

# CYTOTOXIC

## DRUGS AND RELATED WASTE

RISK MANAGEMENT

GUIDE 2008

*making a difference*



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This publication does not represent a comprehensive statement of the law as it applies to particular problems or to individuals or as a substitute for legal advice. You should seek independent legal advice if you need assistance on the application of the law to your situation.

## **ACKNOWLEDGEMENTS**

This guide was prepared by the cytotoxic drugs working party. 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 represent 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.

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- *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. Contact WorkCover NSW.

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# 1 INTRODUCTION

## 1.1 Purpose

This guide provides practical advice to employers and employees 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 work systems that are consistent with the requirements of NSW health and safety laws.

The use of cytotoxic drugs includes their preparation, administration, handling, storage, movement and 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
- 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 and 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 – eg psoriasis and systemic lupus erythromatosis.

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

## Cytotoxic Drug



Occupational 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.

Those most likely to be involved in these activities include:

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

### 1.4 Potential adverse health effects

Where control measures are inadequate, adverse health effects may result from occupational 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 three people 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 occupational exposure to cytotoxic drugs. There are no 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 minimises the incidence of adverse health effects.

Application of the procedures outlined in this guide should give pregnant women and those 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 to not 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 occupational 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 employees, the first priority is to eliminate or minimise the risks to health.

Risk control may be implemented by:

- planning and designing workplace set-up
- 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 employees
- wearing personal protective equipment
- integrating a health monitoring program that:
  - includes the assessment and counselling of prospective employees before they commence any work involving cytotoxic drugs and related waste
  - ensures employee confidentiality.

In occupational settings, 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 occupational health and safety requirements that are relevant when using and handling cytotoxic drugs and related waste. See appendix 2.

### 2.1 Occupational Health and Safety Act 2000

In NSW, there is a legal obligation to provide a healthy and safe workplace. Under the *Occupational Health and Safety Act 2000* (OHS Act), employers have a duty to provide a workplace that is safe and without risks to health. Self-employed people, employees, manufacturers, importers, suppliers of plant, equipment and substances also have an obligation for workplace health and safety.

A person who designs, manufactures or supplies any plant or substance for use by people at work must provide, or arrange for the provision of, adequate information about the plant or substance to the persons to whom it is supplied to ensure its safe use.

The *Occupational Health and Safety Regulation 2001* (OHS Regulation) makes specific provisions for hazardous substances and dangerous goods. But, even when a substance is not classified as a hazardous substance or dangerous goods (see below), information must be provided in accordance with section 8 of the OHS Act to ensure it is safe and without risks to health when properly used. 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 Occupational Health and Safety Regulation 2001

Work involving the handling and transport of cytotoxic drugs falls within the scope of the OHS Regulation, specifically chapter 2, Places of work – risk management and other matters, chapter 6, Hazardous substances, and chapter 6A, Dangerous goods.

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

#### 2.2.1 Risk management

Even when a substance, including a cytotoxic drug, is not classified as a hazardous substance by the manufacturer or importer, the employer must still comply with chapter 2 of the OHS Regulation with respect to that substance, and the employer must ensure that each substance 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 employees
- risks must be eliminated or controlled in consultation with employees
- training must be provided
- information and supervision must be provided
- first aid and emergency procedures must be developed.

Key health and safety information is provided on labels, and more detailed information is provided in material safety data sheets. The material 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, MIMS and technical reports.

### **2.2.2 Hazardous substances**

Chapter 6 of the OHS Regulation aims to protect people against risks to their health and safety when hazardous substances are used at work.

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

- meet the criteria set out in the Australian Safety and Compensation Commission's (ASCC) publication, *Approved criteria for classifying hazardous substances*, or
- be listed in the *List of designated hazardous substances*.

Most cytotoxic drugs will be classifiable as hazardous substances in accordance with the *Approved criteria for classifying hazardous substances*. The WorkCover *Code of practice for the control of workplace hazardous substances* provides practical guidance on complying with the OHS Regulation.

Cyclophosphamide is a notifiable carcinogenic substance under clause 158 of the OHS Regulation and its use must be reported to WorkCover in accordance with clauses 345 and 346. For information on notification procedures, see *Work involving use of carcinogenic substances – guidelines for notification and the notification form*.

When cytotoxic drugs are classified as hazardous substances, any waste they generate is also likely to be classified as a hazardous substance – and the OHS Regulation applies.

The NSW Department of Environment and Climate Change (DECC) also regulates the transport of cytotoxic waste, particularly bulk transports. See the chapter on waste management for further information.

### **2.2.3 Duties of manufacturers, importers and suppliers of hazardous substances**

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

They are required to:

- determine whether a substance is a hazardous substance
- prepare and provide specific information in the form of material safety data sheets and labels to employers who use their substances.

Suppliers (excluding retailers) are required to:

- provide employers with a copy of the manufacturer's or importer's material safety data sheets

- ensure that containers of hazardous substances are 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 the workplace, how a cytotoxic drug is used, or is to be used, determines the appropriate label that is required. The NSW *Poisons and Therapeutic Goods Regulation 2002* requires packaging and labelling of controlled or restricted drugs to comply with the Commonwealth *Standard for the uniform scheduling of drugs and poisons*. 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 *National code of practice for the labelling of workplace substances* [NOHSC:2012 (1994)], or its successors (this code has been adopted by the OHS Regulation).

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

To meet the legal requirements for labelling, suppliers and employers must first determine whether a cytotoxic drug that is also a scheduled poison is to be used for purposes of work, such as healthcare facilities and veterinary practices, or domestic use.

Under the OHS Regulation, suppliers and employers have specific responsibilities for labelling cytotoxic drugs that are hazardous substances. In NSW, the supplier must ensure hazardous substances are appropriately labelled (see clause 156).

An employer must ensure that a container that holds a hazardous substance used at work, including one supplied to or produced within the employer's place of work, is appropriately labelled and that the label is not removed, defaced or altered (see clause 163).

The label must:

- clearly identify the hazardous substance
- provide basic health and safety information about the substance, including any relevant risk phrases and safety phrases.

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

- *Code of practice for the labelling of workplace substances*
- *Code of practice for the control of workplace hazardous substances*
- *Reading labels and material safety data sheets*
- *Standard for the uniform scheduling of drugs and poisons (SUSDP)*.

**Table 1: Workplace labelling for hazardous substances and dangerous goods**

Label items	Capacity of container		
	Greater than 500 mL (g)	500 mL (g) or less (small containers)	Container too small to attach label
Identification information:			
• product name	Yes	Yes	Yes
• chemical name	Yes	Yes	No
• United Nations number, class and subsidiary risk (where required by ADG Code)	Yes	Yes	No
• ingredients and formulation	Where relevant	No	No
Risk phrases	Yes	Yes (at least the most significant phrases)	No
Safety phrases	Yes	Yes (at least the most significant phrases)	No
Direction for use	Where appropriate	No	No
First aid procedures	Yes	Yes	No
Emergency procedure	Yes	No	No
Details of manufacturer or importer	Yes	Yes	Yes
Expiry date	Where relevant	No	No
Reference to the material safety data sheet	Yes	Yes	No

Source: *Guide for handling cytotoxic (anti neoplastic) drugs and related waste*, 2005, Queensland Department of Industrial Relations.

### 2.2.5 Material Safety Data Sheets

The material safety data sheet (MSDS) is a document that describes the chemical and physical properties of a material, and provides advice on the safe handling and use of the material. The material 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 materials.

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

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

Employers must ensure that material 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 material safety data sheets, refer to the:

- *National code of practice for the preparation of material safety data sheets, 2nd edition* (NOHSC: 2011 (2003)), Australian Safety and Compensation Council
- *Code of practice for the control of workplace hazardous substances*, July 1996, WorkCover
- *Reading labels and material safety data sheets*, 2006, WorkCover.

#### **2.2.6 Duty of supplier supplying carcinogenic substances**

A person who supplies a notifiable carcinogenic substance (cyclophosphamide) for use at work must keep a record containing:

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

The record must be retained for at least five years.

#### **2.2.7 Summary of duties of employers who use hazardous substances**

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

In summary, the OHS Regulation requires employers to:

- obtain a copy of the manufacturer's or importer's material safety data sheet and ensure that it is accessible to workers
- ensure all containers of hazardous substances are labelled according to legislation
- set-up a hazardous substances register (see appendix 5)
- assess employees' risk to health from exposure to hazardous substances
- eliminate or control the risk associated with the use of hazardous substances

- provide employees with information, instruction and training
- consult with employees.

### **2.2.8 Transport of cytotoxic drugs as dangerous goods**

WorkCover is the competent authority on dangerous goods in NSW. However, the NSW Department of Environment and Climate Change (DECC) 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 Dangerous Goods Code* and DECC requirements.

### **2.2.9 Plant and equipment**

Chapter 5 of the OHS 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.

Employers, self-employed persons, designers, manufacturers, suppliers and installers of plant have obligations under chapter 5. 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 work systems include:

- drugs and poisons legislation administered by NSW Health
  - *Poisons and Therapeutic Goods Act 1966*
  - *Poisons and Therapeutic Goods Regulation 2002*
  - *Standard for the uniform scheduling of drugs and poisons*, Therapeutic Goods Administration
- waste management legislation administered by NSW Department of Environment and Climate Change (specifically by the Environment Protection Authority)
  - *Protection of the Environment Operations Act 1997*
  - *Protection of the Environment Operations (Waste) Regulation 2005*
  - *Environmental guideline – assessment, classification and management of liquid and non-liquid wastes*, Department of Environment and Climate Change (NSW).

- transport of dangerous goods legislation administered by NSW Department of Environment and Climate Change
  - *Road and Rail Transport (Dangerous Goods) Act 1997*
  - *Road and Rail (Dangerous Goods)(Rail) Regulation 1999*
  - *Road and Rail (Dangerous Goods)(Road) Regulation 1998*
  - *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.
- the Professional Standards of 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* endorsed by the SHPA
- policy directives issued by the NSW Health.

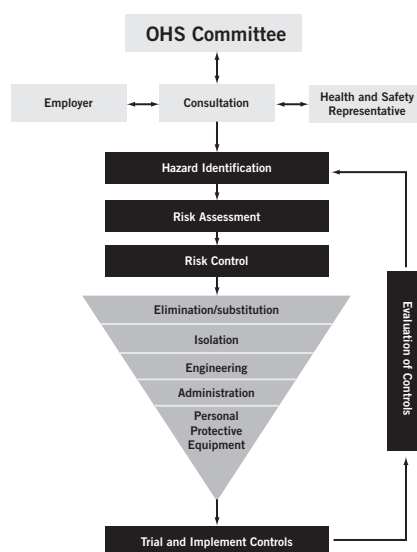
Various agency and institutional policies and policy directives assist in interpreting legislation. For further information, see appendix 2.

## 2.4 Integrating health and safety into the workplace

Effective management of health and safety is essential to protecting the health of employees. An employer should ensure that all managers, contractors, supervisors and employees 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 occupational 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. Occupational 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 a risk management approach is to eliminate or minimise the risk of illness or injury associated with work. The process is outlined in chapter 2 of the OHS Regulation. Generally, it is a process of:

- 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 management system.

An overview for managing the risks associated with cytotoxic drugs and body waste is provided in chapter 3 and appendix 10.

## **2.6 Consultation**

The OHS Act places a duty to consult on each employer. This enables employees 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 OHS Act also requires employers to consult with employees about consultative arrangements. These arrangements include:

- an occupational health and safety committee comprised of employer and employee representatives
- occupational health and safety representatives elected by employees
- other agreed arrangements
- a combination of the above.

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

Consultative arrangements should include a mechanism to ensure the views of non-English speaking background employees are canvassed and considered. Enough time must be allowed for health and safety representatives to confer with employees and relay their ideas back to employers.

Employers 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 combinations 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
- when reviewing the effectiveness of control measures
- prior to changing premises, work environment, plant, systems of work or substances used for work, including material safety data sheets.

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

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

Volunteers are not employees and the duty to consult, therefore, does not apply. However, the employer does owe volunteers a duty of care to ensure they are not exposed to risks to their health and safety under the OHS Act, and consultation is most valuable in assisting the employer to meet this duty of care.

Refer to the *WorkCover Code of practice for OHS consultation* for detailed information, advice and legal obligations on consultation.

### 3 RISK MANAGEMENT

This chapter outlines the risk management process that employers should follow for identifying the hazard, assessing the risk, and controlling the risk. It leads employers through the risk management process in a logical progression. Use it to design a risk management strategy. Employees should be consulted at every stage of the risk management process, as per agreed consultation arrangements that reflect the OHS Act.

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 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 substances register</li> <li>• hazardous substances (cytotoxic drugs) register (appendix 5)</li> <li>• risk assessment reports.</li> </ul>
Identify cytotoxic drugs and create a register	Ways of achieving this include: <ul style="list-style-type: none"> <li>• taking note of label warnings</li> <li>• noting additional information from sources/ references – 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 material safety data sheet</li> <li>• if a material safety data sheet is not available, obtaining safety information about the relevant cytotoxic drug from the manufacturer or importer.</li> </ul>
Identify adverse effects.	Ways of achieving this include: <ul style="list-style-type: none"> <li>• a material 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 substances (cytotoxic drugs) register.	Ways of achieving this include: <ul style="list-style-type: none"> <li>• having cytotoxic drugs in your hazardous substances register <ul style="list-style-type: none"> <li>• checking the material safety data sheet and label to identify cytotoxic drugs that are classified as hazardous substances – the material safety data sheet will state whether the product is classified as hazardous</li> </ul> </li> <li>• listing the product names of all cytotoxic drugs used at the workplace</li> <li>• referring to appendix 5.</li> </ul>

Consult with employees.	Ways of achieving this include: <ul style="list-style-type: none"> <li>• OHS committees</li> <li>• OHS representative</li> <li>• other agreed arrangements</li> <li>• direct consultation with employees</li> <li>• referring to section 2.6</li> </ul>
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### 3.2 Assess the risks

The risk assessment determines whether there is a risk to employees' 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 individual drugs, 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 employees, health and safety representatives, supervisors managers and OHS personnel.	What to look for: <ul style="list-style-type: none"> <li>• appropriate skills, knowledge and experience to evaluate the risks</li> <li>• a practical understanding of work being undertaken at the workplace</li> <li>• an understanding of health and safety legislation</li> <li>• the ability to deal with the complexity of the assessment process or the work being assessed.</li> </ul>
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#### 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 substance.	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 material safety data sheet or other available information for each drug for details of the properties and hazard associated with the substance	<p>This may include:</p> <ul style="list-style-type: none"> <li>• health hazard information</li> <li>• precautions for use</li> <li>• safe handling information.</li> </ul>
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### Step 3: Evaluate the nature of the work involving cytotoxic drugs

Divide up the workplace and determine where cytotoxic drugs are used and stored.	<p>This may include:</p> <ul style="list-style-type: none"> <li>• drug preparation in the pharmacy</li> <li>• drug administration in the ward or day clinic</li> <li>• community settings</li> <li>• veterinary practices</li> <li>• handling, transporting and disposing of cytotoxic waste on the premises</li> <li>• patient care after administration.</li> </ul>
Examine the work practices and conditions.	<p>What to look for:</p> <ul style="list-style-type: none"> <li>• how the substance is used in various jobs</li> <li>• the quantities used</li> <li>• level of potential exposure</li> <li>• frequency and duration of use</li> <li>• the number of employees that may be exposed</li> <li>• risk control measures already in place and their effectiveness</li> </ul> <p>Involve employees who are working with the cytotoxic drugs.</p>
Review information relating to incidents or symptoms of exposure monitoring and health surveillance.	<p>What to look for:</p> <ul style="list-style-type: none"> <li>• incident records</li> <li>• problems associated with storage and transport of cytotoxic drugs</li> <li>• employee reports of any adverse effects</li> <li>• record of any spills</li> <li>• reported incidents and follow-up</li> <li>• monitoring health surveillance records.</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:

<p><b>No likelihood of injury or illness.</b> Risk assessment indicates a high degree of confidence that work practices are sound and that employees are protected.</p>	<p>It may be reasonable to make such a conclusion when:</p> <ul style="list-style-type: none"><li>• risks have been eliminated/minimised as far as is practicable</li><li>• work methods employ best practice control</li><li>• drug packaging features in-built breakage prevention systems</li><li>• cytotoxic drugs are handled in an enclosed area such as a properly operational cleanroom with a laminar flow cytotoxic drug safety cabinet</li><li>• needleless drug administration systems or retractable needles are used.</li></ul>
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or

<p><b>Likelihood of injury or illness is uncertain.</b> Risk assessment indicates whether work practices are adequate to protect employees.</p>	<p>It may be reasonable to make such a conclusion where employers are not sure if there is a risk to health. It may require employers to do more evaluation of the workplace, such as:</p> <ul style="list-style-type: none"><li>• 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</li><li>• eliminate or minimise exposure as far as is practicable.</li></ul>
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or

<p><b>Likelihood of injury or illness.</b> Risk assessment indicates that work practices need improvement.</p>	<p>It may be reasonable to make such a conclusion, when:</p> <ul style="list-style-type: none"><li>• work methods do not employ effective control strategies</li><li>• drug preparation is not conducted within a properly operational cleanroom with a laminar flow cytotoxic drug safety cabinet</li><li>• drug administration does not employ needleless or other safety systems</li><li>• housekeeping is poor</li><li>• some activities involve skin contact</li><li>• appropriate personal protective equipment is not worn</li><li>• the workforce has not received appropriate training</li><li>• control measures are not maintained or serviced</li><li>• no spill management system exists</li><li>• there is poor compliance with the material safety data sheet or other guidance material</li><li>• staff are not reporting incidents or symptoms of exposure.</li></ul>
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### 3.3 Record, review and revise the risk assessment

<p><b>Record the risk assessment.</b></p> <p>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 indicate areas of improvement.</p>	<p>What to include:</p> <ul style="list-style-type: none"> <li>• name of the assessor</li> <li>• nature and level of consultation</li> <li>• names of those consulted</li> <li>• date of the assessment</li> <li>• the workplace/unit</li> <li>• the substance for which the material safety data sheet or equivalent information has been reviewed</li> <li>• the controls in place to prevent a risk to health</li> <li>• a summary of the process</li> <li>• hazard information on the substances</li> <li>• the degree of exposure or nature of risk identified</li> <li>• why decisions about the risk were made</li> <li>• any information that assisted in reaching a conclusion</li> <li>• conclusions and recommendations</li> <li>• signatures of people involved in the risk assessment</li> <li>• make the records accessible to employees.</li> </ul>
<p><b>Review and revise the risk assessment.</b></p> <p>The risk assessment should be reviewed and revised as necessary and at least every five years.</p>	<p>Ways of achieving this include:</p> <ul style="list-style-type: none"> <li>• scheduling regular reviews once every five years to ensure that the assessment is valid and still applies</li> <li>• establishing the circumstances that would trigger a review or revision, such as: <ul style="list-style-type: none"> <li>○ an incident or near miss resulting from the failure of the control measures used</li> <li>○ symptoms reported which may be related to the substance used</li> <li>○ a change in the product used (including its form)</li> <li>○ introduction of a new work process or changes to an existing process</li> <li>○ increase in the hours worked or frequency and duration of exposure</li> <li>○ increase in the quantities used</li> <li>○ availability of new information about the health hazards of the substances</li> </ul> </li> <li>• ensuring that management, supervisors, health and safety representatives and purchasing officers feed back the outcome of the review into the assessment process</li> <li>• recording the date of the review or revision of the assessment, including the outcome, any action required to be taken, by when and by whom.</li> </ul>

### 3.4 Control the risk

The OHS Regulation sets out a hierarchy of control (or ranking of controls) to manage workplace risks. The employer's primary duty is to eliminate any risk to health arising from the use of a hazardous substance. Where elimination of risk is not practicable, employers must control the risk.

### 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

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

<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 substance or a substance 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 least 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 impermeable packaging for delivery to administration areas</li><li>• designating a cytotoxic drug administration area, which only permits entry to authorised people.</li></ul>

<p><b>Engineering controls</b> – plant or processes that minimise the generation of substances, suppress or contain substances, or limit the area of contamination in the event of spills and leaks</p>	<p>Ways of achieving this include:</p> <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>
<p><b>Administrative controls</b> – safer ways of doing a job, which helps to minimise employee exposure to cytotoxic drugs and related waste.</p> <p>The effective use of administrative controls relies on the full cooperation of employees, 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 employee exposure to cytotoxic drugs and related waste.</p>	<p>Ways of achieving this include:</p> <ul style="list-style-type: none"> <li>• allocating responsibilities for health and safety</li> <li>• minimising the number of employees who work with cytotoxic drugs</li> <li>• cleaning work areas regularly</li> <li>• keeping containers of cytotoxic drugs secure</li> <li>• incorporating handling techniques that minimise aerosol generation</li> <li>• prohibiting eating, drinking and smoking in work areas</li> <li>• developing and implementing safe work procedures (safe working procedures) for all work activities</li> <li>• providing appropriate information, education and training to employees and carers</li> <li>• using cytotoxic signs and labels to clearly identify all cytotoxic drugs</li> <li>• storing cytotoxic drugs in specific, clearly identified areas</li> <li>• storing cytotoxic waste in specific, clearly identified areas, separate from other waste</li> <li>• developing emergency procedures to deal with spills.</li> </ul>
<p><b>Personal protective equipment</b> – something worn that provides a barrier between the person and the hazard.</p>	<p>This may include</p> <ul style="list-style-type: none"> <li>• impermeable coveralls and gowns</li> <li>• head covering</li> <li>• closed footwear</li> <li>• overshoes</li> <li>• gloves of appropriate material and thickness</li> <li>• safety glasses</li> <li>• respiratory protective devices – respiratory filters must be inspected and maintained regularly (see appendix 9).</li> </ul>

### 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.

Employers must ensure that all employees 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

Employers need to ensure that all control measures are properly used and maintained. Employers 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 employees 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

<p><b>Risk control plan</b></p> <p>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.</p> <p>The OHS Regulation requires the risk control plan to be developed in consultation with employees.</p>	<p>This may include:</p> <ul style="list-style-type: none"><li>• a history of health and safety activities for work involving cytotoxic drugs, including any current control measures and their effectiveness</li><li>• the immediate, interim and long-term control measures</li><li>• the priorities for putting controls in place</li><li>• the date controls are to be implemented</li><li>• the names of those responsible for overseeing the implementation</li><li>• the date of completion and 'sign off' by a management-nominated person</li><li>• the relevant policies and procedures for work involving cytotoxic drugs</li><li>• training</li><li>• consultation</li><li>• documentation of activities</li><li>• regular review of management systems</li><li>• provisions for those at special risk<ul style="list-style-type: none"><li>– eg pregnant women, disabled workers.</li></ul></li></ul>
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### 3.8 Maintain risk controls

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

<p><b>Maintain control measures</b> Maintain risk control measures to ensure that they perform as originally intended and continue to provide adequate risk control.</p>	<p>This may include:</p> <ul style="list-style-type: none"><li>• auditing compliance with safe work practices</li><li>• inspections</li><li>• equipment testing</li><li>• preventive maintenance</li><li>• checking and replacing of cabinet filters</li><li>• checking and replacing personal protective equipment</li><li>• review of employee competencies</li><li>• monitoring health surveillance results</li><li>• periodic environmental monitoring</li><li>• incident investigation.</li></ul>
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### 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.

<p><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.</p> <p>Criteria for triggering a review of risk control measures are the same as for review of risk assessments.</p>	<p>This may include:</p> <ul style="list-style-type: none"><li>• comparison with standards and guidelines, especially if these have been updated or reviewed with advances in technology and knowledge in the field</li><li>• consultation with employees</li><li>• conduct of 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 employees and manage the work systems. Personnel management involves employee health monitoring and counselling, reporting and record-keeping.

Employers have a duty to provide supervision to employees who handle cytotoxic drugs and related waste. However, in the case of unplanned exposure to cytotoxic drugs – eg spills or sharps injuries – options for specific health supervision or surveillance are limited.

### **4.2 What is health surveillance?**

The OHS Regulation requires employers to provide health surveillance of employees when the risk assessment identifies substances in the workplace that are hazardous to health. Health surveillance is the monitoring and counselling of individuals to identify changes to health status due to occupational exposure to a substance. Health monitoring may include biological monitoring, which is the measurement and evaluation of a substance, or its metabolites, in the body tissue, fluids or exhaled air of an exposed person.

Employers have a responsibility to ensure that they remain aware of, and apply current developments for, monitoring the health of employees 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.

Unfortunately, there is currently no test that meets all these requirements – nor is there one test that can be used to detect the presence of all cytotoxic drugs. As a consequence, there is conflicting information and opinion about the value of routine biological tests in monitoring the health of employees handling cytotoxic drugs and related waste.

### **4.4 What type of health surveillance should be provided?**

Employers should implement a health surveillance program for cytotoxic drugs. Clause 165 of the OHS Regulation requires employers to provide health surveillance for employees exposed to hazardous substances when the risk assessment indicates that this is necessary and a suitable test is available. In practical terms, all cytotoxic drugs are hazardous substances.

In NSW, cyclophosphamide is a cytotoxic drug that is also recognised as a notifiable carcinogenic substance under the OHS Regulation. However, the type of health surveillance to be undertaken for cyclophosphamide is not specified in the Regulation.

The need for biological monitoring to detect exposure to a scheduled carcinogenic substance, 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 surveillance that can detect the early signs of hazardous exposure or disease.

Health surveillance must continue throughout the period of use of a scheduled carcinogenic substance.

The health surveillance program must meet the needs of employees by providing security of personal information, care, freedom of selecting an authorised 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.</p> <p>Appointment means that the employer has a formal arrangement with a medical practitioner. All employees 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>• core competencies that represent a minimum standard for performing health monitoring are provided by the NOHSC <i>Competencies for health surveillance</i> (1998).</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 NOHSC <i>Competencies for health surveillance</i> (1998) and <i>Guidelines for health surveillance</i> (1995).</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>• employees and health and safety representatives must be involved in the development and management of the program</li> <li>• the employer must ensure that the appointed medical practitioner is provided with access to the workplace and information required</li> <li>• the employer must involve the appointed medical practitioner in the risk management strategies of the workplace, such as health and safety committee meetings</li> <li>• history of incidents and health and safety performance.</li> </ul>

Factors in implementing a health monitoring program	Considerations
4. Prospective employees are counselled and provided information about the risks of working with cytotoxic drugs.	The counselling must include: <ul style="list-style-type: none"> <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>• the control measures in place.</li> </ul>
5. Baseline health monitoring is conducted by the appointed medical practitioner before an employee commences work with cytotoxic drugs.	Baseline health monitoring, as outlined in appendix 7, provides: <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 employer and prospective employee.</li> </ul>
6. Health monitoring is conducted during the period that the employee works with cytotoxic drugs.	Health monitoring conducted during the period the employee works with cytotoxic drugs, as outlined in appendix 7, provides: <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 employees at any time during their employment.	Employees may arrange a consultation with the appointed medical practitioner at any time.
8. Employees are provided with freedom of choice and have the right not to work with cytotoxic drugs.	Appropriate and suitable alternative duties should be provided to employees who choose not to, or are unable to, work with cytotoxic drugs. In such cases, employees should not suffer disadvantage in relation to loss of pay and conditions, and continuity of service. All entitlements must be maintained.
9. The results of health monitoring are provided to the employee to whom the results relate.	The results should be available as soon as reasonably possible.

Factors in implementing a health monitoring program	Considerations
10. An employee's medical records are confidential.	Where any form of health monitoring is undertaken, confidentiality of an employee's medical records must be ensured. Access to an employee's medical records can be obtained only with the written consent of the employee.
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 employee's employment each employee must receive a written statement that includes:</p> <ul style="list-style-type: none"> <li>• the name of the carcinogenic substance or substances involved</li> <li>• the period of exposure or potential exposure</li> <li>• details of how and where records of the exposure or potential exposure can be obtained</li> <li>• 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.</li> </ul>
12. Biological monitoring issues	<p>No one test can be used to detect the presence of all cytotoxic drugs.</p> <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 employees on appropriate biological monitoring to be carried out.</p> <p>Obtain informed consent from employees to do tests.</p>

Factors in implementing a health monitoring program	Considerations
13. Consultation	<p>Employers to consult with employees 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 material safety data sheets</li> <li>• where appropriate, when an employee's circumstances change – eg pregnant women and immuno-compromised individuals.</li> </ul> <p>Accurate and relevant safety information must be made available to employees and others.</p>

Risk control is the key to protecting the health of employees. Take 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

Employees who are pregnant, breast-feeding or planning parenthood and are involved in the preparation or administration of cytotoxic drugs and the 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 to not do so. 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 employer must keep the following records:

- the name of any employee exposed to a notifiable carcinogenic substance (cyclophosphamide), including:
  - their date of birth
  - their address while employed by the employer
  - this record must be kept for at least 30 years from the date of the last record
- a register of all hazardous substances (including cytotoxic drugs) that are used in the workplace, along with the current material safety data sheet for each substance listed
- a copy of each notification to WorkCover of an intention to carry out work that involves the use of a carcinogenic substance (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 substances
- individual employee 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 a notifiable carcinogenic substance.

On the termination of an employee's employment, the employer must provide an employee who has been, or is likely to have been, exposed to a notifiable carcinogenic substance with a written statement that includes the following:

- the name of the carcinogenic substance or substances involved
- 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 employee should keep copies of their records.

## 5 INFORMATION, INSTRUCTION AND TRAINING

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

Training should be undertaken:

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

Employers should ensure that only employees 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 staff 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 staff/carers potentially affected include:

Level 1 training should be given to staff 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 staff or carers who have limited contact with cytotoxic drugs and are at low risk, including:

- supervisors and managers
- maintenance personnel
- stores personnel
- cleaners
- on-site waste transporters
- couriers and porters
- waste handlers
- carers
- ambulance officers
- patient transport personnel.

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

## 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, the NSW Cancer Institute, or 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:

- occupational 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 surveillance and reporting
- any written safe work 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, substance, work practices or control measure, or
  - at least every two years.

Oncology and haematology specialists should review any written competencies regularly. Following all incidents and accidents, the training program should be reviewed to ensure its adequacy.

#### **5.4 Keep training records**

Employers must keep records of employees' training for at least five years after the date the record was created. Training records should include:

- date of the session
- topics dealt with at the session
- name of the person who conducted the session
- names of the employees (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 occupational exposure to personnel.

Exposure may occur through:

- skin, eye or mucous membrane contact with cytotoxic material
- 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* (2000), The Society of Hospital Pharmacists of Australia (SHPA).

Key risk controls include:

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

When people are working in isolation:

- working-alone arrangements should be in place – eg duress alarm
- access should be controlled.

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

- AS 1386-1989 *Cleanrooms and clean workstations*
- *Guidelines for preparing plans and specifications for an 'aseptic' (cleanroom) suite, 'cytotoxic drug suite' or 'combined suite' in a hospital or related facility*, Technical Bulletin No. 3, Therapeutic Goods Administration.

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 2567-1994 *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 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 material 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. Damaged packages should be handled with care. Badly damaged packages should be safely contained and returned to the manufacturer or supplier with suitable warning labels.

In the drug preparation area, 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 DECC also have requirements for drug storage 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 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 – eg 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 IV lines in the cytotoxic drug safety cabinets.

## 6.5 Safe work procedures for preparing cytotoxic drugs

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

All preparations must be undertaken in cytotoxic drug safety cabinets as specified in AS2567-1994 *Laminar flow cytotoxic drug safety cabinets* and AS4273-2002 *Guidelines for the design, installation and use of pharmaceutical isolators*.

### 6.5.1 Parenteral preparations

Safe work 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, topical creams and ophthalmic preparations should be prepared under the same conditions as parenteral cytotoxic drugs. Additional safe work 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 on cytotoxic drug containers (including syringes and IV 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 Talex/polyvinyl gloves and use spatula to apply'

- Cytotoxic drugs that are vesicants should have an extravasation warning label
- Additional labelling should be used if required by 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) – see 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.

### **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 - eg 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 in a vehicle, drug containers should be placed in the boot.

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 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 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 employees
- identification of faulty cabinets – eg attach a lock-out tag and do not use until fixed
- repair of faulty cabinet faults, and recertification prior to use
- routine performing and recording of microbial and air-particle testing.

### **6.9.3 Cleaning drug preparation facilities**

Safe work 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"/>
• Safe work 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 this guide	
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 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. To ensure that control measures and safe work practices are developed, understood, implemented and maintained, education, training and supervision are crucial.

### 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 – eg 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 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 system of the ward or day clinic is 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 material safety data sheets, in a place accessible to employees

- 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 (see 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**

Safe work 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 – eg after intrapleural, intravesicular 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 – eg 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 the 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"/>
• Safe work procedures	<input type="checkbox"/>

Control measures referred to elsewhere in this guide	
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

## 8 MANAGING CYTOTOXIC CONTAMINATED BODY WASTES

After cytotoxic drugs have been administered, nursing, medical and pathology staff, and others, may care for patients. Ambulance 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, 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 – see appendix 10.

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 and maintained, 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 a 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 system of the patient care centre, a safe work procedure must be developed and maintained.

### 8.2 Assessment of body waste contamination

To assist in determining whether body wastes are 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 waste disposal bin is available
- laundry bag is provided
- an area to store personal protective equipment.

#### **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.

#### **8.3.3 Safe work procedures**

Safe work procedures should be adopted and 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 a hot pan flusher or a toilet with a lid, and the contents of colostomy or urostomy bags, incontinence aids, disposable nappies and heavily exuding dressing materials into bags and in a cytotoxic waste bin
- 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 personal protective equipment when handling body waste or cytotoxic contaminated equipment.

#### **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 (only in a spill or for incontinence on the floor)
- 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 while drug administration is in progress, the following control measures should be implemented:

- constant supervision by medical or nursing staff
- immediate access to emergency assistance in the event of a spill
- immediate access to a spill kit
- those at the patient's new destination must be aware of cytotoxic procedures.

#### **8.4.2 By ambulance**

When transporting a patient by ambulance, the control measures outlined in this chapter should be implemented.

The ambulance service should be made aware that the patient is undergoing cytotoxic drug treatment.

### **8.5 Laundering**

#### **8.5.1 Contaminated 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.

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.

### 8.5.2 Contaminated linen

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

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

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

### 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"/>
• Safe work 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 this guide	
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
- 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 employer should establish a spill management strategy with the assistance of those involved in preparing, administering, transporting and managing cytotoxic drugs. 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.

### 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 its contents have not deteriorated.

A spill kit may include:

- instructions on how to use – eg safe work procedures for the management of a cytotoxic spill
- signs to identify and isolate the spill
- personal protective equipment
- adequate quantities of absorbent materials - eg swabs, absorbent towels, spill pillow, chemical absorbent pads, protective mats (bluey or 'chemomat')

- a small scoop to collect any glass fragments
- two plastic waste bags, clearly identified as cytotoxic
- incident report forms.

Water can be used for cleaning, rinsing or dampening a spill. Detergent should also be used.

## **9.5 Spill containment**

### **9.5.1 In health care settings**

The following procedure is recommended, but may be adapted for local requirements.

- Alert all those in the immediate vicinity that a cytotoxic spill has occurred, and tell them to stay clear
- Open the cytotoxic spill kit - display signs, restrict access, and call for assistance if required
- Don a particulate 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
- Wash area several times with detergent and water, working from area of least contamination
- Rinse area thoroughly with water
- 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 contaminated personal protective equipment and inner gloves into the outer bag and seal it
- 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. See appendix 12.

### **9.5.3 On carpets**

The use of carpets 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 water
- 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 – the eyes – 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

Employers 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 a spills 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 *Guidelines for medical practitioners in health monitoring for cytotoxic drugs* (refer: appendix 7).

### 9.7.1 Notification of incidents

It is a legal requirement of the employer and/or the occupier of a workplace to notify WorkCover of any spill involving cyclophosphamide.

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

For further information on notification requirements, refer to *The new simple way to notify work-related incidents* and *The community services safety pack*.

## 9.8 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?
• Setting-up a spill management strategy	<input type="checkbox"/>
• Managing spills	<input type="checkbox"/>
• Safe work procedures	<input type="checkbox"/>
• Personal protective equipment	<input type="checkbox"/>
• Reporting procedures	<input type="checkbox"/>

Control measures referred to elsewhere in this guide	
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 safe work 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 2005* (the 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.

*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 DECC legislative requirements, see chapter 2. Specific information regarding clinical and related waste is available on the DECC web site [www.environment.nsw.gov.au/waste/ClinicalWaste.htm](http://www.environment.nsw.gov.au/waste/ClinicalWaste.htm)

### 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 drugs
- used HEPA or chemical filters and other disposable contaminated equipment
- contaminated personal protective equipment – eg 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 – eg disposable vomit bags
- dressings, bandages, nappies, incontinence aids and ostomy bags
- heavily soiled and contaminated bedding that is unable to be cleaned
- contaminated specimens from the laboratory.

Cytotoxic waste is defined in the POEO Act and DECC *Waste classification guidelines – Part 1: classifying waste* (DECC 2008) – [www.environment.nsw.gov.au/waste/envguidlns/index.htm](http://www.environment.nsw.gov.au/waste/envguidlns/index.htm). 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.’

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 or classified as hazardous waste. Effective separation and segregation of the different waste streams in a clinical setting are 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 *Waste management guidelines for health care facilities*.

## 10.2 Risk management

Employers 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 must be treated by thermal destruction, or by a chemical process that removes their cytotoxic and other hazardous characteristics. Cytotoxic wastes may not be disposed of to landfill in NSW.

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

*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 *Management of clinical and related waste* and HB 202 *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 *Management of clinical and related wastes and Waste management guidelines for health care facilities* specify the following colours and symbol for cytotoxic waste:

- containers and bags must be purple/lilac
- the container must have a white label with the symbol of a cell in late telophase
- the correct labelling words are 'CYTOTOXIC WASTE'.

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

### 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 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.

The storage of sharps should be undertaken according to AS/NZ 3816 *Management of clinical and related wastes* and AS/NZ 4031 *Non-reuseable containers for the collection of sharp medical items used in health care areas*, and *Waste management guidelines for health care facilities*. The DECC has specific requirements with regard to the transport of sharps.

Sharps waste 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 (eg needles, syringes with needles, or surgical instruments)
- that are designed for such a purpose
- that have the potential to cause injury or infection,

but does not include any such waste that has been treated by a method approved in writing by the Director-General of the Department of Health.'

All contaminated sharps must be placed into a rigid-walled, puncture-resistant container that meets the requirements of AS/NZ 4031 *Non-reuseable 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.

### 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 *Waste management guidelines for health care facilities*, AS/NZ 3816 *Management of clinical and related wastes* and HB 202 *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 the *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 Waste Regulation. The waste must be packaged in accordance with the August edition of *NSW Health: Waste management guidelines for health care facilities* issued by the Department of Health.

Environment protection standards that need to be complied with include:

- storing the waste in an environmentally safe manner

- not storing the waste with, or having 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 [www.environment.nsw.gov.au/waste/exemption.htm](http://www.environment.nsw.gov.au/waste/exemption.htm)

However, the transport of clinical and related waste, including the transport of cytotoxic waste interstate, needs to be tracked pursuant to schedule 1 of the Waste Regulation. Part 3 of the Waste Regulation sets out the waste-tracking and record-keeping requirements for waste that must be tracked.

DECC has developed an internet-based waste tracking system (online waste tracking) as an alternative to paper-based waste tracking. Further information is available on [www.environment.nsw.gov.au/owt/aboutowt.htm](http://www.environment.nsw.gov.au/owt/aboutowt.htm)

### **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 – eg wheelie bins, handcarts and trolleys – to move cytotoxic waste around the facility
- ensure such equipment – eg 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 (eg visiting hours, meal times and change of shifts)
- 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, secured, 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, decontaminated and maintained to acceptable hygiene standards.

### 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, and must be consistent with other relevant regulations. Employers 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 licences 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 – eg material safety data sheets – from the waste generator
- use of labelling, signage and vehicle placards to identify contaminated waste
- development of emergency procedures in the event of a spill or vehicle accident
- training of drivers and waste-handling workers
- use of designated transport vehicles for clinical or cytotoxic waste – they 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.

Cytotoxic waste should 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 hazardous substances (including cytotoxic waste) should be in accordance with the International Air Transport Association (IATA) *Dangerous Goods Regulations*. Contact the airlines for specific advice.

The United Nations (UN) *Recommendations on the transport of dangerous goods* has been internationally adopted, and federal, state and territory jurisdictions are incorporating these recommendations in their dangerous goods legislation. The recommendations specifically identify Class 6.2 as infectious substances that have the greatest impact in health care wastes. Class 6.2 has three UN classifications:

UN 3291	Clinical waste, unspecified, N.O.S. or (bio) medical waste, N.O.S. or regulated medical waste, N.O.S.
UN 2814	Infectious substance, affecting humans
UN 2900	Infectious substance, affecting animals

The most equitable UN number to be associated with health care wastes appears to be UN 3291.

For further information on the transport of clinical and related waste (including cytotoxic waste), see AS/NZ 3816 *Management of clinical and related waste*.

#### **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 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 regarding display information, as outlined in the ADG code. The vehicle must display the Class 6.1 and Class 6.2 dangerous goods label. The transporter is likely to convey both the cytotoxic (Class 6.1 toxic) waste and the clinical (Class 6.2 infectious) waste.

#### **10.8.3 Other requirements for cytotoxic waste transporters that do not have to be licensed**

Waste-tracking requirements for unlicensed waste transporters are the same as those for licensed transporters. If the waste transported from the premises is over 200 kg per load, the transporter must be licensed.

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 occupational health and safety legislation.

## 10.9 Waste disposal and treatment

Waste treatment facilities receiving and treating hazardous waste, restricted solid waste and 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 DECC 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 DECC 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 economic to transport the waste to a licensed facility.

### 10.9.3 Record-keeping requirements

Record-keeping requirements relating to occupiers of waste facilities are outlined in part 3 of the Waste Regulation. The generator, transporter and facility receiving the waste must keep records and the tracking documentation for four years and provide any reports, as may be required, to the DECC.

## 10.10 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?
• 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"/>

Control measures referred to elsewhere in this guide	
Chapter 3	Risk Management
Chapter 4	Personnel Management
Chapter 5	Information, Instruction and Training
Chapter 9	Spill Management

# 11 CARING FOR PATIENTS IN COMMUNITY SETTINGS

## 11.1 Doctor's surgery and ambulatory care facility

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

### 11.1.1 Risk management

Health care establishments unable to provide facilities, equipment or a level of care as outlined in this guide 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 employees 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.

Employees 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

Employers 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 this guide 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** because 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 employees, maintaining spill kits and developing safe work procedures for spills in health care settings.

### **11.2 Caring for patients at home**

The information in this section relates primarily to carers – ie 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, but 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 (see 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 seweried toilet (although this may not be available in all rural areas)
- appropriate waste disposal – eg cytotoxic waste bins.

A patient care area should be set up 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**

Safe work 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 (see 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)
- details about impermeable mattresses and furniture protectors for incontinent patients.

### **11.2.6 Administering cytotoxic drugs**

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 – ie 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 disposable gloves if possible – ie clean-up contaminated waste, then wash affected area with water and detergent. 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
- washing 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 a vehicle, for disposal in a cytotoxic waste bin. When there is no community health care worker, a patient or carer should dispose of the waste into a sealed plastic bag, 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 – eg 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 Laundering

The treating facility should inform the patient and carer patients 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
- put the gloves into a plastic bag, then into the household garbage.

Once laundered, contaminated linen can be reused.

### 11.2.10 Safe work procedures

With the assistance of the treating facility, safe work 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 generating 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 situation
- have information on the contents of a spill kit
- 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 this guide	
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	Safe Handling of Cytotoxic Contaminated 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 and maintained.

### 12.1 Information, instruction and training

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

Employers should also ensure that only employees who have received appropriate training, and have attained the required level of proficiency, 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.

Employers 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.

Employees 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 Risk management**

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

The risk determines whether there is a risk to employees' 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 assessed and identified, control measures may 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 substances 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 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
- 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 to avoid creating aerosolisation
- review health and safety information about cytotoxic drugs before making a decision to purchase them.

These control options should be considered a priority. A policy may assist to build these control measures into the health and safety 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 and 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 employees, 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 when preparing 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 clean room suite, alternative arrangements should be made to obtain the cytotoxic drugs in a ready-to-use single dose.

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.

Preparing and dispensing cytotoxic drugs for animals should be the same as for humans. See chapters 5 and 6.

### **12.5.1 Labelling and packaging of cytotoxic drugs**

Appropriate warning labels should be on all cytotoxic drug containers, including syringes, IV 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
- 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 material 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 excreted in the urine also. Appendix 10 deals with excretion rates in humans but it may provide a useful approximation for animals.

### **12.8 Spill management**

A spill management strategy will 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. Safe 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 – eg 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 restricted access to unauthorised 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 material safety data sheets, in a place accessible to employees.

### **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 Safe work procedures**

Safe work procedures should be developed and should emphasise the need to:

- place a 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 – ie hose gently, do not pressure hose
- ensure that animals are immediately washed down if they become contaminated and avoid the generation 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:

- impermeable coverall or gown (preferably disposable)
- protective gloves
- protective eyewear
- rubber boots
- waterproof apron
- P2 respirators.

This equipment is suitable to wear when cleaning cages.

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**

Employers must have a system in place for employees to report any spill or employee 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).

Under occupational health and safety law, in cases of spills involving cyclophosphamide, a medical review with a medical practitioner must be arranged as outlined in appendix 7. Consideration should be given to providing medical attention following spills involving any cytotoxic drugs.

#### **12.11.1 Notification of incidents involving cyclophosphamide to WorkCover**

WorkCover must be notified of any spill involving cyclophosphamide. This is a legal requirement of the employer and/or occupier of a workplace.

While the legal requirement to notify WorkCover is restricted to cyclophosphamide because it is a notifiable carcinogenic substance, consideration should be given to notifying WorkCover of spills involving any cytotoxic drugs.

For further information on notification requirements, *The new simple way to notify work-related incidents* and *The community services safety pack (chapter 4 – Preparing for and managing incidents and claims)*.

#### **12.11.2 Notification of cyclophosphamide use to WorkCover**

Cyclophosphamide is a notifiable carcinogenic substance under the OHS Regulation and, therefore, its use must be reported to WorkCover.

See *Work involving use of carcinogenic substances – guidelines for notification* and *Work Involving use of carcinogenic substances – notification form* for guidance on notification procedures.

### **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 employees 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 safe work 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, the DECC regulates this type of waste.

For more information on DECC 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/lilac
- the container must have a white label with the symbol of a cell in late telophase
- the correct labelling words are 'CYTOTOXIC WASTE'.

Storage areas should also be appropriately signed to identify cytotoxic waste from general or infectious waste, particularly if different waste management contractors are used.

### **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.

### **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 disposable 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. 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 of 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?
• Risk management	<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"/>
• Safe work 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 this guide	
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 1 – GLOSSARY

<p><b>A</b></p> <p>absorption</p> <p>administration (of drugs)</p> <p>administrative control</p> <p>ADG Code</p> <p>aerosol</p> <p>ALARA</p> <p>alginate bag</p> <p>allergic</p> <p>ampoule</p> <p>ASCC</p> <p>aseptic manipulation</p> <p>aseptic suite</p> <p>auto-immune disease</p>	<p>a route of exposure – see dermal absorption, mucosal</p> <p>the giving of cytotoxic drugs to a patient – common methods include parenteral, oral and topical administration</p> <p>a type of control measure which involves minimising the risk through the use of procedures or instruction eg SOPs, labelling, training</p> <p><i>Australian code for the transportation of dangerous goods by road and rail</i>, as published by the Commonwealth of Australia and amended from time to time</p> <p>very fine droplets or particles that are homogeneously dispersed in air</p> <p>‘as low as reasonably achievable’</p> <p>bag made of artificial fibres spun from a constituent of kelp – the fibres become gelatinous when moist and so are biodegradable</p> <p>unduly sensitive to some substances</p> <p>small sealed bulb, usually of glass, typically designed to contain a single dose of a drug for injection</p> <p>Australian Safety and Compensation Council – national body that leads and coordinates national efforts to prevent workplace death, injury and disease in Australia, formerly known as National Occupational Health and Safety Commission (NOHSC)</p> <p>activity performed so as to exclude micro-organisms</p> <p>work space free from micro-organisms in the working area</p> <p>alteration of the function of the immune system causing it to attack the body’s own cells</p>
<p><b>B</b></p> <p>biological monitoring</p> <p>body substances</p>	<p>measurement and evaluation of hazardous substances or their metabolites in the body tissue, fluids or exhaled air of a person</p> <p>includes urine, faeces, vomitus, bile, sweat, blood and fluid drained from body cavities</p>
<p><b>C</b></p> <p>carers</p> <p>carcinogen</p> <p>catheter bag (urinary)</p>	<p>a patient’s family members and friends, or volunteers, who are involved in providing care and support for the patient</p> <p>substance or physical agent with the potential to cause cancer in certain circumstances or to make cancer more likely to occur</p> <p>a urine-collecting bag connected to a tube inserted into the bladder</p>

code of practice	<p>an approved industry code of practice is a practical guide to employers and others who have obligations under the <i>Occupational Health and Safety Act 2000</i> (OHS Act) and the <i>Occupational Health and Safety Regulation 2001</i> (OHS Regulation) with respect to occupational health, safety and welfare.</p> <p>An approved industry code of practice should be used in conjunction with the requirements of the OHS Act and the OHS 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 OHS Act or OHS Regulation, failure to observe a relevant approved industry code of practice is admissible as evidence concerning an offence under the OHS Act or OHS Regulation</p>
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	<p>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:</p> <ul style="list-style-type: none"> <li>• in the case of a container designed to hold gas – a container that has a capacity of more than 500 litres</li> <li>• 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</li> </ul>
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

<p><b>D</b></p> <p>DECC</p> <p>dermatitis</p> <p>dermal absorption</p>	<p>NSW Department of Environment and Climate Change</p> <p>inflammation of the skin</p> <p>a route of exposure – taking in cytotoxic drug or related waste through the skin</p>
<p><b>E</b></p> <p>elimination</p> <p>employer</p> <p>employee</p> <p>engineering control</p> <p>equipment</p> <p>exposed</p> <p>exposure standards</p> <p>extravasation</p>	<p>a type of control measure in which the hazard is eliminated</p> <p>a person who employs persons under contracts of employment or apprenticeship</p> <p>an individual who works under a contract of employment or apprenticeship</p> <p>a type of control measure which uses technological means to isolate or remove hazards</p> <p>see plant</p> <p>a person is exposed to a hazardous substance 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</p> <p>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</p> <p>unplanned escape of a liquid from a vessel or tube into surrounding body tissues</p>
<p><b>F</b></p> <p>faeces</p> <p>foetal</p> <p>foetus</p>	<p>waste from the intestines</p> <p>to do with a foetus</p> <p>developing baby in the womb (except for the very early stage, when it is called an embryo)</p>
<p><b>H</b></p> <p>hazard</p> <p>hazardous substance</p>	<p>a hazard is the potential for a substance to adversely affect the health and safety of people in the workplace</p> <p>substance listed in the <i>List of designated hazardous substances</i> produced by the Australian Safety and Compensation Council (ASCC), or a substance that meets the criteria for a hazardous substance set out in the <i>Approved criteria for classifying hazardous substances</i> declared by the ASCC</p> <p>Note: the list and the criteria are now part of the electronic database called the <i>Hazardous substances information system</i> (HSIS) administered by the ASCC</p>

hazardous substances register	regularly maintained list of the product names of all hazardous substances used in a workplace accompanied by an up-to-date material safety data sheet for each substance
HAZCHEM 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 that are specified in appendix 4 of the ADG code (6th edition, 1998) 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	monitoring of individuals for the purpose of identifying changes to health status due to occupational exposure to a substance
health surveillance	the monitoring of persons to identify changes (if any) in their health due to exposure to a hazardous substance, 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 per cent 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 substance from the blood by the liver – from the liver, the excreted substance passes into the intestine and the faeces
<b>I</b>	
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 (eg transplants) and abnormal cells (eg 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 – ie 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
<b>L</b>	
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
<b>M</b>	
manufacturer	an obligation holder under the OHS Act
respirator	respirator used as personal protective equipment
material safety data sheet (MSDS)	a document that describes the properties and uses of a substance – identity, chemical and physical properties, health hazard information, precautions for use and safe handling information
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
MSDS	see material safety data sheet
mucosal absorption	a route of exposure – taking in cytotoxic drug or waste through mucus membranes – eg in the mouth, eyes or nose
mutagen	substance with the potential to change DNA, the part of a body cell that controls its growth and multiplication – being a mutagen also gives a substance the potential to cause cancer
<b>N</b>	
NOHSC	<i>National Occupational Health and Safety Commission</i> – see ASCC (Australian Safety and Compensation Council)
<b>O</b>	
obligation	a legal requirement to take specified action under the OHS Act or OHS Regulation
occupational exposure	exposure to cytotoxic drugs during a work activity

OHS committee	an occupational health and safety committee or committees established by the employer and employees for the place of work or the employer's undertaking
OHS representative	an occupational health and safety representative or representatives elected by the employees to represent them
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
<b>P</b>	
parenteral	administration of cytotoxic drug by methods other than through alimentary canal, such as intravenous, subcutaneous, intramuscular, intrapleural, intraperitoneal, intravesical
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 substances 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 substance 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 OHS Act )
plant	includes machinery, equipment, appliances, pressure vessels, implement and tools; personal protective equipment; and any components, fittings, connections and accessories to plant
PPE	personal protective equipment
premises	under the OHS Act, includes any place and, in particular, includes: <ul style="list-style-type: none"> <li>• any land, building or part of any building</li> <li>• any vehicles, vessel or aircraft</li> <li>• any installation on land, on the bed of any waters or floating on any waters</li> <li>• any tent or movable structure</li> </ul>
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 (eg drawing liquid cytotoxic drug into a syringe from a vial), and crushing or dissolving tablets or emptying capsules to prepare part doses
PVC	abbreviation for polyvinyl chloride – a common type of plastic with good resistance to water, acids and alkalis

<p><b>R</b></p> <p>renal excretion</p> <p>reproducible test result</p> <p>respirable</p> <p>respirator</p> <p>respiratory protective equipment</p> <p>risk</p>	<p>removal of a substance from the blood by the kidneys – from the kidneys, the excreted substance passes into the urine</p> <p>extent to which multiple measurements of a characteristic by a particular test are likely to be in agreement</p> <p>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</p> <p>see respiratory protective equipment</p> <p>equipment that is designed to prevent inhalation of contaminated air</p> <p>a risk is the likelihood that a substance 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 substance used and the duration and frequency of exposure</p>
<p>risk assessment</p> <p>risk control</p> <p>risk management</p> <p>risk phrase(s)</p>	<p>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 substance 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</p> <p>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 (eg local exhaust ventilation), administrative controls, personal protective equipment</p> <p>analysis and judgment that uses the results of risk assessments to produce decisions about environmental actions to be initiated – ie the giving of priorities to various risks, the delivery of risk-averting outcomes and the continuing audit of outcomes and trends</p> <p>a labelling requirement for hazardous substances in accordance with the determined hazard classification and intended to convey a general description of the substance and give notice of the hazards present with the normal or reasonably foreseeable use of the substance – eg harmful if swallowed</p>
<p><b>S</b></p> <p>safety phrase(s)</p>	<p>information on a label that provides information on safe storage, handling and personal protection, taking into account the intended use eg wear suitable protective clothing and gloves</p>

self-employed person	a person who works for gain or reward otherwise than under contract of employment or apprenticeship, whether or not employing others (OHS 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
special waste	DECC 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 <i>Poisons and Therapeutic Goods Act 1966</i> '.
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
safe work 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 substance or process with a less hazardous one
supplier	an obligation holder under the OHS Act
surveillance	see health surveillance
SWP	see safe work procedure
systemic	affecting a person's inner organs
<b>T</b>	
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 topical cytotoxic drugs	a method of administration cytotoxic drugs prepared in the form of a cream or ointment for direct application to the skin
<b>U</b> UN Number  urostomy  use (of cytotoxic drugs)	in relation to dangerous goods: <ul style="list-style-type: none"> <li>• the number assigned to the dangerous goods by the UN Committee of Experts on the Transport of Dangerous Goods</li> <li>• the substance identification serial number shown in the list of dangerous goods mentioned in appendix 2, column 1 of the ADG code (6th edition, 1998) – eg cytotoxic drugs that meet the classification criteria of Class 6.1 are listed in the ADG code as UN 2810 or UN 2811</li> </ul> <div style="margin-top: 10px;">diversion of urine away from a diseased or defective bladder through a surgically created opening in the skin of the abdominal wall</div> <div style="margin-top: 10px;">includes administration, preparation, handling, storage, movement and disposal of cytotoxic drugs and related waste</div>
<b>V</b> vesicants  vial (phial)	cytotoxic drugs that induce blistering  small glass jar with a stopper that contains one or more doses of a drug for injection
<b>W</b> work workplace work injury  workplace incident	work as an employee or as a self-employed person OHS Act see place of work  <ul style="list-style-type: none"> <li>• 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</li> <li>• 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</li> <li>• any serious bodily injury, if the injury was caused by work, a workplace, a work activity or specified high risk plant</li> </ul> <div style="margin-top: 10px;">an incident resulting in a person suffering a work injury or a work-related injury or an incident resulting in a dangerous event</div>

## 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 OCCUPATIONAL HEALTH AND SAFETY LEGISLATION

#### Acts and regulations

- *Occupational Health and Safety Act 2000*
- *Occupational Health and Safety Regulation 2001*

#### Codes of practice

- *Code of practice for the control of workplace hazardous substances*. WorkCover NSW, 12 July 1996
- *Code of practice for the labelling of workplace substances*. WorkCover NSW, 12 July 1996
- *Code of practice for OHS consultation*. WorkCover NSW, 2001
- *Code of practice for risk assessment*. WorkCover NSW, 2001

#### Guidance material

- *Handling cytotoxic drugs in health care establishments: Training competencies*. New South Wales Government, 1997
- *Risk management at work 2001*
- *Reading labels and material safety data sheets: How to find out about chemicals at your workplace 2006*. Revised 3rd edition 2006
- *Pregnancy and work 2002*
- *Hazpack – Making your workplace safer: A practical guide to basic risk management*
- *The new simple way to notify work-related incidents*. 2003.
- *The community services safety pack:– A guide to occupational health and safety* (CD). January 2004
- *List of designated hazardous substances* in Hazardous Substances Information System (HSIS) on [www.ascc.gov.au](http://www.ascc.gov.au) (previously available as *List of designated hazardous substances* [NOHSC: 10005 (1999)]) Australian Safety and Compensation Council
- *Approved criteria for classifying hazardous substances* in Hazardous Substances Information System (HSIS) on [www.ascc.gov.au](http://www.ascc.gov.au) (previously available as *Approved criteria for classifying hazardous substances* 3rd Edition [NOHSC: 1008 (2004)]) Australian Safety and Compensation Council
- *Adopted national exposure standards for atmospheric contaminants in the occupational environment* in Hazardous Substances Information System (HSIS) on [www.ascc.gov.au](http://www.ascc.gov.au) (previously available as *Adopted national exposure standards for atmospheric contaminants in the occupational environment* [NOHSC: 1003 (1995)]) Australian Safety and Compensation Council
- *National code of practice for the preparation of material safety data sheets (2nd Edition)* [NOHSC:2011(2003)] Australian Safety and Compensation Council

## **OTHER NSW LEGISLATION**

### **Acts and regulations**

- *Poisons and Therapeutic Goods Act 1966* (NSW Department of Health)
- *Poisons and Therapeutic Goods Regulation 2002* (NSW Department of Health)
- *Protection of the Environment Operations Act 1997* (NSW Department of Environment and Climate Change)
- *Protection of the Environment Operations (Waste) Regulation 2005* (NSW Department of Environment and Climate Change)
- *Road and Rail Transport (Dangerous Goods) Act 1997* (NSW Department of Environment and Climate Change)
- *Road and Rail (Dangerous Goods)(Rail) Regulation 1999* (NSW Department of Environment and Climate Change)
- *Road and Rail (Dangerous Goods)(Road) Regulation 1998* (NSW Department of Environment and Climate Change)

### **Guidance material**

- Department of Environment and Climate Change (NSW), *Environmental guidelines: assessment, classification and management of liquid and non-liquid wastes*. May 1999 (reprinted June 2004)
- NSW Department of Health. *Waste management Guidelines for Health Care Facilities* (August 1998). PD2005\_132

## **AUSTRALIAN STANDARDS**

- AS 1386-1989 *Cleanrooms and clean workstations*
- AS/NZS 1715-1994 *Selection, use and maintenance of respiratory protection devices*
- AS/NZS 1716-1994 *Respiratory protective devices*
- AS/NZS 1716-1994/Amdt1-1996 *Respiratory protective devices*
- AS 2013-1989 *Cleanroom garments – Product requirements*
- AS/NZS 2243.1:2005 *Safety in laboratories – Planning and operational aspects*
- AS/NZS 2243.2:1997 *Safety in laboratories – Chemical aspects*
- AS/NZS 2243.3:2002 *Safety in laboratories – Microbiological aspects and containment facilities*
- AS 2243.4:1998 *Safety in laboratories – Ionizing radiations*
- AS 2243.5:1993/Amdt 1-1994 *Safety in laboratories – Non-ionizing radiation*
- AS 2243.6:1990 *Safety in laboratories – Mechanical aspects*
- AS 2243.7:1991 *Safety in laboratories – Electrical aspects*
- AS/NZS 2243.8:2001 *Safety in laboratories – Fume cupboards*
- AS 2243.9:1991 *Safety in laboratories – Recirculating fume cabinets*
- AS 2243.10:1993 *Safety in laboratories – Storage of chemicals*
- AS 2567-1994 *Laminar flow cytotoxic drug safety cabinets*

- AS 2639-1994 *Laminar flow cytotoxic drug safety cabinet - installation and use*
- AS/NZS 2982.1:1997 *Laboratory design and construction - General requirements*
- AS/NZS 3831 – 1998 *Waste management – Glossary of term*
- AS 4031-1992 *Non-reusable containers for the collection of sharp medical items used in health care areas*
- AS 4031-1992/Amdt1-1996 *Non-reusable containers for the collection of sharp medical items used in health care areas*
- AS 4273-2002 *Guidelines for the design, installation and use of pharmaceutical isolators*
- AS 4273-1999/Amdt1-2000 *Guidelines for the design, installation and use of pharmaceutical isolators*
- HB 202 *A management system for clinical and related wastes – Guide to application of AS/NZS 3816-1998, Management of clinical and related wastes*. Standards Australian, 2000
- HB 436 *Risk management guidelines – Companion to AS/NZS 4360: 2004, Risk Management*. Standards Australia, December 2005

## **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 material 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**

- *SHPA Standards of practice for the safe Handling of cytotoxic drugs in pharmacy departments*, SHPA Committee of Specialty Practice in Oncology, J Pharm Pract Res 2005; 35(1); 44-52
- *Standards of practice for the transportation of cytotoxic drugs from pharmacy departments*. Aust J Hosp Pharm 2000; 30(3): 116-17
- *National guidelines for waste management in the health care industry*, National Health and Medical Research Council, Commonwealth of Australia 1999
- *Guide for the prevention of eye damage*, Worksafe Australia, Australian Government Publishing Service, Canberra, December 1989
- *Competencies for health surveillance* (1998), Australian Safety and Compensation Council (ASCC)
- *Guidelines for health surveillance* (1995), Australian Safety and Compensation Council (ASCC)
- *A guide to risk control plans*. September 2001, WorkSafe Victoria, Victorian Government

- *Recommendations on the transport of dangerous goods*, Model Regulations Volume 1, United Nations, New York and Geneva. 14th revised edition, 2005

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

- *Handling cytotoxic drugs in the workplace*. WorkSafe Victoria, January 2003
- *Guide for handling cytotoxic drugs and related waste*, Workplace Health and Safety, Queensland 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, 2004

### **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 employees*. 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. (2006) *Validation protocol and analytical quality in biological monitoring of occupational exposure to antineoplastic drugs*. Toxicol Lett 162:256-62
- 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 (ie are cytotoxic) through damaging DNA, or processes involving cell replication.

In listing drugs that warrant attention in relation to this guide, 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. This guide provides 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 this guide is reasonably applicable.

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

DRUG	TRADE NAMES	USUAL METHOD OF ADMINISTRATION
Altretamine	Hexalen	oral
Amsacrine (AMSA)	Amsidyl	infusion
L-Asparaginase	see Colaspase	injection
Erwinia Asparaginase	–	infusion
Azathioprine	Imuran Azamun Azahexal	oral, injection, infusion
Bleomycin (BLEO)	Blenoxane Bleomycin sulfate	injection, infusion
Busulfan (BUS)	Myleran	oral, infusion
Capecitabine	Xeloda	oral
Carboplatin (PP)	Carboplatin	infusion
Carmustine (BCNU)	BiCNU	infusion
Chlorambucil (CLB)	Leukeran	oral
Cisplatin (DDP)	Cisplatin	infusion

DRUG	TRADE NAMES	USUAL METHOD OF ADMINISTRATION
Cladribine (2-CDA)	Leustatin	infusion
Colaspase (L-Asp)	Leunase	infusion
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
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

DRUG	TRADE NAMES	USUAL METHOD OF ADMINISTRATION
Oxaliplatin	Eloxatin	infusion
Paclitaxel (TAX)	Anzatax Taxol	infusion
Procarbazine (PCZ)	Natulan	oral
Raltitrexed	Tomudex	injection
Streptozotocin (STN)	Zanosar	infusion
Temozolomide	Temodal	oral
Teniposide (VM-26)	Vumon	infusion
Thioguanine (TG)	Lanvis	oral
Thiotepa (TT)	Thiotepa	injection, infusion
Topotecan (TOPO)	Hycamtin	infusion
Tretinoin	Vesanoid	oral
Valganciclovir	Valcyte	oral
Vinblastine (VLB)	Velbe Vinblastine sulfate	infusion
Vincristine (VCR)	Oncovin Vincristine sulfate	infusion
Vindesine	Eldisine	infusion
Vinorelbine (NVB)	Navelbine	oral, infusion

\*This list contains cytotoxic drugs currently used; however this listing is not exhaustive. The information provided is current at the time of writing this guide. When any new cytotoxic drug enters the workplace, it must be listed, and a risk assessment and a risk management plan must be developed.

## APPENDIX 4 – MATERIAL SAFETY DATA SHEET (MSDS)

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

### 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
- Risk phrase(s)
- Safety phrase(s)

### SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

#### Substance

- Chemical identity of the pure substance
- 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, eg water)
- Specify gravity or density

Information for flammable materials, including:

- Flash point and method of decanting flash point
- Upper and lower flammable (explosive) limits in air
- 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 (eg Class 4 or 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 MSDS\*

### *Additional information*

- Key/legend to abbreviations and acronyms used in the MSDS.*
- Literature references.*
- Sources for data.*

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

This checklist outlines the necessary information to prepare the 16-header MSDS format required under chapter 6 (Hazardous Substances) of the OHS Regulation.

Reference: *National code of practice for the preparation of material safety data sheets*, 2nd Edition, [NOHSC:2011(2003)], Australian Safety and Compensation Council (ASCC).

**APPENDIX 5 – HAZARDOUS SUBSTANCES (CYTOTOXIC DRUGS) REGISTER**

<b>Company:</b>	
<b>Site/area:</b>	
<b>Date:</b>	
<b>Person compiling register:</b>	

Product name	Location or process where product used	Notification to WorkCover NSW? Yes /No /NOT REQUIRED	MSDS*		Risk assessment		Actions/Comments
			Yes/No	Date	Yes/No	Date	
			<b>Date for review of register:</b>				

For information on this appendix refer to chapter 3.

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

# 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>			
Possible health effects	Routes of exposure	Current control measures	Are additional control measures required (if yes state what & reason)	Actions	

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

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

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

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

### 1. Baseline health monitoring

1.	<b>Collection of demographic data</b>	<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.	<b>Occupational history</b>	<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.	<b>Medical history</b>	<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 employee taking immuno-suppressive therapy?</li> <li>• is the employee pregnant or breast-feeding?</li> <li>• is the employee planning a family or considering pregnancy some time in the future?</li> </ul>
4.	<b>Physical examination</b>	<ul style="list-style-type: none"> <li>• general physical examination.</li> </ul>

5.	<b>Investigation</b>	<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>
6.	<b>Health advice and counselling</b>	<p>The appointed medical practitioner should provide medical advice and counselling to the employee, including:</p> <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 employees planning parenthood, or those who are breast-feeding or pregnant.</li> </ul>
7.	<b>Report</b>	<ul style="list-style-type: none"> <li>• the appointed medical practitioner should provide a report to the employer and prospective employee advising that the employee 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 employee concerned</li> <li>• privacy issues should be considered.</li> </ul>

**2. Ongoing health monitoring during the period that the employee works with cytotoxic drugs**

8.	<b>Data for inclusion in health records</b>	<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.	<b>Health advice and counselling</b>	<ul style="list-style-type: none"> <li>• as described in point 6</li> <li>• this should be offered by the employer annually and may be initiated at any time by the employee.</li> </ul>

10.	<b>Medical review</b>	<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 employee 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.	<b>Control measures</b>	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.	<b>Accidental exposure</b>	<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.	<b>Data to be collected</b>	<p>The following data should be collected:</p> <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.	<b>Final medical examination</b>	<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 employer and employee. Medical reports regarding individual employees should be provided to the employer with the written consent of the employee.</li> </ul>

For information on this appendix, see chapter 4.

## **APPENDIX 8 – RECORD KEEPING**

Records should be kept for the following:

### **Employer**

- Copy of any notification to WorkCover
- WorkCover penalty notices – eg fines, improvement notices
- Record of cytotoxic drug waste kept in the workplace
- Risk assessment reports
- Register
- Workplace monitoring reports
- Audit reviews
- Assurance reports
- WorkCover penalty notices – eg fines, improvement notices
- 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 – eg cytotoxic drug safety cabinet, personal protective equipment
- Medical records for each employee. These records must be kept confidential. Medical reports regarding individual employees should only be provided to the employer with the written consent of employees.

### **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 – eg treatment, biological monitoring
- Recommendations for preventative action.

#### **OHS Regulation requirements**

- Notification of use of cytotoxic drugs in the workplace
- Risk assessment reports
- Register
- Workplace monitoring reports (if required)
- Audit reviews (if required)
- Incident reports
- Health monitoring records (if required)
- Training records.

The 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 (PPE)

Type of PPE	Description	Task/Use	Cleaning/ Disposal	Australian Standard
<b>Coveralls and Gowns</b>	<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, eg 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>	<ul style="list-style-type: none"> <li>• AS 2013.1-1989 <i>Cleanroom garments – Product requirements.</i></li> </ul>

Type of PPE	Description	Task/Use	Cleaning/ Disposal	Australian Standard
<b>Head covering</b>	<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>	<ul style="list-style-type: none"> <li>AS 2013.1-1989 <i>Cleanroom garments – Product requirements.</i></li> </ul>
<b>Gloves</b>	<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 (eg 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> </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> </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>Australian Standard AS 2013.1-1989 <i>Cleanroom garments – Product requirements.</i></li> </ul>

Type of PPE	Description	Task/Use	Cleaning/ Disposal	Australian Standard
Gloves (cont)	<ul style="list-style-type: none"> <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> <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>	<ul style="list-style-type: none"> <li>• Laundry – handling cytotoxic contaminated linen bag</li> <li>• Ancillary workers handling cytotoxic waste containers</li> </ul>		

Type of PPE	Description	Task/Use	Cleaning/ Disposal	Australian Standard
<b>Protective eyewear</b>	<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 personal protective equipment.</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>• Cytotoxic drug administration and patient care – if risk assessment indicates risk of splash in eyes (eg 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>	<ul style="list-style-type: none"> <li>• Australian Standard AS 2013.1-1989 <i>Cleanroom garments – Product requirements.</i></li> </ul>

Type of PPE	Description	Task/Use	Cleaning/ Disposal	Australian Standard
<b>Respiratory Protective Equipment (RPE)</b>	<ul style="list-style-type: none"> <li>Suitable RPE should be selected, used, stored and maintained as recommended in AS/NZS1715: 1994 – <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 – inside a cytotoxic drug safety cabinet (CDSC)</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</li> <li>repair of equipment</li> </ul> </li> <li>Reusable facepiece RPE should have the facepiece 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>	<ul style="list-style-type: none"> <li>AS/NZS 1715-1994 <i>Selection use and maintenance of respiratory protective devices.</i></li> </ul>

Type of PPE	Description	Task/Use	Cleaning/ Disposal	Australian Standard
<b>Shoe covers or overshoes</b>	<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 Chapter 13 – Waste Management.</li> </ul>	<ul style="list-style-type: none"> <li>• Australian Standard AS 2013.1-1989 Cleanroom garments – Product requirements.</li> <li>• Australian Standard AS 2013.1-1989 Cleanroom garments – Product requirements.</li> </ul>

## APPENDIX 10 – SAFE HANDLING OF CYTOTOXIC CONTAMINATED BODY SUBSTANCES 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				
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 24hrs	7 days		
Daunorubicin	2 days	20% in 1st 24hrs	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
Epirubicin	7 days		5 days		
Etopophos	5 days				
Etoposide	4 days	40-60% mainly unchanged	7 days	15% excreted in faeces	

DRUG	URINE	EXCRETION RATE	FAECES	EXCRETION RATE	OTHER
<b>Fludarabine</b>	2 days	Bolus: 60% in 1st 24hrs Infusion: 40% metabolised in 24hrs & 60% in 72hrs			
<b>Fluorouracil</b>	2 days	Bolus: 15% unchanged in 1st 24hrs Infusion: 4% unchanged over 24hrs	5 days		
<b>Fotemustine</b>	4 days	30-40% in 1st 24hrs		50% excreted in faeces	
<b>Gemcitabine</b>	7 days	Almost complete elimination in form of metabolites in 24hrs		1% excreted in faeces	
<b>Hydroxyurea</b>	1 day	50-80% in 24hrs			
<b>Idarubicin</b>	4 days		7 days		
<b>Ifosfamide</b>	2 days	62% unchanged with another 20% as metabolites			
<b>Imatinab mesylate</b>	7 days		7 days		
<b>Irinotecan</b>	2 days				
<b>Liposomal Doxorubicin</b>	unknown	Plasma clearance slower than for Doxorubicin			
<b>Lomustine</b>	1 day	66% in 1st 24hrs			
<b>Melphalan</b>	2 days	28% in 1st 24hrs after PO, 56% in 1st 24hrs after IV	7 days	20-50% after PO administration	
<b>Mercaptopurine</b>	2-3 days	50% in 1st 24 hrs	5 days		
<b>Methotrexate</b>	3 days	majority in 1st 8hrs, low dose: 40-50% in 48hrs, high dose: up to 90% in 48hrs	7 days	9% after IV	
<b>Mitomycin</b>	1 day	10% as active drug			Small amount in bile
<b>Mitoxantrone</b>	6 days	6.5% unchanged drug, 3.6% metabolised drug	7 days	18% over 5 days	

DRUG	URINE	EXCRETION RATE	FAECES	EXCRETION RATE	OTHER
<b>Oxaliplatin</b>	3 days	40-50% of the dose in 1st 24hrs			
<b>Pacitaxel</b>	1 day	13% unchanged drug	5 days		
<b>Pemetrexed</b>	3 days	70-90% of dose unchanged in urine in 1st 24hrs			
<b>Procarbazine</b>	2 days	5% as unchanged drug and 70% as metabolites in 1st 24hrs		Good absorption from GIT, 12% of dose eliminated from GIT in 4 days	
<b>Raltitrexed</b>	8 days				
<b>Temozolomide</b>	unknown	10% of dose in 1st 24hrs			
<b>Teniposide</b>	5 days	10% of dose in 1st 24hrs	2 days		
<b>Thioguanine</b>	1 day	85% unchanged and metabolites			
<b>Thiotepa</b>	3 days	60% as metabolites in 1st 24hrs			
<b>Topotecan</b>	2 days				
<b>Vinblastine</b>	4 days		7 days		
<b>Vincristine</b>	4 days		7 days		
<b>Vindesine</b>	4 days		7 days		
<b>Vinorelbine</b>	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 this guide. When any new cytotoxic drug enters the workplace, it must be listed and a risk assessment and a risk management plan be developed.

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 to 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.

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# 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                       Safety goggles  
 Purpose manufactured cytotoxic gloves       Respirator (P2)

### 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 all floors with warm, soapy water after a body fluid or chemotherapy spill
- Wash contaminated equipment with warm soapy water

## DISPOSAL ISSUES

Place contaminated disposable items, ie dressings, into a cytotoxic drug bin.

Signature:	Print:
Designation:	Date:

For further information, contact the Oncology Clinic at the nearest Area Health Service

Name of Area Health Service: \_\_\_\_\_ Contact No.: \_\_\_\_\_

# 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, ie 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 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.
5. 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, ie closest to you
  - take the battery out of the pump
  - 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)
  - remove gloves and place in the other clip seal bag, dispose of bag and gloves into household rubbish
  - wash your hands with soap and water.
6. Phone the following contacts and make an appointment to have the problem fixed as soon as possible:
  - Monday to Friday \_\_\_\_\_ am to \_\_\_\_\_ pm/Saturday & Sunday \_\_\_\_\_ am to \_\_\_\_\_ pm
    - Hospital/ward \_\_\_\_\_ Telephone number \_\_\_\_\_
    - Other contact \_\_\_\_\_ Telephone number \_\_\_\_\_
  - All other times
    - Hospital/ward \_\_\_\_\_ Telephone number \_\_\_\_\_
    - Hospital/ward \_\_\_\_\_ Telephone number \_\_\_\_\_
    - Other contact \_\_\_\_\_ Telephone number \_\_\_\_\_

## **FURTHER INFORMATION**

### **WorkCover NSW**

WorkCover Assistance Service

Phone: 13 10 50

[www.workcover.nsw.gov.au](http://www.workcover.nsw.gov.au)

### **NSW Department of Health**

Phone: (02) 9391 9000 (contact addresses)

[www.health.nsw.gov.au](http://www.health.nsw.gov.au)

### **NSW Department of Environment and Climate Change (DECC)**

Environment Line

Phone: 13 15 55

[www.environment.nsw.gov.au](http://www.environment.nsw.gov.au)

### **The Community Services & Health Industry Skills Council (CS&HISC)**

[www.cshisc.com.au](http://www.cshisc.com.au)

### **NSW Nurses' Association**

Phone: (02) 8595 2124 (metropolitan) or (02) 1300 367 962 (regional)

[www.nswnurses.asn.au](http://www.nswnurses.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)







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