplier name/address/telephone no/emergency phone number

### SECTION 2 – HAZARDS IDENTIFICATION

- Hazard classification, including a statement of overall hazardous or dangerous nature
- Pictogram and Signal word
- Hazard and Precautionary statement

### SECTION 3 – COMPOSITION/INFORMATION ON INGREDIENTS

#### CHEMICAL

- Chemical identity of the pure chemical
- Common name(s), synonym(s)
- CAS Number(s)

#### MIXTURE

- Chemical identity of ingredients
- Proportion of ingredients
- CAS Number(s) for ingredients

### SECTION 4 – FIRST AID MEASURES

- Description of necessary measures according to routes of exposure
- Indication of medical attention and special treatment needed including description of most important symptoms, acute and delayed

#### Additional information

- Aggravated medical conditions caused by exposure

## SECTION 5 – FIRE FIGHTING MEASURES

- Suitable extinguishing media
- Hazards from combustion products
- Special protective precautions and equipment for fire fighters

### Additional information

- Hazchem Code

## SECTION 6 – ACCIDENTAL RELEASE MEASURES

- Emergency Procedures
- Methods and materials for containment and clean up

## SECTION 7 – HANDLING AND STORAGE

- Precautions for safe handling
- Conditions for safe storage, including any incompatibilities

## SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

- National exposure standards
- Biological limit values
- Engineering controls
- Personal protective equipment

## SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

- Appearance (colour, physical form, shape)
- Odour
- pH
- Vapour pressure
- Vapour density
- Boiling point/range
- Freezing/melting point (specify which)
- Solubility (specify solvent, for example – water)
- Specific gravity or density

### Information for flammable materials, including:

- Flash point and method of decanting flash point
- Upper and lower flammable (explosive) limits in air, and
- Ignition temperature.

#### Additional information

- Specific heat value
- Particle size
- Volatile organic compounds (VOC) content
- Evaporation rate
- Viscosity
- Percent volatile
- Octanol/water partition coefficient
- Saturated vapour concentration (include reference temperatures)
- Additional characteristics not noted above may also be provided if applicable to the material
- Flame propagation or burning rate of solid materials
- Properties of both flammable and non-flammable materials that may initiate or uniquely contribute to the intensity of a fire (for example - Class 4 or Class 5)
- Potential for dust explosion
- Reactions that release flammable gases or vapours
- Fast or intensely burning characteristics
- Non-flammables that could contribute unusual hazards to a fire, such as strong oxidizing and reducing agents or peroxide formers
- Release of invisible flammable vapours and gases
- Decomposition temperature

## SECTION 10 - STABILITY AND REACTIVITY

- Chemical stability
- Conditions to avoid
- Incompatible materials
- Hazardous decomposition products
- Hazardous reactions

## SECTION 11 - TOXICOLOGICAL INFORMATION

- Health effects from the likely routes of exposure

## SECTION 12 – ECOLOGICAL INFORMATION

- Ecotoxicity
- Persistence and degradability
- Mobility

### Additional information

- Environmental fate (exposure)
- Bioaccumulative potential

## SECTION 13 – DISPOSAL CONSIDERATIONS

- Disposal methods and containers
- Special precautions for landfill or incineration

## SECTION 14 – TRANSPORT INFORMATION

- UN number
- UN proper shipping name
- Class and subsidiary risk
- Packing group
- Special precautions for user
- Hazchem Code

## SECTION 15 – REGULATORY INFORMATION

- The regulatory status of a material (including its ingredients) under relevant Australian health, safety and environmental legislation

### Additional information

- Additional national and/or international regulatory information

## SECTION 16 – OTHER INFORMATION

- Date of preparation or last revision of the SDS\*

### Additional information

- Key/legend to abbreviations and acronyms used in the SDS.

### Literature references

- Sources for data

\*SDS should be no more than five years old.

This checklist outlines the necessary information to prepare the 16 header SDS format required under Chapter 6 (Hazardous chemicals ) of the WHS Regulation.

**Reference:** *Model Code of Practice-Preparation of Safety Data Sheets for Hazardous Chemicals, Safe Work Australia.*

# APPENDIX 4A – SDS REQUIREMENTS UNDER GHS (minimum information required on an SDS)

From 1 January 2017, Globally Harmonised System of classification and labelling (GHS) comes into effect. All Safety Data Sheets must be GHS compliant and must be prepared as per the Safe Work Australia *Code of practice 2011 for the preparation of safety data sheets for hazardous chemicals*

Minimum information for an SDS	
1. Identification of the substance or mixture and of the supplier	<ul style="list-style-type: none"> <li>a. GHS product identifier;</li> <li>b. Other means of identification;</li> <li>c. Recommended use of the chemical and restrictions on use;</li> <li>d. Supplier's details (including name, address, phone number, etc);</li> <li>e. Emergency phone number.</li> </ul>
2. Hazards identification	<ul style="list-style-type: none"> <li>a. GHS classification of the substance/mixture and any national or regional information;</li> <li>b. GHS label elements, including precautionary statements; (Hazard symbols may be provided as a graphical reproduction of the symbols in black and white or the name of the symbol, eg – flame, skull and crossbones.)</li> <li>c. Other hazards which do not result in classification (eg – dust explosion hazard) or are not covered by GHS.</li> </ul>
3. Composition/information on ingredients	<p><b>Substance</b></p> <ul style="list-style-type: none"> <li>a. Chemical identity;</li> <li>b. Common name, synonyms, etc;</li> <li>c. CAS number and other unique identifiers;</li> <li>d. Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance.</li> </ul> <p><b>Mixture</b></p> <p>The chemical identity and concentration or concentration ranges of all ingredients that are hazardous within the meaning of the GHS and represent above their cut off levels.</p> <p><b>Note:</b> For information on ingredients, the component authority rule for CBI take priority over rules for product identification.</p>
4. First aid measures	<ul style="list-style-type: none"> <li>a. Description of necessary measures, subdivided according to the different routes of exposure, ie – inhalation, skin and eye contact and ingestion;</li> <li>b. Most important symptoms/effects, acute and delayed;</li> <li>c. Indication of immediate medical attention and special treatment needed, if necessary.</li> </ul>

## Minimum information for an SDS

5. Firefighting measures	<ul style="list-style-type: none"><li>a. Suitable (and unsuitable) extinguishing media;</li><li>b. Specific hazards arising from the chemical (eg – nature of any hazardous combustion products);</li><li>c. Special protective equipment and precautions for firefighters.</li></ul>
6. Accidental release measures	<ul style="list-style-type: none"><li>a. Personal precautions, protective equipment and emergency procedures;</li><li>b. Environmental precautions;</li><li>c. Methods and materials for containment and cleaning up;</li></ul>
7. Handling and storage	<ul style="list-style-type: none"><li>a. Precautions for safe handling;</li><li>b. Conditions for safe storage, including any incompatibilities.</li></ul>
8. Exposure controls/personal protection	<ul style="list-style-type: none"><li>a. Control parameters (eg – occupational exposure limit values or biological limit values);</li><li>b. Appropriate engineering controls;</li><li>c. Individual protection measures, such as personal protective equipment.</li></ul>
9. Physical and chemical properties	<ul style="list-style-type: none"><li>a. Appearance (physical state, colour etc);</li><li>b. Odor;</li><li>c. Odor threshold;</li><li>d. pH;</li><li>e. Melting point/freezing point;</li><li>f. Initial boiling point and boiling range;</li><li>g. Flash point;</li><li>h. Evaporation rate;</li><li>i. Flammability (solids, gas);</li><li>j. Upper/lower flammability or explosive limits;</li><li>k. Vapor pressure;</li><li>l. Vapor density;</li><li>m. Relative density</li><li>n. Solubility(ies)</li><li>o. Partition coefficient: n-octanol/water;</li><li>p. Auto-ignition temperature;</li><li>q. Decomposition temperature;</li><li>r. Viscosity.</li></ul>
10. Stability and reactivity	<ul style="list-style-type: none"><li>a. Reactivity;</li><li>b. Chemical stability;</li><li>c. Possibility of hazardous reactions;</li><li>d. Conditions to avoid (eg – static discharge, shock or vibration);</li><li>e. Incompatible materials;</li><li>f. Hazardous decomposition products.</li></ul>

## Minimum information for an SDS

11. Toxicological information	Concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects, including: <ul style="list-style-type: none"><li>a. Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact);</li><li>b. Symptoms related to the physical, chemical and toxicological characteristics;</li><li>c. Delayed and immediate effects and also chronic effects from short and long-term exposure;</li><li>d. Numerical measures of toxicity (such as acute toxicity estimates).</li></ul>
12. Ecological information	<ul style="list-style-type: none"><li>a. Ecotoxicity (aquatic and terrestrial, where available);</li><li>b. Persistence and degradability;</li><li>c. Bioaccumulative potential;</li><li>d. Mobility in soil;</li><li>e. Other adverse effects.</li></ul>
13. Disposal considerations	Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.
14. Transport information	<ul style="list-style-type: none"><li>a. UN Number;</li><li>b. UN Proper shipping name;</li><li>c. Transport Hazard class(es);</li><li>d. Packaging group, if applicable;</li><li>e. Environmental hazards (eg - Marine pollutant (Yes/No));</li><li>f. Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code);</li><li>g. Special precautions that a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises.</li></ul>
15. Regulatory information	Safety, health and environmental regulations specific for the product in question.
16. Other information including information on preparation and revision of the SDS	



# APPENDIX 6 - RISK ASSESSMENT TEMPLATE FOR CYTOTOXIC DRUGS

<b>Process description:</b>				
<b>Cytotoxic drugs used:</b>		<b>Name of person(s) performing assessment:</b>		
<b>Date:</b>				
<b>Possible health effects</b>	<b>Routes of exposure</b>	<b>Current control measures</b>	<b>Are additional control measures required (if yes state what and reason)</b>	<b>Actions</b>

# APPENDIX 7 – CYTOTOXIC DRUG HEALTH MONITORING GUIDELINES FOR MEDICAL PRACTITIONERS

In regard to the issue of privacy in relation to medical practitioners providing reports to PCBUs, the following must be considered:

- reporting must comply with all privacy requirements and government policy
- records that are not related to work health and safety screening should not be used in relation to health monitoring.

If baseline health monitoring is part of a managing risk approach, the following should be considered.

1. Baseline health monitoring	
1. Collection of demographic data	<ul style="list-style-type: none"><li>• name and unique company identification number</li><li>• date of birth</li><li>• gender</li><li>• address</li><li>• date commencing employment</li><li>• descriptive job title – to include the Australian Bureau of Statistics <i>Australian standard classification of occupations</i> (ASCO) and <i>Australian standard industrial classification</i> (ASIC)</li><li>• places of previous employment.</li></ul>
2. Occupational history	<ul style="list-style-type: none"><li>• past work history, including previous work with cytotoxic drugs</li><li>• potential current exposure</li><li>• whether suitable control measures are in place for handling cytotoxic drugs.</li></ul>
3. Medical history	<ul style="list-style-type: none"><li>• presence of symptoms</li><li>• general health</li><li>• smoking history</li><li>• personal history of cancer</li><li>• family history of cancer in first relatives</li><li>• history of asthma or other systemic allergic reactions or states (examples include systemic reaction to bee sting or allergic skin disorders)</li><li>• is the worker taking immuno-suppressive therapy?</li><li>• is the worker pregnant or breast-feeding?</li><li>• is the worker planning a family or considering pregnancy sometime in the future?</li></ul>
4. Physical examination	<ul style="list-style-type: none"><li>• general physical examination.</li></ul>
5. Investigation	<ul style="list-style-type: none"><li>• no diagnostic test currently gives a sensitive, specific and interpretable indication of early or likely health effects arising from occupational exposure to cytotoxic drugs or their metabolites</li><li>• the medical practitioner should focus on the risk factors outlined in the occupational history, and the outcome of the physical examination</li><li>• the medical practitioner should perform any investigations that may be appropriate as a result of the examination.</li></ul>

## 1. Baseline health monitoring

- |                                  |  |
|----------------------------------|--|
| 6. Health advice and counselling | The appointed medical practitioner should provide medical advice and counselling to the worker, including: <ul style="list-style-type: none"><li>• the potential health effects associated with exposure to cytotoxic drugs and related waste</li><li>• the optimum standard of control measures to expect in the workplace</li><li>• the results of the health monitoring, including any abnormal findings</li><li>• the potential risks of workers planning parenthood, or those who are breast-feeding or pregnant.</li></ul> |
| 7. Report                        | <ul style="list-style-type: none"><li>• The appointed medical practitioner should provide a report to the PCBU and prospective worker advising that the worker has received assessment and health advice.</li><li>• Confidentiality of medical records is to be maintained. Access to medical records is to be by written consent of the worker concerned.</li><li>• Privacy issues should be considered.</li></ul>  |

## 2. Ongoing health monitoring during the period that the worker works with cytotoxic drugs

- |   |  |
|---|--|
| 8. Data for inclusion in health records | <ul style="list-style-type: none"><li>• Any risk assessments carried out at the workplace.</li><li>• Descriptive job titles, with relevant start and finish dates. Jobs within areas where cytotoxic drugs are used should be clearly identified.</li><li>• Results of workplace monitoring such as wipe tests or performance testing of control measures.</li><li>• Results of the investigation of spills and exposure events.</li></ul>   |
| 9. Health advice and counselling        | <ul style="list-style-type: none"><li>• as described in point 6</li><li>• this should be offered by the PCBU annually and may be initiated at any time by the worker.</li></ul>  |
| 10. Medical review                      | <ul style="list-style-type: none"><li>• conduct a medical review as soon as possible in the following situations:<ul style="list-style-type: none"><li>- after a reportable spill or sharps injury occurs</li><li>- if an worker advises she is pregnant, considering pregnancy, or is breast-feeding</li></ul></li><li>• the review should take account of the previous medical examination and include:<ul style="list-style-type: none"><li>- health advice and counselling</li><li>- report</li></ul></li><li>• follow-up the review in one month.</li></ul> |
| 11. Control measures                    | Monitor the availability, type, maintenance and frequency of use of control measures (for example, needleless injection sets should be in place to eliminate the potential for sharps injuries).   |
| 12. Accidental exposure                 | <ul style="list-style-type: none"><li>• report all accidental exposures</li><li>• determine extent of exposure</li><li>• record all accidental exposures.</li></ul>  |

### 3. Exit monitoring of employment where cytotoxic drugs are used

- |                               |   |
|-------------------------------|---|
| 13. Data to be collected      | The following data should be collected: <ul style="list-style-type: none"><li>• date of termination</li><li>• reason for termination:<ul style="list-style-type: none"><li>- ill health (provide details)</li><li>- other reasons</li><li>- date and cause of death if in service.</li></ul></li></ul>  |
| 14. Final medical examination | <ul style="list-style-type: none"><li>• conduct a medical examination including the factors already described:<ul style="list-style-type: none"><li>- medical history</li><li>- physical examination</li><li>- investigation</li><li>- health advice and counselling</li></ul></li><li>• Provide a report to the PCBU and worker. Medical reports regarding individual workers should be provided to the PCBU with the written consent of the worker.</li></ul> |

For information on this Appendix, see chapter 4.

# APPENDIX 8 – RECORD KEEPING

Records should be kept for the following:

## PCBU

- Copy of any authorisation obtained from and any notification to SafeWork NSW
- SafeWork NSW penalty notices (for example – fines, improvement notices, probation notices etc.)
- Record of cytotoxic drug waste kept in the workplace
- Risk assessment reports
- Hazardous Chemicals Register
- Workplace monitoring reports
- Audit reviews
- Assurance reports
- Incident reports
- Health monitoring records
- Training records.

## PERSONNEL

- Personnel trained to undertake cytotoxic drug preparation and administration
- Competency status of operators
- Records of staff who actually worked with cytotoxic drugs
- The work activity of individual personnel in the preparation and administration of these drugs that take account of:
  - number of products
  - type of products
  - time spent on tasks
- Control measures used (for example – cytotoxic drug safety cabinet, personal protective equipment)
- Medical records for each worker. These records must be kept confidential. Medical reports regarding individual workers should only be provided to the PCBU with the written consent of workers.

## DRUG PREPARATION EQUIPMENT

- Activities of the cytotoxic drug safety cabinet such as maintenance, testing dates, operating times, cabinet relocations, repairs and breakdowns
- Maintenance schedules for all equipment
- Test results.

## SPILLS, SHARPS INJURIES AND CONTAMINATION

- Day, date, name and signature of management
- Nature of spill
- Drug under preparation or administration
- Approximate volume and concentration of drug spilt
- Form of the drug
- Part of the body affected or exposed
- Time spent in attending to the incident or spill
- Any action taken (for example – treatment, biological monitoring)
- Recommendations for preventative action.

## WHS REGULATION REQUIREMENTS

- Copy of any authorisation obtained from and any notification to SafeWork NSW
- Risk assessment reports
- Register
- Workplace monitoring reports (if required)
- Audit reviews (if required)
- Incident reports
- Health monitoring records (if required)
- Training records.

The WHS Regulation requires most of these reports to be kept for at least five years and all the adverse reports and adverse health monitoring results be kept for 30 years. As most of the health impacts of the cytotoxic drugs are chronic (long term), it is advisable to keep all records for 30 years.

For more on information on record-keeping requirements, see chapters 4, 5 and 9.

# APPENDIX 9 – PERSONAL PROTECTIVE EQUIPMENT

Type of PPE	Description	Task/Use	Cleaning/ Disposal
Coveralls and gowns	<p>Gowns are usually worn for tasks involving the administration of cytotoxic drugs and patient care. Coveralls are most commonly worn in drug preparation areas.</p> <p>Selection considerations for coveralls or gowns include:</p> <ul style="list-style-type: none"> <li>• should be made of impermeable material (for example – bonded polyethylene fibre)</li> <li>• should have a closed front and long sleeves with elastic cuff</li> <li>• may be disposable or processed through an appropriate laundry facility capable of handling garments contaminated with cytotoxic drugs</li> <li>• should be changed at least daily, or immediately if overt contamination occurs</li> <li>• care should be taken in removal of gowns to minimise the risk of personal contamination</li> <li>• Coveralls may incorporate head coverings – recommended for drug preparation</li> <li>• Oversleeves give added protection to the forearms (a vulnerable area of exposure)</li> </ul>	<ul style="list-style-type: none"> <li>• Preparation of cytotoxic drugs – inside an isolated cytotoxic drug safety cabinet (CDSC)</li> <li>• Cleaning of cytotoxic drug preparation areas and equipment</li> <li>• Drug administration and patient care</li> <li>• Cleaning solid or liquid cytotoxic spills</li> <li>• Laundry – handling cytotoxic contaminated linen bag</li> <li>• Ancillary workers handling cytotoxic contaminated waste containers</li> </ul>	<ul style="list-style-type: none"> <li>• Refer to manufacturer's and supplier's instructions</li> <li>• Gowns should be used for a maximum of one shift.</li> <li>• Contaminated garments should be removed immediately and disposed of or laundered as appropriate.</li> <li>• Reusable coveralls and gowns should be stored for laundering – see chapter 10</li> <li>• Reusable coveralls and gowns have a limited life span and should be discarded when full protection can no longer be guaranteed by the manufacturer or supplier.</li> <li>• Disposable coveralls and gowns should be disposed of as cytotoxic waste.</li> <li>• Gowns should not be shared.</li> </ul>
Head covering	<ul style="list-style-type: none"> <li>• Head coverings should be worn to contain hair and minimise contamination. They should cover exposed hair, including beards and moustaches.</li> <li>• Hooded coveralls are recommended for drug preparation – hoods should fit snugly around the face.</li> <li>• Caps should fit snugly around the head.</li> <li>• Facial enclosures or covers should be designed in conjunction with hoods and other coverings.</li> <li>• Hoods, caps and facial enclosures should not interfere with respiratory protection.</li> </ul>	<ul style="list-style-type: none"> <li>• Preparation of cytotoxic drugs – inside a cytotoxic drug safety cabinet (CDSC)</li> <li>• Cleaning of cytotoxic drug preparation areas and equipment</li> </ul>	<ul style="list-style-type: none"> <li>• Refer to manufacturer's and supplier's instructions</li> <li>• Reusable coveralls and gowns – see above.</li> <li>• Disposable coveralls and gowns should be disposed of as cytotoxic waste.</li> </ul>

Type of PPE	Description	Task/Use	Cleaning/ Disposal
Gloves	<ul style="list-style-type: none"> <li>Glove use is essential.</li> <li>Gloves must be chosen to maximise protection by minimising permeability</li> <li>Permeability of gloves to drug materials is related to chemical properties of the drug and the glove material (for example - polarity) and glove thickness.</li> <li>Standard surgical gloves may not provide required level of protection due to drug and/ or carrier permeability in the case of liquid cytotoxic drugs.</li> <li>Gloves must be long enough to cover wrist cuffs of coveralls or gowns while arm is bent or stretched</li> <li>Choice of gloves currently includes purpose manufactured or manufacturer recommended; and surgical disposable gloves</li> <li>Purpose manufactured or manufacturer recommended gloves will minimise permeability through design. As no glove is completely impermeable, they must still be regularly replaced in accordance with the drug manufacturer's recommendations or permeation studies.</li> </ul>	<ul style="list-style-type: none"> <li>Preparation of cytotoxic drugs - inside a cytotoxic drug safety cabinet (CDSC)</li> <li>Cleaning of cytotoxic drug preparation areas and equipment</li> <li>Drug administration and patient care</li> <li>Cleaning solid or liquid cytotoxic spills</li> <li>Laundry - handling cytotoxic contaminated linen bag</li> <li>Ancillary workers handling cytotoxic waste containers</li> </ul>	<ul style="list-style-type: none"> <li>Refer to manufacturer's and supplier's instructions</li> <li>Gloves should be disposed of as cytotoxic waste.</li> </ul>
	<ul style="list-style-type: none"> <li>Operators not wearing special-purpose gloves should be double gloved. This can be done with two pairs of powder-free latex gloves,</li> <li>Latex gloves used in drug preparation should be sterile and powder free.</li> <li>With double gloving, both gloves must be changed.</li> <li>Gloves should be changed at intervals recommended by the manufacturer, or at intervals of 30 minutes, or when punctured, torn or contaminated.</li> </ul>		

Type of PPE	Description	Task/Use	Cleaning/ Disposal
Protective eyewear	<ul style="list-style-type: none"> <li>This is provided to prevent exposure to the mucous membranes of the eye from liquid splashes.</li> <li>Eye protection can be provided by: <ul style="list-style-type: none"> <li>goggles or protective eyewear with side shields</li> <li>a transparent full-face chemical splash shield</li> <li>full eye protection provided by full-face respiratory protective equipment (RPE).</li> </ul> </li> <li>A risk assessment should be used to determine whether a worker wearing prescription glasses should use additional protection. This should be taken into account in selection and fitting of PPE.</li> </ul>	<ul style="list-style-type: none"> <li>Preparation of cytotoxic drugs <ul style="list-style-type: none"> <li>inside a cytotoxic drug safety cabinet (CDSC)</li> </ul> </li> <li>Cleaning of cytotoxic drug preparation areas and equipment</li> <li>Cytotoxic drug administration and patient care - if risk assessment indicates risk of splash in eyes (for example - intrathecal injection)</li> <li>Cleaning solid or liquid cytotoxic spills</li> </ul>	<ul style="list-style-type: none"> <li>Refer to manufacturer's and supplier's instructions</li> <li>Reusable eyewear should be cleaned with a neutral detergent solution and rinsed thoroughly at the end of the shift or when contaminated.</li> <li>Disposable eyewear should be disposed of as cytotoxic waste.</li> </ul>
Respiratory Protective Equipment (RPE)	<ul style="list-style-type: none"> <li>Suitable RPE should be selected, used, stored and maintained as recommended in AS/NZS1715: 2009 - <i>Selection, use and maintenance of respiratory protective devices or comparable internationally accepted standard.</i></li> <li>To contain cytotoxic spills which may generate aerosols, respiratory protective equipment with a particulate filter P2 (N95) is recommended.</li> <li>A requirement for a worker to wear prescription glasses should be taken into account in selection and fitting of RPE.</li> <li>Surgical respirators do not offer sufficient respiratory protection against exposure to powders, liquids or aerosols (particulates).</li> </ul>	<ul style="list-style-type: none"> <li>Preparation of cytotoxic drugs <ul style="list-style-type: none"> <li>inside a cytotoxic drug safety cabinet (CDSC)</li> </ul> </li> <li>Cleaning of cytotoxic drug preparation areas and equipment</li> <li>Cytotoxic drug administration and patient care - if risk assessment indicates risk of aerosol exposure</li> <li>Cleaning solid or liquid cytotoxic spills (where spill kit needed)</li> </ul>	<ul style="list-style-type: none"> <li>Refer to manufacturer's and supplier's instructions</li> <li>An effective storage and regular maintenance program should be implemented for reusable RPE with procedures covering: <ul style="list-style-type: none"> <li>cleaning and disinfection;</li> <li>replacement of filter</li> <li>inspection for defects; and</li> <li>repair of equipment.</li> </ul> </li> <li>Reusable face piece RPE should have the face piece washed after each daily use or following any contaminating incident.</li> <li>Replaceable filters are to be disposed of as cytotoxic waste at the end of service life.</li> <li>Disposable RPE are to be disposed of as cytotoxic waste after each use or following any contamination incident.</li> </ul>

Type of PPE	Description	Task/Use	Cleaning/ Disposal
Shoe covers or overshoes	<ul style="list-style-type: none"> <li>Shoe covers must be made of impervious material.</li> <li>Overshoes of a similar impermeable material as the coverall or gown.</li> <li>Overshoes should be high enough to cover the trouser cuff of the coverall and designed so they do not slip down.</li> <li>The soles should be made of a skid-resistant plastic or other suitable non-shedding material.</li> <li>Disposable shoe covers do not provide sufficient protection from cytotoxic spills.</li> </ul>	<ul style="list-style-type: none"> <li>Preparation of cytotoxic drugs – inside a cytotoxic drug safety cabinet (CDSC)</li> <li>Cleaning of cytotoxic drug preparation areas and equipment</li> <li>Cleaning solid or liquid cytotoxic spills</li> </ul>	<ul style="list-style-type: none"> <li>Refer to manufacturer's and supplier's instructions</li> <li>Contaminated non-disposable footwear should be cleaned with a detergent solution and rinsed thoroughly after each use.</li> <li>Disposable shoe covers should be disposed of as cytotoxic waste.</li> <li>Reusable overshoes should be stored for laundering. (See Ch 13 – Waste Management.)</li> </ul>

# APPENDIX 10 – SAFE HANDLING OF CYTOTOXIC CONTAMINATED BODY CHEMICALS

## SELECTIVE LIST OF CYTOTOXIC DRUGS

Drug	Urine	Excretion rate	Faeces	Excretion rate	Other
Amsacrine	3 days	20% in 1st 8hrs	2 days		
Asparaginase	Trace amounts				
Bleomycin	3 days	Up to 68% in 1st 24hrs			
Busulphan	12-24hrs		Trace amounts		
Capecitabine	1 day				
Carboplatin	1-2 days	60-80% in 1st 24hrs			
Carmustine	4 days	60-70% as metabolites		1% of dose	10% as CO <sub>2</sub>
Chlorambucil	2 days				
Cisplatin	7 days				
Cladribine	3 days				
Cyclophosphamide	3 days (IV)	25% unchanged drug in 1st 48hrs, total of 62% over 48hrs	5 days after PO dose	4% excreted after IV	In sweat and saliva for 72hrs
Cytarabine	1 day				
Dacarbazine	6hrs				
Dactinomycin	5 days	20% in 1st 24 hrs	7 days		
Daunorubicin	2 days	20% in 1st 24 hrs	7 days		20% excreted via gallbladder in 1st 24hrs
Docetaxel	7 days		7 days	80% in 1st 48hrs	
Doxorubicin	6 days		7 days		Bile 5 days
Doxorubicin liposomal	5 days		7 days		
Epirubicin	7 days		5 days		
Etopophos	5 days				

Drug	Urine	Excretion rate	Faeces	Excretion rate	Other
Etoposide	4 days	40–60% mainly unchanged	7 days	15% excreted in faeces	
Fludarabine	2 days	Bolus: 60% in 1st 24hrs Infusion: 40% metabolised in 24hrs and 60% in 72hrs			
Fluorouracil	2 days	Bolus: 15% unchanged in 1st 24hrs Infusion: 4% unchanged over 24hrs	5 days		
Fotemustine	4 days	30–40% in 1st 24 hrs		50% excreted in faeces	
Gemcitabine	7 days	Almost complete elimination in form of metabolites in 24hrs		1% excreted in faeces	
Hydroxyurea	1 day	50–80% in 24hrs			
Idarubicin	4 days		7 days		
Ifosfamide	2 days	62% unchanged with another 20% as metabolites			
Imatinib mesylate	7 days		7 days		
Irinotecan	2 days				
Liposomal Doxorubicin	Unknown	Plasma clearance slower than for Doxorubicin			
Lomustine	1 day	66% in 1st 24 hrs			
Melphalan	2 days	28% in 1st 24hrs after PO, 56% in 1st 24hrs after IV	7 days	20–50% after PO administration	
Mercaptopurine	2–3 days	50% in 1st 24 hrs	5 days		
Methotrexate	3 days	Majority in 1st 8 hours, low dose: 40–50%, high dose: up to 90% in 48hrs	7 days	9% after IV	
Mitomycin	1 day	10% as active drug			Small amount in bile
Mitoxantrone	6 days	6.5% unchanged drug, 3.6% metabolised drug	7 days	18% over 5 days	
Nimustine	4 days				
Oxaliplatin	3 days	40–50% of the dose in 1st 24 hrs			
Paclitaxel	1 day	13% unchanged drug	5 days		

Drug	Urine	Excretion rate	Faeces	Excretion rate	Other
Pemetrexed	3 days	70–90% of dose unchanged in urine in 1st 24 hrs			
Procarbazine	2 days	5% as unchanged drug and 70% as metabolites in 1st 24 hrs		Good absorption from GIT, 12% of dose eliminated from GIT in 4 days	
Raltitrexed	8 days				
Streptozocin	3 days				
Temozolomide	Unknown	10% of dose in 1st 24 hrs			
Teniposide	5 days	10% of dose in 1st 24 hrs	2 days		
Thioguanine	1 day	85% unchanged and metabolites			
Thiotepa	3 days	60% as metabolites in 1st 24 hrs			
Topotecan	2 days				
Vinblastine	4 days		7 days		
Vincristine	4 days		7 days		
Vindesine	4 days		7 days		
Vinorelbine	4 days		7 days		

\*This list contains cytotoxic drugs currently used. However this listing is not exhaustive. The information provided is current at the time of writing the guidelines. When any new cytotoxic drug enters the workplace, it must be listed and risks be managed.

**Disclaimer:** The compilation of information shown here is the data derived from the references cited below. The information shown on this site is not complete, current, accurate or free from error. For current and complete information contact the appropriate agency or refer the current medical journals.

**Reference:**

Cass Y & Musgrave CF, August 1992, Am J Hosp Pharmacy, vol 49, pp 1957-1958, *Guidelines for the safe handling excreta contaminated by cytotoxic agents*.  
Oncology Nursing Society, 2003, p28, *Safe handling of hazardous drugs*.  
Gullo Shirley, 1995, *Safe handling of antineoplastic drugs: Translating the recommendations into practice*, Oncology Nursing Forum, vol 22 no 3, pp517-525.  
Quapos 3, Quality Standard for the Oncology Pharmacy Service (English translation), published by the Institute for Applied Healthcare Sciences for the German Society of Oncology Pharmacy Jan 2003 – <http://www.esop.li/downloads/library/Quapos-en-with-commentary.pdf>  
Workplace Health and Safety Queensland, October 2014, Guide for handling cytotoxic drugs and related waste.

# APPENDIX 11 – CYTOTOXIC DRUG PRECAUTIONS ALERT PROFORMA

## CYTOTOXIC DRUG PRECAUTIONS ALERT

Surname of patient: \_\_\_\_\_

Given names of patient: \_\_\_\_\_

MRN: \_\_\_\_\_ Date of birth: \_\_\_\_\_

Chemotherapy given	Date

### PROTECTIVE MEASURES

Protective equipment needed:

- Impermeable cytotoxic gown
- Purpose manufactured cytotoxic gloves
- Respirator (P2)
- Safety goggles

To be worn for all the following activities:

- Drug administration
  - for oral administration wear gloves only
  - **do not** crush or cut tablets
- Drug/equipment disposal
- Body fluid disposal
- Drug/body fluid spill clean up

Cease cytotoxic precautions:

On (date): \_\_\_\_\_ At (time): \_\_\_\_\_ Days from last treatment: \_\_\_\_\_

### CLEANING CONTAMINATED EQUIPMENT

- Place contaminated linen in a plastic bag then into a linen bag
- Wash contaminated equipment with warm soapy water
- Wash all floors with warm, soapy water after a body fluid or chemotherapy spill

### DISPOSAL ISSUES

Place contaminated disposable items (such as - dressings into a cytotoxic drug bin).

Signature: \_\_\_\_\_ Print: \_\_\_\_\_

Designation: \_\_\_\_\_ Date: \_\_\_\_\_

For further information, contact the Oncology Clinic at the nearest Local Health District

Name of Local Health District: \_\_\_\_\_

Contact number: \_\_\_\_\_

# APPENDIX 12 – CYTOTOXIC DRUG HOME SPILLS PROFORMA

## YOUR CONTINUOUS INFUSION DEVICE PUMP AND CHEMOTHERAPY SPILL AT HOME

If you should have a chemotherapy spill after you have been discharged from hospital (such as – a leak from a connection in the tubing, a break or cut in the tubing or a leak from the cassette that is attached to the pump) you must act immediately by doing the following:

1. Get your spill pack, containing:
  - 2 blue plastic backed sheets
  - Disposable gloves
  - 2 clip seal plastic bags
2. Put two pairs of disposable gloves on
3. Check where the leak is coming from
4. If the leak is due to a complete disconnection of the line:
  - clamp your central venous access device if possible
  - reconnect the tubing and clamp the line
  - discard your gloves into one of the plastic bags provided and then into your household rubbish bin
  - wash your hands with soapy water
  - wash contaminated clothes/towels etc in your washing machine separately to other clothes and hang outside to dry
  - **Do NOT attempt to restart the infusion until you have spoken to someone on the telephone numbers you have been given**
5. If it is a leak from a faulty connection:
  - try to reconnect the tubing correctly
  - when reconnected, wash the tubing and skin that has been in contact with the chemotherapy with soapy water
  - discard your gloves into one of the plastic bags provided and then into your household rubbish bin
  - wash your hands with soapy water
  - wash contaminated clothes/towels etc in your washing machine separately to other clothes and hang outside to dry
6. If the leak is from a break or cut in the tubing or cassette, still with your gloves on:
  - put clamp on the line above the break (such as – closest to you)
  - take the battery out of the pump (if applicable)
  - push the clamps on the tubing to close/off
  - wrap the pump and tubing in the blue plastic backed sheets (found in your spill pack)
  - place the wrapped up pump and tubing in one of the plastic bags (found in your spill pack)
  - wash your hands with soap and water
7. Phone the following contacts and make an appointment to have the problem fixed **as soon as possible**:
  - Monday to Friday \_\_\_\_\_ am to \_\_\_\_\_ pm / Saturday and Sunday \_\_\_\_\_ am to \_\_\_\_\_ pm
  - Hospital/ward \_\_\_\_\_ Telephone number \_\_\_\_\_

# FURTHER INFORMATION

## **SafeWork NSW**

SafeWork Assistance Service Phone: 13 10 50  
[www.safework.nsw.gov.au](http://www.safework.nsw.gov.au)

## **SafeWork NSW**

TestSafe Lab Phone: 02 9473 4000  
[www.testsafe.com.au](http://www.testsafe.com.au)

## **Ministry of Health**

Phone: 02 9391 9000 (contact addresses)  
[www.health.nsw.gov.au](http://www.health.nsw.gov.au)

## **NSW Environment Protection Authority (NSW EPA)**

Environment Line Phone: 13 15 55  
[www.epa.nsw.gov.au](http://www.epa.nsw.gov.au)

## **NSW Nurses' and Midwives Association**

Phone: 02 8595 1234 (metropolitan) or 1300 367 962 (regional)  
[www.nswnma.asn.au](http://www.nswnma.asn.au)

## **Clinical Oncology Society of Australia (COSA)**

Phone: 02 9036 3100  
[www.cosa.org.au](http://www.cosa.org.au)

## **Society of Hospital Pharmacists of Australia (SHPA)**

Phone: 03 9486 0177  
[www.shpa.org.au](http://www.shpa.org.au)

## **Health Services Union**

Phone: 02 9229 4944  
[www.hsu.asn.au](http://www.hsu.asn.au)

