

Queensland Workplace Health and Safety Strategy

Guide for handling cytotoxic drugs and related waste

Think Safe – **Work Smart**

Queensland **the Smart State**



Contents

| | | |
|-------------|------------------------------------------------------|-----|
| Chapter 1 | Introduction | 2 |
| Chapter 2 | Legal requirements | 6 |
| Chapter 3 | Managing the risks | 14 |
| Chapter 4 | Training | 22 |
| Chapter 5 | Personal protective equipment (PPE) | 25 |
| Chapter 6 | Personnel management | 35 |
| Chapter 7 | Drug preparation | 42 |
| Chapter 8 | Drug administration | 50 |
| Chapter 9 | Risk management in healthcare facilities | 55 |
| Chapter 10 | Risk management in community settings | 58 |
| Chapter 11 | Cytotoxic contaminated laundry | 66 |
| Chapter 12 | Spill management | 70 |
| Chapter 13 | Waste management | 74 |
| Chapter 14 | Drug administration in veterinary practice | 80 |
| | | |
| Appendix 1 | Glossary of terms | 85 |
| Appendix 2 | Commonly used Cytotoxic drugs | 92 |
| Appendix 3 | Legislation | 94 |
| Appendix 4 | Sample Cytotoxic drugs register | 95 |
| Appendix 5 | Sample risk assessment of hazardous substances | 96 |
| Appendix 6 | Sample audit checklist | 99 |
| Appendix 7 | Training modules for working with Cytotoxic drugs | 105 |
| Appendix 8 | Guidelines for health monitoring for Cytotoxic drugs | 109 |
| Appendix 9 | Excretion times of some Cytotoxic drugs | 111 |
| Appendix 10 | Full list of standard operating procedures | 112 |
| Appendix 11 | Further information | 119 |

Disclaimer

The information provided in this publication is distributed by the Queensland Government as an information source only. The information is provided solely on the basis that readers will be responsible for making their own assessment of the matters discussed herein and are advised to verify all relevant representations, statements and information.

For specific information on matters discussed in this publication please refer to the *Workplace Health and Safety Act 1995*.

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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 to protect workers 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 employers and others who have obligations 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 *Workplace Health and Safety Act 1995* (the WHS Act) imposes obligations on people at the workplace to ensure that workers and others are not exposed to risks to their health and safety. Obligation holders include employers, self-employed people and people conducting a business or undertaking. Ensuring workplace health and safety involves identifying and managing exposure to the risks at a workplace. Chapter 2 deals with the applicable legislation in detail.

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

Exposure standards* for acceptable levels of exposure of workers do not exist for pharmaceutical products as they do for other hazardous substances, therefore control measures must be implemented to reduce exposure to levels ‘as low as reasonably achievable’ (ALARA).

Research has shown that good work practices and properly implemented control measures significantly reduce exposure, and, consequently, the risks of adverse health effects. However, if compliance with control measures is inadequate, then exposure is more likely to occur, and the health and safety of workers cannot be ensured.

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 that 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, and a full list of all general and chapter specific SOPs appears in appendix 10.

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 that 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 that complies with company and government regulations

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

- 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 written or rewritten when new information suggests benefits from modifying work behaviours to improve performance.

Workers should receive information, instruction and training as determined by the risk assessment to implement standard operating procedures.

Section 33(1) of the *Health Regulation* 1996 specifies that written policies and standard operating procedures 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. Employers and others have obligations to ensure workers and others are not exposed to risks to their health and safety. 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 regulating agency.

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

- *Workplace Health and Safety Act 1995*
- *Workplace Health and Safety Regulation 1997*
- *Dangerous Goods Safety Management Act 2001*
- *Dangerous Goods Safety Management Regulation 2001*
- *Health Act 1937*
- *Health Regulation 1996*
- *Health (Drugs and Poisons) Regulation 1996*
- *Environmental Protection Act 1994*
- *Environmental Protection (Waste Management) Regulation 2000*
- *Transport Operation (Road Use Management) Act 1998*
- *Transport Operation (Road Use Management) Regulation 1998*

Other references include:

- *WHS Hazardous Substances Advisory Standard (Code of Practice) 2003*
- *WHS Risk Management Advisory Standard (Code of Practice) 2000*
- *Standard for the Uniform Scheduling of Drugs and Poisons*
- Australian Standards

2.1 Legislative provisions relating to handling cytotoxic drugs and related waste

This guide is designed to assist employers, self-employed people and workers to comply with the provisions of the *Workplace Health and Safety Act 1995*, and the *Workplace Health and Safety Regulation 1997* 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 and contractors are also considered. This guide does not necessarily deal with patient care, except in the context of workplace health and safety.

Legislative provisions are cited where appropriate throughout this guide. The abbreviation '[s.]' is used to denote the relevant section, and refers to the WHS legislation unless otherwise stated.

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 that the guide be read in conjunction with the legislation and other standards referenced.

Workplace health and safety legislation mainly comprises the *Workplace Health and Safety Act 1995* and the *Workplace Health and Safety Regulation 1997*. Appendix 3 lists all relevant Acts and Regulations that impact on the management and use of cytotoxic drugs and related waste.

2.2 The Workplace Health and Safety Act 1995

The objective of the *Workplace Health and Safety Act* (the WHS Act) is to prevent a person's death, injury or illness being caused by a workplace, by a relevant workplace area, by work activities, or by plant or substances for use at a workplace [s.7]. This is achieved by minimising exposure to risk through establishing a framework which imposes workplace health and safety obligations on certain people, such as employers, self-employed people and workers.

2.2.1 Workplace health and safety obligations

The following people have obligations under the WHS Act:

- people conducting a business or undertaking; including employers & self employed people
- people in control of workplaces
- manufacturers and suppliers of substances for use at workplaces (e.g. cytotoxic drugs)
- workers.

People may owe obligations in more than one capacity. For example, a hospital owes obligations as an employer to the workers it employs, and also owes obligations as a person conducting a business or undertaking to people who perform work activities on its behalf (e.g. contract cleaners). See section 2.5 for specific details of obligations.

2.2.2 How workplace health and safety obligations can be discharged

Workplace health and safety can generally be managed by following the risk management process [s.27A(1)]. People who have workplace health and safety obligations can meet those obligations by following the relevant provisions of the WHS Act, Regulation, ministerial notices and codes of practice. Penalties apply for breaches.

Obligations may be fulfilled in many other ways, and may include one or more of the following [s.29]:

- providing and maintaining a safe and healthy work environment
- providing and maintaining safe plant and equipment
- ensuring the safe use, handling, storage and transport of substances
- ensuring safe systems of work
- providing information, instruction, training and supervision to ensure health and safety.

2.2.3 Workplace consultative arrangements

Part 7 of the WHS Act provides for a process under which employers and workers identify and resolve workplace health and safety issues through workplace health and safety representatives and committees. If there are 30 or more workers normally employed at the workplace, an employer must appoint a suitably qualified person as a workplace health and safety officer (WHSO). Part 8 of the WHS Act provides for the appointment of workplace health and safety officers (WHSOs) by an employer to assist them to fulfil their obligations.

The role of the workplace health and safety officer

Sections 96 and 96A of the WHS Act state that the functions of a WHSO include:

- telling the employer about the overall state of health and safety at the workplace
- conducting inspections and assessments at the workplace to identify any hazards and unsafe or unsatisfactory workplace health and safety conditions and practices
- working with the workplace health and safety committee, if established, to determine the workplace health and safety assessment criteria and the specified intervals for assessment
- recording actions the WHSO recommends be taken to rectify hazards, and unsafe or unsatisfactory workplace health and safety conditions and practices

- providing an assessment report to the employer and to the workplace health and safety committee
- reporting any workplace incident or immediate risk to the employer
- investigating or assisting in the investigation of all workplace incidents at the workplace
- establishing appropriate educational programs in workplace health and safety.

2.2.4 Obligations in relation to plant and equipment and substances

As well as the general obligation to ensure workplace health and safety, there are specific obligations with respect to plant. The WHS Act defines plant broadly as including machinery, equipment, appliances, pressure vessels (e.g. autoclaves), 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.

Obligation holders include employers, self-employed people, people conducting a business or undertaking, people in control of workplaces, designers, manufacturers, suppliers, owners and installers of plant [ss.28-33 and 35]. Obligations with respect to plant are stated in the WHS Act and include:

- providing and maintaining safe plant [s.29]
- ensuring that the risk of injury or illness from any plant is minimised when used properly [s.30]
- ensuring that plant is designed and manufactured to be safe when used properly [ss. 32, 33]
- examining and testing of plant to ensure it is safe [ss.32, 32B].

Safe use of substances is also covered, with obligations on manufacturers and suppliers to ensure that substances are safe when used properly, and are accompanied by relevant information [ss.34,34A].

Manufacturers and suppliers of cytotoxic drugs must comply with these requirements.

2.2.5 Notification of incidents

Workplace Health and Safety Queensland must be notified in the approved form of an incident resulting in a person suffering a work injury that is a serious bodily injury or a work caused illness, or of a dangerous event occurring in a workplace. These terms are fully defined in schedule 3 of the WHS Act. Work includes a workplace, a work activity or plant or substances for use at a workplace.

Work injury includes:

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

Serious bodily injury includes an injury to a person that causes their death or the loss of a distinct part or organ of their body, or causes them to be absent from their employment for more than four days.

Work caused illness includes an illness contracted by a person to which work was a significant contributing factor, or the recurrence, aggravation, acceleration, exacerbation or deterioration in a person of an existing illness, if work was a significant contributing factor.

A dangerous event includes an event caused by specified high risk plant, or an event at a workplace or relevant workplace area, if the event involved or could have involved exposure of people to risk

to their health and safety because of, for example, implosion, explosion or fire, or escape, spillage or leakage of any hazardous material or dangerous goods.

2.3 Workplace Health and Safety Regulation 1997

The *Workplace Health and Safety Regulation 1997* (WHS Regulation) deals with specific hazards or workplace health and safety issues.

2.3.1 Hazardous substances regulations

Cytotoxic drugs meet the Australian Safety and Compensation Council's* approved criteria for classifying hazardous substances because of the carcinogenic, mutagenic and teratogenic risk they pose to healthcare workers, and they are therefore hazardous substances. Their use must comply with the requirements of part 13 of the WHS Regulation. This part contains a number of provisions relating to material safety data sheets, labelling, risk assessments, health surveillance and records. Reference to the full text of the WHS Regulation is required to ensure that employers and other obligation holders comply with the requirements, although specific sections are referenced throughout this document as appropriate.

2.3.2 Plant registration and plant design registration

Certain plant (e.g. autoclaves of a specific capacity) may require registration or plant design registration under part 2, and schedules 3 and 4, of the WHS Regulation.

2.4 Codes of practice

A code of practice is a publication that contains detailed information on managing exposure to a risk. An obligation holder may discharge their workplace health and safety obligation by adopting the code of practice, or by adopting another way to manage the risk that gives the same level of protection against the risk.

Workplace Health and Safety Queensland has a number of codes of practice relevant to managing the risk of exposure to cytotoxic drugs and related waste:

- *Hazardous Substances Advisory Standard 2003*** sets out ways to manage risks from exposure to hazardous substances in a workplace.
- *Risk Management Advisory Standard 2000* is a generic risk management document which describes the five-step process for managing exposure to health and safety risks. There are two supplements: *Supplement No.1 - Personal Protective Equipment* and *Supplement No.2 - Training*.
- *First Aid Advisory Standard 2004* provides practical advice about the selection, provision, maintenance and use of first aid facilities and services at a workplace.
- *Manual Tasks Advisory Standard 2000* states ways to prevent or minimise exposure to risk factors that can contribute to or aggravate work-related musculoskeletal disorders.
- *Plant Code of Practice 2005* gives practical advice on ways to manage exposure to risks related to the use of plant, including its safe design, manufacture and installation. It outlines the obligations of people involved with plant, and provides information on risks and their control.

*Formerly National Occupational Health and Safety Commission

**From 1 January 2005, all advisory standards and industry codes of practice are known as codes of practice. The expiry date has been extended to ten years from their date of making. Their legal status is unchanged. Titles will gradually be amended as the publications are reviewed.

2.5 Obligations under the *Workplace Health and Safety Act 1995*

A number of people owe obligations under the WHS Act, including employers, self-employed people, manufacturers, suppliers, workers and people conducting a business or undertaking. Further reference will be made to these obligations in relevant sections of this guide.

2.5.1 Obligations of persons conducting a business or undertaking

Under part 3 of the WHS Act, certain persons have an obligation to ensure that workers and others (e.g. patients, visitors, contractors, community care workers) are not exposed to risks to their health and safety.

A number of specific obligations are also required under part 13 of the WHS Regulation. These include:

- making an assessment of the risk to the health of people in a workplace from a hazardous substance and recording certain information about the risk assessment [ss.105-106]
- controlling exposure by preventing or reducing the exposure [s.107]
- obtaining, recording and displaying material safety data sheets (MSDSs) [ss.101, 102]
- labelling containers [s.103]
- providing monitoring and health surveillance of workers [ss.108, 109]
- maintaining confidentiality of workers' medical records [s.110]
- maintaining registers and records as prescribed [ss.111, 112]
- inducting and training workers about hazardous substances, and keeping records with certain information about training [s.113].

2.5.2 Obligations of manufacturers

Under the WHS Act, the manufacturer of plant and substances used at a workplace has an obligation to ensure that the plant and substances are manufactured, tested and examined to ensure they are safe and without risk to health when used properly [ss.32A, 34]. Information must be provided about the plant or substance, or about the way the plant or substance must be used to ensure health and safety. Manufacturers of cytotoxic drugs would be required to fulfil these obligations.

Under part 13, division 2 of the WHS Regulation, manufacturers have obligations including:

- preparing, amending, reviewing and providing MSDSs [ss.90, 91]
- notifying use of generic names of certain ingredients and disclosing an ingredient's chemical name [ss.92, 93]
- providing a NICNAS* summary report and other information [s.94].

2.5.3 Obligations of suppliers

A supplier of plant and substances also has obligations with respect to health and safety [ss.32B, 34A]. Suppliers must either examine and test plant, or ensure that the manufacturer has done so, to ensure it is safe and without risk to health when used properly. The supplier must also provide information about safe use. Suppliers of substances must take all reasonable steps to ensure that the substance is safe and without risk to health when used properly, and to ensure that it is accompanied by relevant information. Under part 13 of the WHS Regulation, suppliers have obligations, including providing MSDSs and labelling containers [ss.97, 98].

*National Industrial Chemicals Notification and Assessment Scheme

2.5.4 Obligations of workers

Section 36 of the WHS Act requires workers to:

- cooperate with their employer by following instructions given for workplace health and safety
- use the personal protective equipment provided for the work being done
- behave in a way that does not endanger themselves or others in the workplace.

2.6 Other Queensland legislation

Other legislation important to specific areas includes the following.

2.6.1 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, PPE, air supply and exhaust systems).

The Health Regulation also requires that the packaging and labelling of controlled or restricted drugs comply with the Commonwealth *Standard for the Uniform Scheduling of Drugs and Poisons*. For more information on the labelling requirements of the standard, see section 7.1.3 of this guide.

For more information on Queensland Health requirements and supporting information, visit their website at www.health.qld.gov.au.

2.6.2 Environmental Protection Agency

The Environmental Protection Agency (EPA) administers the *Environmental Protection Act 1994*, the *Environmental Protection (Waste Management) Policy 2000* and the *Environmental Protection (Waste Management) Regulation 2000*, to coordinate and clarify waste management practices and to 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 Regulation and Policy. These requirements cover packaging, labelling, handling and transportation.

The legal provisions relating to cytotoxic waste management include:

Environmental Protection Act 1994:

- Section 319—a person must not undertake an activity that may cause environmental harm, unless that person has taken all reasonable precautions to prevent or minimise that harm.
- Section 369—a person cannot undertake waste management works (primarily waste transport, but also may involve storage) within a local government area without the approval of the local government.

Environmental Protection (Waste Management) Regulation 2000:

- Part 4 covers requirements for the management of clinical and related waste, including cytotoxic wastes. All cytotoxic waste must be disposed of into purple containers so that it can be easily identified and incinerated. A clinical and related waste management plan is to be prepared and implemented. The generator of the waste must also ensure that the person they give the waste to is licensed to transport and dispose of the waste.
- Part 5 requires all trackable waste to be tracked from point of generation to disposal. Cytotoxic waste is a trackable waste.
- Schedule 1 requires certain activities, many relating to the management of regulated wastes, to be licensed.

- Schedule 7 outlines the wastes that are categorised as regulated wastes. Cytotoxic waste is a regulated waste. In some cases, a healthcare facility may require a regulated waste transport licence, if transporting more than 250 kg per load or undertaking the activity for fee or reward.
- Schedule 8 must still be complied with in cases where a licence is not required. This schedule states the design requirements for waste transport vehicles.

The EPA requires that all cytotoxic waste be placed into compliant bags or containers that are appropriately identified, specifying the following colours and symbol coding:

- containers and bags must be purple—the EPA stipulates ‘Lilac P23’
- the container must have a white label with the symbol of a cell in telophase
- the correct labelling words are ‘Cytotoxic waste’.

In some cases, the *Integrated Planning Act 1997* may also apply, where a development approval is required or a material change of use is involved (e.g. if a facility proposes to treat waste on-site).

For more information on waste regulations and supporting information, visit the EPA website at www.epa.qld.gov.au, or contact one of the EPA offices.

2.6.3 Department of Emergency Services

The Department of Emergency Services (DES) administers the *Dangerous Goods Safety Management Act 2001* to protect the safety of people, and prevent harm to property and the environment, from hazardous materials. It establishes requirements for the safe storage and handling of dangerous goods and combustible liquids, and the safe operation of major hazard facilities. It also authorises the giving of advice and help in hazardous materials emergencies. This Act applies to everyone who, as a result of the storage or handling of hazardous materials at a place, may affect the safety of people or harm property or the environment. For more information on these issues, visit the DES website at www.emergency.qld.gov.au, or contact Workplace Health and Safety Queensland (details on the back of this publication).

2.6.4 Transport and storage of cytotoxic drugs or cytotoxic waste

Transport and storage issues are dealt with by a number of government agencies. Healthcare facilities that are 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*, (latest edition), Australian Department of Transport and Regional Services
- *Technical Instructions for the Safe Transport of Dangerous Goods by Air*, (2003–04 edition) International Civil Aviation Organization
- *International Maritime Dangerous Goods Code 2004*, International Maritime Organization.

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

- Queensland Transport – www.transport.qld.gov.au
- Department of Emergency Services – www.emergency.qld.gov.au
- Environmental Protection Authority – www.epa.qld.gov.au
- International Maritime Organization – www.imo.org
- Department of Transport and Regional Services – www.dotars.gov.au/transreg/dgoods.htm
- International Civil Aviation Organization – www.icao.int

2.7 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 EPA. The local council should therefore be contacted regarding handling, storage, disposal and transport of cytotoxic contaminated waste, to ascertain relevant requirements.

2.8 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 that procedure (e.g. new equipment, new legislation, new products)
- be documented and meet relevant record keeping requirements.

Chapter 3: Managing the 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 are exposed to cytotoxic drugs and related waste
- how cytotoxic drugs and related waste should be handled
- how exposures can be controlled.

3.1 Legislative requirements—the risk management process

Risk management is the process specified in the WHS Act (s.27A) as a way of ensuring workplace health and safety.

Part 13 of the WHS Regulation includes the following provisions relating to risk assessments:

- Section 105—an employer or self-employed person must assess the risk to the health of the employer, self-employed person or a worker from a hazardous substance that is used, or is to be used, at the workplace. The provision states when the assessment must be done and what it must include.
- Section 106—the employer or self-employed person must, as soon as practicable after doing an assessment, record certain information about the assessment.

The *Workplace Health and Safety Risk Management Advisory Standard 2000* is a generic risk management guide which describes the five-step process for managing exposure to health and safety risks that can arise from workplace hazards. This standard applies to all Queensland workplaces covered by the WHS Act.

The steps in the risk management process are:

1. identifying hazards
2. assessing risks that result because of the hazards
3. deciding on control measures to prevent, or minimise the level of, the risks
4. implementing control measures
5. monitoring and reviewing the effectiveness of the measures.

3.1.2 Deciding who will undertake the risk management process

If there are 30 or more workers normally employed at the workplace, an employer must appoint a suitably qualified person as a workplace health and safety officer (WHSO). One of the functions of the WHSO is to conduct inspections and assessments at the workplace to identify any hazards and unsafe or unsatisfactory workplace health and safety conditions and practices. A WHSO must record actions to be taken to rectify hazards, and unsafe or unsatisfactory workplace health and safety conditions and practices. An assessment report is to be provided to the employer and to the workplace health and safety committee, if established. For more information on the role of the WHSO, see section 2.2.3 of this guide.

In smaller workplaces, the risk management process is usually undertaken by an employer or manager, in cooperation with the workers. An external consultant or advisor may be engaged for certain steps, however, the responsibility for the accuracy of the assessment and the implementation of control measures is still held by the employer. The consultant should have sufficient knowledge and skills to evaluate the risks arising from the use of cytotoxic substances and to recommend appropriate, effective control measures.

Consultation with workers at each stage of the risk management process will help achieve better health and safety outcomes. Parts 7 and 8 of the WHS Act also provide for consultation through workplace health and safety representatives, workplace health and safety officers and workplace health and safety committees.

3.2 Step 1 - Hazard identification

A hazard is something that can cause harm. Cytotoxic drugs in themselves are hazards, and the way that they are handled can also be seen as a hazard. In identifying the hazards relating to the handling of cytotoxic drugs and related waste, the following issues 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).

Hazard identification may be assisted by:

- consulting with people who may potentially be exposed to cytotoxic drugs and related waste, including various workers, contractors, workplace health and safety officers, representatives and committees
- conducting a cytotoxic drug safety audit
- analysing incident records, industry safety data, scientific information and research
- using information provided by manufacturers and suppliers of equipment and cytotoxic drugs (e.g. MSDSs, safe use manuals, maintenance recommendations)
- undertaking environmental and medical monitoring.

3.2.1 Identify the cytotoxic drugs used

Cytotoxic drugs may be identified by referring to stock lists and to the registers of hazardous substances and MSDSs. All locations where there are cytotoxic drugs or related waste should also be identified.

See appendix 4 for a Sample Cytotoxic Drugs Register.

3.2.2 Obtain information about the drugs used

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.

Material safety data sheets

The material safety data sheet (MSDS) for each drug must be consulted when conducting the risk assessment. The WHS Regulation [s.97] requires suppliers to provide an MSDS for all cytotoxic drugs supplied to the employer when first supplying the substance, and on request from the employer, worker or worker's representative. MSDSs are an important source of information about a substance, because they provide full details of the properties and hazards associated with it. They provide information about identification of the substance, health hazards, and precautions for use and safe handling.

Scientific studies and research papers

It is recommended that employers and self-employed people keep abreast of the latest findings with respect to risks associated with cytotoxic drugs and related waste. Issues include new drugs, exposure rates, the health risks of exposure and the latest in health surveillance and monitoring. This information can be incorporated into the risk assessment.

3.2.3 Inspect the workplace

Identify the tasks which may expose workers to cytotoxic drugs and related waste. Tasks include:

- cytotoxic drug preparation
- cytotoxic drug administration in healthcare facilities and in community settings
- 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).

Identify 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.

Identify the characteristics of an exposure:

- frequency and duration
- volume of cytotoxic drug or cytotoxic contaminated waste
- the number of workers and others who may be exposed.

Identify the control measures currently in place and determine whether:

- workers and others have received information or 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.

Identify hazards associated with storage and transport of cytotoxic drugs and related waste with respect to:

- 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.

3.2.4 Determine the people who may be exposed

The greatest risk of occupational exposure to cytotoxic drugs is during their preparation and administration. Other aspects of patient care such as spill and waste management also pose a risk of occupational exposure.

The risk assessment should consider the range of workers and others who may be at risk from exposure to cytotoxic drugs and related waste. These may include:

- nurses and medical officers
- contract workers
- ambulance officers
- biomedical technicians
- pharmacy workers
- pharmaceutical workers
- laboratory workers
- research 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
- mortuary/funeral home workers
- laundry workers
- administrative workers
- workers responsible for ordering or purchasing cytotoxic equipment, PPE, etc.
- planners/designers/schedulers of work/workplaces
- delivery workers
- couriers and porters
- allied health workers.

In addition to the above workers, the following people may also be exposed and should be considered in identifying hazards:

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

3.3 Step 2 - Risk assessment

3.3.1 When the risk assessment is to be done

The WHS Regulation [s.105] requires that a cytotoxic drugs and related waste risk assessment be done as soon as practicable after it is used*; and:

- within five years after the last assessment
- when a work practice involving cytotoxic drugs and related waste is changed
- when new information is available about the cytotoxic substance's hazards
- if health surveillance shows control measures need to be reviewed
- when new or improved control measures are implemented.

For more information on the risk management process, please refer to the *Hazardous Substances Advisory Standard 2003* or the *Risk Management Advisory Standard 2000*.

3.3.2 What the risk assessment must include

It is a requirement of the WHS Regulation [s.105(3)] that this risk assessment must include:

- an identification of the hazardous substance
- if the substance's MSDS is available, a review of the MSDS
- if the substance's MSDS is not available, a review of available equivalent information
- if the substance is contained in a consumer package, a review of the package's label
- a decision whether any workers may be exposed to the substance
- a decision about the control measures, health surveillance and monitoring needed for the substance.

*Note that 'use' includes administration, preparation, handling, storage, movement and disposal of cytotoxic drugs and related waste.

This assessment may be a generic assessment prepared for workplaces where the particular substance is used in the same or similar circumstances.

See appendix 5 for a Sample Risk Assessment of Hazardous Substances.

3.3.3 Assessing the risk and determining likelihood and consequences

This part of a risk assessment results in a prioritised list of risks for further action. The following method is detailed in the *Risk Management Advisory Standard 2000*, although other methods may be used to develop the priority list.

For each risk identified, and bearing in mind existing control measures:

- determine the *likelihood* of an incident occurring at your workplace:
 - very likely - could happen frequently
 - likely - could happen occasionally
 - unlikely - could happen, but rarely
 - very unlikely - could happen, but probably never will.
- determine the consequences of an incident occurring at your workplace:
 - extreme - death or permanent disablement
 - major - serious bodily injury or serious work caused illness
 - moderate - moderate injury or illness requiring casualty treatment
 - minor - minor injury or illness requiring first aid only, no lost work time.
- combine the likelihood and consequence estimates in a risk priority chart by assigning a risk score. While the risk scores have no absolute value, this method gives a basis for ranking risks in terms of their priority for action. The scores (1-7) in the risk priority chart indicate how important it is to do something about each risk, as indicated.

| Likelihood | Consequences | | | | Score | Action |
|---------------|--------------|-------|----------|-------|---------|--------------------------------------|
| | Extreme | Major | Moderate | Minor | | |
| Very likely | 1 | 2 | 3 | 4 | 1, 2, 3 | Immediate action |
| Likely | 2 | 3 | 4 | 5 | 4 or 5 | Take action as soon as possible |
| Unlikely | 3 | 4 | 5 | 6 | 6 or 7 | Immediate action may not be required |
| Very unlikely | 4 | 5 | 6 | 7 | | |

3.3.4 Prioritise the risks

The final stage of risk assessment is to prioritise the identified risks based on their risk score. The risks rated 1, 2 or 3 should be listed first, as they require immediate action. If immediate action cannot be taken to control these risks, then interim measures must be considered to manage exposures. Risks rated 4 or 5 are listed and addressed next, followed by the risks rated 6 or 7.

3.4 Step 3 - Controlling the risks

It is a legislative requirement that if the risk assessment shows that exposure to cytotoxic drugs and related waste may occur, the employer, self-employed person or worker must prevent such exposure, or, if prevention is not practicable, reduce the exposure to as low a level as is practicable [WHS Reg: s.107]. Employers must implement the control measures as soon as practicable, and ensure they are effectively maintained.

The priority list developed during the risk assessment should be used to determine which risks are controlled first. The risk assessment may also have identified some options for control measures.

When considering measures to control exposure, all the possible routes of exposure and routes of entry to the body should be taken into account (see section 3.2.3 above).

3.4.1 Control measures – hierarchy of control

Control measures are usually implemented in a priority order called a hierarchy of control. Firstly, try to eliminate the hazard. Then, if elimination isn't possible, exposure to the risk should be prevented or minimised. For example, the elimination of cytotoxic drugs is not an option; however the elimination of certain activities is an option. Exposure to cytotoxic drugs and related waste may be prevented or minimised by one or more of the following:

- *substituting* a less hazardous material, process or equipment
- *redesigning* equipment or work processes
- *isolating* the hazard.

Lastly, if these measures are impractical or only partially effective, other means such as administrative controls and personal protective equipment (PPE) must be considered.

3.4.2 Control measures to reduce exposure to cytotoxic drugs and related waste

Elimination involves eliminating the hazard. 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 can be used instead of needles.

Isolation techniques use barriers to prevent exposure, for example, a 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 that 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

that 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.

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 2.6 and 7.1.3.

Purple is the recognised colour denoting the presence of cytotoxic substances or waste, and should be stipulated when purchasing items such as sharps and waste containers, plastic bags and laundry bags, and when printing labels or warning stickers. The easily identifiable purple symbol, 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.

Legal requirements must be followed when labelling:

- 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.

Personal protective equipment (PPE) is a primary consideration in managing exposure to cytotoxic drugs and related waste. However 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, and the PPE recommended for particular tasks involving cytotoxic drugs and related waste, are discussed in chapter 5.

3.5 Step 4 - Implementing control measures

Once appropriate control measures have been selected, they must be put into effect in the workplace. Implementation involves:

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

3.6 Step 5 - Monitor and review of control measures

Once introduced, control measures should be examined at regular intervals to ensure their continuing effectiveness. Questions to be asked include:

- Have chosen control measures been implemented as planned?
- Are chosen control measures working?
- Are there any new problems?

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 objective of maintenance is to ensure that any defects, which could result in a loss of efficiency and reduced level of protection of the control measures, are detected and remedied.

See appendix 6 for a Sample Audit Checklist.

3.7 Risk assessment records

It is a legislative requirement [WHS Reg: s.106] that the employer or self-employed person must, as soon as practicable after doing an assessment, record the following information:

- the date when the assessment was done
- whether the degree of risk is assessed to be significant
- the substance's product name or other information
- the control measures for use of the substance that were in place when the assessment was done
- the type of monitoring that is needed and the intervals at which the monitoring must be done
- the type of health surveillance needed and the intervals at which health surveillance must be done.

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, implementing control measures and monitoring and reviewing control measures
- legislative requirements regarding timing and content of risk assessments
- a specific person or position assigned 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
- risk assessment and prioritisation
- control measures selected according to the hierarchy of control
- implementation of control measures
- appropriate checklists and templates developed to support the process
- 'Monitor and review' 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, MSDSs 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 that procedure (e.g. new equipment, new legislation, new products).

Chapter 4: Training

Employers are required to give workers who may be exposed to cytotoxic drugs induction and ongoing training about the substance. Therefore employers must ensure that only those workers who have received appropriate training and instruction carry out work involving cytotoxic drugs and related waste.

4.1 Legislative requirements

Section 113 of the WHS Regulation requires employers to:

- give a worker who may be exposed to hazardous substances (in this case cytotoxic drugs and related waste) induction and ongoing training about the substance, having regard to the level of risk identified in the risk assessment and the workers who may be exposed to the substance
- keep a record of the induction and training for five years (see section 4.3 below).

4.2 Applying the risk management process to training

The risk assessment identifies who is at risk, the tasks that they perform and the routes and characteristics of exposure. Appropriate control measures are selected and the ways of implementing these control measures are considered. This information should 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 that training be undertaken:

- at time 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
- on an annual basis after initial training.

The risk assessment should also be used to determine whether special training programs should be provided to cater for workers who may not be proficient in English, or whether literacy levels should also be considered when deciding on the training delivery mode.

4.2.1 Identify who should be trained

The results of the risk assessment should be used to identify who must or should be trained. The level of training or information required 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) | • laundry workers |
| • contract workers | • maintenance workers | • administrative workers |
| • ambulance officers | • stores and warehouse workers | • workers responsible for ordering or purchasing cytotoxic equipment, PPE, etc. |
| • biomedical technicians | • emergency response workers (e.g. fire wardens, emergency control officers) | • planners/designers/schedulers of work/workplaces |
| • pharmacy workers | • cleaning workers | • delivery workers |
| • pharmaceutical workers | • mortuary/funeral home workers | • couriers and porters |
| • laboratory workers | | • allied health workers |
| • research workers | | |
| • veterinarians and veterinary nurses | | |
| • community care workers | | |

In addition to these 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 that 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.

4.2.2 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 the 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 and information in relation to cytotoxic drugs and related waste should cover at least:

- 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.

4.2.3 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 clinical setting, 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. This should be done each time there is a change in a work practice or a control measure, or at intervals of no greater than one year.

4.3 Records

Hazardous substances training records must be kept [WHS Reg: s.113]. Records must state:

- 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.

4.4 Validation

Employers 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 bona fides of the issuing agency should also be confirmed.

Under section 113 of the WHS Regulation, an employer must give induction and ongoing training about cytotoxic drugs to a worker who may be exposed to these substances at the workplace.

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 before recruitment
- training records management system.

In addition, these SOPs should:

- be developed in consultation with workers
- be developed with regard to manufacturers instructions, MSDSs 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) is defined as any clothing, equipment and substance designed to be worn by a person to protect the person from the risks of injury or illness. Examples of PPE include gowns, respiratory protective equipment and safety glasses.

The use of personal protective equipment is lowest on the list of control priorities in the risk management process (see chapter 3.) Higher level control options (e.g. engineering, substitution) should be fully investigated before PPE is chosen as the primary means of risk control.

5.1 Legislative requirements

Under section 107(3) of the WHS Regulation, where exposure cannot be prevented or reduced other than by using personal protective equipment, employers must ensure that anyone who may be exposed:

- is given PPE
- receives proper instruction in the use of PPE
- uses the equipment when there is a risk of being exposed.

Section 107(4) requires that the employer must ensure that a control measure, in this case, PPE:

- is implemented as soon as practicable at the workplace
- is effectively maintained.

Workplace Health and Safety Risk Management Advisory Standard 2000 – Supplement No.1 – Personal Protective Equipment provides further advice about the selection, use, storage and maintenance of personal protective equipment. This supplement should be read in conjunction with the *Workplace Health and Safety Risk Management Advisory Standard 2000*.

5.2 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 1715:1994: Selection, use and maintenance of respiratory protective devices* and *AS2013.1:1989: Cleanroom garments – Product requirements* is recommended. Also see section 5.3 below.

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 that the RPE be properly fitted to the individual to whom it is assigned. 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.

5.3 Selection and care of PPE

| Type of PPE | Description | Task/use | Cleaning/disposal |
|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Coveralls and gowns | <p>Gowns are usually worn for tasks involving the administration of cytotoxic drugs and patient care. Coveralls are most commonly worn in drug preparation areas.</p> <p>Selection considerations for coveralls or gowns include:</p> <ul style="list-style-type: none"> • should be made of impermeable material (e.g. bonded polyethylene fibre) • should have a closed front and long sleeves with elastic or knit cuffs • may be disposable or can be processed through an appropriate laundry facility capable of handling garments contaminated with cytotoxic drugs • should be changed at least daily, or immediately if overt contamination occurs • care should be taken in removal of gowns to reduce the risk of personal contamination • coveralls may incorporate head coverings—these are recommended for drug preparation • oversleeves give added protection to the forearms (a vulnerable area of exposure). | <p>Tasks and uses include:</p> <ul style="list-style-type: none"> • preparation of cytotoxic drugs inside a cytotoxic drug safety cabinet (CDSC) • cleaning of cytotoxic drug preparation areas and equipment • drug administration and patient care • cleaning solid or liquid cytotoxic spills (where spill kit needed) • laundry—handling cytotoxic contaminated linen bag • ancillary workers handling cytotoxic contaminated waste containers. | <ul style="list-style-type: none"> • Refer to manufacturers and suppliers instructions. • Gowns should be used for a maximum of one shift. • Contaminated garments should be removed immediately and disposed of or laundered as appropriate. • Re-usable coveralls and gowns should be stored for laundering (see chapter 13). • 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. • Disposable coveralls and gowns should be disposed of as cytotoxic waste. • Gowns should not be shared. |

| Type of PPE | Description | Task/use | Cleaning/disposal |
|----------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Head covering | <p>Head coverings should be worn to contain hair and reduce contamination. They should cover exposed hair, including beards and moustaches. Additionally:</p> <ul style="list-style-type: none"> • hooded coveralls are recommended for drug preparation—hoods should fit snugly around the face • caps should fit snugly around the head • facial enclosures or covers should be designed to be used in conjunction with hoods and other coverings • hoods, caps and facial enclosures should not interfere with respiratory protection. | <p>Tasks and uses include:</p> <ul style="list-style-type: none"> • preparation of cytotoxic drugs inside a CDSC • cleaning of cytotoxic drug preparation areas and equipment. | <ul style="list-style-type: none"> • Refer to manufacturers and suppliers instructions. • Re-usable coveralls and gowns—see above. • Disposable coveralls and gowns should be disposed of as cytotoxic waste. |

| Type of PPE | Description | Task/use | Cleaning/disposal |
|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Gloves | <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> <ul style="list-style-type: none"> • purpose-manufactured or manufacturer recommended • surgical powder-free latex gloves. <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"> • operators not wearing special-purpose gloves should be double-gloved. This can be done with two pairs of powder-free latex gloves • latex gloves used in drug preparation should be sterile and powder free • with double-gloving, both gloves must be changed • gloves should be changed at intervals recommended by the manufacturer, or at intervals of 30 minutes, or when punctured, torn or contaminated. | <p>Tasks and uses include:</p> <ul style="list-style-type: none"> • preparation of cytotoxic drugs inside a CDSC • cleaning of cytotoxic drug preparation areas and equipment • drug administration and patient care • cleaning solid or liquid cytotoxic spills (where spill kit needed) • laundry—handling cytotoxic contaminated linen bag • ancillary workers handling cytotoxic waste containers. | <ul style="list-style-type: none"> • Refer to manufacturers and suppliers instructions. • Gloves should be disposed of as cytotoxic waste. |

| Type of PPE | Description | Task/use | Cleaning/disposal |
|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Protective eyewear | <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"> • goggles or protective glasses with side shields • a transparent full-face chemical splash shield • full eye protection provided by full-face RPE. <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"> • preparation of cytotoxic drugs inside a CDSC • cleaning of cytotoxic drug preparation areas and equipment • cytotoxic drug administration and patient care, if risk assessment indicates risk of splash in eyes (e.g. intrathecal injection) • cleaning solid or liquid cytotoxic spills (where spill kit needed). | <ul style="list-style-type: none"> • Refer to manufacturers and suppliers instructions. • Re-usable eyewear should be cleaned with a neutral detergent solution and rinsed thoroughly at the end of the shift or when contaminated. • Disposable eyewear should be disposed of as cytotoxic waste. |

| Type of PPE | Description | Task/use | Cleaning/disposal |
|-----------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Respiratory protective equipment (RPE) | <p>Suitable RPE should be selected, used, stored and maintained as recommended in <i>AS/NZS1715:1994: Selection, use and maintenance of respiratory protective devices</i> or comparable international standards.</p> <p>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.</p> <p>Surgical masks do not offer sufficient respiratory protection against exposure to powders, liquids or aerosols (particulates).</p> | <p>Tasks and uses include:</p> <ul style="list-style-type: none"> • preparation of cytotoxic drugs inside a CDSC • cleaning of cytotoxic drug preparation areas and equipment • cytotoxic drug administration and patient care, if risk assessment indicates risk of aerosol exposure • cleaning solid or liquid cytotoxic spills (where spill kit needed). | <ul style="list-style-type: none"> • Refer to manufacturers and suppliers instructions. • An effective storage and regular maintenance program should be implemented for re-usable RPE with procedures covering: <ul style="list-style-type: none"> - cleaning and disinfection - replacement of filter - inspection for defects - repair of equipment. • Re-usable facepiece RPE should have the facepiece washed after each daily use or following any contaminating incident. • Replaceable filters are to be disposed of as cytotoxic waste at the end of service life. • Disposable RPE is to be disposed of as cytotoxic waste after each use or following any contamination incident. |

| Type of PPE | Description | Task/use | Cleaning/disposal |
|---------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Shoe covers or overshoes | <ul style="list-style-type: none"> • Shoe covers must be made of impervious material. • Overshoes of a similar impermeable material as the coverall or gown. • Overshoes should be high enough to cover the trouser cuff of the coverall and designed so they do not slip down. • The soles should be made of a skid-resistant plastic or other suitable non-shedding material. • Disposable shoe covers do not provide sufficient protection from cytotoxic spills. | <p>Tasks and uses include:</p> <ul style="list-style-type: none"> • preparation of cytotoxic drugs inside a CDSC • cleaning of cytotoxic drug preparation areas and equipment • cleaning solid or liquid cytotoxic spills (where spill kit needed). | <ul style="list-style-type: none"> • Refer to manufacturers and suppliers instructions. • Contaminated non-disposable footwear should be cleaned with a detergent solution and rinsed thoroughly after each use. • Disposable shoe covers should be disposed of as cytotoxic waste. • Re-usable overshoes should be stored for laundering (see chapter 13). |

5.4 PPE for specific tasks

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

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 MSDSs
- 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
- be guided and informed by the risk management process
- be reviewed regularly and when there are incidents or changes to the workplace that affect that procedure (e.g. new equipment, new legislation, new products)
- be part of the induction and ongoing training program
- be 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 institution that 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 surveillance and monitoring programs.

6.1 Legislative requirements

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 legislation for health surveillance, which is defined as the monitoring (including biological monitoring and medical assessment) of a person to identify changes in the person's health because of exposure to a hazardous substance.

Part 13 of the WHS Regulation [s.109] sets out the requirement of an employer to arrange and pay for health surveillance under certain circumstances if an employer or worker has been exposed to a hazardous substance. The health surveillance must be performed by, or under the supervision of, a suitably qualified designated doctor.

There are legislative requirements with respect to information that must be provided to workers. These are outlined in section 6.4 below.

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 that 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 employee, and therefore not recommended for routine use in health surveillance.

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 that meets all these requirements, nor is there one test that can be used to detect the presence of all cytotoxic drugs. As a consequence, there is conflicting opinion about action to take in the absence of routine biological tests in monitoring the health of workers handling cytotoxic drugs and related waste.

However, research continues in this area, and employers have a responsibility to ensure that they remain aware of, and apply, current developments for monitoring the health of workers involved in the handling of 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—employers should use the most appropriate and recent method of health surveillance available.

6.3 Consultation

Consultation is an integral part of good management, and employers should consult with workers, their representatives, or an organisation's workplace health and safety committee about the health and safety issues related to cytotoxic drugs and related waste. Although the responsibility for health and safety decisions rests with the employer, consultation provides an important opportunity for workers to contribute their experiences and suggestions to the decision-making process. In large organisations (more than 30 workers), a workplace health and safety officer (WHSO) must be appointed.

Chapter 2 has more information on the legislative requirements with respect to consultation and the appointment of a WHSO. For more information on the role of the WHSO in undertaking risk management, see sections 2.2.3 and 3.1.2 of this guide.

6.4 Information for workers

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

- A register is to be maintained of all cytotoxic substances used, kept in a central location, and readily accessible to workers during working time [s.111].
- MSDSs must be available in an MSDS register. A copy of the MSDS must also be kept close enough to where the substance is being used to allow a worker who may be exposed to the substance to refer to it easily [s.102].
- A worker may inspect certain records if a risk assessment shows that use of a hazardous substance at a workplace causes a significant risk to health [s.112].
- A worker who may be exposed to a hazardous substance must be given a copy of the monitoring record and be allowed to inspect it at any time [s.108(4)].
- A worker is entitled to receive a health surveillance report and an explanation of the report from the designated doctor who conducts the health surveillance [s.109(3)]. Access must be restricted to ensure confidentiality is maintained.

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 that 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 cytogenetic 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 employer, and discuss redeployment options. This may be relevant if the worker is planning parenthood, or is pregnant or breastfeeding.

In discussions on these issues, the following considerations are important:

- employers have a workplace health and safety obligation to ensure that their workers are not exposed to risks to their health and safety
- workers must cooperate with their employer 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"> • The primary focus is to eliminate, or reduce the risks to health. • Strive for 'best practice' controls. • Ensure that control measures are maintained and working as designed. |
| 2. A medical practitioner is appointed to oversee the program. Appointment means that the employer has a formal arrangement with a medical practitioner. All workers should be made aware of the arrangement. | <ul style="list-style-type: none"> • The appointed medical practitioner may be an occupational physician, local general practitioner, medical officer or 'designated doctor'. • The appointment may be considered in consultation with medical, nursing and workplace health and safety officers. • The appointed medical practitioner should have the necessary knowledge and skills to provide health monitoring. • Core competencies, that represent a minimum standard for performing health monitoring, are provided in <i>Competencies for health surveillance</i> (NOHSC, 1998). |
| 3. Guidance is provided to the appointed medical practitioners. | <ul style="list-style-type: none"> • Guidance is outlined in appendix 8. • General guidance is provided in <i>Competencies for health surveillance</i> (NOHSC, 1998) and <i>Guidelines for health surveillance</i> (NOHSC, 1995). |

| | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 4. The health monitoring program is an integrated part of the workplace. | <ul style="list-style-type: none"> • Workers and health and safety representatives should be involved in the development and management of the program. • The employer should ensure that the appointed medical practitioner is given access to the workplace and any information required. • The employer should involve the appointed medical practitioner in the risk management strategies of the workplace, such as health and safety committee meetings. • history of incidents, and health and safety performance, are recorded. |
| 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"> • the nature of work to be undertaken • potential risks to health (including but not limited to reproductive health and the effects of carcinogens, mutagens and teratogens) • how exposure may occur • the control measures in place. |
| 6. Pre-employment and baseline health monitoring is conducted by the appointed medical practitioner before an employee commences work with cytotoxic drugs and related waste. | <p>Pre-employment health monitoring (as outlined in appendix 8) provides:</p> <ul style="list-style-type: none"> • collection of demographic data • occupational history • medical history • physical examination • investigation (if appropriate) • health advice and counselling • a report to employer and prospective employee. |
| 7. Health monitoring is conducted during the period that the employee works with cytotoxic drugs and related waste. | <p>Health monitoring is conducted during the period the employee works with cytotoxic drugs or related waste (as outlined in appendix 8) and provides:</p> <ul style="list-style-type: none"> • data for inclusion in health records (e.g. health advice and counselling) • medical review after an exposure. |
| 8. Medical advice and counselling is available to workers at any time during their employment. | <p>Workers may arrange a consultation with the appointed medical practitioner at any time.</p> |
| 9. Workers are provided with freedom of choice and have the right not to work with cytotoxic drugs. | <p>Appropriate and suitable alternative duties should be provided 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.</p> |
| 10. The results of health monitoring are provided to the employee to whom the results relate. | <p>The results should be made available as soon as possible.</p> |
| 11. Workers' medical records are confidential. | <p>Where any form of health monitoring is undertaken, confidentiality of workers' medical records should be ensured. Access to an employee's medical records can be obtained only with the written consent of the employee.</p> |

| | |
|-----------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 6) provides:</p> <ul style="list-style-type: none"> • data collection • final medical examination. <p>On termination of employment, a statement should be provided showing:</p> <ul style="list-style-type: none"> • the duration and nature of work involving cytotoxic drugs • the results of any medical review or health monitoring conducted • details of any incidents involving cytotoxic drugs or related waste |
|-----------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

See appendix 8 for Guidelines for Health Monitoring for Cytotoxic Drugs.

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, an employer must keep the following records in accordance with the requirements of parts 7 and 13 of the WHS Regulation:

| | |
|--------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| MSDS register | An employer must keep a register at the workplace containing a list of all hazardous substances used at the workplace, and the current MSDS for each substance [s.111]. |
| Risk assessment | The record must include date, assessed degree of risk, product name, control measures, and the type of monitoring and health surveillance required [s.106]. |
| Duration | Risk assessment, monitoring results and health surveillance reports for hazardous substances with a significant degree of risk to health must be kept for 30 years from the day the record was made [s.112]. Where the degree of risk to health is not significant, records are kept for five years. |
| Confidentiality of workers' records | An employer may only obtain access to, and disclose the contents of, a worker's medical records with the written consent of the worker [s.110]. |
| Training | Records of induction and training about hazardous substances given to a worker must be kept for five years from the date of the last entry in the record [s.113]. |
| Workplace incidents | If an incident resulting in a person suffering a work injury or a work caused illness, or a dangerous event occurs in a workplace, a record of the incident must be made. The person required to make the record must report the incident within 24 hours of becoming aware of the incident, and must keep the record for one year [s.53]. A workplace death must be notified as soon as the employer or self-employed person becomes aware of it and by the quickest possible means. |

It is recommended that incident records and risk assessment records, where appropriate, form part of the worker's health surveillance records.

It is also recommended that the following records be kept:

| Issue | Records |
|--------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Operators (workers trained to undertake cytotoxic drug preparation or administration) | Records to include: <ul style="list-style-type: none"> • competency status of operators • training provided (content and date of training) • estimates of the time spent by individual workers in the preparation and administration of cytotoxic drugs • protective equipment used (e.g. cytotoxic drug safety cabinet, PPE). |
| Drug preparation equipment | Records to include: <ul style="list-style-type: none"> • daily activities of the cytotoxic drug safety cabinet such as cleaning, operating times and spills • maintenance schedules, including breakdowns and repairs effected • testing dates and test results • cabinet relocations and recommissioning. |
| Spills | Records to include: <ul style="list-style-type: none"> • incident details (e.g. day, date, time, location, description of incident) • workers involved (e.g. name, role or position) • drug details (e.g. name, approximate volume, whether liquid or powder) • body substance or cytotoxic waste details • time spent in the cleaning of the spill • PPE used • action taken (e.g. treatment, medical review). |
| Penetrating injuries | Records to include: <ul style="list-style-type: none"> • incident details (e.g. day, date, time, location, description of incident) • workers involved (e.g. name, role or position) • drug details (e.g. name, approximate volume) • action taken (e.g. treatment, medical review). |
| Accidental personal contamination | Records to include: <ul style="list-style-type: none"> • incident details (e.g. day, date, time, location, description of incident) • workers involved (e.g. name, role or position) • part affected (e.g. eyes or skin) • drug details (e.g. name, approximate volume, whether liquid or powder) • action taken (e.g. treatment, medical review) • PPE in use at the time. |
| Individual worker reports | In view of the long latency period for some toxic effects, adequate records must be maintained such that, on termination, a worker is provided with a statement showing: <ul style="list-style-type: none"> • the duration and nature of work involving cytotoxic drugs • the results of any medical review or health monitoring conducted • details of any incidents involving cytotoxic drugs or related waste. |

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 surveillance requirements
- regular research to identify biological monitoring techniques that 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 that 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. Employers should ensure that 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 that workers do not eat, drink, smoke, chew gum, apply cosmetics or store food in or near the preparation area.

7.1 Legal requirements

7.1.1 Obligations of manufacturers and suppliers of substances for use at the workplace

The WHS Act [ss.34, 34A] imposes the following obligations:

- A manufacturer of a substance for use at a workplace has an obligation to ensure that:
 - the substance is safe and without risk to health when used properly
 - the substance is tested and examined to ensure it is safe and without risk to health when used properly
 - the substance, when supplied to another person, is accompanied by relevant information for the substance.
- A supplier of a substance for use at a workplace has an obligation to take all reasonable steps to ensure the substance is safe and without risk to health when used properly, and to ensure the substance is accompanied by relevant information for the substance.
- Manufacturers and suppliers must take action that WHSQ reasonably requires to prevent the use of an unsafe substance at a workplace.

The obligations as stated above relate to cytotoxic drug use. Specific requirements relating to relevant information for hazardous substances that must be provided, such as material safety data sheets and labelling, are set out in the WHS Regulation.

7.1.2 Obligations—plant

Persons conducting a business or undertaking have obligations with respect to plant, which may include providing and maintaining safe plant and ensuring safe systems of work [WHS Act: s.29]. This applies to cytotoxic drug preparation facilities and equipment. A person in control of a workplace also has an obligation to ensure the risk of injury or illness from any plant and equipment provided for the performance of work by someone other than the person's workers is minimised when used properly [WHS Act: s.30].

7.1.3 Obligations—labelling

In the workplace, the appropriate label for cytotoxic drugs is determined by how it is used or is to be used at work. The Health Regulation 1996 requires that the packaging and labelling of controlled or restricted drugs comply with the Commonwealth *Standard for the Uniform Scheduling of Drugs and Poisons*. However the labelling requirements of the standard do not apply to a poison that:

- is packed and sold solely for dispensary, industrial, laboratory or manufacturing purposes
- is labelled in accordance with the *National Code of Practice for the Labelling of Workplace Substances* [NOHSC*:2012 (1994)] or its successors.

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

Under the WHS Regulation, suppliers and employers have specific responsibilities for labelling cytotoxic drugs that are hazardous substances. For more information, see sections 2.5.1 and 2.5.4 of this guide.

Cytotoxic drugs that are to be used for domestic use must be labelled in accordance with the Health Regulation 1996 (see section 2.6.1 of this guide). However, cytotoxic drugs that are packed and sold solely for dispensary, industrial, laboratory or manufacturing purposes must be labelled in accordance with the requirements of the WHS Regulation. That is, containers of cytotoxic drugs supplied to or used in a workplace must be labelled with the drug's product (generic) name, and risk and safety phrases of the substance [ss.98, 103].

If a cytotoxic drug is transferred from one container into a second container, and the second container's contents are not used immediately, the employer must ensure the second container is fixed with a label stating the substance's product name and the risk and safety phrases [WHS Reg: s.103].

Second containers that 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 left), 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.

Transport of cytotoxic drugs

Where cytotoxic drugs are classified as dangerous goods in accordance with the Australian Dangerous Goods Code (ADG Code), and are supplied to or used in the workplace, they should be marked in accordance with the provisions of that code.

*National Occupational Health and Safety Commission, now known as the Australian Safety and Compensation Council.

Recommended information for workplace label for hazardous substances and dangerous goods

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

Reference: Adapted from the draft Code of Practice for Labelling Substances in the Workplace (Hazardous Substances and Dangerous Goods), 2nd edition, 2001.

Healthcare facilities that are involved in the external transport of cytotoxic drugs must consult with the appropriate local, state and national agencies for current legislative requirements. For more information see section 2.6.4 of this guide.

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:

- AS1386:1989: Parts 1-7 – Cleanrooms and clean workstations
- AS1715:1994: Selection, use and maintenance of respiratory protective devices
- AS/NZS1716:2003: Respiratory protective devices
- AS1807:2000: Cleanrooms, workstations, safety cabinets and pharmaceutical isolators - Methods of test - List of methods and apparatus (various parts as appropriate)

- *AS 2013.1:1989: Cleanroom garments – Product requirements*
- *AS2567:2002: Laminar flow cytotoxic drug safety cabinets*
- *AS2639:1994: Laminar flow cytotoxic drug safety cabinets - Installation and use*
- *AS4273:1999: 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 *AS2567:2002: Laminar flow cytotoxic drug safety cabinets*. Installation and use of CDSCs should be in accordance with the specifications of *AS2639:1994: Laminar flow cytotoxic drug safety cabinets - Installation and use*
- a pharmaceutical isolator which complies with *AS4273:1999: 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 Division 4 of the Queensland Health Regulation 1996, which includes sections on:

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

Drug preparation equipment also includes syringes, needles, syringe tip connectors, air venting devices, ampoules, etc., and safe working procedures should be developed for using these 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 that can not 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 that 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 that pharmacists and pharmacy technicians spend a maximum period of two hours in the CDSC before a short break is taken.

For more information on fatigue, please refer to WHSQ's *Fatigue management guide* at www.dir.qld.gov.au/.

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, mask, 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, 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.

CDSCs, 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 AS2639). 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 AS2639. 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 AS2639. 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 AS2639.

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 that might generate particulate matter, should be avoided.

Drug administration workers may 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 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 that 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 MSDS for each drug in the area. Storage areas should be secured, and access limited to authorised workers.

A dedicated storage area should be provided for the unpacking of cytotoxic drugs. Damaged packages of cytotoxic drugs received 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.

Other agencies such as Queensland Health, Environmental Protection Agency and Department of Emergency Services also have requirements for drug storage that must be complied with.

7.10 Drug packaging for transport

Manufacturers and suppliers of cytotoxic drugs have legislative obligations to ensure that their products are safe and without risk to health when used properly [WHS Act, ss.34, 34A]. Appropriate control measures must be in place to ensure that 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 that 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 Environmental Protection Agency, Queensland Transport and the Department of Emergency Services. For more information, see section 2.6 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, 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, see 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, MSDSs 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 that 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, employers 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 that 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 the 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, see sections 2.6 and 7.1 of this guide.

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

*Waste containers must comply with schedule 4 of the Environmental Protection (Waste Management) Regulation 2000.

8.3 Recommendations for establishing a cytotoxic drug administration area

When designing and setting up a cytotoxic drug administration area, consideration should be given to:

- allocating an area that 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 MSDSs, in a place accessible to employees
- providing readily accessible cytotoxic spill kits
- providing access to a shower in event of contamination.

8.4 General precautions for administration of all 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 MSDS 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
- providing readily accessible cytotoxic spill kit.

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.

The risk assessment should include the work flow and activities conducted, and should 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 consideration—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 that 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 must 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

*Sharps disposal containers must comply with AS4031:1992: Non-reusable containers for the collection of sharp medical items used in healthcare areas. Waste containers must comply with Schedule 4 of the Environmental Protection (Waste Management) Regulation 2000. See section 13.3.2 of this guide for further information.

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

Standard operating procedures – 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, MSDSs 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 that 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 health care 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

Hazard identification should 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 and training requirements should also be identified during the risk management process, to ensure that the safe work practices that 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.

9.2.1 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 that 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 system 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, MSDSs 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 that 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 employer 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 that 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 that 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 that 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 that 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 following legislative requirements create health and safety obligations relevant to the use of cytotoxic drugs.

10.3.1 Obligations of the referring healthcare facility

Referring healthcare facilities that supervise patients receiving cytotoxic drug therapy in their

homes or in community settings may have obligations to ensure that other people—for example, 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 substances (see section 2.5.4 of this guide), including information about safe use.

It is recommended that 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 obligations 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 that the information provided to that 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 Obligations 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. Employers of community care workers have obligations to ensure the health and safety of their workers in peoples' homes. They must conduct a risk assessment and implement appropriate control measures. They may also consider information and directions provided by a referring healthcare facility.

Employers must provide a safe environment for workers going into the home. Patients may be requested by the employer 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 that 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 that comply with EPA requirements. 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 that 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 that are contaminated with cytotoxic drugs can be safely disposed of in most household toilets, using a full flush. 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 that 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 that 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 that 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 that 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 that 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 the supervised burial to a landfill of untreated cytotoxic waste. Such a landfill facility must be licensed to accept cytotoxic waste
- 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.

Cytotoxic contaminated waste may be stored for a period of time at a patient's home in a suitable container, provided that 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 that 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 that 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 that 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 click-down 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 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 that 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 that 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 that 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 that 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 procedures – 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 that 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 that 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 that 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 that only linen that 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 that safe work practices be developed following consultation between workplace health and safety officers, hospital workers, laundry workers and contractors to ensure that 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, stickers, etc.
- 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 the 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 that are labelled as cytotoxic.

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

11.3 Patient care areas

Results of the risk assessment and consultation with laundry workers should be used to ensure that 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 that 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 that 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 that 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, MSDSs 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 that 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 handled, stored, transported and disposed. People in the immediate vicinity of a cytotoxic spill should be alerted immediately that a spill has occurred and requested to stay clear. 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

The risk assessment should be used to determine the contents appropriate to the situation in which the cytotoxic spill kit will be used. Appropriate locations for storing 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, 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 that 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 that 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 spills within a cytotoxic drug safety cabinet and a 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

Employers must have a system in place for workers to report any spill or workers contamination as soon as practicable. Supervisors should be notified immediately and be trained in appropriate procedures. The supervisor or workplace health and safety officer 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 on the approved form of an incident resulting in a person suffering a work injury that is a serious bodily injury or a work caused illness, or of a dangerous event occurring in a workplace. For more information, see section 2.2.5 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, MSDSs 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 that 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 workers must be protected from the risk of exposure 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 Environmental Protection Regulation and Policy, administered by the Queensland EPA. These requirements cover packaging, labelling, handling and transportation. For more information on EPA legislative requirements, see chapter 3.

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 employer 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 EPA 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—labelling requirements

Identifying contaminated waste is essential to reduce the risk of exposure to cytotoxic materials and to ensure the safe and correct disposal of cytotoxic waste.

The EPA requires that all cytotoxic waste be placed into compliant bags or containers that are appropriately identified. The EPA specifies the following colours and symbol coding for cytotoxic waste:

- containers and bags must be purple—the EPA stipulates ‘Lilac P23’
- the container must have a white label with the symbol of a cell in telophase
- the correct labelling words are ‘CYTOTOXIC WASTE’.

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

See sections 2.6 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 EPA legislation (see section 2.6.2 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

The EPA has specific requirements with respect to storage and transport of sharps. Sharps are defined as pointed or cutting implements that are capable of inflicting a penetrating injury, and include hypodermic, intravenous or other medical needles, Pasteur pipettes, scalpel blades, lancets, scissors, glass slides and broken glass such as vials, bottles and laboratory glass.

All cytotoxic contaminated sharps must be placed into rigid-walled, puncture-resistant containers that meet *AS4031:1992: Non-reusable containers for the collection of sharp medical items used in healthcare areas*. Sharps containers should be labelled 'CYTOTOXIC SHARPS', and 'INCINERATE AT 11000 CELSIUS'. Once the sharps container has been sealed and secured, it can be placed directly into a secondary container for internal movement or transportation.

13.3.3 Waste segregation

Cytotoxic waste should be segregated from other waste streams through the development and implementation of appropriate control measures, which may include:

- development of procedures, in consultation with workers in areas that generate cytotoxic waste and those responsible for the provision of support services
- incorporation of efficient waste disposal methods into patient care procedures
- segregation of waste at the point of generation
- appropriate signage at all collection and storage areas
- separation of cytotoxic waste from general and clinical waste during internal transport and storage
- ensuring that non-rigid receptacles are placed in a rigid-walled container such as a wheelie bin (of the appropriate colour and labelling) for transport to a collection or storage area
- ensuring that containers and bins are secured with mobile or fixed stands.

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

- do not overfill cytotoxic waste containers
- locate cytotoxic waste collection bins as close as practicable to the site of generation and to transport corridors
- use dedicated, rigid-walled, puncture-resistant containers 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 according to EPA requirements, 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 that waste disposal chutes 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 should be transported to a dedicated, secure storage area to await collection for disposal and treatment. Cytotoxic waste bins should be sealed or otherwise secured prior to waste collection and not re-opened on-site once they have been secured.

A cytotoxic waste storage area should be:

- a dedicated storage area with adequate lighting and ventilation
- clearly separated from other waste streams, if situated within a main waste storage area
- appropriately identified and signed according to legislative requirements
- able to be secured
- located away from stormwater drains and other sensitive areas
- designed for ease of cleaning, decontamination and maintenance of hygiene standards
- refrigerated, where cytotoxic waste 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

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 relevant regulations. Management should ensure that 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 that appropriate permits and licences are obtained.

Workers and others involved in transporting and handling cytotoxic waste must be protected from the risk of exposure to cytotoxic waste. 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. Re-usable 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 EPA 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. Recommendations for minimum or optimal temperatures for incinerating individual pharmaceuticals should be sought from the Queensland EPA. All incinerators used for the treatment of cytotoxic waste must be licensed and meet the prescribed standards.

13.7.2 Stockpiling of cytotoxic waste

Stockpiling of cytotoxic waste may be an alternative for an isolated area without access to a licensed incineration facility. The waste may be stockpiled and stored in a dedicated area, until there is sufficient quantity to make it economical to transport the waste to licensed facility. Storage requirements would be the same as for section 13.5 above.

13.7.3 Disposal to supervised landfill

The option of disposal to supervised landfill may be considered as an interim alternative where the cytotoxic waste generation facility is isolated or where there is insufficient space for stockpiling. Generally, landfill disposal is an unsatisfactory method of disposal for cytotoxic wastes, due to the possible risks to workers, the public and the environment. However, where landfill disposal may be necessary, measures can be taken to minimise the risk.

The local council should be contacted to discuss requirements, and to ascertain that the intended landfill is licensed to accept cytotoxic waste. Usually, the cytotoxic waste must be placed in a designated area of the landfill that is inaccessible to the public. The waste disposal should be supervised by an authorised person to ensure that the waste is disposed of according to the requirements for supervised burial to landfill.

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
- disposal and treatment of cytotoxic contaminated waste at licensed treatment 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, MSDSs 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 that 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 that 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, employers 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 that the number of trained workers who perform tasks involving cytotoxic drugs and related waste be 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. Employers should ensure that workers do not prepare cytotoxic drugs unless they are trained in the preparation of cytotoxic drugs and have the appropriate facilities.

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 that 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 that 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 that 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 that 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 that 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. The gloves should then be discarded in a 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 that 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. 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. If bedding is to be disposed of, place it in a strong plastic bag, seal and place 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
- 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 that 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 care-givers:

- 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, MSDSs 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 that procedure (e.g. new equipment, new legislation, new products)
- be documented and meet record keeping requirements.

Appendix 1 – Glossary of terms

A

| | |
|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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, labelling, training, PPE) |
| ALARA | ‘as low as reasonably achievable’ |
| ASCC | Australian Safety and Compensation Council—national body that leads and coordinates national efforts to prevent workplace death, injury and disease in Australia— formerly known as NOHSC |

B

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| biological monitoring | for a hazardous substance, means testing for the presence of a hazardous substance, its metabolites or a biochemical change on a person’s body tissues, exhaled air or fluid |
| body substances | urine, faeces, vomitus, bile and fluid drained from body cavities |

C

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| carcinogen | substance which causes cancer |
| code of practice | guide published by WHSQ, providing guidance 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 | (WHS Regulation) means a thing (other than a bulk container or tank as defined in the ADG Code) in which a hazardous substance is, or has been, completely or partly cased, contained, covered, enclosed or packed, but does not include an enclosed system |
| control measure | a measure implemented to prevent or reduce the risk of injury from a particular hazard |
| 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 |

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| 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. For more information see section 13.1 of this guide |

D

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| dangerous event | an event that must be notified to Workplace Health and Safety Queensland (WHS Act)—includes an event caused by specified high risk plant, or an event at a workplace caused by a work activity, if the event involves or could have involved exposure of people to risk to their health and safety because of, for example, implosion, explosion or fire, or escape, spillage or leakage of any hazardous material or dangerous goods |
| dermal absorption | a route of exposure—taking in cytotoxic drug or related waste through the skin |
| designated doctor | a doctor who is registered as a specialist registrant in the specialty of occupational medicine under the <i>Medical Practitioners Registration Act 2001</i> , or who has satisfactorily completed a health surveillance training program supplied by the chief executive (WHS Regulation) |

E

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| elimination | a type of control measure in which the hazard is eliminated |
| employer | an obligation holder under the WHS Act |
| engineering control | a type of control measure which uses technological means to isolate or remove hazards |
| equipment | see 'plant' |
| exposed | a person is exposed to a hazardous substance if they are in a situation where they absorb or are likely to absorb the substance by ingestion, inhalation or through the skin or mucous membrane. Exposure may also occur as a result of percutaneous injuries |
| exposure standards | exposure standards are the calculated airborne concentrations of individual chemical substances which, according to current knowledge, should neither impair the health of, nor cause undue discomfort to, nearly all workers. The exposure standards serve as guides only. The control measures selected must ensure that the applicable exposure standard is not exceeded |

H

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| hazard | a hazard is the potential for a substance to adversely affect the health and safety of people in the workplace |
| healthcare facility | includes hospitals, day hospitals, clinics and medical practices |
| health surveillance | the monitoring (including biological monitoring and medical assessment) of a person to identify changes in the person's health because of exposure to a hazardous substance |
| health surveillance report | information, other than a medical record, about the effects on a person's health related to the person's exposure to a hazardous substance at a workplace, and the need (if any) for remedial action (WHS Regulation, s.109) |

I

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

M

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| material safety data sheet | an information sheet provided by a supplier or manufacturer containing information about a particular substance. Also known as an MSDS |
| manufacturer | an obligation holder under the WHS Act |
| mask | see 'RPE' |
| MSDS | see 'material safety data sheet' |
| 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 |

N

NOHSC National Occupational Health and Safety Commission—now known as Australian Safety and Compensation Commission—see ‘ASCC’

O

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

obligation holder a person who has an obligation under WHS legislation—see also ‘employer’, ‘worker’, ‘self-employed person’, ‘person conducting a business or undertaking’, ‘person in control of a workplace’, ‘manufacturer’, ‘supplier’

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

P

parenteral a method of cytotoxic drug administration—includes subcutaneous, intraocular, intramuscular, intrapleural, intraperitoneal, intra-arterial, intrathecal and intravesical

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
an obligation holder under the WHS Act

or undertaking

person in control of a workplace
an obligation holder under the WHS Act

personal protective equipment clothing, equipment and substances designed to be worn by a worker to protect them from the risk of injury or illness. Also known as PPE

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

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.

R

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| respirator | see 'respiratory protective equipment' |
| respiratory protective equipment | equipment used by a worker to prevent or minimise exposure to airborne hazardous substances. Also known as RPE |
| risk | the likelihood that a substance or hazard will cause illness or injury in the conditions of its use. The risk to health and safety usually increases with the severity of the hazard, the amount of hazardous substance used, and the duration and frequency of exposure |
| risk assessment | an examination of the ways in which hazards occur and the health risks involved. The assessment is used to enable decisions to be made about appropriate control measures |
| risk management | a process for identifying workplace hazards and risks, and managing them to ensure the health and safety of workers in the workplace |
| risk phrases | a labelling requirement for hazardous substances in accordance with the determined hazard classification, and intended to convey a general description of the substance and give notice of the hazards present with the normal or reasonably foreseeable use of the substance (e.g. 'Harmful if swallowed') |
| RPE | see 'respiratory protective equipment' |

S

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| safety phrase | information on a label that provides information on safe storage, handling and personal protection, taking into account the intended use (e.g. 'Wear suitable protective clothing and gloves') |
| self-employed person | an obligation holder under the WHS Act |
| serious bodily injury | (WHS Act) an injury to a person that causes death or the loss of a distinct part or an organ of the body, or causes the person to be absent from their employment for more than four days |
| sharps | pointed or cutting implements that 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 |

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| substitution | a type of control measure that substitutes a hazardous substance or process with a less hazardous one |
| supplier | an obligation holder under the WHS Act |
| surveillance | see health surveillance |

T

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| 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 |

U

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| use (of cytotoxic drugs) | includes administration, preparation, handling, storage, movement and disposal of cytotoxic drugs and related waste |
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W

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| WHS | workplace health and safety |
| WHS Act | <i>Workplace Health and Safety Act 1995</i> —the principal legislation relating to workplace health and safety in Queensland |
| WHSO | see workplace health and safety officer |
| WHSQ | Workplace Health and Safety Queensland—the regulating state government agency for workplace health and safety |
| WHS Regulation | Workplace Health and Safety Regulation 1997—the principal legislation relating to workplace health and safety in Queensland |
| work caused illness | means an illness contracted by a person to which work, a workplace, a relevant workplace area, a work activity, or plant or substances for use at a workplace was a significant contributing factor, or the recurrence, aggravation, acceleration, exacerbation or deterioration in a person of an existing illness if work, a workplace, a relevant workplace area, a work activity, or plant or substances for use at a workplace was a significant contributing factor to the recurrence, aggravation, acceleration, exacerbation or deterioration |
| worker | a person who does work, other than under a contract for services, for, or at the direction of an employer. A person may be a worker even though they are not paid for the work |
| workplace | any place where work is, or is to be, performed by a worker or a person conducting a business or undertaking |

| | |
|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| workplace health and safety officer | a person employed to assist an employer to manage workplace health and safety |
| work injury | (a) an injury to a person that requires first aid or medical treatment, if the injury was caused by work, a workplace, a relevant workplace area, a work activity, or plant or substances for use at a workplace (b) the recurrence, aggravation, acceleration, exacerbation or deterioration of an existing injury in a person, if first aid or medical treatment is required for the injury, and it was caused by work, a workplace, a relevant workplace area, a work activity, or plant or substances for use at a workplace (c) any serious bodily injury, if the injury was caused by work, a workplace, a relevant workplace area, a work activity, or plant or substances for use at a workplace |
| workplace incident | an incident resulting in a person suffering a work injury or a work caused illness or an incident resulting in a dangerous event |

Appendix 2 – Commonly used cytotoxic drugs

This list contains cytotoxic drugs currently used, however this listing is not exhaustive. The information provided is current at the time of writing this guide.

| Drug | Trade names |
|------------------------|--------------------------------|
| Altretamine | Hexalen |
| Amsacrine | Amsidyl |
| L-Asparaginase | See Colaspase |
| Bleomycin | Blenoxane, Blenamax, Bleomycin |
| Busulfan | Myleran |
| Capecitabine | Xeloda |
| Carboplatin | ? |
| Carmustine | Bicnu |
| Chlorambucil | Leukeran |
| Cisplatin | Cisplatin |
| Cladribine | Leustatin, Litak |
| Colaspase | Leunase |
| Cyclophosphamide | Cycloblastin, Endoxan |
| Cytarabine | Cytarabine |
| Dacarbazine | Dacarbazine |
| Dactinomycin | Cosmegen |
| Daunorubicin | Daunorubicin |
| Daunorubicin liposomal | Dauno Xome |
| Docetaxel | Taxotere |
| Doxorubicin | Adriamycin, Doxorubicin |
| Doxorubicin liposomal | Caelyx |
| Epirubicin | Pharmorubicin, Epirubicin |
| Etoposide Phosphate | Etopophos |
| Etoposide | Etoposide, Vepesid |
| Fluorouracil | Efudix, Fluorouracil |
| Fludarabine | Fludara |
| Fotemustine | Muphoran |
| Ganciclovir | Cymevene |
| Gemcitabine | Gemzar |
| Hydroxyurea | Hydrea |
| Idarubicin | Zavedos |
| Ifosfamide | Holoxan |
| Irinotecan | Camptosar |
| Lomustine | Cee Nu |

| | |
|----------------|------------------------------------------|
| Melphalan | Alkeran |
| Mercaptopurine | Puri-nethol |
| Methotrexate | Ledertrexate, Methoblastin, Methotrexate |
| Mitozantrone | Novantrone, Mitozantrone, Onkotrone |
| Mitomycin-C | Mitomycin C |
| 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, Vinblastine |
| Vincristine | Oncovin, Vincristine |
| Vindesine | Eldisine |
| Vinorelbine | Navelbine, Vinorelbine |

Appendix 3 – Legislation

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

- *Workplace Health and Safety Act 1995*
- Workplace Health and Safety Regulation 1997
- Health Regulation 1996
- Health (Drugs and Poisons) Regulation 1996
- *Environmental Protection Act 1994*
- Environmental Protection (Waste Management) Regulation 2000
- Environmental Protection (Waste Management) Policy 2000
- *Integrated Planning Act 1997*
- *Dangerous Goods Safety Management Act 2001*
- Dangerous Goods Safety Management Regulation 2001
- *Transport Operations (Road Use Management) Act 1998*
- Transport Operations (Road Use Management) Regulation 1998

The full text of all Queensland legislation can be obtained at the following website:
www.legislation.qld.gov.au.

Workplace Health and Safety Queensland codes of practice

- *First Aid Advisory Standard (Code of Practice) 2004*
- *Hazardous Substances Advisory Standard (Code of Practice) 2003*
- *Risk Management Advisory Standard (Code of Practice) 2000*
- *Risk Management Advisory Standard (Code of Practice) - Supplement No. 1 - Personal Protective Equipment 2000*
- *Risk Management Advisory Standard (Code of Practice) - Supplement No. 2 - Training 2000*
- *Manual Tasks Advisory Standard (Code of Practice) 2000*
- *Plant Code of Practice 2005*

Appendix 5: Sample risk assessment of hazardous substances

[Keep for 30 years from date of assessment if risk significant, five years if not significant]

| Work unit (job) | | Person/s exposed: | | Assessment team: | | Work area: | |
|------------------------------------------------------|-------------------------------------------------|-------------------|-----------------------------------------------------|-----------------------------------------------------------|-------------------------------|---------------------------------------------------------------------------------------------|-----------------|
| Summary of process: | | | | | | Date: | |
| Hazardous substance product name (see MSDS) | Hazard information on health effects (see MSDS) | Task/s | Exposure routes (where applicable) | Current controls | | RISK CALCULATION BASED ON CURRENT CONTROLS (refer over page for explanation of these terms) | |
| | | | | 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 | | | | IS HEALTH SURVEILLANCE REQUIRED (refer over page): Yes/No | | | |
| If yes - type: | | Intervals: | | If yes - type: | | Intervals: | |
| Assessor/s name/s: | | Signature/s: | | Date | | | |
| Approved by/name: | | Signature: | | Date: | | | |
| Name of Substance: | | | | | | | |

P.T.O FOR INFORMATION ON RISK SCORING AND RISK CONCLUSIONS AND HEALTH SURVEILLANCE

Risk Rating Chart*

Risk Score - 1,2,3 = Immediate; 4,5 = ASAP; 6,7 = may not need immediate attention.

*Risk Management Advisory Standard 2000

| 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 |

Factors affecting LIKELIHOOD of exposure:

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

Factors affecting CONSEQUENCES of exposure:

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

More information on conclusions about risk can be found in: Hazardous Substances Advisory Standard (Code of Practice) 2000.

HEALTH SURVEILLANCE: See *Workplace Health and Safety Regulation 1997*, section 109. In general, health surveillance is required if a substance is listed in schedule 6 of the Regulation and risk is significant; or there is an identifiable work-related health effect from exposure to the substance, and a valid technique or monitoring procedure exists to detect the adverse health effect.

Conclusion from the risk assessment

Conclusion 1: Risks NOT SIGNIFICANT* now and not likely to increase in the future. This conclusion applies where it is unlikely that the use of the hazardous substance 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 substance are 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 substance 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 monitoring or health surveillance 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 substance is likely to constitute a risk, and further investigation (e.g. 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 substances 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 atmospheric monitoring or health surveillance 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. Atmospheric monitoring might be required to estimate the level of exposure. For a hazardous substance absorbed through the skin, ingested or inhaled, biological monitoring might be required. The employer should seek specialist advice if necessary.

***Significant risk** – means that the work with a hazardous substance 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

Employers and self-employed people at a workplace where cytotoxic drugs are used must comply with all sections of part 13 of the Workplace Health and Safety Regulation 1997. This checklist is a guide only.

Date: _____ Workplace name: _____

Workplace registration: _____ WHSO: _____

Auditor: _____

A = Audited NC = No compliance NA = Not applicable Yes/No answers go in remarks column

| | | A | NC | NA | Remarks |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|----|----|---------|
| 1.0 | Material Safety Data Sheets (MSDS) | | | | |
| 1.1 | Is there a current MSDS for each cytotoxic drug used? | | | | |
| 1.2 | Is the MSDS easily accessible for workers to refer to? | | | | |
| 2.0 | Register | | | | |
| 2.1 | Are copies of the MSDSs in a register? | | | | |
| 3.0 | Labelling | | | | |
| 3.1 | Are cytotoxic drugs labelled with the drug's product name, risk and safety phrases and the chemical name of the drug? | | | | |
| 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 substance's product name, safety phrases and risk phrases? | | | | |
| 4.0 | Risk assessment | | | | |
| 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"> • drug preparation • drug administration • patient care • spill management • waste management • general cleaning • laundry • maintenance • stores and transport? | | | | |
| 4.2 | Does the risk assessment include: <ul style="list-style-type: none"> • identification of the cytotoxic drug • review of the MSDS if available • if MSDS is not available, review of available equivalent information • if the substance is contained in a consumer package, a review of the package's label • a decision whether any workers may be exposed to cytotoxic drugs or related waste • a decision about control measures, health surveillance and monitoring needed for the substance? | | | | |

| | | A | NC | NA | Remarks |
|------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|----|----|---------|
| 4.3 | Have systems been implemented to make sure that the risk assessment is done at least every five years? | | | | |
| 4.4 | Have systems been implemented to make sure that the risk assessment is done if: <ul style="list-style-type: none"> • a work practice involving the substance is significantly changed • health surveillance or monitoring shows that control measures need to be reviewed • new information about the substance's hazard becomes available • new or improved control measures are implemented? | | | | |
| 5.0 | Controlling exposure | | | | |
| 5.1 | Can workers exposure to cytotoxic drugs and related waste be prevented? | | | | |
| 5.2 | If prevention is not 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? | | | | |
| 6.0 | Training | | | | |
| 6.1 | Have workers who may be exposed to cytotoxic drugs and related waste been provided with induction and training about the substance? | | | | |
| 7.0 | Records | | | | |
| 7.1 | Are records kept of: <ul style="list-style-type: none"> • the risk assessment record—30 years • monitoring results—30 years • health surveillance record—30 years • induction and training—5 years? | | | | |

| | | A | NC | NA | Remarks |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|----|----|---------|
| 7.2 | Does the risk assessment record include the following information: <ul style="list-style-type: none"> • the date when the assessment was done • whether the degree of risk is assessed to be significant • the substance's product name and other information • the control measures for the use of the substance that were in place when the assessment was done • the type of monitoring that is needed and the intervals at which the monitoring must be done • the type of health surveillance that is needed and the intervals at which the monitoring must be done? | | | | |
| 7.3 | Does the training record include the following information: <ul style="list-style-type: none"> • the date of the session • the topics dealt with at the session • the name of the person who conducted the session • the names of the workers who attended the session? | | | | |
| 8.0 | Drug preparation | | | | |
| 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 AS1386? | | | | |
| 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? | | | | |

| | | A | NC | NA | Remarks |
|------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|----|----|---------|
| 8.15 | Are general cleaning workers provided with information 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 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"> • training requirements • spill management in CDSC • procedure for decontamination of cabinet and re-assembly • management of spill in clean room, anteroom or storeroom • management of skin penetrating injuries and cytotoxic drug exposure • incident reporting • use of specifically dedicated equipment for compounding cytotoxic preparations • operational specifications for the use of drug preparation facilities including CSDSs • maintenance and certification of equipment and facilities • reconstitution procedures • labelling and packaging prepared drugs for internal and external transportation • routine and emergency cleaning and decontamination protocols in the cleanroom • procedures for storage areas (e.g. receipt, handling and storage of cytotoxic drugs) • selection, use, maintenance and disposal of PPE • handling cytotoxic contaminated laundry for collection • waste management? | | | | |
| 9.0 | Drug administration | | | | |
| 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? | | | | |

| | | A | NC | NA | Remarks |
|-------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|----|----|---------|
| 9.4 | <p>Are there written procedures for:</p> <ul style="list-style-type: none"> • training requirements • selection, use, maintenance and disposal of PPE • administration of parenteral, oral and topical cytotoxic drugs • extravasation incidents • management of skin penetrating injuries and blood or body substance exposures • management of cytotoxic drug exposures • spill management • incident reporting • waste management • cytotoxic contaminated laundry management • transportation of patient with chemotherapy in situ • home care information for patients and carers? | | | | |
| 10.0 | Patient care | | | | |
| 10.1 | <p>Are there written procedures for:</p> <ul style="list-style-type: none"> • training requirements • selection, use, maintenance and disposal of PPE • management of patient waste • cleaning or disposal of equipment used in patient care • laundry management • spill management • transportation of patients with chemotherapy in situ • management of skin penetrating injuries and blood or body substance exposures • management of cytotoxic drug exposures • incident reporting • home care information for patients and carers? | | | | |
| 11.0 | Spill management | | | | |
| 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? | | | | |
| 12.0 | Waste management | | | | |
| 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? | | | | |

| | | A | NC | NA | Remarks |
|-------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---|----|----|---------|
| 12.4 | <p>Are there written procedures for:</p> <ul style="list-style-type: none"> • identification, segregation and containment of cytotoxic waste • on-site transport of waste to collection area • spill management • training requirements for waste handlers • management of skin penetrating injuries and cytotoxic drug and related waste exposures • incident reporting • cleaning procedure (e.g. trolleys, wheelie bins, and storage area) • location and requirements for cytotoxic waste collection area • arrangements for waste disposal sub-contractors? | | | | |
| 13.0 | Laundry | | | | |
| 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"> • identification, segregation and containment of cytotoxic contaminated linen • safe handling of linen contaminated with cytotoxic drugs and related waste • spill management • training requirements laundry workers • management of skin penetrating injuries and cytotoxic drug and related waste exposures • incident reporting • laundry washing procedures? | | | | |

Appendix 7 – Training modules for working with cytotoxic drugs

All modules may be incorporated into training schedules at time of induction into the workplace and at annual refreshers. The 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).

| |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p>Module 1 – Introduction to cytotoxic concepts</p> <p>To ensure all workers are aware of, and understand the risks associated with the handling and use of cytotoxic drugs and related waste.</p> <p>Teaching points:</p> <p>1.1 Risks associated with occupational exposure to cytotoxic drugs and related waste:</p> <ul style="list-style-type: none">• health risks and toxic effects• reproductive health risks. <p>1.2 Rationale for use of cytotoxic drug therapy.</p> <p>1.3 Legislative requirements for the management of cytotoxic hazards, MSDSs, risk assessment, employer and worker obligations.</p> <p>1.4 Institutional policies and procedures.</p> <p>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:</p> <ul style="list-style-type: none">• define 'carcinogenic' 'mutagenic' and 'teratogenic'• concepts of cell replication• drug classifications and pharmacological action on cellular reproduction. <p>1.6 Health surveillance for workers working with cytotoxic drugs;</p> <ul style="list-style-type: none">• health assessment of workers after unprotected exposure to cytotoxic drugs:<ul style="list-style-type: none">○ rationale○ health assessment required in response to an unprotected exposure• principles for initial and ongoing health assessment:<ul style="list-style-type: none">○ rationale for personnel management○ the purpose of health assessment○ limitations of current health surveillance methods. <p>1.7 The importance of accurate record keeping (e.g. an activity log, records of spills and penetrating injuries). Storage requirements for health surveillance documentation to ensure confidentiality, perpetual safe keeping and retrieval.</p> <p>1.8 Incidents and spill management</p> <p>1.9 Safe disposal methods for cytotoxic drugs and related waste. Safe storage, packaging, consigning and transport of cytotoxic waste:</p> <ul style="list-style-type: none">• the rationale for the identification, segregation and safe handling of cytotoxic waste• institution policies and procedures as they apply to:<ul style="list-style-type: none">○ segregation of cytotoxic waste○ containment of cytotoxic waste○ transport of cytotoxic waste○ management of cytotoxic drug and related waste spills. <p>1.10 PPE requirements, including, selection, use, fit, maintenance, storage, cleaning and disposal.</p> |
| <p>Module 2 – Preparation of cytotoxic drugs</p> <p>To train workers in the safe preparation of cytotoxic drugs.</p> <p>Teaching points – to include Module 1, plus:</p> <p>2.1 Facility requirements:</p> <ul style="list-style-type: none">• minimum requirements for a cytotoxic preparation facility as defined by <i>AS 2567-2002: Laminar flow cytotoxic drug safety cabinets</i> and <i>AS 2639-1994:Laminar flow cytotoxic drug safety cabinets</i> - Installation and use |

- principles of clean spaces, their creation and maintenance as described in *AS 1386.1-1989: Cleanrooms and clean workstations - Principles of clean space control*:
 - 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 lyophilized 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 that are vesicants and those that are irritants
- principles of safe handling and administration of intrathecal cytotoxic drugs:
 - identify cytotoxic drugs that 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, colostomies etc.

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 drug exposure

| 1. Pre-employment and baseline health monitoring before the employee commences work with cytotoxic drugs | |
|-----------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1. Collection of demographic data | <ul style="list-style-type: none"> • name and unique company identification number, date of birth, gender • address • date commencing employment • 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). |
| 2. Occupational history | <ul style="list-style-type: none"> • places and duration of previous employment, including work with cytotoxic drugs • potential current exposure • whether suitable control measures are in place for handling cytotoxic drugs. |
| 3. Medical history | <ul style="list-style-type: none"> • presence of symptoms • general health • smoking history • personal history of cancer, family history of cancer in first relatives • history of asthma or other systemic allergic reactions or states (examples include systemic reaction to bee sting or allergic skin disorders) • whether the employee taking immuno-suppressive therapy • whether the employee pregnant or breast-feeding. |
| 4. Physical examination | <ul style="list-style-type: none"> • general physical examination. |
| 5. Investigation | <ul style="list-style-type: none"> • 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 • the appointed medical practitioner should focus on the risk factors outlined in the occupational history, and the outcome of the physical examination • the appointed medical practitioner should perform any investigations that may be appropriate as a result of the examination. |
| 6. Health advice and counselling | <p>The appointed medical practitioner should provide medical advice and counselling to the employee, including:</p> <ul style="list-style-type: none"> • the potential health effects associated with exposure to cytotoxic drugs and related waste (including but not limited to carcinogens, mutagens and teratogens) • the optimum standard of control measures to expect in the workplace • the results of the health monitoring, including any abnormal findings • the potential risks to workers planning parenthood, or those who are breast-feeding or pregnant. |
| 7. Report | <ul style="list-style-type: none"> • the appointed medical practitioner should provide a report to the employer and prospective employee advising that the employee has received assessment and health advice • confidentiality of medical records is to be maintained. Access to medical records is to be only by written consent of the employee concerned. |

| 2. During the period that the employee works with cytotoxic drugs | |
|-----------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8. Data for inclusion in health records | <ul style="list-style-type: none"> any risk assessments carried out at the workplace descriptive job titles, with relevant start and finish dates. Jobs within areas where cytotoxic drugs and related waste are used should be clearly identified results of workplace monitoring such as wipe tests or performance testing of control measures results of the investigation of spills and exposure events. |
| 9. Health advice and counselling | As described in point 6, advice and counselling should be offered by the employer annually and may be initiated at any time by the employee. |
| 10. Medical review | <ul style="list-style-type: none"> conduct a medical review as soon as possible in the following situations: <ul style="list-style-type: none"> after a reportable spill or penetrating injury occurs if a worker advises she is pregnant, or is breastfeeding if a worker advises they are planning parenthood. the review should take account of the previous medical examination and include health advice and counselling and a written report a follow-up review should be conducted after one month. |
| 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). |
| 3. On termination of employment where cytotoxic drugs and related waste are used | |
| 12. Data to be collected | <p>The following data should be collected:</p> <ul style="list-style-type: none"> date of termination reason for termination—ill-health (provide details) or other reasons (state reason) date and cause of death if in service. |
| 13. Final medical examination | <p>Conduct a medical examination including the factors already described, including:</p> <ul style="list-style-type: none"> medical history physical examination investigation health advice and counselling. <p>Provide a report to the worker. Medical reports regarding individual workers are to be provided to the employer only with the worker's written consent. However aggregated data may be provided to the employer for the purposes of analysis and review.</p> |

Appendix 9 – Excretion times of some cytotoxic drugs

The following table lists cytotoxic drugs that 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 – Full list of standard operating procedures

Standard operating procedures – General

The following general recommendations may be considered, where appropriate, in conjunction with those given for the specific chapters. 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 manufacturer's instructions, MSDSs 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
- designate the PPE to be worn
- be reviewed regularly and when there are incidents or changes to the workplace that affect that procedure (e.g. new equipment, new legislation, new products)
- incorporate emergency procedures, including the location of cytotoxic spill kits
- address cytotoxic waste disposal and management of cytotoxic contaminated laundry
- be documented and meet relevant record keeping requirements
- integrate smoothly and be consistent with other organisational policies
- be guided and informed by the risk management process
- be part of the induction and ongoing training program
- be documented and meet relevant record keeping requirements.

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

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 is developed for notification of changes to relevant legislation and subsequent review of affected documentation and practices.

Standard operating procedures – Chapter 3

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

- the risk management process includes: identify hazards, assess risk, determine control measures, implement control measures and monitor and review control measures
- legislative requirements regarding timing and content of risk assessments
- a specific person or position is assigned to manage the risk management process
- hazard identification includes 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
- risks assessment and prioritisation
- control measures are selected according to the hierarchy of control
- implementation of control measures
- appropriate checklists and templates are developed to support the process
- 'monitor and review' included in SOPs for all activities and tasks
- the risk management process adopted by the organisation is applied consistently
- records of the risk management process are maintained.

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/verification of training provided by other agencies
- verification of qualifications of workers before recruitment
- training records management system.

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 Material Safety Data Sheets
- 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 is 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.

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 surveillance requirements
- regular research to identify biological monitoring techniques that 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.

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 manufacturer's and supplier's 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.

Standard operating procedures – 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.

Standard operating procedures – Chapter 9

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

- use of the risk management system 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.

Standard operating procedures – 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.

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.

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 eg drug preparation suite, cytotoxic drug administration area, in transit, community care setting
- appropriate PPE is 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.

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 eg drug preparation suite, cytotoxic drug administration area, collection and storage areas, vehicles, waste treatment facilities
- identification, segregation and containment of cytotoxic waste—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
- disposal and treatment of cytotoxic contaminated waste at licensed treatment facilities
- emergency procedures for personal contamination, including incident reporting, which are integrated with organisational emergency policies and reporting procedures.

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 eg treatment rooms, animal cages, cytotoxic drug storage areas, waste treatment facilities
- identification, segregation and containment of cytotoxic contaminated waste and laundry—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/carers, including information on their use.
- return of unused cytotoxic drugs from owners for disposal.

Appendix 11 - Further information

Australian Standards

- *AS1386:1989: Parts 1-7 – Cleanrooms and clean workstations;*
- *AS1715:1994: Selection, use and maintenance of respiratory protective devices*
- *AS/NZS1716:2003: Respiratory protective devices*
- *AS1807:2000: Cleanrooms, workstations, safety cabinets and pharmaceutical isolators - Methods of test - List of methods and apparatus (various parts as appropriate)*
- *AS 2013.1:1989: Cleanroom garments – Product requirements*
- *AS2567:2002: Laminar flow cytotoxic drug safety cabinets*
- *AS2639:1994: Laminar flow cytotoxic drug safety cabinets - Installation and use*
- *AS4273:1999: Design, installation and use of pharmaceutical isolators*
- *AS4031:1992: Non-reusable containers for the collection of sharp medical items used in healthcare areas.*

Australian Safety and Compensation Council (ASCC – formerly NOHSC) <http://www.nohsc.gov.au/OHSInformation/NOHSCPublications/>

- *National code of practice for the control of workplace hazardous substances* [NOHSC:2007 (1994)]
- *National code of practice for the labelling of workplace substances* [NOHSC:2012 (1994)]
- *Approved criteria for classifying hazardous substances* [NOHSC:1008 (2004)]
- *Exposure standards for atmospheric contaminants in the occupational environment - database* [NOHSC:3008 (1995)]
- *Guidelines for health surveillance* [NOHSC:7039 (1995)]
- *National Code of Practice for the Control of Scheduled Carcinogenic Substances* [NOHSC:2014 (1995)]
- *Guide: Atmospheric contaminants* (1989)
- *Guidance note for placarding stores for dangerous goods and specified hazardous substances* [NOHSC:3009 (1990)]
- *Guidance note on the interpretation of exposure standards for atmospheric contaminants in the occupational environment*, 3rd edition [NOHSC:3008 (1995)]
- *Guidance note for the assessment of health risks arising from hazardous substances in the workplace* [NOHSC:3017 (1994)]
- *Managing Workplace Hazards fact sheet - Hazardous substances*
- *Managing Workplace Hazards fact sheet - Reproductive health and pregnancy*
- *Competencies for health surveillance* (1998)
- *Guidelines for health surveillance* (1995).

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). www.cdc.gov/niosh/topics/hazdrug/.

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*, www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html.

Worksafe Victoria. 2003. *Handling cytotoxic drugs in the workplace*. www.workcover.vic.gov.au/dir090.

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 - www.legislation.qld.gov.au/Legislation.htm
- Department of Industrial Relations - www.dir.qld.gov.au
- Queensland Health - www.health.qld.gov.au
- Environmental Protection Authority - www.epa.qld.gov.au
- Department of Emergency Services - www.emergency.qld.gov.au
- Queensland Transport - www.transport.qld.gov.au
- International Maritime Organization - www.imo.org
- Australian Department of Transport and Regional Services - www.dotars.gov.au/transreg/dgoods.htm
- International Civil Aviation Organization - www.icao.int
- Australian Safety and Compensation Commission - www.nohsc.gov.au



Workplace Health and Safety Queensland
Telephone: 1300 369 915
Website: www.dir.qld.gov.au

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