

# Guide for handling cytotoxic drugs and related waste

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This guide has primarily been updated to reflect recent legislative changes in Queensland and does not represent a review of technical content. It is proposed that a full review of this guide will be carried out at a later time.

Some changes to this guide were adapted from the Safe Handling of Cytotoxic Drugs and Related Wastes: Guidelines for South Australian Health Services 2012 produced by SA Health.

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# Chapter 1: Introduction

Cytotoxic drugs are intended primarily for the treatment of cancer. They are known to be highly toxic to cells, principally through their action on cell reproduction. Many have proved to be carcinogens, mutagens or teratogens.

Patients receiving therapeutic doses of these drugs have exhibited a long list of acute and chronic adverse effects, including cancers. Workers who come into contact with cytotoxic drugs and related waste are also at risk of exposure and possible adverse effects.

Cytotoxic drugs are used in a variety of healthcare settings, in laboratories, manufacturing and research facilities and veterinary clinics. As well as their application in the treatment of cancers, cytotoxic drugs are also being used for the treatment of other medical conditions such as multiple sclerosis, psoriasis and systemic lupus erythematosus. These drugs are also applied topically in ophthalmology for an increasing number of indications.

## 1.1 Purpose, scope and application

The *Guide for handling cytotoxic drugs and related waste* applies to the clinical use of cytotoxic drugs and related waste. The purpose is to give practical advice on how to prevent or minimise occupational exposure to cytotoxic drugs and related waste.

Use of cytotoxic drugs and related waste includes preparation, administration, handling, storage, movement and disposal.

The guide is intended to assist a person conducting a business or undertaking (PCBU) and others who have duties with respect to cytotoxic drugs. It is meant to act as a tool to assist in the development of necessary policies and procedures to ensure the health and safety of workers and others who may be exposed, and to provide information about legislative requirements.

In addition to primary healthcare settings such as hospitals, the guide is applicable to general practice and medical centres, community care, commercial laundries, veterinary practice, and waste management.

Appendix 1 provides a glossary of many of the terms used in this guide. Some currently used cytotoxic drugs are listed in appendix 2.

## 1.2 Legislation to protect workers

The *Work Health and Safety Act 2011* (the WHS Act) outlines the general health and safety duties of PCBUs, officers of companies, unincorporated associations, government departments and public authorities (including local governments), workers and other people at a workplace.

These general duties require the duty holder to ensure health and safety, so far as is reasonably practicable, by eliminating risks to health and safety. If this is not possible, risks must be minimised so far as is reasonably practicable. Chapter 2 outlines legislation applicable to the safe use, storage and handling of cytotoxic drugs.

## 1.3 Occupational exposure

Little is known of the specific long-term effects of occupational exposure to cytotoxic drugs and related wastes. However, there is sufficient evidence to indicate adverse health effects may result and that measures are required to protect workers and others.

In the workplace, exposure to cytotoxic drugs and related waste may occur where control measures fail or are not in place. Workers may be exposed during drug preparation, drug administration, patient care activities, spill management, waste disposal, when handling patient body substances and when handling cytotoxic contaminated laundry.

For the purposes of this document, 'body substances' has been defined as 'urine, faeces, vomitus, bile, and fluid drained from body cavities'. Where there is a risk of exposure to blood, workers should adopt standard precautions.

### **1.3.1 Effects of exposure**

Where control measures are not adequate, adverse health effects may result from occupational exposure to cytotoxic drugs and related waste. Various studies have been conducted with people preparing and administering cytotoxic drugs. Some of the reported effects include:

- contact dermatitis, local toxic or allergic reaction—may be as a result of direct contact with skin or mucous membranes
- cytogenic abnormalities and mutagenic activity related to biological uptake by exposed workers
- alterations to normal blood cell counts
- excretion of the drugs or metabolites in the urine of exposed workers
- abdominal pain, hair loss, nasal sores and vomiting
- liver damage
- fertility changes
- foetal loss and malformations of the offspring of exposed pregnant women.

### **1.3.2 Exposure routes**

Exposure to cytotoxic drugs may occur through:

- inhalation
- ingestion
- dermal absorption
- mucosal absorption
- percutaneous injury.

### **1.3.3 Activities where there is a risk of exposure**

Exposure may occur when:

- preparing cytotoxic drugs
- handling cytotoxic drugs in liquid, solid or cream form during administration
- handling cytotoxic drug containers
- handling a treated patient's body substances
- handling or emptying a treated patient's bedpans, urine bottles, urinary catheter bags, ostomy bags, nappies and vomitus bowls or bags
- handling bed linen or clothing soiled with a treated patient's body substances, or potentially contaminated with unchanged drug or active metabolites
- cleaning spills or leakages of cytotoxic drugs and related waste.

### **1.3.4 Workplaces**

Exposure to cytotoxic drugs and related waste may occur in a wide range of workplaces including:

- hospitals, day hospitals, doctors surgeries, medical practices
- pharmacies—hospital and community
- commercial cytotoxic drug manufacturers
- analytical or research laboratories
- residential care homes
- homes of patients
- veterinary clinics
- vehicles, including ambulances, pharmacy and pathology courier services, waste collection vehicles
- laundries—hospital and commercial
- mortuaries and funeral homes
- waste disposal facilities.

## **1.4 Exposure standards for occupational exposure**

There are no exposure standards for acceptable levels of exposure to pharmaceutical products as there are for other hazardous chemicals, such as lead, therefore control measures should be implemented to reduce exposure to levels 'as low as reasonably achievable' (ALARA).

Research has shown good work practices and properly implemented control measures significantly reduce exposure, and, consequently, the risks of adverse health effects.

## **1.5 Standard operating procedures for the handling of cytotoxic drugs and related waste**

A standard operating procedure (SOP) is 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 process an individual or group performs. SOPs are an administrative control measure.

This guide provides a range of SOPs on a number of issues relating to the use and handling of cytotoxic drugs and related waste. It is intended users of the guide consider the information provided, and select or adapt the procedures or control measures to develop their own SOPs, which are specific to the particular workplace or workplace activity. SOPs are provided at the end of each chapter.

Effective use of SOPs involves:

- development of safe work procedures and SOPs in relation to implemented control measures. Management, supervision and worker responsibilities may need to be clearly defined in the work procedures
- communication to inform workers and others about the procedures to be implemented. It is important to clearly communicate the reasons for any changes
- providing training and instruction for workers, supervisors and others in relation to the procedures
- providing adequate supervision to verify SOPs are being used correctly
- maintenance of SOPs to ensure their ongoing effectiveness.

### **1.5.1 Importance of SOPs**

Standard operating procedures:

- provide workers with the safety, health, environmental and operational information required to perform a job properly and safely
- provide a procedure compliant with company and government regulations
- provide an explanation of a process that can be reviewed when an incident occurs
- ensure consistency and quality control
- assist in protecting the health and safety of workers and others.

SOPs should undergo an on-the-job trial before final application in the workplace. They should be reviewed when any changes or modifications are made to equipment, machinery, buildings or other structures, or to procedures within the immediate work area that might affect performance of a job or the 'environment' in which it is performed. SOPs should also be updated when new information suggests benefits from modifying work behaviours to improve performance.

Workers should receive information, instruction and training in order to implement SOPs.

The Health Regulation 1996 specifies that written policies and SOPs should be drawn up, and be readily available for workers in cytotoxic (antineoplastic) drug preparation facilities.

### **Standard operating procedures – Chapter 1**

SOPs and policies should be developed for the following general areas. More information is provided in other chapters as indicated:

- legislative requirements to be incorporated into SOPs where relevant – Chapter 2
- relevant risk management elements – Chapter 3
- training of workers and others who may be at risk of exposure – Chapter 4
- protection against exposure through use of personal protective equipment – Chapter 5
- review and documentation of personnel management practices – Chapter 6
- preparation of cytotoxic drugs – Chapter 7

- establishment of safe systems of work for drug administration – Chapter 8
- managing risk in healthcare facilities – Chapter 9
- managing risk in community settings – Chapter 10
- management of cytotoxic contaminated laundry – Chapter 11
- management of cytotoxic spills – Chapter 12
- management of cytotoxic contaminated waste – Chapter 13
- appropriate control measures for cytotoxic use in veterinary practice – Chapter 14.

## Chapter 2: Legal requirements

There are a number of legal requirements that must be met when using and handling cytotoxic drugs and related waste. PCBU's and others have a duty to ensure the health and safety of workers and other people, so far as is reasonably practicable. As the main focus of this guide is the safe handling of cytotoxic drugs and related waste, detailed information is provided only about workplace health and safety legislation. Other legislation is referenced where appropriate, and further information on these matters should be referred to the relevant regulating agency.

Legislation relevant to the safe handling of cytotoxic drugs in the workplace includes:

- *Work Health and Safety Act 2011*
- Work Health and Safety Regulation 2011
- *Health Act 1937*
- Health Regulation 1996
- Health (Drugs and Poisons) Regulation 1996
- *Environmental Protection Act 1994*
- Environmental Protection Regulation 2008
- *Waste Reduction and Recycling Act 2011*
- Waste Reduction and Recycling Regulation 2011
- *Transport Operations (Road Use Management) Act 1995*
- Transport Operations (Road Use Management-Dangerous Goods) Regulation 2008
- *Civil Aviation Act 1988*
- Civil Aviation Safety Regulations 1998
- *Navigation Act 2012*

Other references include:

- Managing Risks of Hazardous Chemicals in the Workplace Code of Practice 2013
- How to Manage Work Health and Safety Risks Code of Practice 2011
- Standard for the Uniform Scheduling of Medicines and Poisons
- Australian Standards

### 2.1 Legislative provisions relating to handling cytotoxic drugs and related waste

This guide is designed to assist PCBU's and workers to comply with the provisions of the *Work Health and Safety Act 2011* (the WHS Act), and the Work Health and Safety Regulation 2011 (the WHS Regulation) and associated codes of practice that apply to the handling of cytotoxic drugs and related waste.

While the main focus of the legislation is the protection of workers, others in the workplace, such as patients, visitors, volunteers, carers, contractors and contractors' workers are also considered. This guide does not necessarily deal with patient care, except in the context of workplace health and safety.

Where the word 'must' is used in the guide, it indicates a legal requirement under the provisions of a specific Act or regulation. The observance of the guideline is therefore mandatory. The words 'should' or 'recommended' are used to describe recognised good practice for specific work situations.

When drafting policies and procedures for individual workplaces and activities, it is recommended the guide be read in conjunction with the legislation and other standards referenced.

Work health and safety legislation mainly comprises the *Work Health and Safety Act 2011* and the *Work Health and Safety Regulation 2011*. Appendix 3 lists all relevant Acts and regulations that impact on the management and use of cytotoxic drugs and related waste.

## **2.2 Work health and safety legislation**

The WHS Act provides a framework to protect the health, safety and welfare of all workers at work. It also protects the health and safety of all other people who might be affected by the work.

### **2.2.1 Work health and safety duties**

The WHS Act places a primary health and safety duty on a PCBU who must ensure, so far as is reasonably practicable, the health and safety of workers at the workplace. Duties are also placed on other people including:

- officers of a PCBU
- people with management or control of workplaces
- manufacturers, importers and suppliers of substances for use at workplaces including suppliers of prohibited and restricted carcinogens
- designers, manufacturers, importers and suppliers of plant or structures
- workers.

People may have more than one duty. For example, a hospital has a duty to the workers it employs as well as to people who perform work activities on its behalf (e.g. contract cleaners).

### **2.2.2 General duties of a person conducting a business or undertaking**

There are specific duties which a PCBU must comply with as part of their general duty so far as is reasonably practicable. These include:

- providing and maintaining a working environment which is safe and without risks to health, including the entering and exiting of the workplace
- providing and maintaining plant, structure and systems of work that are safe and do not pose health risks
- ensuring the safe use, handling, storage and transport of substances
- providing information, instruction, training or supervision needed for work to be carried out safely and without risk to health
- monitoring the health of their workers and the conditions of the workplace under their management and control to prevent injury or illness
- maintaining any accommodation owned or under their management and control to ensure the health and safety of workers occupying the premises.

### **2.2.3 Hazardous chemicals**

There are specific requirements for substances which are considered a hazardous chemical under Chapter 7 of the WHS Regulation. Generally, a hazardous chemical is one where a substance or mixture meets the criteria for a hazard class in the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (3<sup>rd</sup> revised edition). However, substances or mixtures that meet the criteria solely for some hazard classes are not considered a hazardous chemical. For further information on the classification of hazardous chemicals refer to the Safe Work Australia (SWA) *Guidance on the classification of hazardous chemicals*.

Most cytotoxic drugs and any waste generated will be classified as hazardous chemicals.

Manufacturers and importers of substances supplied to a workplace must determine if a chemical is hazardous and correctly classify the chemical according to schedule 9 of the WHS Regulation. In addition, they are required to:

- prepare and provide a safety data sheet (SDS) to any person who is likely to be affected by the hazardous chemical and asks for the SDS

- correctly label all hazardous chemicals (including hazardous waste products).

Suppliers of hazardous chemicals must provide the manufacturer's or importer's current SDS with the hazardous chemical (this excludes retailers and consumer products). Hospital departments, such as pharmacies, which supply cytotoxic drugs to other hospitals, other facilities or services may be considered as suppliers.

Cyclophosphamide is a restricted carcinogen under the WHS Regulation. In certain circumstances, hospitals and oncological treatment facilities must be authorised by Workplace Health and Safety Queensland to use, handle or store this substance when used in preparation for therapeutic use. Suppliers of cyclophosphamide must have evidence their customers have the required authorisation to use, handle or store the substance prior to supply.

#### **2.2.4 Plant and equipment**

As well as the general duties, there are specific duties with respect to plant and equipment. Plant includes machinery, equipment (e.g. autoclaves), appliances, pressure vessels, implements and tools, components of plant and fittings, connections and accessories to plant. With respect to cytotoxic drugs and related waste, plant may include, but is not limited to cytotoxic drug safety cabinets (CDSCs), trolleys for carrying cytotoxic drug administration equipment, drug delivery devices, patient furniture, washing machines and laundry equipment. Plant also includes personal protective equipment (PPE).

PCBUs, designers, manufacturers, suppliers, owners, persons with management or control of plant and installers of plant have duties which include:

- providing and maintaining safe plant
- ensuring the risk of injury or illness from any plant is minimised when used properly
- ensuring plant is designed and manufactured to be safe when used properly
- examining and testing of plant to ensure it is safe.

The *Managing Risks of Plant in the Workplace Code of Practice 2013* provides guidance about specific control measures for plant and equipment.

### **2.3 Codes of practice**

An approved code of practice is a practical guide to achieving the standards of health, safety and welfare required under the WHS Act and the WHS Regulation. In most cases, following an approved code of practice would achieve compliance with the health and safety duties under the Act with regard to the subject matter of the code.

There are a number of codes of practice relevant to managing the risk of exposure to cytotoxic drugs and related waste including:

- *Managing Risks of Hazardous Chemicals in the Workplace Code of Practice 2013* sets out ways to manage health and safety risks associated with hazardous chemicals.
- *Labelling of Workplace Hazardous Chemicals Code of Practice 2011* provides guidance on how to correctly label hazardous chemicals.
- *Preparation of Safety Data Sheets for Hazardous Chemicals Code of Practice 2011* is a guide on how to prepare a safety data sheet.
- *How to Manage Work Health and Safety Risks Code of Practice 2011* is a guide for persons who have duties under the WHS Act and Regulations to manage risks to health and safety.
- *First Aid in the Workplace Code of Practice 2014* provides practical advice about the selection, provision, maintenance and use of first aid facilities and services at a workplace.
- *Hazardous Manual Tasks Code of Practice 2011* gives guidance on how to manage the risk of musculoskeletal disorders arising from hazardous manual tasks.
- *Managing Risks of Plant in the Workplace Code of Practice 2013* provides practical advice on managing risks related to the use of plant, including its safe design, manufacture and installation.



## 2.4 Other Queensland legislation

Other legislation important to specific areas includes the following.

### 2.4.1 Queensland Health

The Health (Drugs and Poisons) Regulation 1996 and the Health Regulation 1996 apply to the handling of cytotoxic drugs. Part 4 of the Health Regulation sets out the general requirements for a dispensary, and the preparation of antineoplastic drugs (e.g. cabinets, personal protective equipment (PPE), air supply and exhaust systems).

The Health (Drugs and Poisons) Regulation requires the packaging and labelling of controlled or restricted drugs and scheduled poisons comply with the Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons. For more information on the labelling requirements of the standard, see section 7.1 of this guide.

For more information on Queensland Health requirements and supporting information, visit their website at [health.qld.gov.au](http://health.qld.gov.au).

### 2.4.2 Department of Environment and Heritage Protection

The Department of Environment and Heritage Protection (EHP) administers the *Environmental Protection Act 1994*, *Environmental Protection Regulation 2008*, *Waste Reduction and Recycling Act 2011* and the *Waste Reduction and Recycling Regulation 2011*, to coordinate environmental approvals, clarify waste management practices and provide environmental waste safeguards.

As cytotoxic waste is hazardous to human health and the environment, it is a regulated waste and subject to the requirements of the Environmental Protection Act and subordinate legislation. These requirements cover treatment, storage, transportation, tracking handling, packaging and labelling. The *Waste Reduction and Recycling Act 2011* and subordinate legislation regulate the segregation of clinical and related waste, waste container design requirements, and aspects of storage, treatment and disposal of clinical or related waste.

In some cases, the *Sustainable Planning Act 2009* may also apply, where a development approval is required for a material change of use to carry out an environmentally relevant activity (ERA).

For more information on waste regulations and supporting information, visit [ehp.qld.gov.au](http://ehp.qld.gov.au) and the Queensland Business and Industry Portal at [business.qld.gov.au](http://business.qld.gov.au) or contact one of the EHP offices.

### 2.4.3 Transport and storage of cytotoxic drugs or cytotoxic waste

Transport and storage issues are dealt with by a number of government agencies. Healthcare facilities involved in the external transport of cytotoxic drugs must consult with the appropriate local, state and national agencies for current legislative requirements. Cytotoxic drugs and related waste are classified as dangerous goods with respect to transport and storage.

Cytotoxic drugs, classified as dangerous goods that are being transported or are in transit, must comply with:

- *Australian Code for the Transport of Dangerous Goods by Road and Rail* (also known as the Australian Dangerous Goods Code), National Transport Commission
- *Technical Instructions for the Safe Transport of Dangerous Goods by Air*, International Civil Aviation Organization
- *International Maritime Dangerous Goods (IMDG) Code*, International Maritime Organization.

For more information on regulations regarding transport and storage of dangerous goods and supporting information, visit the following websites:

- Department of Transport and Main Roads – [tmr.qld.gov.au](http://tmr.qld.gov.au)
- Department of Environment and Heritage Protection – [ehp.qld.gov.au](http://ehp.qld.gov.au)
- Department of Infrastructure and Regional Development – [infrastructure.gov.au](http://infrastructure.gov.au)
- International Maritime Organization - [imo.org](http://imo.org)
- International Civil Aviation Organization - [icao.int](http://icao.int)

## 2.5 Local government requirements

Local councils—cities, towns and shires—usually develop local laws with respect to waste handling and health-related matters. They have certain powers invested by other agencies such as Queensland Health and the Department of Environment and Heritage Protection. Contact the appropriate local council for further information on handling, storage, disposal and transport of cytotoxic contaminated waste.

## 2.6 Duty of disclosure

All prospective workers should be counselled regarding the precise nature of the work to be undertaken relating to the handling of cytotoxic drugs and related waste. This counselling should include as a minimum:

- potential health risks associated with exposure to cytotoxic drugs or related waste
- how exposure may occur
- the safe handling procedures used to prevent or minimise exposure (e.g. use of personal protective equipment).

## Standard operating procedures – Chapter 2

In developing SOPs that comply with legislative requirements, the following factors should be considered:

- identification and incorporation of relevant legislation
- compliance with the provisions of relevant legislation
- provisions of relevant legislation incorporated into SOPs as appropriate
- a process developed for notification of changes to relevant legislation and subsequent review of affected documentation and practices.

In addition, these SOPs should:

- be developed in consultation with workers
- be guided and informed by the risk management process
- be part of the induction and ongoing training program
- be reviewed regularly and when there are incidents or changes to the workplace that affect the procedure (e.g. new equipment, new legislation, new products)
- be documented and meet relevant record keeping requirements.

## Chapter 3: Managing risks

In the healthcare industry, drug preparation poses the greatest risk of occupational exposure to cytotoxic drugs due to the frequency of use, and the quantities and concentrations used. Drug administration and aspects of patient care such as handling body substances, spill and waste management also pose a risk of occupational exposure.

The major issues to be considered with the handling of cytotoxic drugs and related waste include:

- how workers and other people may be exposed to cytotoxic drugs and related waste
- how cytotoxic drugs and related waste should be handled
- how exposures can be controlled.

Risks to health and safety must be eliminated so far as is reasonably practicable, and if it is not reasonably practicable to do so, those risks must be minimised so far as is reasonably practicable.

Deciding what is ‘reasonably practicable’ to protect people from harm requires taking into account and weighing up all relevant matters, including:

- the likelihood of the hazard or risk concerned occurring
- the degree of harm which might result from the hazard or risk
- knowledge about the hazard or risk, and ways of eliminating or minimising the risk
- the availability and suitability of ways to eliminate or minimise the risk

- after assessing the extent of the risk and the available ways of eliminating or minimising the risk, the cost associated with available ways of eliminating or minimising the risk, including whether the cost is grossly disproportionate to the risk.

Guidance on the interpretation and application of the term ‘reasonably practicable’ can be found in the SWA guide *How to determine what is reasonably practicable to meet a health and safety duty*.

Risk management involves four steps:

- identify hazards – find out what could cause harm
- assess risks if necessary – understand the nature of the harm which could be caused by the hazard, how serious the harm could be and the likelihood of it happening
- control the risks – implement the most effective control measure which is reasonably practicable in the circumstances
- review control measures to ensure they are working as planned.

A risk assessment should consider foreseeable failures of plant and equipment, and control measures such as a power failure which may impact on the operation of a mechanical ventilation system.

Refer to the *Managing Risks of Hazardous Chemicals in the Workplace Code of Practice 2013* for detailed information on how to manage risks to health and safety.

### 3.1 Consultation

The WHS Act and Regulation places a duty on PCBU's to consult, so far as is reasonably practicable, with workers. Consultation involves the sharing of information, giving workers a reasonable opportunity to express views and taking those views into account before making decisions on health and safety matters. Where workers are represented by a health and safety representative, the consultation must involve that representative.

Consultation with workers is required at each step of the risk management process including:

- when identifying cytotoxic drugs and associated hazards
- during the risk management process
- when determining what control strategies should be applied to eliminate or minimise risks associated with the handling of cytotoxic drugs
- when reviewing the effectiveness of controls
- prior to changing premises, work environment, plant, systems of work or chemicals used for work, including SDSs.

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

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

### 3.2 Hazard identification

Identifying hazards involves finding things and situations which could potentially cause harm to people. Cytotoxic drugs in themselves are hazards, and the way in which they are handled can also be seen as a hazard. Information must be obtained about the particular cytotoxic drugs being used, routes of exposure, health effects, recommended control measures and other actions to prevent or minimise risks.

Cytotoxic drugs may be identified by referring to stock lists, the register of hazardous chemicals and SDSs. All locations where there are cytotoxic drugs or related waste should also be identified.

See appendix 4 for a sample cytotoxic drugs register.

It is recommended PCBU's keep up-to-date with latest findings regarding risks associated with cytotoxic drugs and related waste. Issues include new drugs, exposure rates, the health risks of exposure and the latest in health monitoring. This information can be incorporated into any risk assessment.

### 3.3 Assess the risk

A risk assessment involves considering what could happen if someone is exposed to a hazard and the likelihood of it happening. A risk assessment can help determine:

- how severe a risk is
- whether any existing control measures are effective
- what action can be taken to control the risk
- how urgently the action needs to be taken.

#### 3.3.1 When should a risk assessment be carried out?

A risk assessment is not mandatory for hazardous chemicals. However a risk assessment is the best way to determine the measures that should be used to control risks. Do a risk assessment when:

- there is uncertainty about how a hazard may result in injury or illness
- the work activity involves a number of different hazards and there is a lack of understanding about how the hazards may interact with each other to produce new or greater risks
- changes at the workplace occur which may impact on the effectiveness of control measures.

For more information on managing risks, please refer to the *How to Manage Work Health and Safety Risks Code of Practice 2011* or the *Managing Risks of Hazardous Chemicals in the Workplace Code of Practice 2013*.

#### 3.3.2 Work out how severe the harm could be

In estimating the severity of harm which could result from cytotoxic drugs and related waste consider how many people may be exposed in and outside the workplace. The workers and others who may be at risk from exposure to cytotoxic drugs and related waste should be identified including:

- |  |   |
|--|---|
| • nurses and medical officers  | • mortuary/funeral home workers   |
| • contract workers   | • laundry workers   |
| • ambulance officers   | • administrative workers  |
| • biomedical technicians   | • workers responsible for ordering or purchasing cytotoxic equipment, PPE, etc. |
| • pharmacy workers   | • planners/designers/schedulers of work/workplaces                              |
| • pharmaceutical workers   | • delivery workers  |
| • laboratory workers   | • couriers and porters  |
| • research workers   | • allied health workers.  |
| • veterinarians and veterinary nurses  |   |
| • community care workers   |   |
| • waste handlers (internal/external, on/off site)                            |   |
| • maintenance workers  |   |
| • stores and warehouse workers   |   |
| • emergency response workers (e.g. fire wardens, emergency control officers) |   |
| • cleaning workers   |   |

The following people may also be exposed:

- patients, family and friends
- outpatients and their home care-givers
- families of pets undergoing cytotoxic drug therapy
- volunteers.

The following issues could influence the severity of harm and should be considered:

- the work environment (e.g. layout, lighting, access, ventilation)
- manual tasks (e.g. working in cramped surroundings, handling heavy laundry bags)
- activities (e.g. preparation, administration, patient transport, spill management)
- locations (e.g. treatment areas, pharmacies, diagnostic facilities, waste storage areas, laundries, community settings)
- roles (e.g. nurse, medical officer, pharmacist, technician, cleaner, laundry worker, carer)
- functions (e.g. administration, laundry, transport, delivering and receiving cytotoxic drugs, waste disposal).

### **3.3.3 Work out how hazards may cause harm**

The greatest risk of occupational exposure to cytotoxic drugs is during their preparation and administration within healthcare facilities and in community settings.

Other aspects of patient care may also pose a risk of occupational exposure and include:

- handling of body substances
- handling cytotoxic contaminated laundry
- handling, transport and disposal of cytotoxic contaminated waste
- cleaning up cytotoxic spills
- maintenance work (e.g. CDSC).

Consider the routes of occupational exposure (i.e. entry into the body) for all cytotoxic drugs used:

- inhalation of aerosols and drug particles or droplets
- ingestion through poor hand hygiene, resulting in contaminated food or cigarettes
- dermal absorption through splashes, spills or contact with cytotoxic contaminated laundry
- mucosal absorption through splashes into the eye or mouth
- percutaneous injuries.

The storage and transport of cytotoxic drugs and related waste should also be considered including:

- packaging of prepared cytotoxic drugs
- transport of drugs between drug preparation and drug administration areas
- cytotoxic spill, while patients receiving cytotoxic therapy are transported in a healthcare setting
- segregation, storage and transport of cytotoxic contaminated body substances or laundry and cytotoxic contaminated waste
- exposure risks for carers and workers in community settings.

### **3.3.4 Work out the likelihood of harm occurring**

In working out the likelihood that someone will be harmed consider:

- frequency and duration of exposure to cytotoxic drugs and waste
- volume of cytotoxic drug or cytotoxic contaminated waste a person may be exposed to.

Identify the control measures currently in place and determine whether:

- workers and others have received information, instruction and training regarding the control measures
- the existing control measures are implemented, used and maintained properly
- the existing control measures are effective in controlling the risk.

The likelihood of harm occurring can be rated as one of the following:

- certain to occur – expected to occur in most circumstances
- very likely – will probably occur in most circumstances

- possible – might occur occasionally
- unlikely – could happen at some time
- rare – may happen only in exceptional circumstances.

Risk increases as the likelihood of harm and the severity of the harm increases.

A risk assessment may be a generic assessment prepared for workplaces where the particular cytotoxic drug or waste is used, handled or stored in the same or similar circumstances. See appendix 5 for a sample risk assessment.

### **3.4 Control the risks**

Eliminating risks so far as is reasonably practicable, or if that is not possible, minimising the risks so far as is reasonably practicable is the most important step in managing risks from exposure to cytotoxic drugs and related waste.

#### **3.4.1 The hierarchy of risk control**

The WHS Regulation sets out a hierarchy of risk controls which a PCBU must work through when managing risks. This hierarchy ranks ways of controlling risk from the highest level of protection and reliability to the lowest as follows:

- eliminate the hazard  
If elimination is not possible, minimise the risk so far as is reasonably practicable
- substitute the hazard with something safer
- isolate the hazard from people
- use engineering controls.

If a risk still remains, that remaining risk must be further minimised, so far as is reasonably practicable, by implementing administrative controls.

In most circumstances, PPE should not be relied on to control risk. It should be used only as a last resort when all other reasonably practicable control measures have been used and the risk has not been eliminated, or as interim protection until higher level controls are implemented. There may be some situations when the use of other controls is not practicable.

#### **3.4.2 Controls for cytotoxic drugs and related waste**

It may not be possible to eliminate cytotoxic drugs from the workplace, however it may be possible to eliminate or discontinue a dangerous activity that exposes workers to risk. For example, to eliminate preparation of drugs outside a CDSC or pharmaceutical isolator, drugs can be sourced from a pharmacy or commercial supplier that has the appropriate control measures including isolation, engineering controls and suitably trained workers.

Substitution of another less toxic drug or treatment is usually not possible, however substituting techniques or processes with less hazardous ones may be practical options for consideration. For example, needleless systems instead of needles.

Isolation techniques use barriers to prevent exposure, for example, closed-system drug transfer device or pharmaceutical isolator.

Engineering controls use technological means to isolate or remove hazards from the workplace. Examples include CDSCs to minimise exposure to workers, or limit the possibility of contamination in the event of spills or leaks.

Administrative controls are work practices that assist people to work in safer ways. They also refer to controls which limit the extent to which exposure occurs by altering the ways in which tasks are performed.

Important administrative controls include:

- standard operating procedures—it is essential written procedures are developed for all work activities involving cytotoxic drugs and related waste, including plant and equipment cleaning, inspection and maintenance. This guide includes suggestions for standard operating procedures in relevant chapters. These can be taken into consideration when drafting procedures for

individual workplaces and workplace activities. Where appropriate, responsibilities for the different tasks in the procedures should be allocated. For more information, see section 1.5 of this guide

- education and training—designed to teach workers about the hazardous nature of the substances used and the means of protecting both themselves and others from exposure. This is an important element in the process of selecting and implementing controls. All workers and others handling cytotoxic products should recognise the cytotoxic symbol and so be reminded of the special control measures to prevent exposure. For more information, see chapter 4
- cytotoxic signs and labels—identification of the potential and actual presence of cytotoxic drugs and related waste is an important aspect of risk control. Cytotoxic drugs must be clearly labelled so workers can identify them and take appropriate precautions to manage their risk of exposure. Cytotoxic contaminated laundry and cytotoxic contaminated waste must also be appropriately labelled, and storage areas should be clearly signed.



*The cytotoxic symbol.*

Various agencies have legal requirements with respect to labelling of cytotoxic drugs and related waste. These issues are addressed in detail in other parts of this guide: for more information, see sections 2.2.3 and 7.1.

Residual risk of exposure to cytotoxic drugs and waste may be minimised by using PPE. The success of this control measure depends on the correct PPE being chosen and fitted correctly, being worn by the worker for whom it was selected (where appropriate), and being properly stored and maintained in good condition. Considerations in the selection of PPE for particular tasks involving cytotoxic drugs and related waste, are discussed in chapter 5.

### **3.4.3 Implementing controls**

When control measures are put into place ensure they are supported by:

- work procedures and SOPs which describes the task, identifies the hazards and documents how the task is to be performed. Management, supervision and worker responsibilities may need to be clearly defined in the work procedures
- training, instruction and information which informs workers, supervisors and others how to perform the task safely. It is important to clearly communicate the reasons for any changes
- adequate supervision suitable to the level of risk and experience of the workers
- a way to maintain the control measure to ensure it remains effective.

### **3.5 Review of control measures**

Control measures should be examined at regular intervals to ensure they are still effective.

Questions to be asked include:

- Have the control measures been implemented as planned?
- Are the control measures working?
- Is there any new hazard or risk identified?

Control measures must be reviewed in certain circumstances under the WHS Regulations including:

- when the control measure is not effective in controlling the risk
- before a change at the workplace which is likely to give rise to a new or different health and safety risk that the control measure may not effectively control
- if a new hazard or risk is identified
- if the results of consultation indicate a review is necessary
- following any change to the SDS for a hazardous chemical or the register of hazardous chemicals
- if a health monitoring report indicates a worker has elevated levels of metabolites in his or her body for a hazardous chemical, or test results indicate a worker may have contracted a disease, injury or illness
- if monitoring of an airborne contaminant determines the airborne concentration exceeds the relevant exposure standard.

Controls should also be reviewed by evaluating data on near misses, incidents, injuries or reports of work caused illness. An important consideration in working with cytotoxic substances is ongoing monitoring of how well safe working practices, including the correct use of PPE, are being followed.

Routine maintenance schedules must be established for items of plant (e.g. CDSC or isolator) used in drug preparation areas. The routine maintenance is to ensure any defects, which could result in a loss of efficiency and reduced level of protection of the control measures, are detected and fixed.

See appendix 6 for a sample audit checklist.

### **3.6 Risk management records**

Keeping records of the risk management process demonstrates potential compliance with the WHS Act and Regulation. The detail and extent of recording will depend on the size and level of risk of the workplace. It is recommended information is kept on:

- the identified hazards, assessed risk and control measures
- how and when control measures were implemented, monitored and reviewed
- who you consulted with
- training records
- any plans for changes.

### **Standard operating procedures – Chapter 3**

In developing SOPs for the risk management process, the following factors should be considered:

- the risk management process, including identifying hazards, assessing risk, determining control measures and reviewing control measures
- assignment of a specific person or position to manage the risk management process
- hazard identification, including identifying cytotoxic drugs used, workplaces and workplace activities where workers may be at risk of exposure, workers at risk of exposure, routes of exposure and implemented control measures
- control measures selected according to the hierarchy of control
- appropriate checklists and templates developed to support the process
- review of control measures included in SOPs for all activities and tasks
- the risk management process adopted by the organisation applied consistently
- records of the risk management process maintained.

In addition, these SOPs should:

- be developed in consultation with workers
- be developed with regard to manufacturers' instructions, SDSs or other information about the equipment, substances or products being used
- be part of the induction and ongoing training program
- be reviewed regularly and when there are incidents or changes to the workplace that affect the procedure (e.g. new equipment, new legislation, new products).



## Chapter 4: Training

The PCBU must give workers who may be exposed to cytotoxic drugs information, training and instruction which is suitable to the nature of the work and associated risks. PCBUs must ensure only those workers who have received appropriate training and instruction carry out work involving cytotoxic drugs and related waste.

### 4.1 When is training needed?

Training, instruction and information are necessary to support control measures which are being used in a workplace to manage health and safety risks. Information collected during the risk management process can be used to:

- identify who should be trained
- identify what training is needed and the most effective delivery methods
- evaluate the training program.

It is recommended training is undertaken:

- as part of induction to a unit where cytotoxic drugs and related wastes are used. Use includes administration, preparation, handling, storage, movement and disposal
- prior to commencement of duties involving cytotoxic drugs and related wastes
- when new cytotoxic drugs or equipment are introduced or procedures change.

#### 4.1.1 Identify who should be trained

The level of training, instruction and information required for a worker should reflect their work activity and level of exposure to cytotoxic drugs or contaminated waste. The following workers may require training:

- |                                       |  |   |
|---------------------------------------|--|---|
| • nurses and medical officers         | • waste handlers (internal/ external, on/off site)                           | • administrative workers  |
| • contract workers                    | • maintenance workers  | • workers responsible for ordering or purchasing cytotoxic equipment, PPE |
| • ambulance officers                  | • stores and warehouse workers   | • planners/designers/schedulers of work/workplaces                        |
| • biomedical technicians              | • emergency response workers (e.g. fire wardens, emergency control officers) | • delivery workers  |
| • pharmacy workers                    | • cleaning workers   | • couriers and porters  |
| • pharmaceutical workers              | • mortuary/funeral home workers  | • allied health workers   |
| • laboratory workers                  | • laundry workers  |   |
| • research workers                    |  |   |
| • veterinarians and veterinary nurses |  |   |
| • community care workers              |  |   |

The following people may also be exposed and should be considered for the provision of information and training:

- patients, family and friends
- outpatients and their home care-givers
- families of pets undergoing cytotoxic drug therapy
- volunteers.

It is important to develop a procedure to ensure casual or temporary workers (such as maintenance workers), called in to areas such as clean rooms, are properly informed and supervised with regard to safety procedures and the wearing of correct PPE. The same applies to workers doing short-term relieving for ancillary workers, such as stores and warehouse workers and nurses employed on a casual basis to work in an environment when cytotoxic drugs and related waste are managed.

#### **4.1.2 Identify what training is needed**

Modules and elements to be included in training for specific work areas should be decided after considering:

- the level of risk identified in a risk assessment
- the work activities performed in the area
- the different workers and groups involved
- the content of current training programs.

Ancillary workers may require a different level of training from other workers. Decisions should also be made with regard to the required level of knowledge about a particular element, and how knowledge will be evaluated.

Training programs must be provided in a way that is readily understandable by any person to whom it is provided. Therefore special consideration should be given to training, instruction or information provided to workers who may not be proficient in English or may have low levels of literacy.

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

- workplace health and safety legislative requirements
- legislative requirements of other agencies
- risk management
- potential health risks and toxic effects
- reproductive health risks
- control measures and work practices to be adopted when handling cytotoxic drugs and related waste
- control measures and work practices to be adopted when carrying out maintenance work (e.g. clean room maintenance)
- control measures and work practices to be adopted when carrying out general cleaning duties
- correct selection, use, fit, maintenance, storage, cleaning and disposal of PPE
- correct storage, treatment, disposal and transport of cytotoxic drugs and related waste
- procedures to be adopted in the event of exposure, accident, injury, or spill.

See appendix 7 for a summary of recommended training modules for handling cytotoxic drugs and related waste.

#### **4.1.3 Evaluate and review the training program**

An evaluation program should be in place to assess the effectiveness of the training. Assessment methods should include testing the participant's:

- ability to define basic concepts and specific terms
- knowledge, through tests or practical demonstrations
- ability to demonstrate transference in the workplace of knowledge and skills learnt.

Assessment methods should also include:

- monitoring work practices to determine if control measures are being used, and being used correctly
- monitoring work performance annually to ensure continued competency, and to determine if further training is required
- reviewing the training program.

The overall training program, including induction and ongoing training, should be reviewed to ensure the modules and topics required in the training are applicable to the work being carried out.

## **4.2 Records**

It is recommended that records of training on the use, storage and handling of cytotoxic drugs be kept. Records include:

- the date of the session
- the topics dealt with

- the name of the person who conducted the session
- the names of the workers who attended.

Further details may be kept as determined by organisational policy or other requirements.

### 4.3 Validation

A PCBU should have a system in place to verify the qualifications and ensure the competency of workers who have undergone their training elsewhere. Certificates or other such statements of attainment should be checked and validated with the issuing agency or institution. The credentials of the issuing agency should also be confirmed.

### Standard operating procedures - Chapter 4

In developing SOPs for training, the following factors should be considered:

- identification and incorporation of mandatory training requirements
- incorporation of risk management outcomes into training
- organisational training policies
- identification of workers requiring training, considering special needs such as literacy
- determination of appropriate training content and delivery mode
- development of a training evaluation process
- regular review of training, including incorporating changes to legislation, safe systems of work and SOPs
- validation and verification of training provided by other agencies
- verification of qualifications of workers.

In addition, these SOPs should:

- be developed in consultation with workers
- be developed with regard to manufacturers' instructions, SDSs or other information about the equipment, substances or products being used
- be documented and meet relevant record keeping requirements.

## Chapter 5: Personal protective equipment (PPE)

Personal protective equipment (PPE) means anything used or worn by a person to minimise risk to the person's health and safety. Examples of PPE include gowns, respiratory protective equipment and safety glasses.

The use of PPE is lowest on the list of control priorities in the risk management process and should only be used to minimise any risk remaining after higher order controls (such as engineering or substitution) have been implemented (see chapter 3.) However there may be some situations when other controls are not reasonably practicable.

The PCBU must provide required PPE to workers and ensure it is:

- selected to minimise risk to health and safety
- suited to the nature of the work
- suitable size and fit and reasonably comfortable
- maintained, repaired, in good working order, clean and hygienic or replaced
- used or worn by the worker, so far as is reasonably practicable.

A worker must be provided with information, training and instruction in relation to the safe use, storage and maintenance of the PPE and must use the PPE in accordance with the information, training or reasonable instruction.

### 5.1 Selection of PPE

Considerations in the selection of PPE should include:

- suitability for the task
- suitability for the wearer and the environment

- compatibility with other PPE in use
- condition of the PPE (e.g. not worn or contaminated)
- correct fitting and wearing
- manufacturers recommendations on lifespan and care (e.g. frequency of replacement)
- whether suitability extends to emergency situations as well as day-to-day use.

Further reference to AS/NZS 1715:2009 - Selection, use and maintenance of respiratory protective equipment is recommended. Also see section 5.3 for information on PPE for specific tasks.

### 5.2.1 Screening for effectiveness of respiratory protective equipment

Any PPE is only effective if it is correctly worn and fits the wearer. Respiratory protective equipment (RPE) requires special attention, as any type of RPE may impose some physiological and psychological stress on the user. Therefore, the following factors should be considered when selecting RPE for workers.

#### Physiological considerations

- the weight of certain RPE may place an extra burden on cardiac and respiratory systems, so an individual worker's ability to support the additional weight over prolonged periods should be considered
- factors which may preclude the use of RPE in situations other than emergency evacuation are chronic lung conditions, circulatory diseases and epileptic seizures
- use of spectacles, presence of facial hair, and facial characteristics or shape may cause RPE facepiece sealing problems.

#### Psychological considerations

- full-facepiece RPE, especially when combined with full body protection, may give rise to feelings of isolation, anxiety and claustrophobia in some people. Such people may find it difficult to perform their work satisfactorily under these conditions

Consideration may therefore be given to providing medical assessment for workers who are routinely required to wear RPE, to determine if they are able to wear the particular RPE selected as a control measure. Facial fit tests are considered essential in order for the designed performance to be achieved by RPE. It is essential the RPE is properly fitted to the individual using it. Fitting tests should be performed at appropriate intervals, particularly when there is a change in the wearer's facial characteristics (e.g. loss of teeth or excessive changes in weight), or where biological tests indicate excessive exposure to a contaminant. Facial fit tests should be adopted as routine when any close fitting RPE is being worn.

## 5.2 Selection and care of PPE

Type of PPE	Description	Task/use	Cleaning/disposal
<i>Coveralls and gowns</i>	Gowns are usually worn for tasks involving the administration of cytotoxic drugs and patient care. Coveralls are most commonly worn in drug preparation areas. Selection considerations for coveralls or gowns include: <ul style="list-style-type: none"> <li>• should be made of impermeable material (e.g. bonded polyethylene fibre)</li> <li>• should have a closed front and long sleeves with elastic or knit cuffs</li> <li>• may be disposable or can be processed through an appropriate laundry facility capable of</li> </ul>	Tasks and uses include: <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 (where spill kit needed)</li> </ul>	<ul style="list-style-type: none"> <li>• Refer to manufacturers' and suppliers 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>• Re-usable coveralls and gowns should be stored for laundering (see chapter 13).</li> </ul>

	<p>handling garments contaminated with cytotoxic drugs</p> <ul style="list-style-type: none"> <li>• should be changed at least daily, or immediately if overt contamination occurs</li> <li>• care should be taken in removal of gowns to reduce the risk of personal contamination</li> <li>• coveralls may incorporate head coverings—these are 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>• laundry—handling cytotoxic contaminated linen bag</li> <li>• ancillary workers handling cytotoxic contaminated waste containers.</li> </ul>	<ul style="list-style-type: none"> <li>• Re-usable 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>
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Type of PPE	Description	Task/use	Cleaning/disposal
<i>Head covering</i>	<p>Head coverings should be worn to contain hair and reduce contamination. They should cover exposed hair, including beards and moustaches.</p> <p>Additionally:</p> <ul style="list-style-type: none"> <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 to be used in conjunction with hoods and other coverings</li> <li>• hoods, caps and facial enclosures should not interfere with respiratory protection.</li> </ul>	<p>Tasks and uses include:</p> <ul style="list-style-type: none"> <li>• preparation of cytotoxic drugs inside a CDSC</li> <li>• cleaning of cytotoxic drug preparation areas and equipment.</li> </ul>	<ul style="list-style-type: none"> <li>• Refer to manufacturers and suppliers instructions.</li> <li>• Re-usable coveralls and gowns—see above.</li> <li>• Disposable coveralls and gowns should be disposed of as cytotoxic waste.</li> </ul>

Type of PPE	Description	Task/use	Cleaning/disposal
<i>Gloves</i>	<p>Glove use is essential. Gloves must be chosen to maximise protection by minimising permeability. Permeability of gloves to drug materials is related to chemical properties of the drug and the glove material (e.g. polarity) and glove thickness. Standard surgical gloves may not provide required level of protection due to drug and carrier permeability in the case of liquid cytotoxic drugs.</p> <p>Gloves must be long enough to cover wrist cuffs of coveralls or gowns while arm is bent or stretched. Choice of gloves currently includes:</p>	<p>Tasks and uses include:</p> <ul style="list-style-type: none"> <li>• preparation of cytotoxic drugs inside a 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 (where spill kit needed)</li> <li>• laundry—handling cytotoxic</li> </ul>	<ul style="list-style-type: none"> <li>• Refer to manufacturers' and suppliers instructions.</li> <li>• Gloves should be disposed of as cytotoxic waste.</li> </ul>

	<ul style="list-style-type: none"> <li>• purpose-manufactured or manufacturer recommended</li> <li>• surgical powder-free latex gloves.</li> </ul> <p>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. Additionally:</p> <ul style="list-style-type: none"> <li>• operators not wearing special purpose gloves should be double-gloved. This can be done with two pairs of powder-free latex gloves</li> <li>• latex gloves used in drug preparation should be sterile and powder free</li> <li>• with double-gloving, both gloves must be changed</li> <li>• gloves should be changed at intervals recommended by the manufacturer, or at intervals of 30 minutes, or when punctured, torn or contaminated.</li> </ul>	<p>contaminated linen bag</p> <ul style="list-style-type: none"> <li>• ancillary workers handling cytotoxic waste containers.</li> </ul>	
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Type of PPE	Description	Task/use	Cleaning/disposal
<i>Protective eyewear</i>	<p>This is provided to prevent the mucous membranes of the eye being exposed through liquid splashes.</p> <p>Eye protection can be provided by:</p> <ul style="list-style-type: none"> <li>• goggles or protective glasses with side shields</li> <li>• a transparent full-face chemical splash shield</li> <li>• full eye protection provided by full-face RPE.</li> </ul> <p>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.</p>	<p>Tasks and uses include:</p> <ul style="list-style-type: none"> <li>• preparation of cytotoxic drugs inside a 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 (e.g. intrathecal injection)</li> <li>• cleaning solid or liquid cytotoxic spills (where spill kit needed).</li> </ul>	<ul style="list-style-type: none"> <li>• Refer to manufacturers' and suppliers instructions.</li> <li>• Re-usable 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>

Type of PPE	Description	Task/use	Cleaning/disposal
<i>Respiratory protective equipment (RPE)</i>	<p>Suitable RPE should be selected, used, stored and maintained as recommended in AS/NZS 1715:2009 - Selection, use and</p>	<p>Tasks and uses include:</p> <ul style="list-style-type: none"> <li>• preparation of cytotoxic drugs inside a CDSC</li> </ul>	<ul style="list-style-type: none"> <li>• Refer to manufacturers and suppliers instructions.</li> </ul>

	<p>maintenance of respiratory protective equipment or comparable international standards. For example, to contain cytotoxic spills which may generate aerosols, respiratory protective equipment with a particulate filter (P2) is recommended. A requirement for a worker to wear prescription glasses should be taken into account in selection and fitting of RPE. Surgical masks do not offer sufficient respiratory protection against exposure to powders, liquids or aerosols (particulates).</p>	<ul style="list-style-type: none"> <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>• An effective storage and regular maintenance program should be implemented for re-usable 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>• Re-usable 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 is to be disposed of as cytotoxic waste after each use or following any contamination incident.</li> </ul>
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Type of PPE	Description	Task/use	Cleaning/disposal
<i>Shoe covers or overshoes</i>	<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>	<p>Tasks and uses include:</p> <ul style="list-style-type: none"> <li>• preparation of cytotoxic drugs inside a CDSC</li> <li>• cleaning of cytotoxic drug preparation areas and equipment</li> <li>• cleaning solid or liquid cytotoxic spills (where spill kit needed).</li> </ul>	<ul style="list-style-type: none"> <li>• Refer to manufacturers and suppliers 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>• Re-usable overshoes should be stored for laundering (see chapter 13).</li> </ul>

### 5.3 PPE for specific tasks

Preparation of cytotoxic drugs – inside a CDSC	<p>PPE:</p> <ul style="list-style-type: none"> <li>sterile coverall with hood</li> <li>two pairs of sterile, powder-free latex gloves or one pair of sterile purpose manufactured gloves</li> <li>protective eyewear</li> <li>shoe covers or overshoes</li> <li>Class P2 (N95) RPE.</li> </ul>
Cleaning of cytotoxic drug preparation areas and equipment	<p>PPE:</p> <ul style="list-style-type: none"> <li>sterile coverall with hood</li> <li>two pairs of sterile, powder-free latex gloves or one pair of sterile purpose manufactured gloves</li> <li>protective eyewear</li> <li>Class P2 (N95) RPE</li> <li>shoe covers or overshoes.</li> </ul>
Drug administration and patient care	<p>PPE:</p> <ul style="list-style-type: none"> <li>gown or coverall</li> <li>two pairs of powder-free latex gloves or one pair of purpose manufactured gloves</li> <li>Class P2 (N95) RPE, based on a risk assessment</li> <li>protective eyewear, based on risk assessment.</li> </ul>
Cleaning solid or liquid cytotoxic spills (where spill kit needed)	<p>PPE:</p> <ul style="list-style-type: none"> <li>gown or coverall</li> <li>two pairs of powder-free latex gloves or one pair of purpose manufactured gloves</li> <li>Class P2 (N95) RPE</li> <li>protective eyewear</li> <li>impervious shoe covers or overshoes.</li> </ul>
Contaminated laundry – handling linen bags	<p>PPE:</p> <ul style="list-style-type: none"> <li>gown or coverall</li> <li>protective eyewear, based on risk assessment</li> <li>two pairs of powder-free latex gloves or one pair of purpose manufactured gloves.</li> </ul>
Ancillary workers handling waste containers	<p>PPE:</p> <ul style="list-style-type: none"> <li>gown or coverall</li> <li>two pairs of powder-free latex gloves or one pair of purpose manufactured gloves</li> <li>protective eyewear, based on risk assessment.</li> </ul>
Contaminated waste transport, treatment and disposal	<p>PPE:</p> <ul style="list-style-type: none"> <li>industrial workwear</li> <li>PVC industrial gloves</li> <li>safety boots</li> <li>protective eyewear, based on risk assessment.</li> </ul>

### Standard operating procedures – Chapter 5

In developing SOPs for PPE, the following factors should be considered:

- identification and incorporation of legislative PPE requirements
- information on PPE provided in SDSs
- appropriate Australian Standards referenced when selecting PPE
- information provided by manufacturers and suppliers and relevant Australian Standards, when developing maintenance and cleaning procedures
- workers to receive proper instruction in the use of the PPE



- PPE used in accordance with the appropriate standard for the equipment
- monitoring of workers to ensure PPE is worn, and worn correctly
- PPE selected and fitted to individual, with medical assessment if required.

In addition, these SOPs should be:

- developed in consultation with workers
- guided and informed by the risk management process
- reviewed regularly and when there are incidents or changes to the workplace that affect the procedure (e.g. new equipment, new legislation, new products)
- part of the induction and ongoing training program
- documented and meet relevant record keeping requirements.

## Chapter 6: Personnel management

Where exposure to cytotoxic drugs is an identified risk, occupational health and safety considerations should be taken into account during recruitment and personnel management.

Any requirement for workers to handle cytotoxic drugs and related waste as part of their duties should be reflected in recruitment and management policies and procedures. The following issues may be considered:

- determination of qualifications and competencies required by workers
- appropriate testing of competencies
- verification of qualifications with the institution which awarded them
- disclosure to applicants and workers of the nature of the work, the identified risks and the control measures in use (e.g. any requirement to wear fitted RPE)
- training requirements
- health monitoring programs.

### 6.1 Health monitoring

In a work environment where the risk of exposure to cytotoxic drugs has been identified, appropriate health management procedures should be implemented. There is a legal requirement under WHS Regulation for health monitoring (including biological monitoring and medical assessment) to identify changes in the person's health because of exposure to particular substances.

A PCBU must arrange and pay for health monitoring where a worker is carrying out ongoing work using, handling, generating or storing a hazardous chemical where there is a significant risk to the worker's health. The health monitoring must be carried out by, or under the supervision of, a registered medical practitioner with experience in health monitoring.

For more information on significant risk and health monitoring refer to the *SWA Health monitoring for exposure to hazardous chemicals guide for persons conducting a business or undertaking*.

### 6.2 Biological monitoring

Many diagnostic techniques have been used to investigate the potential health effects of exposure to cytotoxic drugs. These methods have provided results which are often inconclusive and difficult to interpret. A number of published studies have used biological monitoring and biological effect monitoring (measurement and assessment of early biological effects caused by absorption of chemicals) to try and draw inferences about the health of workers exposed to cytotoxic drugs. However, data produced from using these techniques are difficult to interpret in the context of the health of an individual worker, and therefore not recommended for routine use in health monitoring.

There is currently no form of biological monitoring or health assessment technique which is sufficiently specific to adequately predict the effects of exposure to cytotoxic drugs. An ideal test would need to meet several requirements—it would 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 which 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 opinion about action to take in the absence of routine biological tests in monitoring the health of workers handling cytotoxic drugs and related waste.

*The Health Monitoring for Exposure to Hazardous Chemicals Guide for Persons Conducting a Business or Undertaking* recommends that consideration be given to testing for urinary cyclophosphamide in workers where there is a significant risk to their health.

Research continues in this area, and PCBU's have a responsibility to ensure they remain aware of, and apply, current developments for monitoring the health of workers involved in the handling of various cytotoxic drugs. This aspect should be incorporated into policy and standard operating procedures. In general, medical facilities should have a written policy for health monitoring of workers who may be exposed to cytotoxic drugs and related waste. If the need arises—for example, in the case of an unprotected exposure—PCBU's should use the most appropriate and recent method of health monitoring available.

### **6.3 Consultation**

Consultation is an integral part of good management and PCBU's must consult with workers in relation to the selection of the registered medical practitioner. Although the responsibility for health and safety decisions rests with the PCBU, consultation provides an important opportunity for workers to contribute their experiences and suggestions to the decision-making process.

### **6.4 Information for workers**

It is important to ensure workers have access to all information relevant to working with cytotoxic drugs and related waste. The WHS Regulation includes the following provisions:

- A register of hazardous chemicals, including cytotoxic drugs, used, handled or stored must be maintained and readily accessible to workers and anyone else who is likely to be affected by a hazardous chemical.
- An SDS must be readily accessible to a worker, emergency service worker or anyone else who is likely to be exposed to the hazardous chemical.
- A worker who undergoes health monitoring must be given a copy of the health monitoring report as soon as practicable after the PCBU obtains the report. Health monitoring reports must be kept as a confidential record.
- A written statement of exposure that meets the requirements of the WHS Regulation must be given to workers who used, handled or stored cyclophosphamide in a hospital or oncological treatment facility which is authorised under the WHS Regulation at the end of the worker's employment.

### **6.5 Health counselling**

Recruitment and management policies should include disclosure to applicants, and information on counselling workers on the potential health effects of exposure to cytotoxic drugs and related waste. This should be carried out as part of the induction and ongoing training program. Information should be provided about control measures which have been implemented to eliminate or reduce the risk of exposure and the requirement for workers to follow safe work practices and wear designated PPE. They should also be counselled on the potential health risks if work practices are not strictly followed.

Some of the potential adverse effects of exposure to cytotoxic drugs include foetal loss and malformations of the offspring of exposed pregnant women, and cytogenic abnormalities and mutagenic activity related to the biological uptake by exposed workers of both sexes.

Therefore, male and female workers who are considering parenthood, and pregnant and breastfeeding women, should be counselled regarding the potential reproductive health risks from exposure to cytotoxic drugs.

It is considered that engineering controls, safe work practices and the use of PPE reduce the risk of exposure. However, workers should be provided with freedom of choice, and have the right not to work in areas where cytotoxic drugs are used. Workers who have health concerns relating to

beginning or continuing such work should inform their PCBU, and discuss redeployment options. This may be relevant if the worker is planning parenthood, or is pregnant or breastfeeding.

Discussions should consider the following:

- a PCBU has a duty to ensure that workers are not exposed to risks to their health and safety
- workers must cooperate with the PCBU by following instructions given for workplace health and safety, and use the PPE provided for the work being done
- a worker may be offered appropriate and suitable alternative duties which do not involve handling cytotoxic substances and related waste
- where alternative duties or relocation are offered, workers should not suffer disadvantage in relation to loss of pay, entitlements or conditions, or continuity of service.

## 6.6 Health monitoring programs

The risk management process should be used to develop a health monitoring program for the workplace. The following factors and considerations may be useful in designing the program.

### Implementing a health monitoring program

Factors	Considerations
1. Risk control is the key to protecting the health of workers.	<ul style="list-style-type: none"> <li>• The primary focus is to eliminate, or reduce the risks to health.</li> <li>• Strive for 'best practice' controls.</li> <li>• Ensure control measures are maintained and working as designed.</li> </ul>
2. A registered medical practitioner carries out or oversees the program.	<ul style="list-style-type: none"> <li>• The appointed medical practitioner may be an occupational physician, local general practitioner or medical officer.</li> <li>• The appointment must be made in consultation with workers. Consultation with medical, nursing and health and safety representatives should be considered.</li> <li>• The appointed medical practitioner should have the necessary experience and competence to provide health monitoring.</li> <li>• Competencies, which represent a minimum standard for performing health monitoring, are provided in the <i>Health Monitoring for Exposure to Hazardous Chemicals Guide for Medical Practitioners</i> by Safe Work Australia.</li> </ul>
3. Guidance is provided to the appointed medical practitioners.	<ul style="list-style-type: none"> <li>• Guidance is outlined in appendix 8.</li> <li>• General guidance is provided in the <i>SWA Health monitoring for exposure to hazardous chemicals guide for medical practitioners</i>.</li> </ul>
4. The health monitoring program is an integrated part of the workplace.	<ul style="list-style-type: none"> <li>• Workers and health and safety representatives should be involved in the development and management of the program.</li> <li>• The PCBU should ensure the appointed medical practitioner is given access to the workplace and any information required.</li> <li>• The PCBU should 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, are recorded.</li> </ul>
5. Prospective workers are counselled and provided with information about the risks of working with cytotoxic drugs and related waste.	<p>The counselling should include:</p> <ul style="list-style-type: none"> <li>• the nature of work to be undertaken</li> <li>• potential risks to health (including but not limited to reproductive health and the effects of carcinogens, mutagens and teratogens)</li> <li>• how exposure may occur</li> <li>• the control measures in place.</li> </ul>
6. Pre-employment and baseline health monitoring is conducted by the registered medical practitioner before a	<p>Pre-employment health monitoring (as outlined in appendix 8) provides:</p> <ul style="list-style-type: none"> <li>• collection of demographic data</li> <li>• occupational history</li> <li>• medical history</li> <li>• physical examination</li> <li>• investigation (if appropriate)</li> </ul>

worker starts work with cytotoxic drugs and related waste.	<ul style="list-style-type: none"> <li>• health advice and counselling</li> <li>• a report to PCBU and prospective worker.</li> </ul>
7. Health monitoring is conducted during the period the worker works with cytotoxic drugs and related waste.	<p>Health monitoring is conducted during the period a person works with cytotoxic drugs or related waste (as outlined in appendix 8) and provides:</p> <ul style="list-style-type: none"> <li>• data for inclusion in health records (e.g. health advice and counselling)</li> <li>• medical review after an exposure.</li> </ul>
8. Medical advice and counselling is available to workers at any time during their employment.	Workers may arrange a consultation with the appointed medical practitioner at any time.
9. Workers are provided with freedom of choice and have the right not to work with cytotoxic drugs	Appropriate and suitable alternative duties should be provided for workers who choose not to (or are unable to) work with cytotoxic drugs or related waste. In such cases, workers should not suffer disadvantage in relation to loss of pay and conditions, or continuity of service. All entitlements should be maintained.
10. The results of health monitoring are provided to the worker to whom the results relate.	The results should be made available as soon as possible.
11. Workers' medical record confidential.	Where any form of health monitoring is undertaken, confidentiality of workers' medical records must be ensured. A worker's medical records must not be disclosed to another person without the worker's written consent.
12. Health monitoring is offered on termination of employment where cytotoxic drugs were used.	<p>Health monitoring on termination of employment (as outlined in appendix 8) provides:</p> <ul style="list-style-type: none"> <li>• data collection</li> <li>• final medical examination.</li> </ul> <p>Where a hospital or cancer care treatment facility is authorised to use, handle or store cyclophosphamide, on termination of employment a worker must be given a written statement about their potential exposure to cyclophosphamide which must include as a minimum:</p> <ul style="list-style-type: none"> <li>• the time the worker may have been exposed</li> <li>• how and where the worker may obtain records of the possible exposure</li> <li>• whether the worker should undertake regular health assessments, and the relevant test to undertake.</li> </ul> <p>For all other cytotoxic drugs, on termination of employment, a statement should be provided showing:</p> <ul style="list-style-type: none"> <li>• the duration and nature of work involving cytotoxic drugs</li> <li>• the results of any medical review or health monitoring conducted</li> <li>• details of any incidents involving cytotoxic drugs or related waste.</li> </ul>

For more information on health monitoring refer to the *SWA Health monitoring for exposure to hazardous chemicals guide for persons conducting a business or undertaking*.

## 6.7 Emergency procedures

Planning for emergencies is an essential part of risk management. Protocols should be established for the management of a cytotoxic drug and related waste exposure, skin penetrating injury or spill. Any near miss or incident should be reported immediately, according to statutory and local incident reporting procedures. The cause of the near miss or incident should be investigated and determined, and follow-up action taken. The control measures developed during the risk management process should be reviewed and modified if required to prevent recurrence. Appropriate reporting procedures should be clearly identified and followed.

## 6.8 Keeping records

Maintaining records is a standard human resource management function. With respect to workplace health and safety, a PCBU must keep the following records in accordance with the WHS Regulation:

Hazardous chemical register	A register containing a list of all hazardous chemicals used, handled or stored at the workplace.
Safety data sheets	The current SDS for each hazardous chemical used, handled or stored at the workplace.
Prohibited and restricted carcinogens	Where an authorisation to use, handle or store a prohibited or restricted carcinogen has been issued - the full name, date of birth and address of each worker likely to be exposed to the carcinogen during the period of authorisation for 30 years after the authorisation ends. A copy of each authorisation must also be kept for 30 years after the authorisation ends.
Health monitoring	Health monitoring reports as a confidential record for at least 30 years after the record is made.
Workplace incidents	A record of each notifiable incident for at least five years from the day that notice of the incident is given to Workplace Health and Safety Queensland.

## Standard operating procedures – Chapter 6

In developing SOPs for personnel management activities, the following factors should be considered:

- identification and incorporation of relevant legislation into personnel management policies and practices, including confidentiality of records
- incorporation of organisational recruitment and human resource management policies
- identification of health monitoring requirements
- regular research to identify biological monitoring techniques which are able to detect changes in the exposed person, from the current accepted values for the substance being used
- consultation with workers on health issues relating to cytotoxic drugs and related waste
- provision of information to workers about cytotoxic drugs, the risk of exposure and control measures
- verification of qualifications of workers before recruitment, to determine the level of induction and training required
- access by workers and appropriate staff to relevant records
- development of appropriate health monitoring program
- emergency procedures, including incident reporting and health assessment and monitoring
- establishment and effective maintenance of appropriate records.

In addition, these SOPs should:

- be guided and informed by the risk management process
- be part of the induction and ongoing training program
- be checked regularly for compliance through monitoring and supervision
- be reviewed regularly and when there are incidents or changes to the workplace that affect the procedure (e.g. new equipment, new legislation, new products)
- be documented and meet relevant record keeping requirements.

## Chapter 7: Drug preparation

Drug preparation, including manufacture, poses the greatest risk of occupational exposure to cytotoxic drugs, due to the concentration and quantities used. Drug preparation of cytotoxic drugs is a potential hazard to the worker, as incorrect handling may increase the risk of exposure through contamination of themselves or the environment. Drug preparation includes the handling of cytotoxic drugs up to the stage of readiness for administration to the patient. It includes manufacture, forming tablets and capsules, preparing a pre-measured single dose unit (e.g. drawing up cytotoxic drugs in liquid form from a vial into a syringe) and crushing or dissolving tablets or emptying capsules to prepare part doses.

The principal focus of safety during drug preparation should be on operator protection, product protection (maintenance of product sterility and stability), protection of the working environment and protection of the end user, that is, the person who will administer the drug. An additional consideration is environmental protection.

This work should be done by pharmacists and pharmacy technicians trained specifically in the preparation of cytotoxic drugs, and with appropriate facilities. The PCBU should ensure workers do not prepare cytotoxic drugs unless they are trained and validated in the preparation of cytotoxic drugs and have the appropriate facilities.

There should be systems in place to ensure workers do not eat, drink, smoke, chew gum, apply cosmetics or store food in or near the preparation area.

Hospitals and cancer care treatment facilities involved in the manufacture or preparation of cyclophosphamide, a restricted carcinogen, may need to be authorised by Workplace Health and Safety Queensland.

### 7.1 Labelling

Under WHS legislation a PCBU is responsible for ensuring a hazardous chemical is correctly labelled including:

- if it is manufactured at the workplace
- if it is transferred or decanted from its original container
- while the container contains the hazardous chemical.

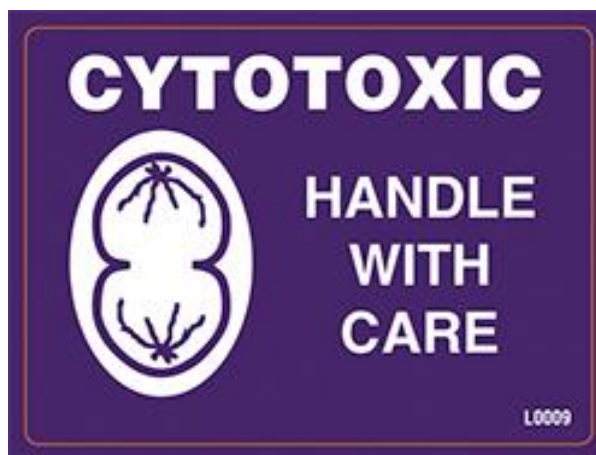
The appropriate label for cytotoxic drugs used in a workplace is determined by how it is used or is to be used. The Health (Drugs and Poisons) Regulation 1996 requires the packaging and labelling of controlled or restricted drugs and scheduled poisons comply with the Commonwealth Standard for the Uniform Scheduling of Medicines and Poisons. However the labelling requirements of the standard do not apply to a scheduled substance which is packed and sold solely for dispensary, industrial, laboratory or manufacturing purposes as these are required to be labelled in accordance with schedule 9 of the WHS Regulation.

To meet the legal requirements for labelling, suppliers and PCBUs must first determine whether a cytotoxic drug which is also a scheduled poison is to be used for industrial workplaces such as healthcare facilities and veterinary practices, or domestic use.

Cytotoxic drugs which are to be used for domestic use must be labelled in accordance with the Health (Drugs and Poisons) Regulation 1996. However, cytotoxic drugs which are packed and sold solely for dispensary, industrial, laboratory or manufacturing purposes must be labelled in accordance with the requirements of the WHS Regulation.

When a cytotoxic drug is transferred from one container into a second container, and the second container's contents are not used immediately, the PCBU must ensure the second container is fixed with a label stating the product identifier, GHS hazard pictogram or hazard statement. Second containers which are not used immediately (e.g. IV solution bags, syringes and pump cartridges) should also be labelled with a permanent adhesive purple cytotoxic warning label and distinctive warning such as 'Cytotoxic, dispose of properly.'

Purple is the recognised colour denoting the presence of cytotoxic substances or waste, and should be stipulated when printing labels or warning stickers. The easily identifiable purple symbol (see an example below), which represents a cell in late telophase, is also used to identify cytotoxic items. Alternatively, a purple label with the word 'Cytotoxic' may be used.



A PCBU should ensure the correct labelling of the following:

- IV solution flasks, syringes and pump cartridges
- containers of oral and topical cytotoxic drugs (e.g. capsules, tablets, powders, ointments, solutions)
- equipment and apparatus used in preparation and administration
- storage areas for cytotoxic substances
- transport containers for cytotoxic drugs
- laundry bags for cytotoxic contaminated laundry
- cytotoxic spill kits
- plastic bags, sharps containers and other rigid walled containers used for storing and transporting cytotoxic contaminated waste.

Suppliers of hazardous chemicals, which may include a hospital pharmacy, must not supply a hazardous chemical to a workplace if the supplier knows, or ought reasonably to know, the chemical is not correctly packed and labelled.

Summary of information for workplace label for hazardous chemicals.

Label items	All containers	Container too small to attach full label	Decanted container	Hazardous waste products
Product identifier: <ul style="list-style-type: none"> <li>• IUPAC name or</li> <li>• CAS name or</li> <li>• technical name</li> </ul>	Yes	Yes	Yes	Yes (should reflect the nature of the waste as closely as possible)
Identity and proportion of each chemical ingredient	Yes	No	No	No
Name and Australian address and business telephone number	Yes	Yes	No	Yes

of the manufacturer or importer				
Hazard pictogram(s)	Yes	Yes or hazard statement	Yes or hazard statement	Yes
Hazard statement(s)	Yes	Yes or hazard pictogram	Yes or hazard pictogram	Yes
Signal word	Yes	No	No	No
Precautionary statement(s)	Yes	No	No	No
First aid and emergency procedure details	Yes when not included in the hazard statement or precautionary statement	No	No	No
Any other information that is reasonably practicable to include	No	Yes	No	No
Expiry date (if applicable)	Yes	No	No	No

Reference: Adopted from the *Labelling of Workplace Hazardous Chemicals Code of Practice 2011*.

### Transport of cytotoxic drugs

Where cytotoxic drugs are classified as dangerous goods in accordance with the Australian Dangerous Goods Code (ADG Code), and are to be transported by road or rail, sea or air they should be marked in accordance with the provisions of that code. For more information refer to section 7.10.

The *Labelling of Workplace Hazardous Chemicals Code of Practice 2011* provides information on the labelling of hazardous chemicals in the workplace.

### 7.2 Cytotoxic drug preparation facilities and equipment

Cytotoxic drug preparation facilities and equipment should be installed and operated in accordance with appropriate state and federal requirements, and conform to relevant Australian Standards.

These include:

- AS/NZS ISO 14644.5:2006 – Cleanrooms and associated controlled environments - Operations
- AS1715:2009 - Selection, use and maintenance of respiratory protective equipment
- AS/NZS 1716:2012 - Respiratory protective devices
- AS 1807:2000 - Cleanrooms, workstations, safety cabinets and pharmaceutical isolators – Methods of test - List of methods and apparatus
- AS 2567:2002 - Laminar flow cytotoxic drug safety cabinets
- AS 2639:1994 - Laminar flow cytotoxic drug safety cabinets - Installation and use
- AS 4273:1999 - Design, installation and use of pharmaceutical isolators.

Dedicated preparation equipment should be used for cytotoxic drugs, and should be clearly labelled as being intended solely for this use.

To provide drug containment and aseptic manipulation, all preparation of cytotoxic drugs should take place in either:

- a separate, dedicated cytotoxic drug safety cabinet (CDSC) which complies with AS 2567:2002 - Laminar flow cytotoxic drug safety cabinets. Installation and use of CDSCs should be in



accordance with the specifications of AS 2639:1994 - Laminar flow cytotoxic drug safety cabinets - Installation and use; or

- a pharmaceutical isolator which complies with AS 4273:1999 - Design, installation and use of pharmaceutical isolators. Pharmaceutical isolators should be located in a dedicated room used only for the isolator and ancillary equipment, and regularly tested to ensure they are working effectively.

A secondary barrier to prevent cytotoxic drug contamination of the outside environment should be provided by high efficiency particulate air (HEPA) filters which supply filtered air to the clean room and the anteroom.

Reference should also be made to the requirements of the Health Regulation 1996, which includes sections on:

- the general requirements for a dispensary
- preparation of antineoplastic drugs—cabinets, PPE, air supply and exhaust systems.

Safe working procedures should be developed for the use of drug preparation equipment including syringes, needles, syringe tip connectors, air venting devices and ampoules and closed system drug transfer devices. Procedures should also address the risk of exposure due to release of excess drug solution or aerosols when priming syringes and other devices.

### **7.3 Alternative supply arrangements**

Healthcare establishments should not provide a cytotoxic drug preparation service unless they are able to provide the safe preparation facilities, equipment and training as specified in these guidelines.

Alternative arrangements for healthcare establishments which cannot safely provide such a service could include:

- the purchase and supply of the prepared cytotoxic drug in a single dose delivery unit from a commercial source
- the establishment of supply arrangements with a healthcare facility which does have the required facilities, equipment and trained workers to provide prepared cytotoxic drug doses.

### **7.4 Work organisation**

Fatigue is a risk factor for workplace health and safety, and may apply where the work activity involves high levels of concentration, visual and manual control to attain the precision and repetition of movements required in drug preparation activities. These matters should be considered in determining appropriate work periods for pharmacists and pharmacy technicians involved in drug preparation.

Control measures may include task rotation and frequent rest breaks, the design of equipment and procedures, and availability of adjustable furniture (e.g. chairs, stools and foot rests) to reduce physical fatigue and the risk of manual task repetition injuries. It is recommended pharmacists and pharmacy technicians spend a maximum period of two hours in the CDSC before a short break is taken.

Refer to [worksafe.qld.gov.au](http://worksafe.qld.gov.au) for more information on fatigue.

### **7.5 Procedure for use of cytotoxic drug suite**

The suite consists of an anteroom where clothing is changed and a clean room housing the CDSC. Cytotoxic clean rooms and anterooms should be designed in accordance with Australian Standards. Workers should follow appropriate aseptic technique to maintain the clean sterile work area of the CDSC. Recommended items of PPE should be sterile, and should not be worn outside the drug preparation suite.

The following procedure is recommended for pharmacists and pharmacy technicians working in the clean room:

- before entering the anteroom, remove all jewellery (e.g. bracelets, earrings, rings and watches)

- enter anteroom, put on overshoes, RPE, protective eyewear and hood or head cover, ensuring that hair is enclosed
- wash hands and forearms in sink in anteroom with antimicrobial soap solution, scrub for two minutes
- rinse hands with water and dry hands with a sterile non-linting wipe or under a hand drier
- put on sterile coverall or gown, two pairs of sterile powder-free latex gloves or one pair of purpose manufactured gloves, and enter preparation area
- while in clean room, change gloves as necessary when torn, punctured, contaminated, as per manufacturers' instructions or as determined by a risk assessment
- at the completion of a work session in the CDSC, remove both pairs of gloves prior to exiting the clean room
- remove other PPE in anteroom.

All cytotoxic waste generated in a CDSC during drug preparation should be placed in an appropriately labelled secure storage container before removal from the cabinet. For more information on waste management, see chapter 13.

## **7.6 Performance, testing and inspection of facilities and equipment**

Equipment used to prepare cytotoxic drugs and air handling facilities must be regularly maintained under a planned maintenance schedule according to manufacturers' recommendations, and with reference to relevant legislative requirements and Australian Standards.

Cytotoxic drug safety cabinets, isolators and HEPA filters should therefore be inspected and tested at regular intervals (at least every twelve months) and after relocation or mechanical or electrical maintenance (see AS 2639-1994). When activity within the cabinet is high (>1000 preparations per month), a maximum of six months between testing should be considered.

The equipment should be assessed under the relevant Australian Standards and certified by a suitably qualified independent agency, as specified in AS 2639-1994. Magnehelic pressure gauges should also be monitored daily and recorded, and appropriate action taken in the event of a failure.

Copies of test reports should be kept in the cytotoxic drug preparation facility, and a certificate summarising the test results attached to each piece of equipment. Technicians servicing these cabinets or changing HEPA filters should be warned of the nature of cytotoxic drugs, and should use the same PPE as a worker dealing with a large spill. Maintenance records should be kept.

## **7.7 Cleaning of cytotoxic drug preparation facilities and equipment**

The drug preparation facility should be cleaned in accordance with AS 2639-1994. Appropriate PPE should be worn (see chapter 5). Daily and weekly routines should be established, and all equipment used in the cleaning should be dedicated for the purpose and considered potentially contaminated. Cleaning should include bench tops and surfaces, grilles, filters, cabinets, floors, walls and ceilings. CDSCs should be cleaned at the beginning and end of each work day in accordance with AS 2639-1994.

Written procedures should be developed for the cleaning of cytotoxic facilities and equipment, and a cleaning log maintained. General cleaning workers who may be involved in cleaning drug preparation suites and associated equipment must be informed of the potential hazards associated with cytotoxic drugs, and be trained in safe cleaning procedures.

## **7.8 Handling of cytotoxic drugs**

Cytotoxic drugs in all forms should be handled in a manner which avoids:

- skin contact
- the liberation of aerosols or powdered drug into the air
- cross-contamination with other drugs.

Crushing of tablets and opening of capsules should not be done outside a CDSC because of the unacceptable risk of exposure. Use of an open mortar for these tasks is also not recommended. The

use of automatic tablet counters, or other equipment for the packaging of cytotoxic drugs which might generate particulate matter, should be avoided.

Drug administration workers should seek advice and assistance from a pharmacist trained in cytotoxic drug preparation in situations where a fraction of a manufactured dose has been prescribed, or the drug is to be administered nasogastrically. Appropriate doses of cytotoxic drugs should then be supplied in such a way as to minimise the risk of exposure to administration workers.

Disposable equipment or re-usable equipment should be designated and labelled specifically for cytotoxic use. Re-usable equipment should be cleaned after each use, by washing twice with water and detergent.

## **7.9 Drug storage**

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

The quantities 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 SDS readily accessible for each drug. Storage areas should be secured and access limited to authorised workers.

A dedicated area should be provided for the unpacking of cytotoxic drugs. Damaged packages of cytotoxic drugs should be handled with care. Badly damaged packages should be safely contained and returned to the manufacturer with suitable warning labels. Damaged packages should be opened in an isolated area by a worker wearing the same PPE as is used in preparation, and with RPE. Contents should be examined for damage or leakage to determine whether they are safe for repackaging, or must be disposed of as contaminated waste.

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

Consideration should be given to the fire and explosion risks, prevention of hazardous reactions between products and the management of leaks and spills.

Other agencies such as Queensland Health and Department of Environment and Heritage Protection also have requirements for drug storage which must be complied with.

## **7.10 Transporting cytotoxic drugs**

Appropriate control measures must be in place to ensure there is no cytotoxic residue contaminating the outside of the primary container or other packaging, which would pose a risk to the health and safety of workers handling the product at subsequent points in the supply chain.

Cytotoxic drugs should be packaged and transported so as to provide adequate physical and chemical protection for the drug during storage and transport, and protection to handlers in the event of spillage. Transport containers should be labelled to allow easy identification of the contained drugs.

Prepared cytotoxic drugs should be packaged as follows:

- with a purple cytotoxic sticker or label
- in a sealed, leak-proof container, with outer bags heat-sealed where possible
- in a container offering protection from light where required
- in the case of drugs for intrathecal use, packaged separately and labelled both on the syringe and on the outer container 'For intrathecal use'
- vinca alkaloids should be labelled appropriately (e.g. 'For IV use only - other use may be fatal' or 'Fatal if administered by any other route')

- in a manner which protects the drugs from breakage in transit
- to contain leakage if breakage occurs
- fitted with childproof caps where appropriate (e.g. tablet containers).

Control measures to reduce the risk of exposure while cytotoxic drugs are being transported must be developed (see section 3.4.2 of this guide). Containers used for transport of prepared cytotoxic drugs should be hard-walled and robust. The container may be made from moulded foam or other suitable packaging material, capable of protecting the product from a shock equivalent to a drop of one metre on to a concrete surface. The container should be securely closed and labelled with cytotoxic warnings.

Workers involved in transporting cytotoxic drugs should be cautioned and trained in the necessary procedures should a spill occur, including sealing off the contaminated area and calling for assistance.

Healthcare facilities which are involved in the external transport of cytotoxic drugs (e.g. transporting supplies to other hospitals or healthcare facilities) must comply with the requirements of other agencies such as the Department of Environment and Heritage Protection and Department of Transport and Main Roads. For more information, see section 2.4 of this guide.

Under the ADG Code, dangerous goods above a certain quantity require the vehicle to be placarded with the class label of the goods being transported in order to alert emergency services responders to the presence of dangerous goods in the vehicle. An emergency procedure guide is to be carried in the vehicle and kept in the right hand door pocket of the vehicle, near the driver.

### **7.11 Spill management**

SOPs should be developed for handling cytotoxic spills in the various drug preparation areas, such as CDSCs, clean rooms, anterooms and storerooms. For rooms fitted with positive pressure devices, a spill switch should be installed which, when activated, will minimise contamination of the external environments. Such systems should be installed correctly and tested on a regular basis to ensure they are still operational. For more information refer to chapter 12.

### **7.12 Waste management**

Contaminated waste generated during the preparation of cytotoxic drugs must be disposed of safely. Special procedures may be developed for waste generated in clean rooms and CDSCs. These may include:

- placing waste in sealed containers before removal from the area
- puncture-resistant containers for contaminated sharps waste
- use of secondary packaging to ensure leaking does not occur.

For more information on cytotoxic waste management, see chapter 13.

## **Standard operating procedures – Chapter 7**

In developing SOPs for cytotoxic drug preparation activities, the following factors should be considered:

- identification and incorporation of relevant legislation regarding handling, storage, packaging and transport
- identification and incorporation of relevant Australian Standards in selection and maintenance of clean rooms and drug preparation facilities and equipment
- selection of plant and equipment as appropriate for cytotoxic drug applications
- incorporation of manufacturers and suppliers specifications and recommendations in installation, maintenance and testing procedures for plant and equipment
- designation of equipment and areas for use only in preparing cytotoxic preparations with appropriate labelling, signage or other identification
- safe systems of work for storage, packaging and transport
- safe systems of work for cytotoxic drug preparation, considering the factor of fatigue
- disposal of cytotoxic waste

- management of cytotoxic contaminated laundry
- emergency management, including location of appropriate spill kit
- emergency and reporting procedures for personal contamination and penetrating injuries
- labelling of cytotoxic drugs at all stages—transport, storage, preparation—according to organisational and legislative requirements
- documentation and records including activity records for workers involved in drug preparation.

In addition, these SOPs should:

- be developed in consultation with workers
- be guided and informed by the risk management process
- be developed with regard to manufacturer's instructions, SDSs or other information about the equipment, substances or products being used
- be part of the induction and ongoing training program
- be checked regularly for compliance through monitoring and supervision
- be reviewed regularly and when there are incidents or changes to the workplace that affect the procedure (e.g. new equipment, new legislation, new products)
- incorporate emergency procedures, including the location of cytotoxic spill kits
- be documented and meet relevant record keeping requirements
- integrate smoothly and be consistent with other organisational policies.

## Chapter 8: Drug administration

There are multiple routes for the administration of cytotoxic drugs. These include parenteral (subcutaneous, intraocular, intramuscular, intrapleural, intraperitoneal, intra-arterial, intrathecal and intravesical), oral and topical.

Healthcare workers are at risk of exposure while administering cytotoxic drugs by any route. To reduce the risk of exposure while administering cytotoxic drugs, PCBUs should consider such measures as workplace design, use of specially designed equipment, safe work practices and personal protective equipment. Education and training is crucial to ensuring control measures and safe work practices are developed, understood, implemented and maintained.

### 8.1 Risks in cytotoxic drug administration

Factors influencing the level of risk of exposure to cytotoxic drugs during administration include:

- patient behaviour, which may increase the difficulty of administration (e.g. unpredictable movements, reflex actions, fear or pain reactions)
- the route of administration
- an inappropriate working environment (e.g. crowded space)
- inadequate education and training, including poor technique
- lack of the correct equipment
- workers, patients and visitors in the drug administration area.

These factors should be considered during a risk assessment, and when developing control measures.

### 8.2 Control measures

A cytotoxic drug administration service should not be offered unless effective control measures can be provided. The following control measures should be considered:

- cytotoxic drugs are supplied in pre-prepared doses. They are to be prepared only by trained workers in a CDSC (see chapter 7)
- cytotoxic drugs intended for administration are appropriately labelled, packaged and ready for administration
- use of safe administration techniques and systems, such as needleless and luer-lock systems
- provide secure labelled cytotoxic-specific sharps disposal and waste containers\*
- readily accessible cytotoxic spill kits

- appropriate and readily available PPE (see chapter 5)
- appropriate training (see chapter 4).

These ‘best practice’ control options should be considered as a priority. A policy will help to build these control measures into the health and safety strategy and day-to-day procedures.

For more information on labelling refer to section and 7.1 of this guide.

There should be systems in place to ensure workers do not eat, drink, smoke, chew gum, apply cosmetics or store food in or near the administration area.

### **8.3 Recommendations for establishing a cytotoxic drug administration area**

When designing and setting up a cytotoxic drug administration area, consider:

- allocating an area which restricts access to unauthorised people
- work flow with respect to treatment, preparation, storage and disposal areas
- allowing sufficient room for movement of people and equipment during drug administration
- providing secure storage for cytotoxic waste, cytotoxic sharps containers and cytotoxic contaminated linen
- establishing a system for obtaining and keeping health and safety information, such as SDSs, in a place accessible to workers
- providing readily accessible cytotoxic spill kits
- providing access to a shower in event of contamination.

The *Australasian Health Facility Guidelines*, Part B – Health facility briefing and planning – 155 Ambulatory care produced by the Australian Health Infrastructure Alliance (AIHA) also provides some guidance on the planning, design and construction of a cytotoxic room.

### **8.4 General precautions for administration of cytotoxic drugs**

The risk management process should determine appropriate control measures for the administration of cytotoxic drugs. The following practices are recommended for all routes of administration:

- follow suppliers and manufacturers recommended procedures for administration of specific drugs, consulting the SDS if necessary
- use PPE (see chapter 5)
- use an appropriate receptacle to contain and carry cytotoxic drugs to the bedside
- use portable trolleys to store administration equipment and to allow movement from patient to patient
- identify all containers (e.g. syringes, IV bags, tablet containers, jars, tubes) used for cytotoxic agents with cytotoxic labels
- dispose of cytotoxic contaminated items in designated, labelled cytotoxic waste containers
- wash hands following administration and disposal of cytotoxic drugs and related waste
- return unused cytotoxic drugs to the pharmacy or dispose of according to SOPs
- provide readily accessible cytotoxic spill kits.

### **8.5 Parenteral cytotoxic drug administration**

Parenteral cytotoxic drugs are generally administered using syringes or by infusion. There is a risk of exposure through inhalation, ingestion, dermal absorption and percutaneous injury. There may be a higher risk of inhalation of airborne contaminants during parenteral drug administration from:

- the expulsion of air from a drug-filled syringe
- the withdrawal of needles from IV administration sets
- the removal of IV-giving sets from flasks containing cytotoxic drugs
- penetrating injuries
- splashes and leakages from faulty or damaged equipment
- spills of cytotoxic drugs.

If a risk assessment is carried out it should consider work flow and activities conducted, as well as list and evaluate existing control measures.

As well as the general control measures listed above, the following control measures are recommended:

- use needleless administration systems or luer-lock fittings on needles, syringes and other IV equipment
- use an appropriate receptacle to contain and carry cytotoxic syringes to the bedside
- prime IV tubing with non-cytotoxic fluids before attaching to IV bags and flasks loaded with cytotoxic drugs
- connect IV bags at waist level on a flat surface
- identify all IV solution flasks, syringes, pump cartridges, etc. with cytotoxic labels
- use disposable gauze squares around injection sites
- use plastic backed absorbent sheets or pads under injection sites
- return syringes containing air to the pharmacy or supplier
- do not recap needles
- ensure cytotoxic sharps disposal containers\* are readily accessible to all operators
- dispose of empty IV bags or flasks with the administration set still attached.

#### **8.5.1 Special considerations – variation from a pre-prepared dose**

In some circumstances, a pre-prepared dose of chemotherapy may need to be altered prior to administration. This situation may occur when a patient's dose is reduced by the treating doctor, for example, in general practice, where administration of methotrexate to a patient with rheumatoid arthritis may vary from visit to visit. In such situations, it may be more efficient to have a supply of pre-prepared syringes in commonly prescribed amounts.

In the event a pre-prepared syringe has more cytotoxic drug than the prescribed dose, and it is impractical to obtain the correct dose from the supplier, the following procedures may be considered in developing control measures to reduce the risk of exposure:

- DO NOT expel the excess cytotoxic drug under ANY circumstances.
- Use a syringe-to-syringe connector—this device facilitates the transferring of syringe contents to another syringe, using a closed system. Seek information about this system and instructions for use from the facility providing the pre-prepared chemotherapy.
- Using a bag of sodium chloride, inject the excess chemotherapy dose into the sodium chloride bag, wearing PPE and using safe handling precautions.

In developing safe systems of work, a risk assessment should be conducted and appropriate control measures developed to reduce the risk of exposure. These control measures should be documented and a standard operating procedure written and provided to all workers who may be at risk from this activity.

#### **8.6 Topical cytotoxic agents**

Topical cytotoxic agents carry the same risk for occupational exposure as other cytotoxic drugs. These agents may be in the form of ointments, lotions or eye drops. There is a risk of exposure through ingestion, and through mucosal and dermal absorption.

As well as the general control measures listed in section 8.5 above, the following control measures are recommended:

- avoid unnecessary contact with topical cytotoxic agents
- minimise contact with any clothing
- apply ointments and lotions as a film, using a disposable spatula
- ensure cytotoxic drug containers are appropriately labelled
- use plastic-backed absorbent sheets or pads under the administration site
- educate patients on the correct method to apply medication
- dispose of all contaminated items (e.g. gloves, spatulas, containers, dressings) as cytotoxic waste
- identify all containers (e.g. syringes, jars, tubes) used for topical cytotoxic agents with cytotoxic labels.

## 8.7 Oral cytotoxic drug administration

Oral cytotoxic drugs carry the same risk for occupational exposure as other cytotoxic drugs. Oral cytotoxic agents are generally given as tablets and capsules. There is a risk of exposure through inhalation of powdered drug, ingestion and mucosal absorption.

As well as the general control measures listed in section 8.5 above, the following control measures are recommended:

- avoid direct handling of oral cytotoxic drugs
- identify all oral cytotoxic drug containers with cytotoxic labels do not crush or break oral cytotoxic drugs for any reason outside of the pharmacy or CDSC
- contact the pharmacy if it is necessary to produce a cytotoxic drug mixture, or if tablets or capsules need to be crushed or broken to deliver the correct dose
- transfer tablets and capsules from their original containers directly into a disposable medication cup
- instruct the patient to take the tablet or capsule directly from the medication cup, with no handling
- discard contaminated medication cups and containers as cytotoxic waste
- return tablets and capsules to the pharmacy when loose powder is observed.

## 8.8 Personal protective equipment (PPE)

PPE is an important control measure in cytotoxic drug administration. It is essential the appropriate PPE is provided by the PCBU and worn correctly by the worker. See chapter 5.

\*Sharps disposal containers must comply with AS 4031:1992 - Non-reusable containers for the collection of sharp medical items used in healthcare areas.

## Standard operating procedure – Chapter 8

In developing SOPs for cytotoxic drug administration, the following factors should be considered:

- identification and incorporation of relevant procedures and information from suppliers and the manufacturers for administering cytotoxic drugs
- identification of all cytotoxic drugs, and disposal or storage containers with correct cytotoxic warning label
- safe systems of work, including safe administration techniques and establishment of a safe administration area
- cytotoxic drugs should only be prepared by trained workers with the appropriate facilities
- selection of appropriate PPE and monitoring and supervision to ensure PPE is worn correctly
- safe systems of work for parenteral cytotoxic drug administration
- safe systems of work for topical cytotoxic drug administration
- safe systems of work for oral cytotoxic drug administration
- disposal of cytotoxic waste
- management of cytotoxic contaminated laundry
- emergency management including location of appropriate spill kit
- emergency and reporting procedures for personal contamination and penetrating injuries.

In addition, these SOPs should:

- be developed in consultation with workers
- be guided and informed by the risk management process
- be developed with regard to manufacturers' instructions, SDSs or other information about the equipment, substances or products being used
- be developed with regard to relevant legislation and organisational protocols
- be part of the induction and ongoing training program
- be checked regularly for compliance through monitoring and supervision
- be reviewed regularly and when there are incidents or changes to the workplace that affect the procedure (e.g. new equipment, new legislation, new products)



- incorporate emergency procedures, including the location of cytotoxic spill kits
- be documented and meet relevant record keeping requirements
- integrate smoothly and be consistent with other organisational policies.

## Chapter 9: Risk management in healthcare facilities

Healthcare facilities involved in handling cytotoxic drugs and related waste include hospitals, day hospitals, clinics and general practices. The risks associated with handling cytotoxic drugs and related waste in healthcare facilities are, in some cases, different to those in community settings such as residential aged care facilities or patients' homes. The health and safety issues for community settings are dealt with in chapter 10.

Procedures to minimise exposure should be developed for workers handling patient blood and body substances. Where there is a risk of exposure to blood, workers should adopt standard precautions.

Please refer to section 1.3 of this guide for more details about occupational exposure, including the routes, activities and workplaces where exposure to cytotoxic drugs or related waste may occur.

### 9.1 Risk management

While a risk assessment is not mandatory, it will help establish who may be at risk, the cytotoxic drugs being used, the routes of exposure, and the specific activities where there is a risk of exposure. Control measures currently in use and their effectiveness should be identified and recorded. Refer to chapter 3 for more information.

Control measures may include correct workplace design and set-up, use of appropriate equipment, safe work practices and personal protective equipment. Information, instruction and training requirements should also be identified during the risk management process, to ensure the safe work practices which have been developed are understood, implemented and maintained in the facility.

### 9.2 Control measures – safe work practices

Safe work practices to manage the risk of exposure may include:

- reviewing the treatment history of patients before undertaking patient care and transporting
- reviewing health and safety information about the administration and handling of cytotoxic drugs and related waste
- using appropriate equipment
- assessing the work environment for task suitability.

#### 9.2.2 Determining when control measures are required

Cytotoxic drugs are primarily eliminated from the patient by renal and biliary excretion. Urine, faeces, vomitus and fluids drained from body cavities may be contaminated with either the unchanged drug or active drug metabolites.

Appendix 9 lists the excretion times of some cytotoxic drugs.

Drug reference charts which list the excretion duration period and the route of excretion should be consulted to help determine the risk of exposure and appropriate control measures. Excretion time may range from 48 hours to seven days, although the period during which body substances may be contaminated with cytotoxic metabolites will differ for individual drugs and patients. It is recommended precautions be taken for a seven-day period from the completion of cytotoxic therapy.

Consideration may be given to developing a procedure to identify and manage patients receiving cytotoxic therapy during the period while the treatment drug may be excreted. This will alert ancillary workers to the need for cytotoxic waste handling procedures in the care of these patients.

#### 9.2.2 Patient records

To assist in determining whether patient body substances are potentially contaminated with cytotoxic drugs, the following should be documented in the patient care record:

- the name of the drug administered

- the route of administration
- the time the drug was administered
- the routes of excretion
- the duration following administration that unchanged drug or active metabolites may be excreted.

This record should be available for reference when needed.

### **9.3 Setting up a patient care area**

The following factors should be considered when designing a patient care area where cytotoxic drugs are administered:

- providing a secure area that allows access to authorised people only
- providing appropriate areas for storage of cytotoxic drugs and preparing for administration
- allowing sufficient room for healthcare workers and others to perform tasks safely
- providing secure cytotoxic contaminated waste storage areas (see chapter 13).

#### **9.3.1 Equipment used in patient care**

Suitable equipment designed to manage the risk of exposure should be used. The following equipment is recommended:

- trolleys or trays to carry administration equipment to the patient
- cytotoxic spill kit, as outlined in chapter 12
- water and detergent
- approved containers for sharps disposal, cytotoxic waste and cytotoxic contaminated linen, where required
- appropriate PPE (for more information, see chapter 5).

### **9.4 Transit within the healthcare setting**

When transporting or relocating patients undergoing cytotoxic drug therapy, there may be a risk of exposure to cytotoxic drugs and contaminated body substances. A risk assessment (for more information, see chapter 3) should be performed for this situation, and appropriate SOPs developed incorporating selected control measures. Healthcare workers should refer to the patient records to determine whether patients to be transported are currently undergoing, or have recently received cytotoxic therapy.

The following control measures should be considered:

- check patient care record before transit to determine the risk of exposure to cytotoxic drugs or cytotoxic related waste
- ensure constant nursing supervision of the patient during the relocation or transport
- ensure workers at destination are informed and prepared
- develop a procedure for managing a cytotoxic spill during transit (e.g. ensuring a cytotoxic spill kit accompanies the patient).

### **Standard operating procedures – Chapter 9**

In developing SOPs for application in healthcare facilities, the following factors should be considered:

- use of the risk management process to identify hazards, assess the risk of exposure and develop and implement appropriate control measures
- establishment and maintenance of patient records to facilitate provision of information about cytotoxic drug risk status
- supply of cytotoxic drugs in required doses from the pharmaceutical supplier
- provision of an appropriate patient care area with suitable equipment, including appropriate PPE
- managing the risk of exposure while transporting patients
- management of cytotoxic contaminated body substances
- disposal of cytotoxic waste
- segregation of cytotoxic contaminated laundry

- spill management and location of appropriate spill kit
- emergency and reporting procedures for personal contamination and penetrating injuries.

In addition, these SOPs should:

- be developed in consultation with workers
- be developed with regard to relevant legislation and organisational protocols
- be developed with regard to manufacturers' instructions, SDSs or other information about the equipment, substances or products being used
- be part of the induction and ongoing training program
- be checked regularly for compliance through monitoring and supervision
- be reviewed regularly and when there are incidents or changes to the workplace that affect the procedure (e.g. new equipment, new legislation, new products)
- be documented and meet relevant record keeping requirements.

## Chapter 10: Risk management in community settings

While most patients undergoing cytotoxic drug therapy are treated in healthcare facilities such as hospitals, day hospitals, clinics and medical practices, the number of patients being treated at home or in residential facilities is increasing. The risk from handling cytotoxic drugs and related waste in community settings is somewhat different to those faced by healthcare facilities, which are dealt with in the previous chapter. This is because a community setting is an uncontrolled environment, and both PCBU and worker have less influence regarding control measures than in a healthcare facility.

People involved with caring for people in their home may include nurses, medical officers, volunteers and carers. Carers include family, friends and personal care workers. Others who may be at risk of exposure include waste collection workers, and tradespeople working around the home.

Cytotoxic drugs should not be prepared in the community setting. Healthcare workers preparing cytotoxic drugs without adequate precautions have been shown to contaminate themselves and their work environment. The risk of exposure may be eliminated or reduced by ensuring cytotoxic drugs are prepared by trained pharmacists or technicians in approved facilities, such as a cytotoxic drug safety cabinet or a pharmaceutical isolator. See chapter 7 for further details.

Health and community care organisations and referring doctors who are unable to have cytotoxic drugs prepared in an approved facility by trained workers should not undertake preparation of these drugs for supply to patients for administration at home.

Alternative arrangements may include:

- having cytotoxic drugs supplied in a prepared single-dose delivery unit, purchased from a commercial source
- establishing supply arrangements with a healthcare facility which has the required facilities, equipment and trained workers to prepare cytotoxic drug doses.

### 10.1 The referring healthcare facility

'Referring healthcare facility' is used in this guide to mean the hospital, pharmacy, medical practice or treating doctor supervising the patient receiving cytotoxic therapy.

The role of the referring healthcare facility is to:

- ensure cytotoxic drugs are appropriately packaged and labelled, and safe for transport
- ensure facilities and equipment meet recommended standards
- provide instruction and written information to patients and home carers.

### 10.2 The community care service

'Community care service' is used in this guide to mean a service provider which provides professional workers or personal care workers to assist people in their homes. Community care workers may provide a range of services, including personal care, domestic duties and professional duties, such as medical treatment and drug administration.

### 10.3 Legislative requirements

The WHS legislation outlines the health and safety duties relevant to the use of cytotoxic drugs.

#### 10.3.1 Duties of the referring healthcare facility

Referring healthcare facilities which supervise patients receiving cytotoxic drug therapy in their homes or in community settings may have duties to ensure other people (e.g. home nurses, personal care workers, waste management workers, tradespeople and carers) are not exposed to cytotoxic drugs. When a referring healthcare facility supplies a cytotoxic drug to a patient, they must comply with the provisions regarding suppliers of hazardous chemicals (see section 2.2 of this guide), including information about safe use.

It is recommended the referring healthcare facility seek information from the patient regarding community care services provided in the patient's home, either for the patient or another member of the household. If necessary, the referring healthcare facility should explain to the patient that precautions may be required for the protection of workers who may come into the home (e.g. a community care worker, or a plumber who needs to work on a blocked drain). The patient should be supplied with information for their own use and to pass on to workers.

The referring healthcare facility may consider obtaining consent (verbal consent is sufficient) from the patient for the referring healthcare facility to inform the community care service of the hazard potential, the need for precautions and the level of protection required.

The duties of the referring healthcare facility may include:

- undertaking the risk management process for the patient's situation
- ensuring the safe use, handling, storage and transport of cytotoxic drugs and related waste
- providing information for the patient to pass on to workers coming into the patient's home. This would include information about the risk of exposure, the need for precautions and the level of protection required (e.g. the PPE to be worn)
- informing the community care service.

Before a patient is discharged, referring healthcare facilities should be prepared to amend generic information or SOPs following consultation with the patient, and if possible, participating community care workers, to ensure the information provided to the patient is appropriate to individual situations.

The referring healthcare facility may also need to consider its common law, privacy and duty of care obligations in these matters.

#### 10.3.2 Duties of the community care service

Community care workers who work in people's homes may be at risk from exposure to cytotoxic drugs and related waste if the patient or client is receiving cytotoxic therapy. The PCBU of a community care service has duties to ensure the health and safety of their workers in peoples' homes. They should conduct a risk assessment and must implement appropriate control measures to meet these duties. Information and directions provided by a referring healthcare facility should be considered during the risk management process.

The PCBU must provide a safe environment for workers going into the home. Patients may be requested by the PCBU to assist by:

- maintaining a safe work environment (e.g. adjusting inadequate lighting)
- passing on instructions or information from the referring healthcare facility
- providing access to patient care equipment (e.g. cytotoxic spill kits, washing facilities, containers for disposal of cytotoxic contaminated waste).

### 10.4 Patient care

Please refer to chapter 9 for relevant information on patient care which is also applicable in the community setting.

#### **10.4.1 Setting up a patient care area at home**

The following facilities should be provided:

- hand washing facilities
- laundry facilities
- access to a toilet
- secured cytotoxic waste storage.

#### **10.4.2 Equipment for patient care at home**

The following items may be required in a patient's home while they are receiving cytotoxic drug therapy or are excreting cytotoxic waste:

- personal protective equipment
- cytotoxic spill kit (see chapter 12)
- dedicated, labelled container for cytotoxic contaminated linen
- approved container for disposal of sharps (if receiving parenteral cytotoxic drug therapy)
- approved container for the disposal of cytotoxic drugs and related waste.

A number of waste management companies will hire out labelled cytotoxic waste bins on a short-term basis, delivering and collecting them from the home, and safely disposing of the contaminated waste.

Some councils operate a sharps containers exchange program, which may be convenient for some home care situations. When making enquiries, the council should be advised the sharps are cytotoxic contaminated.

### **10.5 Cytotoxic spills**

Refer to chapter 12 for the contents of a cytotoxic spill kit, and for the appropriate procedures for dealing with cytotoxic spills. The referring healthcare facility may supply a cytotoxic spill kit to patients, with full instructions for use at home. The kit should include a list of contents, and information regarding the replacement of used items, where appropriate.

#### **10.5.1 Special consideration – leakage of cytotoxic drugs from infusion sites**

Policies and procedures need to be developed to deal with the management of leakage of cytotoxic drugs from administration sites and sets, and leakage of related waste from ostomy sites.

### **10.6 Dealing with cytotoxic waste**

Patients receiving cytotoxic drug therapy in a community setting should have appropriate cytotoxic waste management facilities which comply with environmental protection legislation. All contaminated waste generated as a result of use of cytotoxic drugs should be handled in the same manner as the drugs themselves.

Cytotoxic drugs are primarily eliminated from the patient by renal and biliary excretion. Urine, faeces, vomitus and drained fluids may be contaminated with either the unchanged drug or active drug metabolites. The period of time which the drug stays in the body may range from 48 hours to seven days, depending on the drug prescribed, the route of excretion and the patient. For this time, there is a risk of exposure and appropriate control measures must be taken.

#### **10.6.1 Information required to manage cytotoxic waste in the home**

The referring healthcare facility should provide information regarding:

- what cytotoxic drug is being used and the routes of excretion
- excretion time of the cytotoxic drug being used
- what constitutes cytotoxic waste and ways to separate and contain it
- cytotoxic waste disposal options.

Management of contaminated personal waste, contaminated items and equipment, and transport of cytotoxic contaminated waste is covered in the following sections.

### **10.7 Contaminated personal waste**

Patient body wastes which are contaminated with cytotoxic drugs can be safely disposed of in most household toilets, using a full flush with toilet lid closed to prevent any aerosols being released.

Any splash or spill should be cleaned up immediately with detergent and water, and while using PPE.

Disposal of items such as dressings, nappies, incontinence aids and ostomy bags is covered in section 10.8 below. Treatment of cytotoxic contaminated laundry is dealt with in section 10.10.

#### **10.7.1 Disposal into septic tanks**

It is considered acceptable for cytotoxic contaminated body substances to be disposed of in septic tanks. This is because the dilution effects in the septic tank would reduce the level of risk to those who may come in contact with the effluent. People who may be at risk of exposure are maintenance workers who service the septic tank.

When maintaining septic tanks, maintenance operators are required to wear PPE to protect themselves from exposure to biological hazards. It is considered this control measure would offer sufficient protection from the risk of exposure to cytotoxic contaminated body substances disposed of in septic systems.

#### **10.7.2 Disposal into composting and eco-friendly toilet systems**

The impact of drugs and chemicals on waste water treatment and alternative household waste disposal systems is a contentious issue. Research has been inconclusive, especially with respect to the long-term effects. Also, little definitive research has been found on the specific effects of cytotoxic drugs on the effectiveness of composting toilet systems. Anecdotal evidence suggests there is some effect on the biological performance of aerobic waste water treatment systems, but the full effect is unable to be quantified. It is considered unlikely systems which do not use water would dilute the contaminated waste sufficiently to remove the risk of exposure. In these 'waterless' systems, dry compost is normally buried with a 100 mm soil cover and liquid waste is directed into a subsoil trench.

If there is a risk of these systems being contaminated with cytotoxic drugs and related waste, it is recommended home owners seek the advice of the supplier with respect to the effect of cytotoxic drugs and chemicals on their particular system.

For maintenance and emptying of systems contaminated with cytotoxic drugs and related waste, PPE is recommended to reduce the risk of exposure. It is recommended gloves, covered footwear, coverall or gown, and RPE be worn and disposed of, or cleaned or laundered immediately after use, as appropriate.

### **10.8 Contaminated items and equipment**

Cytotoxic waste generated while the patient is undergoing cytotoxic drug therapy at home must be disposed of safely to reduce the risk of exposure to waste management workers. Such waste may include items such as dressings, nappies, incontinence aids and ostomy bags. Sewerage authorities do not allow disposal of these items to sewer, so they must be safely and hygienically contained and disposed of in other ways. Further information on this aspect can be obtained from the local council or sewerage authority.

Options for disposal include, but are not limited to:

- dispose of contaminated waste into household garbage
- return safely contained cytotoxic waste and unused drugs to the referring healthcare facility
- contact the environmental health office of the local council to arrange for appropriate disposal
- use a commercial waste management company to supply appropriate containers and provide a secure, safe collection service. This may be appropriate for larger residential care facilities, where a number of the residents may be undergoing cytotoxic drug therapy.

### **10.8.1 Disposal into household garbage**

Small amounts of cytotoxic contaminated waste may be disposed of in household garbage. Items suitable for such disposal include empty cytotoxic drug containers (e.g. bottles, tubes), disposable PPE, materials used to clean up spills, ostomy bags, tubing, dressings, nappies and incontinence aids.

Purple bags should not be used for the small amounts of contaminated waste disposed of in this way.

Items to be disposed of should be placed in a plastic bag and sealed, then placed into a larger strong plastic bag before placing into the household garbage bin.

Sharps that are generated in the home must be disposed of into a rigid-walled, puncture resistant container. Containers full of sharps may also be placed into the household waste bin. However, people disposing of sharps in this manner should check with the local council, hospitals, pharmacies or home health care agencies to see whether they will 'take back' containerised sharps. This system should be used in preference to disposal into the household bin.

Cytotoxic contaminated waste may be stored for a period of time at a patient's home in a suitable container, provided no nuisance is created and appropriate storage space is available. The area where the contaminated waste is stored should be secured, and away from a main thoroughfare.

Consideration may be given to hiring cytotoxic waste containers from commercial waste management companies.

### **10.8.2 Return of cytotoxic drugs and related waste to referring healthcare facility**

The referring healthcare facility may provide containers (e.g. plastic bags, sharps containers and waste bins) on loan for the patient's use for storage and disposal of cytotoxic waste. These containers should be used for the duration of therapy or until full. Any such containers to be used for the disposal of cytotoxic waste, and which are to be returned to the referring healthcare facility for disposal, must be purple and be appropriately labelled. See section 10.9 below for information on safe transport. This option is appropriate for management of the 'sharps' waste generated from drug administration, such as syringes. These must be disposed of into a dedicated, rigid-walled, puncture-resistant container which is labelled 'Cytotoxic waste'. The container should be located in a secure area and away from a main thoroughfare.

All unused cytotoxic drugs should be returned to the referring healthcare facility for disposal. For those cytotoxic drugs which may be dispensed by a retail pharmacy (e.g. methotrexate), patients should check with the pharmacist regarding procedure for return of unused drugs.

### **10.9 Safe transport of cytotoxic drugs and related waste**

Transport of cytotoxic drugs and related waste to and from a patient's home may pose a risk of exposure if containers are broken or leak during transport. Control measures to prevent such exposure include:

- cytotoxic waste which includes sharps must be transported in a rigid-walled, puncture-resistant and leak-proof container, which is appropriately labelled as cytotoxic waste
- before transportation, the primary container (the one into which cytotoxic contaminated waste is first placed) should be placed inside a secondary container, which should also be rigid-walled, puncture-resistant and able to be sealed (e.g. a rigid heavy duty plastic carry box with clickdown lid). The secondary container should be clearly and indelibly labelled to facilitate easy identification in case of accident
- cytotoxic contaminated waste should be transported separately from the driver of the vehicle and passengers (e.g. in the boot or luggage area)
- cytotoxic waste containers should be secured to prevent movement during transport.

### **10.10 Laundering of contaminated linen at home**

The referring healthcare facility should provide information on laundering cytotoxic contaminated linen at home. This should include how long after taking cytotoxic drug therapy the laundry needs

to be treated as contaminated. It is recommended only machine washable items (e.g. bed coverings) be used while the patient is undergoing cytotoxic therapy.

Cytotoxic contaminated laundry is defined as linen or clothing which has been contaminated with cytotoxic drugs or body substances, including urine, faeces, vomitus, bile and fluids drained from body cavities. Contaminated laundry may include clothing, bed linen, towels and any other washable item.

It is recommended clothing and bed linen with traces of contamination be laundered immediately, and separately from other uncontaminated items. If washing cannot be done immediately, it may be stored for short periods of time in a sealed plastic bag.

The following procedure is recommended as a minimum standard for contaminated laundry:

- wear two pairs of powder-free latex gloves or one pair of purpose manufactured gloves whenever handling cytotoxic contaminated laundry. After use, place the gloves in a plastic bag and discard with household garbage
- wearing gloves, empty laundry from the container or plastic bag into the washing machine. Wash at the maximum running cycle capacity for two wash and rinse cycles. Hot or cold water may be used
- after washing, laundry can be returned to general use.

For more information on laundry procedures, see chapter 11.

### **10.11 Information for patients and carers**

It is the responsibility of the referring healthcare facility to ensure patients and carers are given the necessary information to ensure the health and safety of the patient and all other people in the patient's home.

Carers of patients receiving cytotoxic drug therapy should be provided with written information about cytotoxic drugs, and the precautions to be taken while caring for patients during the time the drug may be excreted. Carers should be advised about special requirements for the particular drug used.

The information should be in writing, and it is recommended the following issues are covered (more detail on some of these issues is included in this guide):

- reasons for taking precautions in the handling of cytotoxic drugs and related waste
- precautions for care-givers who are pregnant or breastfeeding
- the usual route of excretion of the particular cytotoxic drug administered, and the approximate time cytotoxic residues may continue to be excreted
- equipment needed for home nursing of a patient receiving cytotoxic drug therapy
- home storage of drugs
- how to administer prescribed cytotoxic drugs
- precautions used when handling and disposing of contaminated body wastes, including contents of ostomy bags, nappies or incontinence aids
- how to deal with a cytotoxic spill
- laundering cytotoxic contaminated clothing and linen
- management of cytotoxic waste:
  - disposal of body substances
  - disposal of cytotoxic contaminated sharps and other cytotoxic contaminated waste
  - cytotoxic contaminated items which can be placed into household garbage
  - secure storage of cytotoxic contaminated waste
  - precautions when transporting cytotoxic waste containers
  - use of commercial waste contractors for temporary cytotoxic waste container hire
- emergency procedures for:
  - problems with administration equipment (e.g. cytotoxic drug therapy pump)
  - accidental exposure to patient body waste



- accidental ingestion of cytotoxic drugs by children
- disposal of drugs no longer needed (e.g. by returning to referring healthcare facility).

### **Standard operating procedure – Chapter 10**

In developing SOPs for application in community settings, the following factors should be considered:

- identification and incorporation of relevant legislation
- use of the risk management process to identify hazards, assess the risk of exposure and develop and implement appropriate control measures for community settings
- consultation with patients, carers and community services agencies workers
- development of policy on liaison between the referring healthcare facility and community services agencies regarding home care of patients receiving cytotoxic therapy
- information provided to the patient or carer which covers issues raised in this chapter:
  - information about the nature of cytotoxic drugs and risk of exposure
  - precautions for carers and others
  - patient care area—equipment and set-up of patient care area
  - instructions for administration of cytotoxic drugs, including PPE and waste disposal
  - emergency procedures—cytotoxic spills, personal contamination, penetrating injuries
  - options for dealing with cytotoxic contaminated waste
  - contaminated items and equipment
  - cytotoxic contaminated laundry
  - safe transport of cytotoxic drugs and related waste
- supply of cytotoxic drugs in required doses from the pharmaceutical supplier
- provision of cytotoxic spill kits to patients, including information on their use
- provision of appropriate cytotoxic waste containers to patients, including information on their use and disposal
- return from outpatients of unused drugs or home-generated cytotoxic waste for disposal
- selection of appropriate PPE and monitoring and supervision to ensure PPE is worn correctly
- managing the risk of exposure while transporting patients
- emergency and reporting procedures for personal contamination and penetrating injuries.

In addition, these SOPs should:

- be part of the induction and ongoing training program
- be checked regularly for compliance through monitoring and supervision
- be reviewed regularly and when there are incidents or changes to the workplace that affect the procedure (e.g. new equipment, new legislation, new products)
- be documented and meet relevant record keeping requirements.

## **Chapter 11: Cytotoxic contaminated laundry**

Workers may be at risk of exposure to cytotoxic drugs and related waste when handling contaminated linen or clothing. This chapter provides guidance on the control measures which may be considered to eliminate or reduce cytotoxic drug exposure.

Cytotoxic contaminated laundry is defined as linen or clothing which has been contaminated with cytotoxic drugs or contaminated body substances, including urine, faeces, vomitus, bile, and fluids drained from body cavities. Contaminated laundry may include bed linen, towels, curtains, gowns, coveralls, washable PPE, and any other washable item.

There is currently little evidence to support the suggestion cytotoxic drugs or their metabolites are excreted in significant quantities in sweat, so the risk of exposure by this route is rated as low. Therefore, it is recommended only linen which is obviously wet with perspiration be treated as cytotoxic contaminated laundry. Otherwise the linen can be treated as general laundry.

## **11.1 Risk management**

Workers may be exposed to cytotoxic drugs or contaminated waste through handling of cytotoxic contaminated laundry. A risk assessment should be conducted to determine the characteristics of an exposure to cytotoxic contaminated laundry, and appropriate control measures selected and implemented. Exposure may occur while handling a treated patient's clothing or bed linen, or when handling items used to clean up after a cytotoxic spill. All workers who handle cytotoxic contaminated laundry during transport and processing may be at risk of exposure, and should be consulted during the risk management process.

Refer to chapter 3 for details of the risk management process.

### **11.1.1 Consultation**

In the risk management process, consultation is important to identify and assess risks associated with cytotoxic contaminated laundry and to develop appropriate control measures. It is recommended safe work practices be developed following consultation between workplace health and safety representatives, hospital workers, laundry workers and contractors to ensure all workers are protected at all stages (for more information on risk management, see chapter 3). In developing the most appropriate procedures for laundry management, consultation issues may include:

- sources of cytotoxic contaminated laundry
- movement of cytotoxic contaminated laundry through both healthcare and laundry facilities
- transport of cytotoxic contaminated laundry
- dealing with contaminated washable PPE
- use of alginate bags
- identification of laundry as cytotoxic through use of coloured bags, labels and stickers.
- designation of special collection and storage areas for cytotoxic contaminated laundry
- appropriate warning signs where considered necessary.

## **11.2 Developing control measures**

Policies and procedures on the safe handling and management of cytotoxic contaminated laundry should be developed and implemented. During a risk assessment, existing control measures should be identified and evaluated. If necessary, additional control measures must be developed to eliminate or minimise the risk of workers' exposure to cytotoxic contaminated laundry during handling processes, if existing measures are inadequate.

Cytotoxic contaminated laundry should be segregated at the point of generation (e.g. the ward or unit). Separate receptacles should be provided and clearly labelled for different laundry treatments. Only cytotoxic contaminated laundry should be placed in receptacles labelled as cytotoxic.

Appropriate training must also be provided to ensure workers understand and follow the measures which are developed and implemented. See chapter 4 for more information on training.

## **11.3 Patient care areas**

Results of a risk assessment and consultation with laundry workers should be used to ensure patient care areas are suitably equipped to facilitate the safe segregation and storage of cytotoxic contaminated laundry. Cytotoxic contaminated laundry should be managed at the place of contamination (e.g. bedside, change room) and not carried to a laundry storage area.

When handling cytotoxic contaminated laundry, considerations include, but are not limited to:

- access to and provision of appropriate PPE (see chapter 5)
- supply of alginate and labelled or purple cloth laundry bags for storage of cytotoxic contaminated laundry
- safe procedures for bagging cytotoxic contaminated laundry
- identification of contaminated laundry through colour, labelling and appropriate signage
- safe storage and transport facilities, also appropriately labelled or signed
- access to a cytotoxic spill kit.

A sample procedure for use of alginate bags in handling cytotoxic contaminated laundry in a patient care area may include:

- put on recommended PPE
- take alginate bag and a labelled or purple cloth bag to the contaminated laundry items
- place cytotoxic contaminated laundry in the alginate bag at the point of contamination to half level only
- seal the alginate bag with the tie supplied with the alginate bag
- place in a labelled or purple cloth laundry bag, and seal appropriately
- place the labelled or purple cloth laundry bag in designated, signed area, separate from other soiled linen, to be collected for laundering.

#### **11.3.1 Contaminated bedding**

Contaminated bed mattresses and pillows should be cleaned with detergent and water in such a way as to avoid the generation of aerosols. See chapter 5 for appropriate PPE.

Suitable procedures should be developed for the safe handling and disposal of large items (e.g. mattresses) contaminated with cytotoxic drugs and related waste which are not able to be cleaned. Mattresses and pillows should be discarded as cytotoxic waste if:

- they are heavily soiled or contaminated
- the mattress or pillow covering is split
- the surface cannot be cleaned (e.g. foam egg-shell mattress).

#### **11.4 Laundry operations**

Having identified appropriate control measures during the risk management process, and in consultation with workers in all affected areas, systems should be established to protect laundry workers from exposure to cytotoxic drug residue, and to prevent contamination of other materials being laundered. Cytotoxic contaminated laundry should not be pre-sorted, as there is a risk of exposure through dermal absorption and inhalation.

Procedures and training should be developed for the safe handling of cytotoxic contaminated laundry and safe methods for washing.

Refer to chapter 5 for recommended PPE.

##### **11.4.1 Recommended washing procedures**

The following procedure is recommended as a minimum standard for handling in the laundry, but may be further developed following consultation and considering the local situation:

- put on PPE
- tip the alginate bag directly from the outer cloth bag into the washing machine
- place the outer cloth bag into the washing machine
- wash at the maximum running cycle capacity for two wash and rinse cycles.

Laundry can then be combined with other non-contaminated items for further laundry procedures.

#### **11.5 Commercial laundries**

Cytotoxic contaminated laundry may also be sent to a commercial processing and sterilisation facility. Consultation should be held to develop a suitable procedure for safe storage, transport and handling of cytotoxic contaminated laundry. Medical facilities should ensure the commercial laundry follows recommended washing procedures.

Any facility generating or handling cytotoxic contaminated laundry should also follow the risk management process to ensure the health and safety of their workers when handling cytotoxic contaminated laundry.

Workers in commercial laundries must receive appropriate PPE, instruction and training to ensure safe systems of work. Appropriate training must also be provided to ensure workers understand and follow the measures which are developed and implemented.

## 11.6 Contaminated laundry for patients at home or in community settings

Please refer to section 10.10 of this guide.

### Standard operating procedures – Chapter 11

In developing SOPs for the handling of cytotoxic contaminated laundry, the following factors should be considered:

- identification and incorporation of relevant legislation
- identification of all workplaces and activities where there is a risk of exposure to cytotoxic contaminated laundry
- identification of all workers who may be at risk of exposure
- integration with organisational waste management policies and procedures
- use of the risk management process to identify hazards, assess the risk of exposure and develop and implement appropriate control measures for handling cytotoxic contaminated laundry
- consultation with workers and agencies involved in handling cytotoxic contaminated laundry during the risk management process
- selection of appropriate PPE, and monitoring and supervision to ensure PPE is worn correctly
- safe systems of work for various types of workers handling cytotoxic contaminated laundry
- safe systems of work for:
  - segregation and storage at point of generation, collection areas and laundry
  - transport of cytotoxic contaminated laundry to laundry or collection area
  - disposal of large items such as contaminated bedding
  - washing cytotoxic contaminated laundry
- appropriate labelling of laundry bags and clear signage at all collection and storage locations
- emergency and reporting procedures for personal contamination and penetrating injuries.

In addition, these SOPs should:

- be developed with regard to manufacturers' instructions, SDSs or other information about the equipment, substances or products being used
- be part of the induction and ongoing training program
- be checked regularly for compliance through monitoring and supervision
- be reviewed regularly and when there are incidents or changes to the workplace that affect the procedure (e.g. new equipment, new legislation, new products)
- incorporate emergency procedures, including the location of cytotoxic spill kits
- be documented and meet relevant record keeping requirements
- integrate smoothly and be consistent with other organisational policies.

## Chapter 12: Spill management

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

### 12.1 Sources of cytotoxic spills

A risk assessment should identify all areas where there is a risk of a cytotoxic spill. This includes all areas where cytotoxic drugs and related waste are handled, stored, transported and disposed.

Spills may involve:

- cytotoxic drugs in all forms (e.g. liquid, tablets or creams)
- drugs spilt or leaking during preparation, storage and transport of packaged drugs
- cytotoxic drugs spilt during administration
- transport of patients with cytotoxic drug therapy in situ
- body substances contaminated with cytotoxic drugs

- cytotoxic contaminated laundry
- cytotoxic waste in all forms.

Spills may result in contamination of floors, work surfaces, equipment, bedding and clothing. Workers, patients and other people may be exposed.

## **12.2 Training of workers involved in spill management**

Training in spill containment and decontamination procedures must be provided to workers likely to be involved in spill management. Refer to chapter 4 on training for more information on determining the people to be trained and what information is to be provided.

## **12.3 Spill kit contents**

A 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 the spill kit should be selected and signed appropriately. The following equipment should be considered for inclusion:

- instructions for use or standard operating procedures for the management of a cytotoxic spill
- signs to identify and isolate the spill
- PPE (see chapter 5)
- adequate quantities of absorbent materials (e.g. swabs, absorbent towels or a spill pillow, chemical absorbent pads, protective mats such as a 'bluey' or 'chemomat')
- a small scoop to collect any glass fragments
- bottles of water for rinsing and for dampening pad over a powder spill
- alginate bag and a labelled or purple cloth laundry bag for contaminated linen
- alkaline detergent
- two plastic waste bags, clearly identified as cytotoxic
- incident report forms.

## **12.4 Spill containment**

Spills of cytotoxic drugs and related waste may occur in all areas where they are used or handled. While the following sections provide general guidance, full procedures should be developed after consideration of the local work area and environment. The location of cytotoxic spill kits should be clearly signed and made known to all workers.

### **12.4.1 Cytotoxic spills in medical facilities**

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

1. Alert people in the immediate vicinity that a cytotoxic spill has occurred and direct them to stay clear.
2. Open the cytotoxic spill kit. Display signs, restrict access and call for assistance if required.
3. Put on RPE first, and then appropriate PPE.
4. For liquid spills, wait a few seconds for aerosols to settle, and 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.
5. If the spill involves a powder, carefully place an absorbent mat over the powder, ensuring minimal dust production. Carefully wet the mat so the powder dissolves and is absorbed by the mat.
6. Gather absorbed material, being careful to collect and contain any broken glass.
7. Discard collected waste into a cytotoxic plastic waste bag.
8. Wash the area several times with detergent, working from the area of least contamination.
9. Rinse the area thoroughly with water.
10. Dry the affected area with absorbent towels or other suitable materials.
11. Discard the contaminated cleaning waste into the cytotoxic plastic waste bag.
12. Discard outer gloves into the cytotoxic plastic waste bag. Seal the bag and place it inside a second cytotoxic plastic waste bag.
13. Discard contaminated personal protective equipment and inner gloves into the outer bag and seal.

14. Place cytotoxic plastic waste bag in a cytotoxic waste disposal bin.
15. Wash hands with soap and water.
16. Complete incident reporting as per local requirements.
17. Ensure the cytotoxic spill kit is replenished and maintained.

#### **12.4.2 Cytotoxic spills on carpets**

The above procedures should be followed with respect to use of PPE and disposal of cytotoxic contaminated waste. Cytotoxic spills on carpets should be treated initially using absorbent pads, granules or powder to absorb as much fluid as possible. The carpet should then be cleaned with detergent and water, minimising the seepage into unaffected carpet. Consideration may then be given to cleaning with commercial machines or dry cleaning. Decontamination of carpet cleaning machines is not considered necessary due to the dilution effect.

#### **12.4.3 Cytotoxic spill within a cytotoxic drug safety cabinet and clean room**

Training on spill containment and decontamination must be provided to workers handling cytotoxic drugs in cytotoxic drug safety cabinets and clean rooms. Cleaning methods are set out in appendix C of AS 2639:1994 - Laminar flow cytotoxic drug safety cabinets – Installation and use. Note that within a clean room, all workers are already wearing personal protective equipment.

#### **12.4.4 Cytotoxic spills in the community care setting**

Patients who are being treated at home or in the community care setting should be provided with a cytotoxic spill kit and with clear, easy-to-understand instructions for the correct management of a cytotoxic spill. These may be based on the procedures described above for medical facilities. The kit should include a list of contents, and information on the replacement and disposal of used items.

### **12.5 Contamination of workers**

#### **12.5.1 Contamination of clothing and personal protective equipment**

- Immediately remove outer gloves, gown and any contaminated clothing.
- Place disposable PPE in the cytotoxic waste bin.
- Place washable PPE and contaminated clothing in cytotoxic laundry bag.
- Remove and dispose of inner gloves.

#### **12.5.2 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.

#### **12.5.3 Mucosal exposure of workers – eyes**

- Immediately flood the affected eye with an isotonic saline solution for at least fifteen 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.

### **12.6 Reporting procedures**

A PCBU should have a system in place for workers to report any spill or worker contamination as soon as practicable. Supervisors should be notified immediately and be trained in appropriate procedures. The supervisor or manager should record the type of incident and the procedures taken to manage the spill in a spill register. See also section 6.8 of this guide. A medical review with the appointed medical practitioner should be arranged, as outlined in appendix 8.

#### **12.6.1 Notification of incidents**

Workplace Health and Safety Queensland must be notified of an incident resulting in a person suffering a work injury that is a serious injury or illness, or of a dangerous incident occurring in a workplace. For more information, see section 6.8 of this guide.

## Standard operating procedures – Chapter 12

In developing SOPs for managing cytotoxic spills, the following factors should be considered:

- identification of potential sources of cytotoxic spills
- identification of workers who may be at risk of exposure
- assignment of person or role with responsibility for spill management issues, including risk assessment, and providing and maintaining cytotoxic spill kit supplies
- spill containment strategies for specific locations (e.g. drug preparation suite, cytotoxic drug administration area, in transit, community care setting)
- appropriate PPE identified and provided
- appropriate contents of spill kits, taking into account local work area and environment
- appropriate location of spill kits within the workplace
- emergency procedures for penetrating injuries or personal contamination
- medical review in cases of personal contamination
- integration with organisational emergency policies and reporting procedures.

In addition, these SOPs should:

- be developed in consultation with workers
- be guided and informed by the risk management process
- be developed with regard to relevant legislation and organisational protocols
- be developed with regard to manufacturers' instructions, SDSs or other information about the equipment, substances or products being used
- be part of the induction and ongoing training program
- be checked regularly for compliance through monitoring and supervision
- be reviewed regularly and when there are incidents or changes to the workplace that affect the procedure (e.g. new equipment, new legislation, new products)
- address the disposal of cytotoxic waste generated by the procedure
- be documented and meet relevant record keeping requirements.

## Chapter 13: Waste management

Cytotoxic contaminated waste is a hazard, and the risk of exposure must be managed at all steps in the waste management process, from generation to destruction. A waste management strategy should include the key elements of identification, segregation and containment of waste, transport, storage and disposal of waste, and personal protective equipment. The strategy should define safe systems of work, such as standard operating procedures and spill management, and include training and information for all workers handling and transporting contaminated waste.

As cytotoxic waste is hazardous to human health and the environment, it is a regulated waste and subject to the requirements of the Waste Reduction and Recycling Regulation 2011, *Environmental Protection Act 1994*, and Environmental Protection Regulation 2008 administered by the Department of Environment and Heritage Protection. These requirements cover treatment and disposal, storing, transporting, tracking handling, packaging and labelling, and segregation of clinical and related waste, waste container design requirements.

### 13.1 Definition of cytotoxic waste

Cytotoxic waste includes any residual cytotoxic drug following patient treatment, and the materials or equipment associated with the preparation, transport or administration of cytotoxic drug therapy such as:

- cytotoxic pharmaceuticals past their recommended shelf life, unused or remaining drugs in all forms, contaminated stock, and cytotoxic drugs returned from patients
- contaminated waste from preparation processes
- sharps and syringes, ampoules and vials
- intravenous infusion sets and containers
- empty cytotoxic drug bottles

- cotton wool from bottles containing cytotoxic drug
- used HEPA filters and other disposable contaminated equipment
- contaminated PPE (e.g. gloves, disposable gowns, shoe covers, RPE)
- swabs, cloths, mats and other materials used to clean cytotoxic contaminated equipment or to contain spills
- contaminated body substance receptacles (e.g. disposable vomit bags)
- dressings, bandages, nappies, incontinence aids and ostomy bags
- heavily soiled and contaminated bedding that is unable to be cleaned.

### **13.2 Cytotoxic waste risk management**

Each PCBU should develop and periodically review a comprehensive ‘cradle to grave’ strategy to safely manage cytotoxic waste. The strategy should be developed after a comprehensive audit of all sections of the organisation’s cytotoxic waste handling. Other waste handling requirements may be included to develop a comprehensive waste management strategy.

Guidance to assist with the development of policies and procedures can be obtained from the Department of Environment and Heritage Protection and Queensland Health, which produce various publications dealing with the management of clinical and related wastes. These publications may be of particular assistance to hospitals and similar healthcare establishments.

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. However, wherever possible, procedures should be uniform both within and between the organisations involved, to streamline work activities and provide consistent safe practices for all workers involved.

Key elements of a waste management strategy include:

- designating a person to be responsible for ensuring an efficient waste disposal system
- having a clear statement of the chain of responsibility and involvement of all levels in policy development and implementation
- ensuring compliance with legal requirements
- developing and implementing policies and systems to avoid and minimise waste at point of generation
- ensuring extensive consultation with all workers who may be exposed, including the units generating the waste, waste handlers and waste disposal workers
- developing and implementing appropriate control measures
- regularly monitoring and reviewing the strategy.

#### **13.2.1 Control measures**

Control measures to reduce the risk of exposure to cytotoxic waste may include:

- elimination, substitution or isolation of identified high risk activities
- introduction of engineering or automated methods to reduce the amount of handling
- safe systems of work for identified waste management activities (e.g. segregation, packaging, storage, transport, administration and disposal)
- appropriate PPE for identified waste management activities
- identification of cytotoxic waste through designated labelling, use of purple bags and containers
- a system for managing cytotoxic waste generated by outpatients and domiciliary services under the direction of the referring healthcare facility
- provision of training to workers and others who may be exposed to contaminated waste
- a transport and disposal flowchart covering internal and external activities from waste generation to treatment and destruction.



### **13.3 Waste identification, segregation and containment**

#### **13.3.1 Waste identification**

All bags or other containers used for the collection, storage, transport or disposal of cytotoxic waste must meet the following requirements:

- be purple
- have a white label with the symbol of a cell in telophase
- labelled with the words 'Cytotoxic waste – incinerate at 1100°C'.

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

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

See section and 7.1 of this guide for further details on labelling requirements for cytotoxic drugs and related waste.

#### **13.3.2 Waste containment**

The requirements for containing (packaging) contaminated waste are set out in environmental legislation (see section 2.4.2 of this guide). 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) for the purposes of transport to a collection or storage area, and to a treatment facility. A labelled wheelie bin may be designated for this purpose.

##### **Sharps containment**

There are specific requirements with respect to storage and transport of sharps. Sharps are defined as an object or device having sharp points, protuberances or cutting edges which are capable of inflicting a penetrating injury to humans. Sharps include such things as hypodermic, intravenous or other medical needles, Pasteur pipettes, scalpel blades, lancets, scissors, glass slides and broken glass such as vials, bottles and laboratory glass.

Cytotoxic sharps must be placed into rigid-walled, puncture-resistant containers which are sealed or securely closed and not accessible to another person. When discarding sharps at the premises in which they are generated containers must also comply with:

- Australian/New Zealand Standard for Reusable Containers for the Collection of Sharp Items Used in Human and Animal Medical Applications: AS /NZS 4261-1994; or
- Australian Standard for Non-Reusable Containers for the Collection of Sharp Medical Items Used in Health Care Areas: AS 4301-1992.

#### **13.3.3 Waste segregation**

Cytotoxic waste must be segregated from any other waste streams such as pharmaceutical or chemical waste. The following control measures should be implemented to ensure cytotoxic waste is appropriately segregated at the facility in which it is generated:

- development of procedures to ensure the segregation of waste at the point of generation and during internal transport and storage, in consultation with workers in areas which generate cytotoxic waste and those responsible for the provision of support services
- incorporation of efficient waste disposal methods into patient care procedures
- appropriate signage at all collection and storage areas

#### **13.4 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, treatment or collection point. The use of waste chutes for movement of all clinical or related wastes including cytotoxic waste is prohibited. The following control measures should be implemented to ensure cytotoxic waste is appropriately moved 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 such as wheelie bins, handcarts and trolleys to move cytotoxic waste around the facility
- ensure such equipment (e.g. wheelie bins, handcarts and trolleys) is appropriately labelled and signed 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 (e.g. visiting hours, meal times and changes of shift)
- avoid movement of cytotoxic waste through public areas or general staff thoroughfares
- ensure waste disposal chutes are not used for moving cytotoxic waste
- develop a cytotoxic spill management plan for spills occurring during transport (see chapter 12).

### **13.5 Waste storage**

Cytotoxic waste must be stored in a designated area for storing waste that is not accessible to animals or unauthorised persons. All stored cytotoxic waste must not cause environmental nuisance after it is generated.

Ways to eliminate environmental nuisance generation include:

- sealing or securing cytotoxic waste bins prior to waste collection and not re-opening on-site once they have been secured
- using a storage area with adequate lighting and ventilation
- locating the storage area away from stormwater drains and other sensitive areas
- designing the storage area for ease of cleaning, decontamination and maintenance of hygiene standards
- refrigerating cytotoxic waste which is mostly organic and can decompose, and is to be stored for more than 72 hours prior to disposal.

### **13.6 Off-site waste transport**

It is the responsibility of the person operating the facility which generates cytotoxic waste to make sure this waste is not given to an unlicensed person for transport, storage, treatment or disposal.

Off-site transportation of cytotoxic drugs and related waste is the transport from the generating premises to an appropriately licensed storage, treatment or disposal facility located away from the premises. Contracts with waste transporters and waste disposal sub-contractors should be documented, and specify waste transport and disposal requirements consistent with legislation administered by the EHP. Management should ensure methods of transport, including packaging, labelling and documentation, comply with state transport regulations, the provisions of environmental protection legislation, and local council by-laws, and appropriate permits and licences are obtained.

The risk of exposure to cytotoxic waste must be managed for workers and others involved in its transport and handling. Control measures to eliminate or reduce the risk of exposure may be included in waste disposal contracts.

Control measures may include:

- use of PPE (see chapter 5)
- transport of cytotoxic waste in rigid-walled puncture-resistant containers with a securable 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 for such activities as collection of cytotoxic waste from storage areas, loading waste transport vehicles, securing contaminated loads, and unloading at the treatment facility
- use of labelling, signage and vehicle placards to identify cytotoxic contaminated waste
- development of emergency procedures in case of a cytotoxic spill or vehicle accident
- training of drivers and waste handling workers
- use of designated vehicles or transport of clinical and/or cytotoxic waste which should:

- be used solely for the purpose
- have a system of securing containers to prevent movement during transport
- be designed to protect the driver and the public from the risk of exposure both during transport and in the event of an accident
- be designed to be safe to load, unload and clean.

## 13.7 Waste disposal and treatment

### 13.7.1 Incineration

Waste treatment must render the waste non-infectious and unrecognisable, and must meet EHP requirements to protect the environment. Currently, incineration 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 which is 1100°C. Disposing of cytotoxic waste by incineration requires an environmental authority under the *Environmental Protection Act 1994*.

### Standard operating procedures – Chapter 13

In developing SOPs for managing cytotoxic waste, the following factors should be considered:

- identification and incorporation of relevant legislation, including provisions about transport, disposal and treatment
- identification of sources of cytotoxic waste
- identification of workers who may be at risk of exposure
- consultation during the risk management process with workers and contractors involved in handling cytotoxic contaminated waste
- assignment of person or role with responsibility for cytotoxic waste management issues
- integration with organisational emergency policies and reporting procedures
- waste management strategies for specific locations (e.g. drug preparation suite, cytotoxic drug administration area, collection and storage areas, vehicles, waste treatment facilities)
- identification, segregation and containment of cytotoxic waste (e.g. labelling, compliant containers, signage and security)
- safe systems of work for activities where there is a risk of exposure:
  - segregation and storage at point of generation of cytotoxic waste
  - internal movement of cytotoxic to collection area
  - loading and unloading of containers into or from vehicles
  - cleaning contaminated storage areas, containers and vehicles
- procedure for outpatients for delivering home cytotoxic waste for disposal
- selection of appropriate PPE, and monitoring and supervision to ensure PPE is worn correctly
- development of cytotoxic spill management plans for spills occurring at different stages of waste cycle, including appropriate location of spill kits
- treatment and disposal of cytotoxic contaminated waste at licensed facilities
- emergency procedures for personal contamination, including incident reporting, which are integrated with organisational emergency policies and reporting procedures.

In addition, these SOPs should:

- be guided and informed by the risk management process
- be developed with regard to manufacturers' instructions, SDSs or other information about the equipment, substances or products being used
- be promoted to all workers through instruction, information and training
- be checked regularly for compliance through monitoring and supervision
- be reviewed regularly and when there are incidents or changes to the workplace that affect the procedure (e.g. new equipment, new legislation, new products)
- be documented and address relevant record keeping procedures.

## Chapter 14: Drug administration in veterinary practice

The use of cytotoxic drugs is increasing in veterinary practice and research. Cytotoxic drugs are used primarily for the treatment of cancers in animals such as dogs, cats, birds and horses. Many of the procedures and control measures used in human patient management can be applied in veterinary practices to ensure health and safety of workers.

### 14.1 Risk management

Animals as patients bring special problems. Veterinary workers should already be aware of the risks in treating sick animals, however, the risk management process should be used to identify and assess the unique risks which arise when using cytotoxic drugs in veterinary practice. Particular attention should be paid to:

- identifying cytotoxic drugs used
- developing special procedures for administering cytotoxic drugs to animal patients
- isolating treated animal patients until wastes are no longer contaminated
- preventing environmental contamination from excreta of treated animal patients
- providing appropriate information to owners when animals are allowed to be taken home while still receiving or affected by cytotoxic drug therapy.

### 14.2 Control measures

The control measures to prevent or minimise the risk of exposure are, in many cases, the same as for human patients. When selecting control measures, PCBU's should note the suggestions made in this guide and adopt or adapt them as appropriate for the particular veterinary practice.

A risk assessment will assist in determining appropriate control measures. Workers who may be exposed to cytotoxic drugs and related waste must be provided with induction and ongoing training in the safe handling of cytotoxic drugs and related waste. These workers may include veterinary surgeons, veterinary nurses and ancillary workers, such as animal attendants and cleaners. It is recommended the number of trained workers who perform tasks involving cytotoxic drugs and related waste is restricted.

#### 14.2.1 Drug preparation

Drug preparation includes the handling of cytotoxic drugs up to the stage of readiness for administration to the patient. It includes manufacture, forming tablets and capsules, preparing a pre-measured single dose unit (e.g. drawing up cytotoxic drugs in liquid form from a vial into a syringe) and crushing or dissolving tablets or emptying capsules to prepare part doses.

This work should only be done by pharmacists and pharmacy technicians trained specifically in the preparation of cytotoxic drugs, and with appropriate facilities, such as cytotoxic drug safety cabinets. The PCBU should ensure workers do not prepare cytotoxic drugs unless they are trained in the preparation of cytotoxic drugs and have the appropriate facilities.

Cyclophosphamide is a restricted carcinogen under the WHS Regulation. In certain circumstances, veterinary hospitals and cancer care treatment facilities must be authorised by Workplace Health and Safety Queensland to use, handle or store this substance when used in preparation for therapeutic use.

Cytotoxic drugs should be prepared as detailed in chapter 7. If a clean room suite and the equipment described are not available, cytotoxic drug preparation should not be undertaken.

Alternative arrangements may include:

- having cytotoxic drugs supplied in a prepared single-dose delivery unit, purchased from a commercial source
- establishing supply arrangements with a healthcare facility which has the required facilities, equipment and trained workers to prepare cytotoxic drug doses.

Drugs for individual use must be labelled as set out in Chapter 7 using the purple colour convention previously recommended. A childproof lid should be used, and warnings such as 'For animal treatment only' included.

Refer to section 8.5.1 of this guide for more information on how to manage variations from pre-prepared doses of cytotoxic drugs.

#### **14.2.2 Drug administration**

The administration of cytotoxic drugs should be carried out in accordance with chapter 8. Parenteral or oral cytotoxic drugs should be administered only by suitably trained and qualified workers. The examination table used for the animal receiving the therapy should be clearly labelled with a cytotoxic label. After use, the examination table should be cleaned as soon as possible with water and detergent. A cytotoxic spill kit (see chapter 12) should be readily accessible in the administration area.

#### **14.2.3 Patient care**

Chapter 9 details human patient care practices which may be adapted for veterinary use. Procedures to minimise exposure should be developed for workers handling treated patient blood and body substances. Animal patients receiving cytotoxic drug therapy should be placed in separate cages away from other animals. A warning sign should be put on the cage to indicate the animal is undergoing cytotoxic drug therapy. Phrases such as 'Cytotoxic drugs in use', 'Must use latex gloves' or 'Excreta may be contaminated' should be considered.

#### **14.2.4 Patient waste**

Generally, patient body substances will be contained in the cage the animal is placed in after treatment with cytotoxic drugs. It is recommended that a special cage be provided which has a flushing system built in, and which discharges directly into the sewerage system. If this is not possible, the animal should be placed in a cage which is isolated from other cages. See section 14.6.3 below for management of patient waste in an external environment. See the following sections for procedures for dealing with cytotoxic waste, cytotoxic spills and cleaning cages of treated animals.

### **14.3 Cytotoxic spills**

The procedures described in chapter 12 for spill management are also applicable to the veterinary environment. A cytotoxic spill kit should be readily available to deal with any spill or leakage of cytotoxic drugs and related waste. A spill occurring outside the animal cage should be managed as described in chapter 12. Cytotoxic waste confined to the treated animal's cage should be managed as described in the next section.

For procedures dealing with contamination of workers, refer to chapter 12. If the animal patient becomes contaminated, it should be washed, being careful not to generate aerosols. Appropriate PPE should be worn.

### **14.4 Cleaning animal cages**

Care should be taken to prevent generating aerosols when dealing with contaminated body waste. If the treated animal is to be relocated while the cage is being cleaned, control measures for identifying the animal and the new cage as cytotoxic should be maintained.

The following equipment is needed to clean the cage of an animal undergoing cytotoxic therapy:

- PPE (e.g. gown, protective eyewear, RPE Class 2 particulate filter, two pairs of powder-free latex gloves or one pair of purpose manufactured gloves, apron and rubber boots)
- absorbent materials such as towels and pads
- purple plastic bags
- spill towels made of granular material
- detergent.

It is recommended the following procedures for cleaning the cage be adopted:

- put on PPE
- remove the animal from the cage
- lay absorbent pad over wet excreta
- when excreta is absorbed, pick up absorbent pad and place in purple plastic bag

- use spill towels and detergent to clean and rinse the area, repeat several times
- fully dry area with absorbent towels and place towels in purple plastic bag
- clean cage with water and disinfectant, avoiding splashes
- remove outer gloves and place in purple plastic bag
- seal polythene bag and place in second purple plastic bag along with other PPE (e.g. gown, RPE and glasses). Do not fill bag more than three-quarters full
- remove and discard inner gloves and seal the second bag
- place second bag into approved rigid-walled cytotoxic waste container
- wash hands thoroughly with soap and water.

### **14.5 Cytotoxic waste**

Cytotoxic waste should be managed (identified, segregated, contained and transported) as described in chapter 13. Cytotoxic waste includes materials or equipment used in patient treatment, such as:

- cytotoxic pharmaceuticals past recommended shelf life, or returned from owners
- sharps, syringes, ampoules, IV infusion sets and cytotoxic drug containers
- dressings and bandages
- contaminated PPE (e.g. gloves, RPE, disposable gowns)
- swabs, cloths and materials used to clean and contain cytotoxic spills and body waste
- heavily soiled and contaminated bedding
- animal body waste.

### **14.6 Outpatient care at home**

If cytotoxic drugs are prescribed for administration at home, they should be labelled and packaged correctly, and be safe for transport as set out in chapter 7. Care-givers should be informed in writing of the need for special precautions during the period the drugs are excreted after treatment. It is recommended precautions be taken for a seven-day period from the completion of cytotoxic therapy.

#### **14.6.1 Equipment**

The following equipment should be available in the patient's home during cytotoxic drug therapy:

- a supply of disposable gloves. Gloves are to be used once only, placed in a plastic bag, then disposed of in household garbage
- flushable paper and paper towelling for cleaning up spills
- strong plastic bags
- detergent.

#### **14.6.2 Administration of oral cytotoxic drugs**

Drugs to be administered should be supplied in the correct dose. There is no safe method to break tablets and capsules without the risk of exposure, and care-givers should be advised not to do so. Advice should be given to wear two pairs of disposable gloves when giving the tablet or capsule to the animal. Small amounts of cytotoxic contaminated waste such as gloves and empty cytotoxic drug containers should be placed in a plastic bag and sealed, then placed into a larger strong plastic bag and placed in household garbage.

#### **14.6.3 Patient waste**

Care-givers should be advised to restrict the movements of the animal, and to observe the area where the animal urinates so it can be watered well to dilute urine. They should be warned to be careful with the use of water so there is no splashing. If the animal itself becomes contaminated, it should be washed, again being careful not to generate aerosols. Appropriate PPE should be worn.

Animals should not be walked or allowed to roam in a public place during the period body wastes may be contaminated. To clean up excreta, wear two pairs of disposable gloves, scoop excreta on to a non-absorbent implement such as a shovel, and dispose of in a toilet, using a full flush with the toilet lid closed to prevent aerosols being released. Wash the shovel under running water, being careful to avoid splashing. Excreta which cannot be picked up should be diluted by gentle hosing (without a jet) until it has been well dispersed.

#### **14.6.4 Laundry or disposal of bedding**

Animal bedding or clothing of the care-giver with traces of contamination should be laundered immediately and separately from other items. Two pairs of disposable gloves should be worn when handling cytotoxic contaminated laundry. The procedure outlined in chapter 11 for treatment of cytotoxic contaminated laundry can be used for pet's bedding. Bedding to be disposed of should be placed in a plastic bag and sealed, then placed into a larger strong plastic bag and placed in household garbage.

#### **14.6.5 Cytotoxic spills**

Spills of cytotoxic drugs should be managed as described in chapter 12. A small quantity of patient waste deposited on the floor or on furniture should be dealt with as follows:

- put on two pairs of disposable gloves or one pair of purpose manufactured gloves
- wipe up the spill with flushable paper, and full flush down the toilet with lid closed, or use disposable paper towelling or linen, placing the material in a strong plastic bag
- clean area with water and detergent
- dispose of cleaning cloths and gloves in a plastic bag then place in household rubbish.

Flushable paper should be used wherever possible to reduce the amount of contaminated waste to be placed in household garbage.

#### **14.6.6 Interaction with the patient**

Owners and other family members should be advised to exercise strict personal hygiene practices (i.e. gloves and hand-washing) when handling pets receiving cytotoxic drugs. The time for particular care is during the period the drugs may be excreted. Veterinary practices should provide information about how long pet wastes are likely to be contaminated. It is recommended precautions be taken for a seven-day period from the completion of cytotoxic therapy.

#### **14.7 Information for care-givers**

Owners or other care-givers of animals receiving cytotoxic drug therapy will need to be provided with written information on the hazards of cytotoxic drugs, and precautions to be taken while caring for their animals during the time the drug may be excreted. They should also be advised about the characteristics of the particular drug used, including any side effects, and the approximate time cytotoxic residues may continue to be excreted after administration.

The following issues should be covered in preparing written information for owners and caregivers:

- matters covered in section 14.6 above
- reasons for taking precautions in the handling of cytotoxic drugs and related waste
- precautions to take with interaction between the animal and people in the home (e.g. small children, the aged and women who are pregnant or breastfeeding)
- how to store cytotoxic drugs at home
- emergency procedures for accidental exposure or ingestion of cytotoxic drugs by children
- disposal of drugs no longer needed (e.g. by returning to the clinic).

### **Standard operating procedures – Chapter 14**

In developing SOPs for managing exposure to cytotoxic drugs and related waste in veterinary practice, the following factors should be considered:

- identification and incorporation of relevant legislation
- identification of activities and tasks where workers may be at risk of exposure
- identification of workers who may be at risk of exposure
- consultation during the risk management process with workers and others involved in handling cytotoxic drugs and related waste
- integration with relevant organisational policies and reporting procedures
- exposure management strategies for specific locations (e.g. treatment rooms, animal cages, cytotoxic drug storage areas, waste treatment facilities)

- identification, segregation and containment of cytotoxic contaminated waste and laundry (e.g. labelling, compliant containers, signage and security)
- safe systems of work for activities where there is a risk of exposure:
  - administration of parenteral, oral and topical cytotoxic drugs
  - cleaning of animals, animal body waste and cages
  - disposal of cytotoxic contaminated waste
- selection of appropriate PPE, and monitoring and supervision to ensure PPE is worn correctly
- development of cytotoxic spill management plans for spills occurring at different areas of the workplace, including appropriate location of spill kits
- emergency procedures for personal contamination, including incident reporting, which are integrated with organisational emergency policies and reporting procedures
- information provided to the animal's owner or carer which covers issues raised in this chapter
- supply of cytotoxic drugs in required doses from the pharmaceutical supplier
- provision of cytotoxic spill kits to animal owners and carers, including information on their use
- return of unused cytotoxic drugs from owners for disposal.

In addition, these SOPs should:

- be developed with regard to manufacturers' instructions, SDSs or other information about the equipment, substances or products being used
- be part of the induction and ongoing training program
- be checked regularly for compliance through monitoring and supervision
- be reviewed regularly and when there are incidents or changes to the workplace that affect the procedure (e.g. new equipment, new legislation, new products)
- be documented and meet record keeping requirements.



## Appendix 1 - Glossary of terms

<b>A</b>	
absorption	a route of exposure—see dermal absorption, mucosal absorption
ADG Code	Australian Dangerous Goods Code—sets out technical requirements and guidelines for the transport of dangerous goods by road and rail
administration (of drugs)	the giving of cytotoxic drugs to a patient—common methods include parenteral, oral and topical administration
administrative control	a type of control measure which involves safer work practices to reduce the risk (e.g. SOPs, training)
<b>B</b>	
biological monitoring	for a hazardous chemical, means the measurement and evaluation of a substance, or its metabolites, in the body tissue, fluids or exhaled air of a person exposed to a substance
body substances	urine, faeces, vomitus, bile and fluid drained from body cavities
<b>C</b>	
carcinogen	substance which causes cancer
code of practice	published by WHSQ, providing information on ways to manage a particular risk or group of risks
community care	care of patients in a domestic or domiciliary situation
consultation	discussion with workers regarding workplace health and safety issues
container	anything in or by which a hazardous chemical is, or has been, wholly or partly covered, enclosed or packed, including anything necessary for the container to perform its function as a container
control measure	a measure to eliminate or minimise the risk to health and safety
cytotoxic	toxic to cells
cytotoxic drug	drugs which cause the death of certain cells, and which are used to treat conditions such as cancer, rheumatoid arthritis, multiple sclerosis, 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 drugs.
<b>D</b>	
dangerous incident	an incident in relation to a workplace that exposes a worker or any other person to a serious risk to a person's health or safety emanating from an immediate or imminent exposure to events as defined in section 37 of the <i>Work Health and Safety Act 2011</i> and includes an uncontrolled escape, spillage or leakage of a substance
dermal absorption	a route of exposure—taking in cytotoxic drug or related waste through the skin
duty	a legal requirement to take specified action under the Work Health and Safety legislation
<b>E</b>	
elimination	a type of control measure in which the hazard is eliminated
engineering control	a type of control measure which is physical in nature, including a mechanical device or process
equipment	see 'plant'
exposed	a person is exposed to a hazardous chemical if they are in a situation where they absorb or are likely to absorb the substance by ingestion,

	inhalation or through the skin or mucous membrane. Exposure may also occur as a result of percutaneous injuries
exposure standard	an exposure standard listed in the Workplace Exposure Standards for Airborne Contaminants and represents the airborne concentration of a particular substance or mixture that must not be exceeded
<b>G</b>	
GHS	Globally Harmonised System of Classification and Labelling of Chemicals, Third revised edition, published by the United Nations as modified under schedule 6 of the Work Health and Safety Regulation 2011
<b>H</b>	
hazard	a situation or thing which has the potential to harm a person
hazardous chemical	a substance, mixture or article that satisfies the criteria for a hazard class in the GHS (including a classification mentioned in schedule 6 of the Work Health and Safety Regulation 2011) but does not include a substance, mixture or article that satisfies the criteria solely for one of the following hazard classes – a) acute toxicity – oral – category 5; b) acute toxicity – dermal – category 5; c) acute toxicity – inhalation – category 5; d) skin corrosion/irritation – category 3; e) serious eye damage/eye irritation – category 2B; f) aspiration hazard – category 2; g) flammable gas – category 2; h) acute hazard to the aquatic environment – category 1,2 or 3; i) chronic hazard to the aquatic environment – category 1,2,3 or 4; j) hazardous to the ozone layer.
healthcare facility	includes hospitals, day hospitals, clinics and medical practices
health monitoring	monitoring of a person to identify changes in the persons' health status because of exposure to particular substances
health monitoring report	a report which contains information relating to the health monitoring undertaken for a worker including test results, advice that test results indicate a worker may have contracted a disease, injury or illness due to their occupational exposure and any recommendation that remedial measures are to be taken in the workplace
<b>I</b>	
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
isolation	a type of control measure which uses barriers to prevent exposure
<b>M</b>	
manufacturer	a duty holder under the <i>Work Health and Safety Act 2011</i>
mucosal absorption	a route of exposure—taking in cytotoxic drug or waste through mucus membranes (e.g. in the mouth, eyes or nose)
mutagen	an agent that tends to increase the frequency or extent of relatively permanent change in hereditary genetic material
<b>N</b>	
notifiable incident	means the death of a person, serious injury or illness of a person or a dangerous incident
<b>O</b>	
occupational exposure	exposure to cytotoxic drugs during a work activity

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	a method of cytotoxic drug administration—includes subcutaneous, intraocular, intramuscular, intrapleural, intraperitoneal, intra-arterial, intrathecal and intravesical
PCBU	person conducting a business or undertaking
penetrating injury	an injury caused by a sharp
percutaneous injury	a route of exposure—taking in cytotoxic drug or waste through a puncture of the skin
person conducting a business or undertaking	a duty holder under the <i>Work Health and Safety Act 2011</i>
personal protective equipment	anything used or worn by a person to minimise risk to the person's health and safety, including air supplied respiratory equipment. Also known as PPE
plant	includes machinery, equipment, appliance, container, implement and tool, and any component of any of those things and anything fitted or connected to any of those things
PPE	see 'personal protective equipment'
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 (e.g. drawing liquid cytotoxic drug into a syringe from a vial), and crushing or dissolving tablets or emptying capsules to prepare part doses.
prohibited carcinogen	a substance listed in schedule 10, table 10.1, column 2 of the Work Health and Safety Regulation 2011 and is present in a concentration of 0.1% or more in a solid or liquid, or 0.1% or more concentration for a gas
<b>R</b>	
respiratory protective equipment	equipment used by a worker to prevent or minimise exposure to airborne hazardous chemical or airborne contaminant. Also known as RPE
restricted carcinogen	a substance listed in schedule 10, table 10.2, column 2 of the Work Health and Safety Regulation 2011 for a use listed in column 3 and is present in a concentration of 0.1% or more in a solid or liquid, or 0.1% or more concentration for a gas
risk	the possibility that harm (death, injury or illness) might occur when exposed to a hazard
risk assessment	an examination of what could happen if someone is exposed to a hazard and the likelihood of it happening
risk management	a process for identifying workplace hazards and risks, and managing them to ensure the health and safety of workers in the workplace
RPE	see 'respiratory protective equipment'
<b>S</b>	
safety data sheet	an information sheet provided by a supplier or manufacturer containing information about a particular substance. Also known as an SDS
SDS	see 'safety data sheet'
serious injury or illness	includes injury or illness requiring a person to have immediate treatment as an in-patient in a hospital, medical treatment within 48

	hours of exposure to a substance or immediate treatment for a number of injuries as stated in the <i>Work Health and Safety Act 2011</i>
sharps	pointed or cutting implements which are capable of inflicting a penetrating injury, including hypodermic, intravenous or other medical needles, Pasteur pipettes, scalpel blades, lancets, scissors, glass slides and broken glass such as vials, bottles and laboratory glass
SOP	see ‘standard operating procedures’
standard operating procedures	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
substitution	a type of control measure which substitutes a hazardous chemical or process with something safer
supplier	a duty holder under the <i>Work Health and Safety Act 2011</i>
<b>T</b>	
telophase	the last of four stages in the division of a single body cell into two identical cells
teratogen	an agent that causes structural or functional defects in the developing embryo
topical	a method of administration
<b>U</b>	
use (of cytotoxic drugs)	includes administration, preparation, handling, storage, movement and disposal of cytotoxic drugs and related waste
<b>W</b>	
WHS	work health and safety
WHS Act	<i>Work Health and Safety Act 2011</i>
WHSQ	Workplace Health and Safety Queensland—the regulating state government agency for workplace health and safety
WHS Regulation	Work Health and Safety Regulation 2011
worker	a person who carries out work in any capacity for a person conducting a business or undertaking
workplace	a place where work is carried out for a business or undertaking and includes any place where a worker goes, or is likely to be, while at work

## Appendix 2 - Commonly used cytotoxic drugs

This list contains cytotoxic drugs currently used however this listing is not exhaustive.

Drug	Trade names
Altretamine	Hexalen
Amsacrine	Amsidyl
L-Asparaginase	See Colaspase
Bleomycin	Blenoxane, Blenamax
Busulfan	Myleran
Capecitabine	Xeloda
Carboplatin	Paraplatin, CBDCA
Carmustine	Bicnu
Chlorambucil	Leukeran
Cisplatin	Cisplatin
Cladribine	Leustatin, Litak
Colaspase	Leunase
Cyclophosphamide	Cycloblastin, Endoxan
Cytarabine	Ara-C , Cytosar
Dacarbazine	DTIC
Dactinomycin	Cosmegen
Daunorubicin	Daunorubicin
Daunorubicin liposomal	Dauno Xome
Docetaxel	Taxotere
Doxorubicin	Adriamycin
Doxorubicin liposomal	Caelyx
Epirubicin	Pharmorubicin
Etoposide Phosphate	Etopophos
Etoposide	Etoposide, Vepesid
Fluorouracil	Efudix, 5FU
Fludarabine	Fludara
Fotemustine	Muphoran
Ganciclovir	Cymevene
Gemcitabine	Gemzar
Hydroxyurea	Hydrea
Idarubicin	Zavedos
Ifosfamide	Holoxan
Irinotecan	Camptosar, CPT-11
Lomustine	Cee Nu
Melphalan	Alkeran
Mercaptopurine	Puri-nethol
Methotrexate	Ledertrexate, Methoblastin, MTX
Mitozantrone	Novantrone, Onkotrone
Mitomycin-C	Mutamycin
Nimustine	Nimustine
Oxaliplatin	Eloxatin
Paclitaxel	Anzatax, Paclitaxel Ebewe, Taxol
Pemetrexed	Alimta
Procarbazine	Natulan
Raltitrexed	Tomudex
Temozolomide	Temodal
Teniposide	Vumon

Thioguanine	Lanvis
Thiotepa	Thiotepa
Topotecan	Hycamtin
Vinblastine	Velbe
Vincristine	Oncovin
Vindesine	Eldisine
Vinorelbine	Navelbine

## Appendix 3 – Legislation

Legislation which applies to management of cytotoxic drugs and related waste includes, but is not limited to the following:

- *Work Health and Safety Act 2011*
- Work Health and Safety Regulation 2011
- Health Regulation 1996
- Health (Drugs and Poisons) Regulation 1996
- *Environmental Protection Act 1994*
- Environmental Protection Regulation 2008
- *Waste Reduction and Recycling Act 2011*
- Waste Reduction and Recycling Regulation 2011
- *Transport Operations (Road Use Management) Act 1995*
- Transport Operations (Road Use Management – Dangerous Goods) Regulation 2008
- *Civil Aviation Act 1988*
- Civil Aviation Safety Regulations 1998
- *Navigation Act 1912*

All Queensland legislation can be obtained at the following website:

[legislation.qld.gov.au](http://legislation.qld.gov.au).

### **Workplace Health and Safety Queensland codes of practice**

- *First Aid in the Workplace Code of Practice 2014*
- *Labelling of Workplace Hazardous Chemicals Code of Practice 2011*
- *Managing Risks of Hazardous Chemicals in the Workplace Code of Practice 2013*
- *Preparation of Safety Data Sheets for Hazardous Chemicals Code of Practice 2011*
- *How to Manage Work Health and Safety Risks Code of Practice 2011*
- *Hazardous Manual Tasks Code of Practice 2011*
- *Managing Risks of Plant in the Workplace code of Practice 2013*

## Appendix 4 – Sample cytotoxic drugs register

Company:

Site/area:

Person completing  
register:

Date: / /

[illegible]

Date for review of register: / /



## Appendix 5 – Sample risk assessment of hazardous chemicals

Work unit (job):		Person/s exposed:		Assessment team:		Work area: Date:			
Summary of process:		Health effects (see SDS)	Task/s	Exposure routes (where applicable)	Current controls	Risk calculation based on current controls (refer over page for explanation of these terms)			
Product name						Likelihood of exposure score	Consequence of exposure score	Risk score (1 - 7)	Risk conclusion
				Eyes					
				Skin					
				Inhaled					
				Ingested					
				Percutaneous					
				Eyes					
				Skin					
				Inhaled					
				Ingested					
				Percutaneous					
				Eyes					
				Skin					
				Inhaled					
				Ingested					
				Percutaneous					
Recommendations (example - change to controls): Is air monitoring required (refer over page): Yes / No If yes - type: Intervals:									
Is health monitoring required (refer over page): Yes / No If yes - type: Intervals:									
Assessor/s name/s: Signature/s: Date:									
Approved by name: Signature: Date:									

P.T.O For information on risk scoring and risk conclusions and health monitoring

## Risk rating chart

**Risk score** – 1,2,3 = Immediate; 4,5 = ASAP; 6,7 = may not need immediate attention.

LIKELIHOOD: How likely that it could happen?	CONSEQUENCES: How severely could it hurt someone?			
	EXTREME death, permanent disablement	MAJOR serious bodily injury	MODERATE casualty treatment	MINOR first aid only, no lost time
VERY LIKELY could happen frequently	1	2	3	4
LIKELY could happen occasionally	2	3	4	5
UNLIKELY could happen but rare	3	4	5	6
VERY UNLIKELY could happen, probably never will	4	5	6	7

### Factor affecting LIKELIHOOD of exposure:

- the frequency or duration of time the hazardous chemicals is used
- how many people are using the hazardous chemical
- the skills and experience of the people using the hazardous chemical
- the effectiveness of existing controls.

### Factors affecting CONSEQUENCES of exposure:

- concentrations of hazardous substances (dilute versus concentrated)
- volume of hazardous chemical being used
- hazardous chemical is in a FORM which can be absorbed into the body (e.g. airborne form can be inhaled, liquid onto skin—see SDS).

More information on risk assessments can be found in the *Managing Risks of Hazardous Chemicals in the Workplace Code of Practice 2013*.

**Health monitoring** is generally required where a worker is carrying out ongoing work using, handling generating or storing hazardous chemicals and there is a significant risk to the worker's health because of exposure to a hazardous chemical referred to in schedule 14, table 14.1 of the Work Health and Safety Regulation 2011 or either valid techniques are available to detect the effect on the worker's health or a valid way of determining biological exposure is available.

## Conclusion from the risk assessment

**Conclusion 1: Risk NOT SIGNIFICANT** now and not likely to increase in the future. This conclusion applies where it is unlikely the use of the hazardous chemical will adversely affect the health of people at the workplace and the risk is not likely to increase in the future. For example, the amount or rate of use of a hazardous chemical is too small to constitute a risk, even if controls fail.

**Conclusion 2: Risks are SIGNIFICANT** but effectively controlled, and could increase in the future. This conclusion usually applies to conditions where serious health effects could result if the control measures fail or deteriorate. This usually results from the use of a highly toxic hazardous chemical or where the potential exposure is high. Risks, while presently adequately controlled, could increase in the future owing to, for example, undetected deterioration in the efficiency of control measures; plant including personal protective equipment failure; control measures not used properly; a significant increase in the quantity of the hazardous substance used.

**ACTION REQUIRED:** review controls; determine if air monitoring or health monitoring is required to check on effectiveness of controls.

**Conclusion 3: Risk SIGNIFICANT** now, and not effectively controlled. The following are examples of work conditions where the use of a hazardous chemical is likely to constitute a risk, and further investigation (e.g. air monitoring) might be necessary: Where dusts, mist, fumes are visible in the air (e.g. in light beams), and there are persistent or widespread complaints of illnesses, discomfort, irritation or excessive odour; hazardous chemicals are splashed; control measures are broken, defective or badly maintained (e.g. poorly maintained extraction fan motor); airborne concentrations approach or exceed exposure standards.

**ACTION REQUIRED:** work out if there is a need to stop the process; review controls; determine if air monitoring or health monitoring is required.

**Conclusion 4: UNCERTAIN** about risks: not enough information, or uncertain about degree and extent of exposure. If the level of exposure cannot be estimated with confidence, further investigation is necessary. Air monitoring might be required to estimate the level of exposure. For a hazardous chemical absorbed through the skin, ingested or inhaled, biological monitoring might be required. The PCBU should seek specialist advice if necessary.

**Significant risk** means the work with a hazardous chemical is likely to adversely affect the health of workers and other people at the workplace.

## Appendix 6 – Sample audit checklist

### Cytotoxic drugs and related waste audit

A PCBU at a workplace where cytotoxic drugs are used must comply with requirements of the Work Health and Safety Regulation 2011. This checklist is a guide only.

Date: \_\_\_\_\_ Workplace name: \_\_\_\_\_

Auditor: \_\_\_\_\_

A - Audited NC - No compliance N/A - Not applicable Yes/No answers go in remarks column

		A	NC	NA	Remarks
<b>1.0</b>	<b>Safety data sheets (SDS)</b>				
1.1	Is there a current SDS for each cytotoxic drug used?				
1.2	Is the SDS easily accessible for workers to refer to?				
<b>2.0</b>	<b>Register</b>				
2.1	Are copies of the SDSs in a register?				
<b>3.0</b>	<b>Labelling</b>				
3.1	Are cytotoxic drugs labelled with product identifier, hazard pictogram, hazard statement, signal word and precautionary statement?				
3.2	If a cytotoxic drug is transferred from one container into a second container, and the second container's contents are not entirely used immediately, is the second container labelled with the product identifier, hazard pictogram or hazard statement?				
<b>4.0</b>	<b>Risk assessment</b>				
4.1	Has a risk assessment been carried out to assess the risk to the health of workers from cytotoxic drugs and related waste: <ul style="list-style-type: none"> <li>• drug preparation</li> <li>• drug administration</li> <li>• patient care</li> <li>• spill management</li> <li>• waste management</li> <li>• general cleaning</li> <li>• laundry</li> <li>• maintenance</li> <li>• stores and transport?</li> </ul>				
4.2	Does the risk assessment include: <ul style="list-style-type: none"> <li>• identification of the cytotoxic drug</li> <li>• review of the SDS if available</li> <li>• if SDS is not available, review of available equivalent information</li> <li>• if the substance is contained in a consumer package, a review of the package's label</li> <li>• a decision whether any workers may be exposed to cytotoxic drugs or related waste</li> <li>• a decision about control measures and health monitoring needed for the substance?</li> </ul>				
4.3	Have systems been implemented to make sure that the risk assessment is done if: <ul style="list-style-type: none"> <li>• there is uncertainty about how a hazard may result in injury or illness</li> <li>• the work activity involves a number of different hazards and there is a lack of understanding about how the hazards may interact with each other to produce new or greater risks</li> </ul>				

	• changes at the workplace occur which may impact on the effectiveness of control measures?				
<b>5.0</b>	<b>Controlling exposure</b>				
5.1	Can workers' exposure to cytotoxic drugs and related waste be prevented?				
5.2	If prevention is not reasonably practicable, has workers' exposure been reduced to as low a level as is practicable?				
5.3	Has exposure to cytotoxic drugs and related waste been controlled by ways other than by the use of PPE? Explain.				
5.4	Where exposure cannot be controlled other than by PPE, is appropriate PPE provided?				
5.5	Are workers properly instructed in the use of PPE?				
5.6	Are workers supervised to ensure that PPE is worn when being exposed to cytotoxic drugs and related waste?				
5.7	Have control measures decided under the risk assessment been implemented as soon as practicable?				
5.8	Are control measures, including engineering controls, safe work practices and PPE effectively maintained?				
<b>6.0</b>	<b>Training</b>				
6.1	Have workers who may be exposed to cytotoxic drugs and related waste been provided with information, instruction and training about the substance?				
<b>7.0</b>	<b>Records</b>				
7.1	Are records kept of: <ul style="list-style-type: none"> <li>• restricted carcinogen authorisation — 30 years</li> <li>• details of workers exposed to a restricted carcinogen — 30 years</li> <li>• health monitoring reports — 30 years?</li> </ul>				
7.2	Does the risk assessment record include the following information: <ul style="list-style-type: none"> <li>• the date when the assessment was done</li> <li>• whether the degree of risk is assessed to be significant</li> <li>• the substance's product name and other information</li> <li>• the control measures for the use of the substance that were in place when the assessment was done</li> <li>• the type of monitoring that is needed and the intervals at which the monitoring must be done</li> <li>• the type of health monitoring that is needed and the intervals at which the monitoring must be done?</li> </ul>				
7.3	Does the training record include the following information: <ul style="list-style-type: none"> <li>• the date of the session</li> <li>• the topics dealt with at the session</li> <li>• the name of the person who conducted the session</li> <li>• the names of the workers who attended the session?</li> </ul>				
<b>8.0</b>	<b>8.0 Drug preparation</b>				
8.1	Are cytotoxic drugs prepared by a pharmacist or pharmacy technician who is specifically trained in the preparation of these drugs?				
8.2	Are cytotoxic drugs prepared in a cytotoxic drug safety cabinet (CDSC), or in a pharmaceutical isolator?				
8.3	Does the CDSC comply with AS2567?				
8.4	Does the installation and use of the CDSC comply with AS2639?				
8.5	Does the pharmaceutical isolator comply with AS/NZS4273?				
8.6	Does the drug preparation area consist of a clean room and an anteroom that complies with AS/NZS ISO 14644.5?				
8.7	Do HEPA filters filter the air supply to the clean room and the anteroom?				
8.8	Are CDSCs, isolators and HEPA filters inspected and tested after relocation or mechanical or electrical maintenance, and at regular intervals (at least every 12 months)?				
8.9	Is equipment inspected and tested every six months when the activity within the cabinet >1000 preparations per month?				
8.10	Is equipment certified as specified in AS2639?				

8.11	Are copies of test reports kept in the cytotoxic drug preparation facility?				
8.12	Have technicians been trained in safe operating procedures, which prevent or minimise exposure to cytotoxic drugs when servicing the equipment? Describe.				
8.13	Are drug preparation facilities cleaned in accordance with AS2639?				
8.14	Are general cleaning workers involved in cleaning clean rooms and associated equipment?				
8.15	Are general cleaning workers provided with information, instruction and training about cytotoxic drugs?				
8.16	Are general cleaning workers trained in correct cleaning procedures?				
8.17	Are general cleaning workers provided with appropriate PPE?				
8.18	Are maintenance workers provided with information, instruction and training about cytotoxic drugs?				
8.19	Are maintenance workers provided with appropriate PPE?				
8.20	Is there specifically dedicated equipment used for cytotoxic drug preparation?				
8.21	Is there a dedicated clearly labelled storage area for cytotoxic drugs in the drug preparation facility?				
8.22	Is there an activity record for workers involved in drug preparation?				
8.23	Are there written procedures for: <ul style="list-style-type: none"> <li>• training requirements</li> <li>• spill management in CDSC</li> <li>• procedure for decontamination of cabinet and re-assembly</li> <li>• management of spill in clean room, anteroom or storeroom</li> <li>• management of skin penetrating injuries and cytotoxic drug exposure</li> <li>• incident reporting</li> <li>• use of specifically dedicated equipment for compounding cytotoxic preparations</li> <li>• operational specifications for the use of drug preparation facilities including CSDSs</li> <li>• maintenance and certification of equipment and facilities</li> <li>• reconstitution procedures</li> <li>• labelling and packaging prepared drugs for internal and external transportation</li> <li>• routine and emergency cleaning and decontamination protocols in the cleanroom</li> <li>• procedures for storage areas (e.g. receipt, handling and storage of cytotoxic drugs)</li> <li>• selection, use, maintenance and disposal of PPE</li> <li>• handling cytotoxic contaminated laundry for collection</li> <li>• waste management?</li> </ul>				
<b>9.0</b>	<b>Drug administration</b>				
9.1	Are cytotoxic drugs supplied in pre-prepared doses?				
9.2	Are cytotoxic drugs prepared by trained workers in a CDSC or pharmaceutical isolator?				
9.3	Are IV solution flasks, syringes, pump cartridges containing cytotoxic drugs clearly labelled?				
9.4	Are there written procedures for: <ul style="list-style-type: none"> <li>• training requirements</li> <li>• selection, use, maintenance and disposal of PPE</li> <li>• administration of parenteral, oral and topical cytotoxic drugs</li> <li>• extravasation incidents</li> <li>• management of skin penetrating injuries and blood or body substance exposures</li> <li>• management of cytotoxic drug exposures</li> <li>• spill management</li> <li>• incident reporting</li> </ul>				

	<ul style="list-style-type: none"> <li>• waste management</li> <li>• cytotoxic contaminated laundry management</li> <li>• transportation of patient with chemotherapy in situ</li> <li>• home care information for patients and carers?</li> </ul>				
<b>10.0</b>	<b>Patient care</b>				
10.1	<p>Are there written procedures for:</p> <ul style="list-style-type: none"> <li>• training requirements</li> <li>• selection, use, maintenance and disposal of PPE</li> <li>• management of patient waste</li> <li>• cleaning or disposal of equipment used in patient care</li> <li>• laundry management</li> <li>• spill management</li> <li>• transportation of patients with chemotherapy in situ</li> <li>• management of skin penetrating injuries and blood or body substance exposures</li> <li>• management of cytotoxic drug exposures</li> <li>• incident reporting</li> <li>• home care information for patients and carers?</li> </ul>				
<b>11.0</b>	<b>Spill management</b>				
11.1	Is there a spill kit available where cytotoxic drugs and related waste are handled, stored, transported and disposed of?				
11.2	Are workers who are likely to be involved in spill management trained in spill containment and decontamination procedures?				
11.3	Are operational workers trained in emergency spill containment?				
11.4	Is there written instruction for workers such as storepersons, cleaners, on-site transporters, couriers and porters and waste handlers to report spills to supervisors?				
<b>12.0</b>	<b>Waste management</b>				
12.1	Is there a designated person responsible for ensuring waste disposal complies with legal requirements?				
12.2	Are all cytotoxic sharps discarded in a designated approved sharps container?				
12.3	Is cytotoxic waste stored in a secure dedicated area?				
12.4	<p>Are there written procedures for:</p> <ul style="list-style-type: none"> <li>• identification, segregation and containment of cytotoxic waste</li> <li>• on-site transport of waste to collection area</li> <li>• spill management</li> <li>• training requirements for waste handlers</li> <li>• management of skin penetrating injuries and cytotoxic drug and related waste exposures</li> <li>• incident reporting</li> <li>• cleaning procedure (e.g. trolleys, wheelie bins, and storage area)</li> <li>• location and requirements for cytotoxic waste collection area)</li> <li>• arrangements for waste disposal sub-contractors?</li> </ul>				
<b>13.0</b>	<b>Laundry</b>				
13.1	Are there systems in place to ensure that cytotoxic contaminated linen is isolated from other linen?				
13.2	<p>Are there written procedures for:</p> <ul style="list-style-type: none"> <li>• identification, segregation and containment of cytotoxic contaminated linen</li> <li>• safe handling of linen contaminated with cytotoxic drugs and related waste</li> <li>• spill management</li> <li>• training requirements laundry workers</li> <li>• management of skin penetrating injuries and cytotoxic drug and related waste exposures</li> <li>• incident reporting</li> <li>• laundry washing procedures?</li> </ul>				

## Appendix 7 – Training modules for working for cytotoxic drugs

All modules may be incorporated into training schedules for induction into the workplace and at annual refreshers. A risk assessment should be used to identify the specifics of training (e.g. purpose, who should be trained and when, and what is to be covered by the training).

### Module 1 – Introduction to cytotoxic concepts

To ensure all workers are aware of, and understand the risks associated with the handling and use of cytotoxic drugs and related waste.

#### Teaching points:

- 1.1 Risks associated with occupational exposure to cytotoxic drugs and related waste:
  - health risks and toxic effects
  - reproductive health risks.
- 1.2 Rationale for use of cytotoxic drug therapy.
- 1.3 Legislative requirements for the management of cytotoxic hazards, SDSs, risk assessment, PCBU and worker duties.
- 1.4 Institutional policies and procedures.
- 1.5 Definitions; cell replication; drug classifications, pharmacological actions; rationale for use. Identification of those drugs which are mutagenic, teratogenic and carcinogenic. Cytotoxic drugs as a class of drugs:
  - define ‘carcinogenic’ ‘mutagenic’ and ‘teratogenic’
  - concepts of cell replication
  - drug classifications and pharmacological action on cellular reproduction.
- 1.6 Health monitoring for workers working with cytotoxic drugs;
  - health assessment of workers after unprotected exposure to cytotoxic drugs:
    - rationale
    - health assessment required in response to an unprotected exposure
  - principles for initial and ongoing health assessment:
    - rationale for personnel management
    - the purpose of health assessment
    - limitations of current health monitoring methods.
- 1.7 The importance of accurate record keeping (e.g. an activity log, records of spills and penetrating injuries). Storage requirements for health monitoring documentation to ensure confidentiality, perpetual safe keeping and retrieval.
- 1.8 Incidents and spill management
- 1.9 Safe disposal methods for cytotoxic drugs and related waste. Safe storage, packaging, consigning and transport of cytotoxic waste:
  - the rationale for the identification, segregation and safe handling of cytotoxic waste
  - institution policies and procedures as they apply to:
    - segregation of cytotoxic waste
    - containment of cytotoxic waste
    - transport of cytotoxic waste
    - management of cytotoxic drug and related waste spills.
- 1.10 PPE requirements, including, selection, use, fit, maintenance, storage, cleaning and disposal.



## Module 2 – Preparation of cytotoxic drugs

To train workers in the safe preparation of cytotoxic drugs.

**Teaching points** – to include Module 1, plus:

- 2.1 Facility requirements:
  - minimum requirements for a cytotoxic preparation facility as defined by AS 2567:2002 - Laminar flow cytotoxic drug safety cabinets and AS 2639:1994 -Laminar flow cytotoxic drug safety cabinets - Installation and use
  - principles of clean spaces, their creation and maintenance as described in AS/NZS ISO 14644.5:2006 – Cleanrooms and associated controlled environments - operations:
    - essential elements necessary for the preparation of cytotoxic drugs—clean room, air handling system, peripheral rooms, cytotoxic dispensing facility (e.g. laminar air flow equipment, isolators, cytotoxic drugs safety cabinet)
    - their function and use
  - management of the cytotoxic preparation facility:
    - operation of the cytotoxic drugs safety cabinet or isolator
    - maintenance of the preparation facility
    - approved devices/equipment used in preparing cytotoxic drugs
    - management of cytotoxic spills
    - management of contaminated waste generated in the preparation of cytotoxic drugs
    - preparation records
  - certification reports
  - activity logs
  - pressure differential records
  - environmental monitoring.
- 2.2 Aseptic preparation of a cytotoxic product.
  - principles of aseptic preparation of parenteral solutions
  - specific requirements for aseptic preparation in cytotoxic drug safety cabinets or isolators.
- 2.3 Quality assurance measures required for preparation cytotoxic drugs.
- 2.4 Safe techniques for cytotoxic drugs. Health and safety hazards posed by handling cytotoxic drugs in powder and liquid form:
  - routes of absorption associated with occupational exposure
  - hazards involved when cytotoxic drug aerosols are liberated into a workplace.
- 2.5 Packaging requirements for the safe presentation and receipt of prepared cytotoxic drugs in individual packing:
  - labelling and packaging requirements for the presentation of prepared cytotoxic drug doses
  - procedure for dealing with broken tablets and capsules
  - rationale for the use of primary (e.g. a syringe closure), secondary (e.g. the spill-proof overwrap containing the syringe) and tertiary (e.g. the spill-proof outer transport container) containers for the maintenance of product integrity and its safe handling.
- 2.6 Safe storage and transport of cytotoxic drugs in concentrated form:
  - legislative requirements for the storage and transport of cytotoxic drugs
  - rationale for specific procedures essential for the storage and transport of cytotoxic drugs
  - risks associated with the different presentations of cytotoxic drugs
  - institutional policy and procedures as they apply to receipt of goods, storage of goods, transport of goods, management of cytotoxic drug and related waste spills.
- 2.7 PPE requirements:
  - function and use of PPE—demonstrate appropriate use of PPE:
    - selection
    - putting on
    - concurrent use
  - cleaning, laundry and disposal of used PPE.
- 2.8 Waste management principles of waste containment and segregation:

- contaminated waste disposal
- contaminated patient waste
- cytotoxic waste storage and transport requirements.

2.9 Management in the community.

2.10 Incidents and spill management.

2.11 Record keeping.

## Module 3 – Administration of cytotoxic drugs

To train workers in the safe administration of cytotoxic drugs.

**Teaching points** - Module 1, plus

- 3.1 Risks associated with administration for operator and patient:
  - physical and chemical characteristics of these drugs as they pertain to occupational safety:
    - differences in potential risk between lyophilised drugs, powdered and liquid filled preparations
    - substances requiring protective containment
  - cytotoxic drugs and their rationale for use:
    - cure, control, prophylaxis and palliation
    - drug dosages, routes of administration, delivery methods, calculation of body surface area
    - cytotoxic drug protocols.
- 3.2 Principles of safe handling for all routes of administration. Safe administration techniques for cytotoxic drugs:
  - health and safety hazards posed by handling cytotoxic drugs in liquid form:
    - routes of absorption associated with occupational exposure
    - hazards involved when cytotoxic drug aerosols are liberated into a workplace
  - packaging requirements for the safe presentation and receipt of prepared cytotoxic drugs in individual packing:
    - labelling and packaging requirements for the presentation of prepared cytotoxic drug doses
    - procedure for dealing with broken tablets and capsules
    - rationale for the use of primary (e.g. a syringe closure), secondary (e.g. the spill-proof overwrap containing the syringe) and tertiary (e.g. the spill-proof outer transport container)
    - containers for the maintenance of product integrity and its safe handling
  - identifying safe routes of administration—principles of safe handling and administration of cytotoxic drug injections:
    - demonstrate correct and safe use of cytotoxic drug injectables
    - identify variety of routes by which cytotoxic drugs are administered
    - identify appropriate blood values and assessments prior to drug administration
  - principles of safe handling and administration of cytotoxic drug infusions:
    - identify appropriate equipment for management of infusions of cytotoxic drugs
    - demonstrate correct technique for the connection and disconnection of cytotoxic drug administration equipment
  - principles of safe handling and administration of oral and topical cytotoxic drugs:
    - demonstrate no-touch technique in the administration of oral cytotoxic drug doses
    - no-touch application technique and drug containment procedures when applying topical cytotoxic drugs
  - reasons for the selection of differing vascular access techniques for parenteral cytotoxic drugs:
    - demonstrate techniques of vein access appropriate for intravenous administration of various cytotoxic agents
  - selection of a vascular access site for vesicant and irritant cytotoxic drug administration:

- identify appropriate vascular access site for the cytotoxic drug used
- identify drugs which are vesicants and those which are irritants
- principles of safe handling and administration of intrathecal cytotoxic drugs:
  - identify cytotoxic drugs which can be safely administered by intrathecal route
  - calculate intrathecal drug doses
  - identify risks associated with accidental intrathecal administration of vinca alkaloids
  - identify strategies to reduce risk of accidental intrathecal administration of vinca alkaloids, including transport, packaging, labelling, checking and administration
- safe procedures for the emergency cessation of cytotoxic drug administration (e.g. adverse reaction), demonstrate systematic approach to the containment of cytotoxic drugs during emergency cessation
- management of extravasation—identify critical steps for the management of extravasation
- packaging requirements when transporting cytotoxic drugs within the treatment unit:
  - principles of package containment for cytotoxic drug transport within the treatment unit
  - transport requirements following the addition of needles to prepared syringes.
- 3.3 PPE requirements—function and use of PPE—demonstrate appropriate use of PPE:
  - selection
  - putting on
  - concurrent use
  - cleaning, laundry and disposal of used PPE.
- 3.4 Safe disposal methods for cytotoxic agents and equipment involved in administration:
  - principles of waste containment and segregation as applied to cytotoxic drugs
  - appropriate containers required for cytotoxic waste disposal
  - understand the principles of waste containment and procedures for the disposal of cytotoxic sharps
  - procedure for disposal of related cytotoxic drug administration equipment
  - safe disposal procedure of PPE.
- 3.5 Incidents and spill management:
  - management of cytotoxic drug spills:
    - warning and notification requirements for cytotoxic drug spill management:
      - isolation and warning procedures
      - remedial action in the event of a spill
      - procedure for requesting assistance
    - PPE requirements for cytotoxic drug spill management
    - principles and procedures for cytotoxic drug spill management:
      - equipment necessary to contain the cytotoxic spill
      - decontamination solutions or substances for cytotoxic containment
      - effective use of cytotoxic spill equipment and decontaminants
      - containment and disposal of cytotoxic drug spill materials
    - action required when an unprotected exposure to workers occurs (e.g. topical, mucous membrane, or penetrating injury exposure), identify the appropriate health assessment required in response to unprotected exposure
    - post-spill procedures:
      - reporting procedures
      - health assessment and follow-up.
- 3.6 Patient education requirements and ethical considerations.
- 3.7 Patient handling:
  - management of contaminated body substances from patients undergoing and following cytotoxic drug therapy:
    - major pathways of body excretion of unchanged cytotoxic drugs or active drug metabolites
    - protective period for safe handling of cytotoxic drug body substances:

- standard excretion times (up to seven days)
  - drugs which are excreted over prolonged periods (see appendix 3)
  - factors which may delay excretion
  - procedures for safe handling of body substances and soiled materials used for patient care:
    - use of PPE
    - procedures for containment and disposal
    - special safety precautions associated with contaminated waste material from catheters, peritoneal dialysis and colostomies.
- 3.8 Management in the community.
- 3.9 Record keeping.
- 3.10 Storage and packaging requirements (for transportation and handling).

## Appendix 8 – Guidelines for health monitoring for cytotoxic drugs

<b>1. Pre-employment and baseline health monitoring before a person commences work with cytotoxic drugs</b>	
1. Collection of demographic data	<ul style="list-style-type: none"> <li>• name and unique company identification number, date of birth, gender</li> <li>• address</li> <li>• date commencing employment</li> <li>• descriptive job title—to include the Australian Bureau of Statistics Australian/New Zealand Standard Classification of Occupations (ANZSCO) and Australian Standard/New Zealand Industrial Classification (ANZSIC).</li> </ul>
2. Occupational history	<ul style="list-style-type: none"> <li>• places and duration of previous employment, including work with cytotoxic drugs</li> <li>• potential current exposure</li> <li>• whether suitable control measures are in place for handling cytotoxic drugs.</li> </ul>
3. Medical history	<ul style="list-style-type: none"> <li>• presence of symptoms</li> <li>• general health</li> <li>• smoking history</li> <li>• personal history of cancer, 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>• whether the worker is taking immuno-suppressive therapy</li> <li>• whether the worker is pregnant or breast-feeding.</li> </ul>
4. Physical examination	<ul style="list-style-type: none"> <li>• general physical examination.</li> </ul>
5. Investigation	<ul style="list-style-type: none"> <li>• no diagnostic test is recommended at time of publication as none 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 appointed medical practitioner should focus on the risk factors outlined in the occupational history, and the outcome of the physical examination</li> <li>• the appointed medical practitioner should perform any investigations that may be appropriate as a result of the examination.</li> </ul>
6. Health advice and counselling	<p>The appointed medical practitioner should provide medical advice and counselling to the worker, including:</p> <ul style="list-style-type: none"> <li>• the potential health effects associated with exposure to cytotoxic drugs and related waste (including but not limited to carcinogens, mutagens and teratogens)</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 to workers planning parenthood, or those who are breastfeeding or pregnant.</li> </ul>

7. Report	<ul style="list-style-type: none"> <li>the appointed medical practitioner should provide a report to the PCBU and prospective worker advising that the worker has received assessment and health advice</li> <li>confidentiality of medical records is to be maintained. Access to medical records is to be only by written consent of the worker concerned.</li> </ul>
<b>2. During the period a person works with cytotoxic drugs</b>	
8. Data for inclusion in health records	<ul style="list-style-type: none"> <li>any risk assessments carried out at the workplace</li> <li>descriptive job titles, with relevant start and finish dates. Jobs within areas where cytotoxic drugs and related waste are used should be clearly identified</li> <li>results of workplace monitoring such as wipe tests or performance testing of control measures</li> <li>results of the investigation of spills and exposure events.</li> </ul>
9. Health advice and counselling	As described in point 6, advice and counselling should be offered by the PCBU annually and may be initiated at any time by the worker.
10. Medical review	<ul style="list-style-type: none"> <li>conduct a medical review as soon as possible in the following situations: <ul style="list-style-type: none"> <li>after a reportable spill or penetrating injury occurs</li> <li>if a worker advises she is pregnant, or is breastfeeding</li> <li>if a worker advises they are planning parenthood</li> </ul> </li> <li>the review should take account of the previous medical examination and include health advice and counselling and a written report</li> <li>a follow-up review should be conducted after one month.</li> </ul>
11. Control measures	Monitor the availability, type, maintenance and frequency-of-use of control measures (e.g. needleless injection sets should be in place to eliminate the potential for penetrating injuries).
<b>3. On termination of employment where the cytotoxic drugs and related wastes are used</b>	
12. Data to be collected	<p>The following data should be collected:</p> <ul style="list-style-type: none"> <li>date of termination</li> <li>reason for termination—ill-health (provide details) or other reasons (state reason)</li> <li>date and cause of death if in service.</li> </ul>
13. Final medical examination	<p>Conduct a medical examination including the factors already described, including:</p> <ul style="list-style-type: none"> <li>medical history</li> <li>physical examination</li> <li>investigation</li> <li>health advice and counselling.</li> </ul> <p>Provide a report to the worker. Medical reports regarding individual workers are to be provided to the PCBU only with the worker's written consent. However aggregated data may be provided to the PCBU for the purposes of analysis and review.</p>
14. Statement of exposure	A written statement of exposure must be given to workers who used, handled or stored cyclophosphamide in a hospital or oncological treatment facility that is authorised under the WHS Regulation at the end of their employment.

## Appendix 9 – Excretion times of some cytotoxic drugs

The following table lists cytotoxic drugs which are present in urine and faeces for more than 48 hours.

Drug	Time present after administration	
	Urine	Faeces
Amsacrine	3 days	2 days
Bleomycin	3 days	
Carmustine	4 days	
Cisplatin	7 days	
Cladribine	3 days	
Cyclophosphamide	3 days	5 days
Dactinomycin	5 days	
Daunorubicin	7 days	7 days
Doxorubicin	6 days	7 days
Doxorubicin liposomal	5 days	7 days
Epirubicin	3 days	
Etoposide	3 days	5 days
Etoposide phosphate	5 days	
Fludarabine	3 days	
5-Fluorouracil	2 days	5 days
Gemcitabine	7 days	
Idarubicin	3 days	2 days
Melphalan	2 days	7 days
Mercaptopurine	2 days	5 days
Methotrexate	3 days	7 days
Mitozantrone	6 days	7 days
Nimustine	4 days	
Oxaliplatin	3 days	
Procarbazine	3 days	
Raltitrexed	8 days	
Streptozocin	3 days	
Teniposide	3 days	
Thiotepa	3 days	
Vinblastine	4 days	7 days
Vindesine	4 days	4 days
Vincristine	4 days	7 days
Vinorelbine	4 days	7 days

### References

Eitel A., Scherrer M. & Kummerer K. 1999. Handling cytostatic drugs – A practical guide.

Micromedex Drug Database, 2004.

Polovich, M (ed). 2003. Safe handling of hazardous drugs, Oncology Nursing Society, Pittsburgh, PA.

Wilkes, G.M., Ingwersen, K. & Burke, M.B. 2004. Oncology nursing drug handbook, Jones and Bartlett Publishers.

## Appendix 10 – Further information

### Australian Standards

- AS/NZS ISO 14644.5:2006 - Cleanrooms and associated controlled environments - Operations
- AS/NZS 1715:2009 - Selection, use and maintenance of respiratory protective equipment
- AS/NZS 1716:2012 - Respiratory protective devices
- AS 1807.0:2000 - Cleanrooms, workstations, safety cabinets and pharmaceutical isolators - Methods of test - List of methods and apparatus
- AS 2567:2002 - Laminar flow cytotoxic drug safety cabinets
- AS 2639:1994 - Laminar flow cytotoxic drug safety cabinets - Installation and use
- AS 4273:1999 - Design, installation and use of pharmaceutical isolators
- AS 4031:1992 - Non-reusable containers for the collection of sharp medical items used in health care areas.

### Safe Work Australia

- [Hazardous Chemical Information System](#) (HCIS) Use this database to check for the most current exposure standard information
- [Adopted National Exposure Standards For Atmospheric Contaminants In The Occupational Environment](#) [NOHSC: 1003 (1995)]
- [Guidance on the Interpretation of Workplace Exposure Standards for Airborne Contaminants](#) 2013
- [Health Monitoring for Exposure to Hazardous Chemicals Guide for Persons Conducting a Business or Undertaking](#) 2013
- [Hazardous Chemicals Requiring Health Monitoring Guide](#) 2013
- [Interpretive Guideline - model Work Health and Safety Act - the meaning of 'reasonably practicable'](#) 2011

### Further reading

Blecher C. S., Glynn-Tucker E. M., McDiarmid M. & Newton S. A. 2003. Safe handling of hazardous substances. Oncology Nursing Society, USA.

NIOSH Alert: Preventing occupational exposures to antineoplastic and other hazardous drugs in healthcare settings. 2004. DHHS (NIOSH) Publication Number 2004-165(2004).  
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U.S. Department of Labor. OSHA Technical manual (TED 01-00-015 [TED 1-0.15A]): Section VI: Chapter 2: Controlling occupational exposure to hazardous drugs.  
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Worksafe Victoria. 2003. Handling cytotoxic drugs in the workplace.  
[worksafe.vic.gov.au/forms-and-publications/forms-and-publications/handling-cytotoxic-drugs-in-the-workplace](http://worksafe.vic.gov.au/forms-and-publications/forms-and-publications/handling-cytotoxic-drugs-in-the-workplace)

SA Health. 2012. Safe handling of cytotoxic drugs and related wastes: Guidelines for South Australian Health Services 2012.  
[sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+topics/medicines+and+drugs/hazardous+drugs](http://sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/clinical+topics/medicines+and+drugs/hazardous+drugs)

Commonwealth Standard for the Uniform Scheduling of Drugs and Poisons - Part 2 SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments – SHPA Committee of Specialty Practice in Oncology.

Oncology Nursing Society. 2003. Safe handling of hazardous drugs.



**Useful websites**

- Queensland legislation – [legislation.qld.gov.au](http://legislation.qld.gov.au)
- Office of Industrial Relations – [worksafe.qld.gov.au](http://worksafe.qld.gov.au)
- Queensland Health – [health.qld.gov.au](http://health.qld.gov.au)
- Department of Environment and Heritage Protection – [ehp.qld.gov.au](http://ehp.qld.gov.au)
- Queensland Transport and Main Roads – [tmr.qld.gov.au](http://tmr.qld.gov.au)
- International Maritime Organization - [imo.org](http://imo.org)
- Australian Department of Infrastructure and Regional Development - [infrastructure.gov.au/transport/australia/dangerous/](http://infrastructure.gov.au/transport/australia/dangerous/)
- International Civil Aviation Organization - [icao.int](http://icao.int)
- Safe Work Australia - [safeworkaustralia.gov.au](http://safeworkaustralia.gov.au)