



WORKSAFE VICTORIA

HANDLING CYTOTOXIC DRUGS IN THE WORKPLACE

January 2003

**MANAGING HEALTH & SAFETY
RISKS ASSOCIATED WITH HANDLING
CYTOTOXIC DRUGS IN THE
HEALTHCARE INDUSTRY**



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CORPORATE STATEMENT

In a range of Victorian healthcare settings, use of cytotoxic drugs is of vital importance in the treatment of many cancers and other medical conditions.

Cytotoxic drugs are handled by professionals in numerous healthcare, community and veterinary settings. Yet the ability of cytotoxic drugs to damage and kill cells – so vital to cancer treatment – creates potential risks to those who handle them during the course of their work.

The impetus to produce this guide to handling cytotoxic drugs came from an oncology nurse, with support from the Australian Nursing Federation (Victorian Branch). Following advice from the then Minister for Health, the Hon. John Thwaites, a working party was convened to produce this publication. That group involved expert input from the fields of nursing, pharmacy and medicine, and was facilitated by WorkSafe Victoria.

The result is an extremely comprehensive publication that covers most scenarios involving the occupational handling of cytotoxic drugs. I thank those experts who have contributed to the development of this guide, and hope that it becomes essential reading for Victorian healthcare professionals who work with cytotoxic drugs.

Rob Hulls

Minister for WorkCover



SECTION 1: HANDLING CYTOTOXIC DRUGS

This guide aims to provide practical advice to employers and healthcare workers on how to prevent or reduce the risks associated with handling cytotoxic drugs and related waste.



This document outlines a range of tools designed to assist in the development and implementation of safe work systems. The scenarios and suggestions are consistent with the requirements of health and safety laws and are applicable to healthcare, community and veterinary settings. The guidelines represent current 'best practice' in the healthcare industry and form an industry standard.

This guide has been presented in a logical sequence, describing the importance of risk management in the handling of cytotoxic drugs. Appendices provide practical tools for key stages of handling, preparing and administering cytotoxic drugs, including checklists and samples of helpful documentation.

This guide applies to the clinical handling of cytotoxic drugs and related waste in healthcare settings, and may be used in the following situations:

- *Hospital settings*
- *Pharmacies - hospital and community*
- *Analytical or research laboratories*
- *Doctors' surgeries and medical practice rooms*
- *Domiciliary ambulatory clinics*
- *Homes of patients*
- *Nursing homes and hostels*
- *Veterinary clinics*
- *Ambulance vehicles*
- *Pharmacy and pathology courier services*
- *Waste collection and disposal facilities.*

WHAT ARE CYTOTOXIC DRUGS?

Cytotoxic drugs are therapeutic agents intended for, but not limited to, the treatment of cancer. These drugs are known to be highly toxic to cells, mainly through their action on cell reproduction. Many have proved to be carcinogens, mutagens or teratogens.

Cytotoxic drugs are increasingly being used in a variety of healthcare settings, laboratories and veterinary clinics for the treatment of cancer and other medical conditions such as rheumatoid arthritis, multiple sclerosis and auto-immune disorders.

In the international healthcare arena, cytotoxic materials are identified by a purple symbol representing a cell in late telophase.



SECTION 1: HANDLING CYTOTOXIC DRUGS

POTENTIAL HEALTH EFFECTS OF CYTOTOXIC DRUGS

Current statistics show that one in three people have a life-long risk of developing cancer. There is little scientific evidence currently available relating to whether working with cytotoxic drugs actually increases the risk of developing cancer or not. However, in the absence of such data, a strategy of prudent avoidance is recommended.

In the workplace, occupational exposure may occur where control measures fail or are not in place. Exposure may be through skin contact, skin absorption, inhalation of aerosols and drug particles, ingestion and needle stick injuries resulting from the following activities:

- drug preparation
- drug administration
- handling patient waste
- transport and waste disposal, or
- spills.

Personnel likely to be involved in these activities include:

- nurses and medical officers
- pharmacists
- laboratory staff, and
- cleaning, maintenance and waste disposal staff.

Where control measures are not adequate, adverse health effects may result from occupational exposure. Health effects attributed to cytotoxic drugs exposure amongst people preparing and administering cytotoxic drugs include:

- abnormal formation of cells and mutagenic activity
- alterations to normal blood cell count
- foetal loss in pregnant women and malformations in the offspring of pregnant women
- abdominal pain, hair loss, nasal sores and vomiting
- liver damage, and
- contact dermatitis, local toxic or allergic reaction, which may result from direct contact with skin or mucous membranes.

Health effects attributed to exposure to occupational cytotoxic drugs can be very serious. Research shows that where a high standard of risk control is in place, threats to health are reduced.

No exposure limits are set for cytotoxic drugs. Medical opinion is such that even low-level exposure to cytotoxic drugs should be avoided as much as possible. Research has shown that the implementation of suitable safety precautions reduces the incidence of adverse health effects.

Further information about research references is provided in Appendix 3 - Information Sources.



SECTION 1: HANDLING CYTOTOXIC DRUGS

RISK CONTROL

The greatest risk of occupational exposure to cytotoxic drugs is during drug manufacture and preparation, because of the concentrations and quantities used. The first priority in protecting the health of employees is to eliminate or reduce the risks to health so far as is practicable. This may be implemented through:

- establishment of written policies and protocols to ensure the safe handling of cytotoxic drugs
- effective planning and design of the workplace
- use of 'best practice' control measures and specialised equipment such as cytotoxic drug safety cabinets
- the implementation of stringent handling procedures
- training and education of employees
- wearing personal protective equipment
- an integrated health monitoring program that:
 - includes the assessment and counselling of prospective employees before they commence any work involving cytotoxic drugs and related waste; and
 - ensures employee confidentiality is maintained.

It is paramount in healthcare settings that patients are appropriately educated before treatment, so they understand and appreciate the health and safety requirements for healthcare employees.

WHAT ARE THE LEGAL ISSUES?

Under the Victorian *Occupational Health and Safety Act 1985* employers have a legal obligation to provide and maintain for employees, so far as is practicable, a working environment that is safe and without risks to health. The legal requirements that specifically cover handling of cytotoxic drugs are outlined in the table in Appendix 2 of this guide. Essentially, Victorian employers (including manufacturers, importers and suppliers of substances) have specific and clear obligations.

Work involving the handling of cytotoxic drugs may fall within the scope of the *Occupational Health and Safety (Hazardous Substances) Regulations 1999*.

This guide may be used to assist in ensuring work practices involving cytotoxic drugs meet the employer duties of:

- The *Occupational Health and Safety (Hazardous Substances) Regulations 1999*, for defined hazardous substances, and
- The *Occupational Health and Safety Act 1985*, for substances not meeting the approved criteria.

The *Code of Practice for Hazardous Substances (2000)* gives practical guidance on how to comply with these regulations.

Key messages for employers

Employers who use hazardous substances have the added duty to ensure they adopt a three-pronged approach to mitigating risk:

Step 1 Identify the hazardous substances used in the workplace

Step 2 Assess the risk to health, and

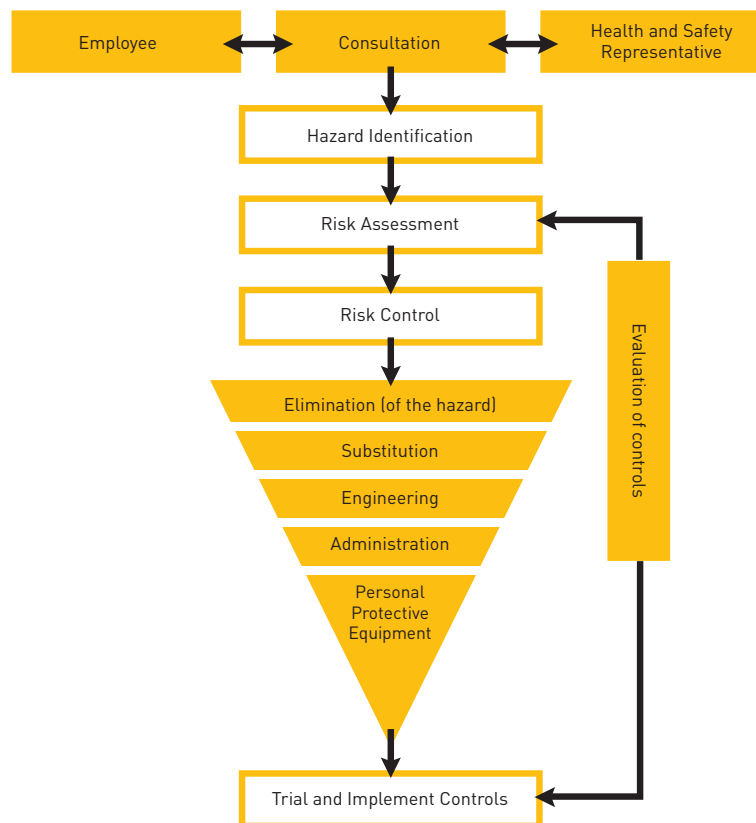
Step 3 Control any risk to health associated with their use.

SECTION 1: HANDLING CYTOTOXIC DRUGS

INTEGRATING HEALTH AND SAFETY LAW INTO THE WORKPLACE

In implementing legal requirements, effective management of health and safety becomes essential to protecting the health of employees. An employer should ensure that all managers, supervisors and employees are aware of their health and safety responsibilities. This should be done by collaborating, documenting responsibilities, and ensuring processes are in place to hold persons accountable for occupational health and safety performance.

Figure 1: The hazard management approach



THE RISK MANAGEMENT APPROACH

The aim of a risk management approach (outlined in Figure 1) is to eliminate or reduce the risk of illness or injury associated with work. This generally involves a process of:

- hazard identification
- risk assessment
- risk control, and
- evaluation of control measures.

Effective management of health and safety also involves:

- consultation
- personnel management
- training
- documentation of activities, and
- regular review of the management system.

SECTION 1: HANDLING CYTOTOXIC DRUGS

THE NEED FOR CONSULTATION

Employers are required to consult with the relevant health and safety representative(s) when assessing and controlling risks arising from the handling of cytotoxic drugs. Consultation directly with employees will draw on their experience and knowledge. Consultation should occur:

- when identifying cytotoxic drugs
- during the risk assessment process
- when determining which control strategies should be applied to eliminate or reduce risks associated with the handling of cytotoxic drugs, and
- when reviewing the effectiveness of control measures.

Consultation should take place as early as possible when planning to introduce new cytotoxic drugs into the workplace. A range of mechanisms can be used to facilitate consultation, including direct discussion, toolbox meetings, quality circles, health and safety committee meetings, quality reports, hazard inspections, special working parties, or combinations of these.

The needs of employees and their health and safety representative(s) who come from non-English speaking backgrounds should be considered. Enough time should be allowed for health and safety representative(s) to confer with employees and feed their ideas back to employers.

When consulting, employers need to ensure that accurate and relevant safety information such as Material Safety Data Sheets (if available), incident records and any other information, are made available to employees and their health and safety representative(s).

Consultation is a vital step in the development of any risk management strategy and, in fact, is a legal requirement. Consultation should occur directly with employees at key stages of strategy development, implementation and review.

Key messages

Cytotoxic drugs are known to be highly toxic. For this reason, employers with staff who handle them occupationally have an obligation to:

- Work to a risk management strategy*
- Keep up-to-date with current practices and standards*
- Consult with employees at key stages of risk strategy development – at planning stage, during implementation, monitoring and review*
- Assess policies and procedures on a regular basis.*

SECTION 2: MANAGING THE RISK



This section outlines the risk management process that employers should follow for identifying the hazard, and assessing - then controlling - the risk. It leads employers through the risk management process in a logical progression. This information may be used to design a risk management strategy. Employees should be consulted at every stage of the risk management process.

BUILDING A RISK ASSESSMENT

STEP 1: Hazard Identification

The table below provides examples of how you can ascertain the cytotoxic drugs that are used in your workplace.

1. IDENTIFY WHICH CYTOTOXIC DRUGS ARE USED AND STORED AT THE WORKPLACE

Obtain a copy of the manufacturer's or importer's Material Safety Data Sheet (MSDS) for all cytotoxic drugs (where available).

Ways of achieving this include:

- Contact the supplier
- If a Material Safety Data Sheet is not available, safety information about the relevant cytotoxic drug should be obtained from the manufacturer or importer.

Ensure all containers of cytotoxic drugs are labelled with the manufacturer's or importer's label.

Ways of achieving this include:

- Check all containers for labels.

Set up and maintain a cytotoxic drugs register.

Ways of achieving this include:

- List the product names of all cytotoxic drugs used at the workplace
- Check the Material Safety Data Sheet and the product label to identify cytotoxic drugs that are classified as hazardous substances. The Material Safety Data Sheet will state whether the product is classified as hazardous.
- Indicate which products are classified as hazardous.

Additional useful information may be added to the register in Appendix 6 - Cytotoxic Drugs Register. A sample Material Safety Data Sheet (MSDS) can be found in Appendix 5.

STEP 2: Risk Assessment

A risk assessment determines whether there is a risk to employees' health from cytotoxic drugs. The risk assessment may be done for a work process, and may cover more than one cytotoxic drug. The following step-by-step procedure may be used to assist with the risk assessment process.

1. DECIDE WHO WILL CARRY OUT THE RISK ASSESSMENT

Select a competent person or team comprising employees, health and safety representatives, supervisors and managers.

What to look for:

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

SECTION 2: MANAGING THE RISK

2. OBTAIN AND REVIEW INFORMATION ABOUT CYTOTOXIC DRUGS USED

<i>Determine the routes of exposure.</i>	<p>These may include:</p> <ul style="list-style-type: none"> • inhalation of aerosols, particulates and droplets • skin or eye contact through splash of liquid • ingestion through poor personal hygiene or splash of liquid • injection resulting from injuries from sharps.
<i>Determine the form of the substance.</i>	<p>This may include:</p> <ul style="list-style-type: none"> • liquid • powder • solid tablet • creams, ointments and lotions for topical application.
<i>Ascertain the potential harmful effects.</i>	<p>These may include:</p> <ul style="list-style-type: none"> • carcinogenic, mutagenic or teratogenic potential • alterations to normal blood cell count • foetal loss in pregnant women and malformations in the offspring of pregnant women • abdominal pain, hair loss, nasal sores, vomiting • liver damage • contact dermatitis, local toxic or allergic reaction, irritation to the skin.
<i>Consult the Material Safety Data Sheet (or other available information for each drug) for details of the properties and hazards associated with the substance.</i>	<p>This may include:</p> <ul style="list-style-type: none"> • health hazard information • precautions for use • safe handling information.

3. EVALUATE THE NATURE OF THE WORK INVOLVING CYTOTOXIC DRUGS

<i>Divide up the workplace and determine where cytotoxic drugs are used.</i>	<p>For example:</p> <ul style="list-style-type: none"> • drug preparation in the pharmacy • drug administration in the ward or daycare centre • handling, transport and disposal of cytotoxic waste on the premises • patient care after administration.
<p><i>Examine the work practices and conditions.</i></p> <p><i>(Involve employees who are working with the cytotoxic drugs).</i></p>	<p>What to look for:</p> <ul style="list-style-type: none"> • how the substance(s) is used in various jobs • the quantities used • level of potential exposure • frequency and duration of use • the number of employees that may be exposed • risk control measures already in place and their effectiveness.
<i>Review information relating to incidents or symptoms of exposure.</i>	<p>What to do:</p> <ul style="list-style-type: none"> • review incident records • identify any problems associated with storage and transport of cytotoxic drugs • determine whether employees have suffered any adverse effects • ascertain whether there have been any spills • determine if incidents have been reported and followed up.

SECTION 2: MANAGING THE RISK

Conclude whether or not an injury or illness is likely to occur as a result of any identified work activity or exposure to cytotoxic drugs and related waste.

4. EVALUATE THE RISKS

No likelihood of injury or illness.

This means that employers have a high degree of confidence that work practices are sound and that employees are protected.

It may be reasonable to make such a conclusion where:

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

Likelihood of injury or illness.

This means it is apparent that work practices need improvement.

It may be reasonable to make such a conclusion where:

- work methods do not employ 'best practice' control
- drug preparation is not conducted within a properly operational cleanroom with a laminar-flow cytotoxic drug safety cabinet
- drug administration does not employ needleless systems
- housekeeping is poor
- some activities involve skin contact
- personal protective equipment such as gloves and skin covering are not worn
- the workforce has not received appropriate training
- control measures are not maintained or serviced
- no spill management system exists.

Likelihood of injury or illness is uncertain.

This means that employers are not sure whether work practices are adequate to protect employees.

It may be reasonable to make such a conclusion where employers are not sure if there is a risk to health – and may require employers to do more work, for example:

- conduct wipe tests and atmospheric monitoring (if valid and interpretable tests are available) to determine whether there is any contamination. These tests must be individualised to each workplace, according to the drug used.
- eliminate or reduce exposure so far as is practicable.



SECTION 2: MANAGING THE RISK

5. RECORD, REVIEW AND REVISE THE RISK ASSESSMENT

<p><i>Record the work done during the risk assessment and the outcomes of the assessment. This will help you measure the effectiveness of risk controls, and may reveal areas for improvement.</i></p>	<p>What to include:</p> <ul style="list-style-type: none"> • name of the assessor • date of the assessment • the workplace/unit • the substance for which the Material Safety Data Sheet (or equivalent information) has been reviewed • the controls in place to prevent a risk to health • a summary of the process • hazard information on the substance(s) • the degree of exposure, or nature of risk identified • why decisions about the risk were made • any information that assisted in reaching a conclusion.
<p><i>Make the results of the assessment accessible to any employee to which the record relates.</i></p>	<p>Ways of achieving this include:</p> <ul style="list-style-type: none"> • keep copies of the assessment in accessible/commonly used files.
<p><i>Review and revise the risk assessment. The risk assessment should be reviewed and revised as necessary and at least every five years.</i></p>	<p>Ways of achieving this include:</p> <ul style="list-style-type: none"> • schedule regular reviews to make sure that the assessment is valid and still applies • establish the circumstances that would trigger a review or revision, such as: <ul style="list-style-type: none"> - an incident, or near miss, resulting from the failure of the control measures - symptoms reported that may relate to the substance used - a change in the product used (including its form) - introduction of a new work process or changes to an existing process - increase in the hours worked or frequency and duration of exposure - increase in the quantities used - availability of new information about the health hazards of the substances • ensure that management, supervisors, health and safety representatives and purchasing officers feed back the outcome of the review into the assessment process • record the date of the review or revision of the assessment, including the outcome, and any action required to be taken, by when and by whom.

Other useful guidance material can be found in Appendix 3 - Information Sources.

STEP 3: Risk Control

The *Occupational Health and Safety (Hazardous Substances) Regulations 1999* set out a hierarchy of control (or ranking of controls) that incorporates a 'best practice' approach to managing risks. The employer's primary duty is to eliminate any risk to health arising from the use of a hazardous substance. Where elimination of risk is not practicable, employers must reduce the risk, so far as is practicable.

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

1. ELIMINATE THE RISK

<p><i>Eliminate the risk.</i></p>	<p>For example:</p> <ul style="list-style-type: none"> • purchase cytotoxic drugs in ready-to-use concentrations, to eliminate pharmacy preparation • establish supply arrangements with a company or healthcare institution that specialises in the preparation of cytotoxic drugs.
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SECTION 2: MANAGING THE RISK

Where eliminating the risk is not practicable, employers must reduce the risk so far as is practicable.

2. REDUCE THE RISK	
Substitution	For example:
<i>Substitution involves using a less hazardous substance or a substance in a less hazardous form.</i>	<ul style="list-style-type: none"> • purchase single-dose preparations • purchase cytotoxic drugs in a liquid form rather than in a powder form • use a more dilute form of cytotoxic drug where possible • incorporate handling techniques that minimise aerosol generation • purchase drugs in vials, not ampoules • purchase drugs in plastic vials, or vials reinforced with plastic casings.
Isolation	For example:
<i>Isolation involves separating people from the substance by distance or barriers to prevent or reduce exposure.</i>	<ul style="list-style-type: none"> • adopt closed-system operations • conduct drug preparation work in a properly designed and secure cleanroom • place dispensed drugs in impermeable packaging for delivery to administration areas • designate a cytotoxic drug administration area, which only permits entry to authorised people.
Engineering controls	For example:
<i>Engineering controls are plant or processes that reduce the generation of substance, suppress or contain substances, or limit the area of contamination in the event of spills and leaks.</i>	<ul style="list-style-type: none"> • install ventilation and air-filtering systems such as laminar-flow cytotoxic drug safety cabinets • use wide-bore needles to transfer liquids from containers in the pharmacy • use needleless injection sets for drug administration • incorporate secure storage facilities.
Administrative controls	For example:
<p><i>If a risk remains, administrative controls should be used to further reduce the risk. Administrative controls include work practices that help to reduce employee exposure to cytotoxic drugs and related waste.</i></p> <p><i>The effective use of administrative controls relies on the full cooperation of employees, and therefore, consultation is important during their development. Adequate supervision and training are paramount if work practices are to play an effective part in reducing employee exposure to cytotoxic drugs and related waste.</i></p>	<ul style="list-style-type: none"> • allocate responsibilities for health and safety • reduce the number of employees who work with cytotoxic drugs • clean work areas regularly • keep containers of cytotoxic drugs secure and tightly lidded when not in use • prohibit eating, drinking and smoking in work areas • develop and implement standard operating procedures for all work activities • provide appropriate information, education and training to employees • use cytotoxic signs and labels to clearly identify all cytotoxic drugs • store cytotoxic waste in specific, clearly identified areas, separate from other waste • develop emergency procedures to deal with spills.
Personal protective equipment	Personal protective equipment includes:
<i>If a risk remains, the risk should be controlled by providing personal protective equipment to employees at risk. Personal protective equipment is something worn that provides a barrier between the person and the hazard.</i>	<ul style="list-style-type: none"> • coveralls • gowns • head covering • closed footwear • overshoes • gloves of appropriate material and thickness • safety glasses • respiratory protective devices.

SECTION 2: MANAGING THE RISK

OTHER INFORMATION ABOUT PERSONAL PROTECTIVE EQUIPMENT

Make sure that the equipment is:

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



Employers must ensure that all employees know how to fit and use personal protective equipment. Guidance may be obtained from the supplier of cytotoxic drugs, suppliers of personal protective equipment and published technical standards. Appendix 9 - Personal Protective Equipment, includes equipment recommended for work with cytotoxic drugs.

Make the workplace safer

Employers need to ensure that all control measures are properly used and maintained. They must not rely exclusively or primarily on administrative controls or personal protective equipment to control the risk, as these measures depend heavily on human behaviour to be effective. The workplace needs to be made safer, rather than placing the onus on employees to work safely in a hazardous environment. It is important to remember that a number of risk controls will need to be used in combination to effectively eliminate or reduce the risk.

Review control measures

Control measures should be regularly maintained, reviewed and, where necessary, improved, extended or replaced. Controls should also be reviewed if indicated by an evaluation of risk assessments and in the cases of near misses, incidents, injuries or a report of work-related ill health.

REVIEW CONTROL MEASURES

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

FOR EXAMPLE:

This may include:

- frequent inspections
- visual checks to ensure that controls are being properly applied in the workplace
- testing of equipment
- preventative maintenance
- remedial work.

STEP 4: Develop a risk control plan

One way of tracking proposed and implemented controls is to prepare a risk control plan. This is a strategy that details a logical series of activities involving consultation, implementation and review. The table below gives an indication of the issues that should be covered.

RISK CONTROL PLAN

A risk control plan sets out the actions required to implement controls over time. It also provides a useful tool to effectively manage this process.

A BASIC STRUCTURE FOR A RISK CONTROL PLAN:

- provide a history of health and safety activities for work involving cytotoxic drugs, including any current control measures and their effectiveness
- specify immediate, interim and long-term control measures
- set priorities for putting controls in place
- indicate when controls are to be implemented
- specify those responsible for overseeing the implementation
- record the date of completion and "sign off" by a person nominated by management
- include or refer to relevant policies and procedures for work involving cytotoxic drugs
- outline plans for the provision of training
- involve employees, through consultation
- provide full documentation of activities
- include a process for the regular review of management systems.

SECTION 3: HEALTH MONITORING



A vital aspect of the risk management program is to monitor the health of employees. This section deals with the issues of employee health monitoring, counselling, reporting and record keeping.

WHAT IS HEALTH MONITORING?

The *Occupational Health and Safety Act 1985* requires employers to "monitor the health" of employees so far as is practicable. What this means is that employers must conduct thorough and regular surveillance of their employees' health.

Where chemicals are used in the workplace, health monitoring refers to the process of checking and counselling individuals to identify changes to health status caused by occupational exposure to a substance. Health monitoring may include biological monitoring, which is the measurement and evaluation of a substance or its metabolites in the body tissue, fluids or exhaled air of an exposed person.

THE CONUNDRUM OF 'BIOLOGICAL MONITORING'

Many methods have been used to investigate potential health effects of exposure to cytotoxic drugs. These methods have provided results that are often inconclusive and difficult to interpret.

The ideal test should meet several requirements – it should be sensitive, specific, quantitative, rapid, reproducible and inexpensive. Importantly, the procedures for taking a sample should be non-invasive, and should not cause unnecessary duress or anxiety to the individual.

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

Therefore, this guide recommends that biological monitoring should not be part of the health monitoring program. Nevertheless, employers have a responsibility to ensure that they remain aware of current developments for monitoring the health of employees involved in the handling of cytotoxic drugs, and apply any new recommendations.

SECTION 3: HEALTH MONITORING

WHAT TYPE OF HEALTH MONITORING SHOULD BE PROVIDED?

A health monitoring program should meet the needs of employees by providing security, care, freedom of choice and elimination of sex bias. Employers must have regard to anti-discrimination, equal employment opportunity and other relevant legislation. Health monitoring should be based on the following factors:

FACTORS IN IMPLEMENTING A HEALTH MONITORING PROGRAM	CONSIDERATIONS
1. Risk control is the key to protecting the health of employees.	<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. <i>Appointment means that the employer has a formal arrangement with a medical practitioner. All employees should be made aware of this arrangement.</i>	<ul style="list-style-type: none"> the medical practitioner may be an occupational physician, oncologist, haematologist or local general practitioner, ideally with a special interest in cytotoxic drugs the 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 by the <i>National Occupational Health and Safety Commission (NOHSC) Competencies for Health Surveillance (1998)</i>.
3. Guidance is provided to the appointed medical practitioners.	<ul style="list-style-type: none"> guidance is outlined in Appendix 8 - Guidelines for medical practitioners in health monitoring for cytotoxic drugs general guidance is provided in the National Occupational Health and Safety Commission (NOHSC) publications <i>Competencies for Health Surveillance (1998)</i> and <i>Guidelines for Health Surveillance (1995)</i>.
4. The health monitoring program is an integrated part of the workplace.	<ul style="list-style-type: none"> employees 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 provided 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, is recorded.
5. Prospective employees are counselled and provided information about the risks of working with cytotoxic drugs.	<p>The counselling should include:</p> <ul style="list-style-type: none"> the nature of work to be undertaken potential risks to health 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.	<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.	<p>Health monitoring is conducted during the period the employee works with cytotoxic drugs (as outlined in Appendix 8) and provides:</p> <ul style="list-style-type: none"> data for inclusion in health records such as health advice and counselling medical review after a spill or sharps injury review of control measures (for example, needleless injection sets should be in place to eliminate the potential for sharps injuries).
8. Medical advice and counselling is available to employees at any time during their employment.	<p>Employees may arrange a consultation with the appointed medical practitioner at any time.</p>
9. Employees 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 employees who choose not to (or are unable to) work with cytotoxic drugs. In such cases, employees should not suffer disadvantage in relation to loss of pay and conditions, or continuity of service. All entitlements must be maintained.</p>

SECTION 3: HEALTH MONITORING

FACTORS IN IMPLEMENTING A HEALTH MONITORING PROGRAM	CONSIDERATIONS
10. <i>The results of health monitoring are provided to the employee to whom the results relate.</i>	The results should be available as soon as possible.
11. <i>Employees' medical records are confidential.</i>	Where any form of health monitoring is undertaken, confidentiality of employees' medical records should be ensured. Access to an employee's medical records can be obtained only with the written consent of the employee.
12. <i>Health monitoring is offered on termination of employment where cytotoxic drugs were used.</i>	Health monitoring on termination of employment, as outlined in Appendix 8, provides: <ul style="list-style-type: none"> • data collection • final medical examination. On termination of employment, the departing employee should receive: <ul style="list-style-type: none"> • a statement indicating the duration and nature of work • the results of the health monitoring conducted • a report of any incidents involving cytotoxic drugs.

EMERGENCY PROCEDURES

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

For further information on emergency procedures involving exposure to employees, refer to Appendix 11 - Procedure for dealing with the contamination of employees.

REPORTING AND KEEPING RECORDS

The employer should keep the following records:

- a register of all hazardous substances used in the workplace, along with the current Material Safety Data Sheet for each substance listed
- risk assessment reports
- health monitoring records (should be kept for 30 years)
- training records for any training provided
- individual employee records (medical records are to be kept confidential)
- a register of drug preparation equipment and processes
- records of spills, sharps injuries and contamination incidents.

Where chemicals are used in the workplace, health monitoring refers to the process of checking and counselling individuals to identify changes to health status caused by occupational exposure to a substance. Likewise, working with cytotoxic drugs demands strict monitoring of employees' health, acting on any changed status, reporting any incidences and keeping appropriate records.

SECTION 4: TRAINING

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



Employers should ensure that only employees who have received appropriate training, and have obtained the required level of proficiency, handle cytotoxic drugs and related waste.

Training should occur:

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

WHO SHOULD BE TRAINED?

The risk assessment results should be used to identify staff requiring specific training. These staff might include:

- pharmacy personnel
- nursing and medical personnel
- laboratory staff
- veterinary surgeons and veterinary nurses
- ambulance officers
- supervisors and managers
- maintenance personnel
- stores personnel
- cleaners
- on-site waste transporters
- couriers and porters
- waste handlers
- waste generators.

IDENTIFY TRAINING REQUIREMENTS

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

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

Training providers can be located in the consultants' directory of WorkSafe Victoria's website at www.workcover.vic.gov.au

SECTION 4: TRAINING

EVALUATE THE TRAINING PROGRAM

The training program should be evaluated to:

- assess the effectiveness of the training (by monitoring how work is being performed) to determine whether control measures are used
- routinely monitor employees' performance to ensure continued competency. Monitoring performance will determine if further training is required.
- review the training program to ensure the modules and topics provided in the training are applicable to the work being carried out. This should be done:
 - each time there is a change in work practices and/or a control measure, or
 - at intervals no greater than two years.

KEEP TRAINING RECORDS

Employers should keep records of each training session provided to employees, including:

- date of the session
- topics dealt with at the session
- the name of the person who conducted the session
- the names of the employees who attended the session
- course evaluations
- the competencies assessed.

A strategy of continuous education should be developed and implemented to keep staff up-to-date with policies and procedures for handling cytotoxic drugs.



SECTION 5: PREPARING AND DISPENSING DRUGS

In the healthcare industry, drug preparation work poses the greatest risk of occupational exposure to personnel. Exposure may occur through:

- skin contact with cytotoxic material
- spills
- inhalation of aerosols and powders
- sharps injuries.



Workplace design, set-up and maintenance should be formulated in accordance with the Australian Standard (as listed in Appendix 3 - Information Sources). Cleanrooms, cytotoxic laminar flow drug safety cabinets, and other specially designed equipment, should be in place to facilitate the safe preparation of cytotoxic drugs. Education and training is crucial, to ensure that control measures and safe work practices are developed, understood, implemented and maintained.

Some examples of 'best practice' controls are:

- outsource cytotoxic drug preparation work to a company that specialises in this sort of work
- purchase cytotoxic drugs in a ready-to-use form, such as pre-filled syringes
- purchase cytotoxic drugs in the safest form available
- review health and safety information about cytotoxic drugs before making a decision to purchase them
- use facilities that meet recommended technical and safety standards
- design and layout the work area according to recommended standards
- adopt closed-system operations.

These control options should be considered as a priority.

The following standards represent best practice in Australia:

- *The Society of Hospital Pharmacists of Australia (SHPA) Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments (1997)*
- *The Society of Hospital Pharmacists of Australia (SHPA) Standards of Practice for the Transportation of Cytotoxic Drugs from Pharmacy Departments (1999)*

ALTERNATIVE SUPPLY ARRANGEMENTS

Healthcare establishments that are unable to provide facilities, equipment and training (as specified in these guidelines) should not undertake to provide a cytotoxic drug service. Alternative arrangements could include:

- supplying prepared cytotoxic drugs in a single-dose delivery unit purchased from a commercial source
- establishing supply arrangements with a healthcare institution that has the required facilities, equipment and trained personnel to provide prepared cytotoxic drug doses.

ESTABLISHING A CYTOTOXIC PREPARATION FACILITY

Drug preparation facilities

Cytotoxic drugs should be prepared in a purpose-designed cleanroom suite consisting of:

- a cytotoxic cleanroom that houses a laminar-flow cytotoxic drug safety cabinet or pharmaceutical isolator for drug preparation
- access only through an anteroom and pass-through hatch. A secondary barrier to prevent cytotoxic drugs contamination of the outside environment should be provided by High Efficiency Particulate Air (HEPA) filters that supply filtered air to the cleanroom and the anteroom.

SECTION 5: PREPARING AND DISPENSING DRUGS

The following technical standards are recommended, as they describe suitable risk controls for facilities and installation of these facilities:

- *Australian Standard AS 1386-1989 Cleanrooms and clean workstations*
- Standards for the provision of drug containment and aseptic manipulation include either:
 - a separate dedicated cytotoxic drug safety cabinet installed with a carbon filter that complies with *Australian Standard AS 2567-2002 - Laminar flow cytotoxic drug safety cabinets*. Installation and use of cytotoxic laminar flow drug safety cabinets should be in accordance with the specifications of *Australian Standard AS 2639-1994 Laminar flow cytotoxic drug safety cabinets - installation and use*, or
 - a pharmaceutical isolator that complies with *Australian Standard AS 4273-1999* and *Australian Standard AS 4273-1999/Amdt1-2000 Guidelines for the design, installation and use of pharmaceutical isolators*.

Work organisation layout and design

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

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

Further design considerations

Additional considerations in designing and setting up a cleanroom and anteroom include:

- provision of access for cleaning
- incorporation of smooth and durable work surfaces and furniture
- installation of recessed lights
- limitation of the number of surfaces and shelves, to minimise particle shedding or the accumulation of particulate matter
- installation of an accessible emergency shower outside the anteroom
- maintenance of an effective airlock between the cytotoxic suite and external environment
- ensuring all equipment used is dedicated to the cytotoxic cleanroom
- ensuring the anteroom provides:
 - the only access to the cleanroom
 - access to only one cleanroom
- change-room facilities for changing into personal protective equipment
- ensuring the pass-through hatch has:
 - no direct access to the external environment unless a High Efficiency Particulate Air (HEPA) filter is used to control emissions
 - interlocking doors, and is supplied with High Efficiency Particulate Air (HEPA) filtered air
- provision of a means of communication between the cleanroom and other areas
- installation of a manometer to monitor the pressure differential within the cytotoxic suite and record daily differential pressure readings
- consideration of the installation of a manometer alarm, in case of inadequate pressure differentials
- installation of a spill switch that reverses the airflow, minimising contamination to the external environment.

SECTION 5: PREPARING AND DISPENSING DRUGS

PREPARING CYTOTOXIC DRUGS

Specific handling techniques and procedures incorporating suitable equipment (designed to reduce the risk of exposure) should be employed, including:

Drug preparation equipment

Equipment used for preparing drugs should incorporate a closed system, where possible, and also reduce the potential for generating high pressure. Specific methods of control include:

- use of Luer-lock syringes and fittings to keep connections together
- use of Luer-slip syringes (only if Luer-lock connections are incompatible) such as intrathecal needles
- use of syringe-to-syringe connectors when transferring solutions from one syringe to another
- use of wide bore needles to reconstitute and draw-up cytotoxic drugs
- use of filter needles only when the cytotoxic drug has been removed from a glass ampoule, or if particulate matter is visible, for example if coring of a vial rubber has occurred
- use of air-venting devices to equalise pressures and to prevent the passage of powder, aerosols and liquids.

STANDARD OPERATING PROCEDURES FOR PREPARING CYTOTOXIC DRUGS

Standard operating procedures for parenteral preparations should be documented, and stress the need to:

- avoid using cytotoxic drugs supplied in glass ampoules. If glass ampoules must be used, open with an ampoule breaker or a low-linting swab
- contain excess drug solutions and air when priming
- use techniques that avoid the generation of pressure differentials.

Tablets, capsules and topical creams should be prepared under the same conditions as parenteral cytotoxic drug preparations.

Specific additional standard operating procedures for non-parenteral preparations (extemporaneous) include:

- using purpose-dedicated equipment
- making mixtures by dispersing tablets in water
- not crushing tablets in an open mortar
- not counting tablets or capsules by machine
- cleaning equipment immediately after use with a strong alkaline detergent with $\text{pH} \geq 10$.

PACKAGING AND TRANSPORTING CYTOTOXIC DRUGS

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

Drug packaging

Cytotoxic drugs should be packaged in a labelled, sealed, leak-proof container, with outer bags heat-sealed where possible, ensuring the container:

- offers protection from light where required
- protects the drugs from breakage in transit
- contains leakage if breakage occurs
- has a childproof lid (if appropriate).

Drug transport

Containers used for transporting prepared cytotoxic drugs should be:

- hard-walled and robust
- made from moulded foam or other suitable packaging material capable of protecting the product from a shock equivalent to a drop of one metre onto a concrete surface
- securely closed and labelled with cytotoxic warnings.

SECTION 5: PREPARING AND DISPENSING DRUGS

PERSONAL PROTECTIVE EQUIPMENT

The following personal protective equipment should be provided, in conjunction with other control measures, to personnel who prepare cytotoxic drugs:

- coverall or gown
- head covering
- closed footwear and overshoes
- protective gloves – long enough to cover the elasticised cuffs of gowns or coveralls
- protective eyewear
- respiratory protective device (where an inhalation risk exists, for example, a large cytotoxic drug spill).

For further information on personal protective equipment, refer to Appendix 9 - Personal Protective Equipment.

MAINTAINING CONTROLS

Equipment used to prepare cytotoxic drugs, and air-handling facilities, should be maintained under a planned maintenance schedule.

Performance testing and inspection of facilities and equipment

Cytotoxic laminar-flow drug safety cabinets and secondary and tertiary barriers should be assessed and certified by a suitably qualified person, as specified in *Australian Standard AS 2639-1994, Laminar Flow Cytotoxic Drug Safety Cabinets - Installation and Use*.

Equipment maintenance

An effective equipment maintenance schedule should incorporate the following:

- inspection of cytotoxic drug safety cabinets, isolators and High Efficiency Particulate Air (HEPA) filters
 - at regular intervals (a minimum of every 12 months)
 - after relocation or mechanical/electrical maintenance
- keeping test records and a summary of results in a place accessible to employees
- not using a cabinet that has failed, until the fault has been rectified and the cabinet recertified
- performing microbial and air-particle testing routinely, and recording the results.

Cleaning drug preparation facilities

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

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

CONTROL MEASURES CHECKLIST

<i>Controls covered in this section</i>	<i>Completed</i>
• <i>'best practice' controls</i>	<input type="checkbox"/>
• <i>establishing a cytotoxic drug preparation facility</i>	<input type="checkbox"/>
• <i>using specially designed and dedicated equipment</i>	<input type="checkbox"/>
• <i>standard operating procedures</i>	<input type="checkbox"/>
• <i>packaging and transporting</i>	<input type="checkbox"/>
• <i>personal protective equipment</i>	<input type="checkbox"/>
• <i>maintaining controls</i>	<input type="checkbox"/>

SECTION 6: ADMINISTERING DRUGS

ADMINISTERING DRUGS

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

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

Workplace design, use of specially designed equipment, safe work practices and personal protective equipment are recommended to ensure that cytotoxic drugs are safely administered. Education and training are crucial to ensuring that control measures and safe work practices are developed, understood, implemented and maintained.

Following are examples of ways to ensure controls are 'best practice':

- do not undertake a drug administration service unless control measures can be provided
- use the safest administration techniques available, such as needleless systems
- require drugs intended for administration to be appropriately packaged, labelled and ready for administration
- use diluted cytotoxic drugs where possible
- provide secure, labelled storage of waste, and use sharps containers to minimise exposure to cytotoxic waste.

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

ESTABLISHING A DRUG ADMINISTRATION AREA

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

- allocating an area that restricts access to unauthorised persons
- allowing sufficient room for movement of personnel during drug administration
- providing secure storage of waste and sharps containers
- providing secure storage for cytotoxic waste ready for disposal
- establishing a system for obtaining and keeping health and safety information, such as Material Safety Data Sheets, in a place accessible to employees
- providing a safety shower.

DRUG ADMINISTRATION EQUIPMENT

The use of the following equipment is recommended to reduce risks:

- needleless administration systems
- portable trolleys to store administration equipment, to allow movement from patient to patient
- disposable injection trays to contain and carry syringes to the patient
- disposable gauze squares around the injection site
- plastic-backed absorbent sheets or pads under the injection site
- plastic, rigid-walled, wide-necked, sharps disposal containers that are readily accessible to all operators
- a spill kit as outlined in Appendix 10 - Procedure for dealing with spills.

SECTION 6: ADMINISTERING DRUGS

STANDARD OPERATING PROCEDURES

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

- follow the recommended procedures (from suppliers and the pharmacy) for the administration of specific cytotoxic drugs
- ensure the patient is involved in the process, and encouraged to alert administration staff of any problems
- maintain close supervision of the patient
- use back-priming techniques
- connect intravenous bags at waist level
- avoid contact with drainage fluid from body cavities following administration of cytotoxic drugs, for example, after intrapleural or intravesicular infusions
- use cytotoxic labels to identify all intravenous solution flasks, syringes and pump cartridges
- manage extravasation incidents promptly
- dispose empty intravenous bags or flasks with the administration set still attached
- discard gloves, at the completion of administration, as cytotoxic waste
- wash hands following administration and disposal of cytotoxic drugs and related waste
- return unused cytotoxic drugs to the pharmacy or to the source of referral.

Practices to be avoided in drug administration:

- do not recap needles
- do not cut down IV (intravenous) infusion sets or cytotoxic drug contaminated needles.

Topical cytotoxic agents

Topical cytotoxic agents may be in the form of ointments, lotions or eyedrops. Specific additional control measures include:

- avoiding unnecessary contact with topical cytotoxic agents
- minimising contact with clothing
- applying ointments and lotions as a film, using a disposable spatula
- educating patients on the correct way to apply medication
- disposing of all contaminated equipment as cytotoxic waste
- wearing gloves at all times.

Oral cytotoxic drug administration

Oral cytotoxic agents are generally given as tablets and capsules. Specific additional control measures include:

- transferring tablets and capsules from their container into a disposable medication cup, so as to avoid direct handling
- not crushing or breaking cytotoxic drugs for any reason (eg. oral, nasogastric or PEG feed) outside of the pharmacy
- returning tablets and capsules to the pharmacy when loose powder is observed
- contacting the pharmacy if it is necessary to produce a cytotoxic drug mixture
- discarding contaminated medication cups as cytotoxic waste.

PERSONAL PROTECTIVE EQUIPMENT

Using the following personal protective equipment is recommended during the administration of cytotoxic drugs (where there is an assessed exposure risk):

- gown
- closed footwear
- protective gloves
- protective eyewear (where there is a risk of eye splash)
- respiratory protective device (where an inhalation risk exists, for example, after a large cytotoxic drug spill).

For further information on personal protective equipment, refer to Appendix 9 - Personal Protective Equipment.

SECTION 6: ADMINISTERING DRUGS

CONTROL MEASURES CHECKLIST

<i>Controls covered in this section</i>	<i>Completed</i>
• <i>'best practice' controls</i>	<input type="checkbox"/>
• <i>establishing a drug administration area</i>	<input type="checkbox"/>
• <i>using specially designed and dedicated equipment</i>	<input type="checkbox"/>
• <i>standard operating procedures</i>	<input type="checkbox"/>
• <i>personal protective equipment</i>	<input type="checkbox"/>



SECTION 7: PATIENT CARE



Nursing, medical staff and other carers might care for patients after cytotoxic drugs have been administered. Ambulance officers might also be involved in caring for and transferring patients who have received cytotoxic drug treatment.

Cytotoxic drugs are primarily eliminated from the patient by renal and hepatic excretion. All body substances might be contaminated with either the unchanged drug or active drug metabolites. Exposure to cytotoxic waste can occur through:

- handling vomitus, blood, excreta and fluid drained from body cavities
- handling bedpans, urinals, emptying urinary catheter bags, colostomy/urostomy bags and vomitus bowls
- handling bed linen or clothing soiled with patient waste, or potentially contaminated with unchanged drug or active metabolites
- cleaning spills.

The period during which body substances may be contaminated with cytotoxic drugs will differ for individual drugs and patients.

Correct workplace design and set-up, use of appropriate equipment and resources, safe work practices and personal protective equipment are all required to ensure that the risks associated with caring for patients are adequately controlled. Education and training is crucial, to ensure that safe work practices are developed, understood, implemented and maintained.

Examples of 'best practice' controls include:

- reviewing the treatment history of patients before undertaking patient care
- addressing the design and set-up of the workplace
- using appropriate equipment and resources
- reviewing health and safety information about the cytotoxic drugs administered.

These control options should be considered as a priority. To build these control measures into the health and safety system of the patient care centre, consider developing a policy for the care of patients who have been administered cytotoxic drugs.

CARING FOR PATIENTS

Before accepting a patient

To assist in determining whether body fluids are potentially contaminated, the following should be documented in the patient care sheet:

- the name of the drug(s) administered
- the route of administration
- when drug(s) was administered
- whether it is being continuously administered, (for example via ambulatory pump).

Setting up a patient care area

Factors to consider when designing and setting up a patient care area, include:

- allocating a secure area that restricts access to unauthorised persons
- allowing sufficient room for personnel to move around
- providing secure storage of waste.

SECTION 7: PATIENT CARE

Patient care equipment

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

- spill kit, as outlined in Appendix 10 - Procedure for dealing with spills
- strong alkaline detergent with $\text{pH} \geq 10$
- container for spills, where access to a waste outlet is not available
- approved container for sharps, where required.

Standard operating procedures

The following standard operating procedures should be adopted:

- avoid skin contact with patient body substances
- prevent the generation of aerosols when handling patients' vomitus, blood, excreta and fluid drained from body cavities
- contain and clean up spills immediately
- dispose waste such as urine, faeces, vomitus, the contents of colostomy/urostomy bags, incontinence aids and disposable nappies, as explained in Section 10 - Waste Management
- document the need to implement cytotoxic precautions when handling body waste during the period of drug excretion. Verbally advise all staff caring for the patient.
- alert carers by providing written instructions to patients and carers for dealing with spills in the home, and information on spill kit contents (as outlined in Appendix 10 of this guide - Procedure for dealing with spills).

Personal protective equipment

The following personal protective equipment is recommended when handling anything potentially contaminated with unchanged drug or active metabolites:

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

For further information on personal protective equipment, refer to Appendix 9 - Personal Protective Equipment.

TRANSPORTING PATIENTS

Transport within an establishment

Patients may need to be relocated to another area of a hospital or treating centre while cytotoxic drug administration is in progress. The following control measures should be in place:

- constant medical or nursing supervision of the patient during the relocation
- immediate access to emergency assistance in the event of a spill of cytotoxic drug or waste.

Transport by ambulance

Control measures used in patient care should be adopted for transporting patients by ambulance.

CARING FOR PATIENTS AT HOME OR IN COMMUNITY SETTINGS

Patients might receive cytotoxic drug therapy in a day hospital, doctor's surgery, domiciliary ambulatory clinic, at home or in a residential aged-care facility. Nursing, medical staff and others often care for patients in these situations.

Healthcare establishments or households unable to provide facilities, equipment and a level of care as specified in these guidelines, should not undertake to provide care to patients receiving cytotoxic drug therapy. Instead, these patients should be transferred to a hospital or centre that has the required facilities, equipment and trained personnel.

SECTION 7: PATIENT CARE

The role of the treating facility

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 of the particular drug used. The role of the treating facility is therefore to:

- ensure cytotoxic drugs are appropriately packaged and labelled
- ensure that facilities and equipment meet recommended standards
- provide instruction to home carers.

Setting up a patient care area

The following facilities should be provided:

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

Equipment used in patient care

The following equipment is recommended:

- spill kit, as outlined in Appendix 10 - Procedure for dealing with spills
- strong alkaline detergent with $\text{pH} \geq 10$
- container for spills, where access to a waste outlet is not available
- approved container for sharps disposal, where required
- waterproof gloves
- cloth or wash gauze
- strong plastic bag.

Standard operating procedures

Standard operating procedures should be developed with the assistance of the treating facility, and stress the need to:

- avoid skin contact with patient body substances
- prevent the generation of aerosols when handling patients' body waste
- dispose of waste such as urine, faeces, vomitus, the contents of colostomy/urostomy bags, incontinence aids and disposable nappies, as outlined in Section 10 - Waste Management
- contain waste generated from drug administration in a dedicated sharps container
- keep waste containers secure and appropriately labelled
- clean up spills immediately
- provide written instructions on how to manage a spill in an ambulatory situation.



SECTION 7: PATIENT CARE

Information for patients and carers

The hospital or domiciliary service should provide the patient and/or carers with written health and safety information. The following information should be included:

- precautions to take where a carer is pregnant or breast-feeding
- the usual routes of excretion of the cytotoxic drug administered
- the approximate time cytotoxic residues might continue to be excreted
- equipment needed for the home nursing of a patient receiving cytotoxic drug therapy
- home storage of drugs
- the correct way to take prescribed medication
- precautions to take when handling body waste
- the correct way to deal with a spill
- the correct way to launder contaminated clothing and bed linen
- management of cytotoxic waste
 - disposal of body waste
 - items that should be discarded
 - secure storage of cytotoxic waste
 - precautions when transporting waste containers
 - emergency procedures
 - accidental exposure to patient body waste
 - first-aid management
 - accidental ingestion of cytotoxic drugs
- disposal of drugs that are no longer required.

CONTROL MEASURES CHECKLIST

<i>Controls covered in this section</i>	<i>Completed</i>
• 'best practice' controls	<input type="checkbox"/>
• setting up a patient care facility	<input type="checkbox"/>
• patient care equipment	<input type="checkbox"/>
• standard operating procedures	<input type="checkbox"/>
• personal protective equipment	<input type="checkbox"/>
• transporting patients	<input type="checkbox"/>
• requirements for patient care at home or in community settings	<input type="checkbox"/>

SECTION 8: DRUG TREATMENT IN VETERINARY PRACTICE



Veterinarians, veterinary nurses, animal attendants and cleaners might be involved in handling cytotoxic drugs and related waste during the treatment and care of animals. Cytotoxic drugs are used primarily for treating animals such as dogs, cats, birds and horses.

In veterinary practice, exposure to cytotoxic drugs can occur when:

- preparing drugs
- administering drugs
- caring for treated animals.

Exposure can occur through:

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

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

The following 'best practice' controls should be considered a priority for implementation:

- purchase cytotoxic drugs in a ready-to-use form to eliminate drug preparation work
- refer animals for cytotoxic drug treatment and care to a veterinary practice equipped to provide the service
- use a diluted form of cytotoxic drugs where possible
- purchase cytotoxic drugs in the safest form available
- review health and safety information about cytotoxic drugs before making a decision to purchase them.

Drug administration should be undertaken (where relevant) as outlined in Section 6 – Administering drugs. Standard operating procedures for veterinary practice include:

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

ANIMAL CARE

Particular attention should be paid to preventing environmental contamination, as contaminated excreta is not as easily contained as for human patients. Additional control measures for veterinary practice include:

Setting up an animal care area

When setting up an animal care area, it is important to:

- allocate a secure area that identifies restricted access to unauthorised personnel
- allow sufficient room for personnel to move
- provide secure storage of waste
- establish a system for obtaining and keeping health and safety information (such as Material Safety Data Sheets) in a place accessible to employees.

SECTION 8: DRUG TREATMENT IN VETERINARY PRACTICE

Suitable equipment for animal care

The following equipment should be provided where possible:

- animal cages designed to contain and flush excreta directly into the sewerage system
- sealable, labelled bags to contain waste products, as outlined in Section 10 - Waste Management
- a spill kit, as outlined in Appendix 10 - Procedure for dealing with spills
- absorbent pads for cleaning.

Standard operating procedures

Standard operating procedures should be developed, and should stress the need to:

- place a sign stating 'receiving cytotoxic drug therapy' on the cage of animals
- use purpose-dedicated equipment
- clean equipment immediately after use with a strong alkaline detergent with $\text{pH} \geq 10$
- avoid skin contact with animal excreta and body fluids
- keep animal cages clean
- adopt cleaning techniques that avoid skin contact, contain waste, and prevent the generation of aerosols
- ensure that animals are immediately washed down if they become contaminated, being careful not to generate aerosols
- dispose of cytotoxic waste as outlined in Section 10 - Waste Management.

Personal protective equipment

The following personal protective equipment should be considered when caring for animals:

- coverall or gown
- protective gloves
- protective eyewear
- rubber boots
- waterproof apron.

For further information on personal protective equipment refer to Appendix 9 - Personal Protective Equipment.

ANIMAL CARE AT HOME

Carers at home might be involved in administering cytotoxic drugs and/or caring for animals receiving cytotoxic drug therapy.

The role of the treating facility

Owners, or other carers of animals receiving cytotoxic drug therapy, should be provided with written information about cytotoxic drugs, and informed of the precautions to be taken while caring for animals during the time the drug may be excreted. Carers should also be advised about special requirements of the particular drug used. The role of the treating facility is to:

- ensure cytotoxic drugs are appropriately packaged and labelled
- provide written instruction to home carers.

SECTION 8: DRUG TREATMENT IN VETERINARY PRACTICE

Information for carers

The following written information should be provided to home carers:

- 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 - especially small children, the aged, and women who are pregnant or breast feeding
- how to store cytotoxic drugs at home
- equipment which might be needed for the animal's care at home
- route of excretion of drugs and how to dispose of body waste
- the approximate duration that cytotoxic residues might be excreted after drug administration
- spills and procedures for cleaning up
- laundering contaminated bedding
- emergency procedures for accidental exposure or accidental ingestion of cytotoxic drugs
- how to dispose of drugs that are no longer required.

Equipment used in animal care

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

- paper towelling
- strong alkaline detergent with $\text{pH} \geq 10$
- a small shovel or implement to scoop-up faeces
- waterproof gloves.

Standard operating procedures

Standard operating procedures should be developed with the assistance of the treating facility, and should stress the need to:

- avoid breaking tablets when administering cytotoxic drugs
- monitor and contain the urinating habits of the animal where possible
- dilute animal excretions by gently hosing down affected areas
- keep animals confined to the home during periods when the drug may be excreted
- clean up faeces by scooping with a shovel and burying
- clean or discard soiled articles after use
- wash hands following any contact with cytotoxic drugs, animals receiving treatment, or related waste products
- dispose of contaminated items (such as gloves) as cytotoxic waste.

CONTROL MEASURES CHECKLIST

<i>Controls covered in this section</i>	<i>Completed</i>
• <i>'best practice' controls</i>	<input type="checkbox"/>
• <i>setting up a drug treatment facility</i>	<input type="checkbox"/>
• <i>use of suitable equipment</i>	<input type="checkbox"/>
• <i>standard operating procedures</i>	<input type="checkbox"/>
• <i>personal protective equipment</i>	<input type="checkbox"/>
• <i>requirements for animal care at home</i>	<input type="checkbox"/>

SECTION 9: SPILL MANAGEMENT

Any person handling cytotoxic drugs and related waste might be involved in dealing with a spill, which might occur:

- when preparing, storing and transporting packaged drugs
- during administration or transport of patients with chemotherapy in-situ
- from body substances contaminated with cytotoxic drugs
- when cytotoxic waste is handled.

This section deals with setting up a spill management strategy, determining who should be trained, managing spills, reporting spills, and standard operating procedures.



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

The way a spill is managed will differ according to the toxicity, form and volume of the cytotoxic drug involved. Spills should be classified according to where they occur, and managed accordingly.

SPILLS	HOW TO MANAGE
<i>In situations including drug administration, patient care and transportation</i>	<ul style="list-style-type: none">• Use the procedure outlined in Appendix 10 - Procedure for dealing with spills.
<i>Within a cytotoxic drug safety cabinet and a cleanroom</i>	<ul style="list-style-type: none">• Use the procedure outlined in Appendix 10 - Procedure for dealing with spills.• As recommended in Appendix C of Australian Standard AS 2639-1994 <i>Laminar flow cytotoxic drug safety cabinets - installation and use.</i>
<i>Outside a cytotoxic drug safety cabinet, but within a cleanroom</i>	<ul style="list-style-type: none">• Use the procedure outlined in Appendix 10 - Procedure for dealing with spills.• As recommended in Appendix C of Australian Standard AS 2639-1994 <i>Laminar flow cytotoxic drug safety cabinets - installation and use.</i>

All areas where cytotoxic drugs and related waste are handled should have the following readily available:

- a spill kit as outlined in Appendix 10 - Procedure for dealing with spills
- adequate supplies of absorbent and cleansing material.

STANDARD OPERATING PROCEDURES

Standard operating procedures should specify:

- the training of employees in spill management
- spill management strategies for all types of spills
- how to deal with contamination of employees
- reporting procedures.

REPORTING PROCEDURES

Employers should have a system in place for employees to report spills or personnel contamination to management as soon as possible. The following information should be included in an incident report:

- the type of incident
- action taken to manage the spill
- action taken to prevent future occurrences.

SECTION 9: SPILL MANAGEMENT

CONTROL MEASURES CHECKLIST

<i>Controls covered in this section</i>	<i>Completed</i>
• <i>setting up a spill management strategy</i>	<input type="checkbox"/>
• <i>managing spills</i>	<input type="checkbox"/>
• <i>standard operating procedures</i>	<input type="checkbox"/>
• <i>reporting procedures</i>	<input type="checkbox"/>



SECTION 10: WASTE MANAGEMENT

This section identifies the key elements when setting up a waste management strategy, identifying, segregating and containing waste, transport, storage and disposal of waste, and personal protective equipment.



Cytotoxic waste includes any residual cytotoxic drug that remains following patient treatment and any materials or equipment potentially contaminated with cytotoxic drugs, such as:

- unused cytotoxic pharmaceuticals
- sharps and syringes
- intravenous infusion sets and containers
- ampoules and vials
- personal protective equipment and clothing
- dressings and bandages
- linen.

As cytotoxic waste is hazardous to human health and the environment, it is a prescribed waste and subject to strict regulation by EPA Victoria. A key element of any waste management strategy is to create policies and systems to avoid and minimise waste.

ESTABLISHING A WASTE MANAGEMENT STRATEGY

Each employer should develop and periodically review a strategy to safely manage cytotoxic waste. Guidance to assist with the development of policies and procedures can be obtained from the EPA Victoria publication entitled *The Manual for the Management and Disposal of Biomedical Wastes in Victoria*.

Key elements of a waste management strategy:

- designate a person to be responsible for ensuring an efficient waste disposal system is maintained and complies with legal requirements
- create policies and systems to avoid and minimise waste
- develop and implement 'cradle to grave' policies for managing cytotoxic waste, in consultation with the units generating the waste, waste handlers and waste disposal staff. There should be an understanding of the chain of responsibility and involvement of all levels in policy development and implementation
- undertake an audit to identify cytotoxic waste generated by the establishment
- develop and implement a control strategy, which includes:
 - procedures for the identification, segregation, packaging, storage, transport, administration and disposal of cytotoxic waste
 - a system for the management of cytotoxic waste generated by outpatients and domiciliary services under the direction of a hospital
 - a transport (internal and external) and disposal flowchart (from the waste generator to the disposal site).

IDENTIFYING, CONTAINING AND SEGREGATING WASTE

Identifying waste

Cytotoxic materials are universally identified by a purple symbol representing a cell late in the process of division, known as telophase. Labels should be dark purple and bear the telophase symbol. The container should be identified with the words "CYTOTOXIC WASTE".



SECTION 10: WASTE MANAGEMENT

Containing waste

The requirement for packaging and transporting cytotoxic waste is set out in Section 4 (Packaging and transport) of *The Manual for the Management and Disposal of Biomedical Wastes in Victoria*. The following control measures should be implemented:

- package the waste inside a multi-walled paper bag with a polyliner, and place in a cardboard carton for transport to the waste disposal facility
- a leak proof plastic bag will be sufficient for use in the home and should be labelled appropriately (refer to Section 7 - Patient Care)
- store sharps in a rigid-walled container according to *Australian Standard AS 4031-1992, Non-reusable containers for the collection of sharp medical items used in healthcare areas*.

Segregating waste

Cytotoxic waste should be segregated from other waste streams through the development and implementation of the following control measures:

- develop procedures in consultation with staff who work in areas that produce waste, and those responsible for the provision of support services
- segregate waste at the point of generation and at the earliest possible stage
- incorporate efficient waste disposal methods into patient care procedures
- ensure 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 the collection area
- keep cytotoxic waste separate from the rest of the waste stream during internal transport and storage
- keep bins secured with mobile or fixed stands.

ON-SITE WASTE TRANSPORT

The following control measures should be implemented when transporting waste within the site:

- when transporting waste from user sites, use dedicated handcarts, trolleys and pails to prevent operator contact with the waste
- ensure handcarts, trolleys and pails are appropriately labelled and kept clean, in accordance with infection control and other relevant standards
- undertake waste collection rounds frequently to minimise housekeeping hazards associated with the accumulation of waste at user sites
- manage spills that occur during on-site transport as outlined in Section 9 - Spill Management
- do not use waste disposal chutes to transport cytotoxic waste, as there is a high potential for breakage.

WASTE STORAGE

Employers should consider the following factors when storing cytotoxic waste:

- store in a dedicated, identified and secure storage area with adequate lighting and ventilation
- locate away from drains and other sensitive areas
- storage areas should facilitate cleaning and decontamination
- seal cytotoxic waste bins prior to collection, and do not open or reprocess on site
- place sealed bins or bagged material in specially designed, large receptacles whilst awaiting collection for off-site transport
- where waste is stored for more than 72 hours prior to disposal, the waste should be refrigerated, particularly where waste is mostly organic and can decompose
- provide appropriate labelling.

Further information about waste storage can be found in Section 3 (Waste storage) of *The Manual for the Management and Disposal of Biomedical Wastes in Victoria*.

SECTION 10: WASTE MANAGEMENT

OFF-SITE WASTE TRANSPORT

Waste generators (such as healthcare facilities) have legal obligations for the cytotoxic waste they generate. These legal obligations extend beyond the on-site handling of the waste. Generators must ensure:

- that any person who transports waste has the required permit
- that the waste is disposed of to a facility licensed to handle cytotoxic waste.

EPA Victoria is responsible for ensuring the proper transport of cytotoxic waste in Victoria. The *Environment Protection Act 1970* and the *Environment Protection (Prescribed Waste) Regulations 1998* regulate the transport of prescribed waste, which includes cytotoxic waste.

There are three principal statutory requirements for the transport of prescribed waste:

- appropriate permits
- transport certificates
- vehicle signage.

Permits

No permit is required if:

- the vehicle transports cytotoxic waste less frequently than three times in any calendar month; and
- its gross load-carrying capacity is less than 1000 kg; and
- no fee or reward is received for transporting the cytotoxic waste.

Transport certificates

Transport certificates are required under the *Environment Protection (Prescribed Waste) Regulations 1998*. Transport certificates help to ensure obligations are discharged by documenting the transfer of each shipment of prescribed waste from the generator to the transporter, and then to the treatment or disposal facility. The waste generator is required to send a copy of the certificate to EPA Victoria. Transport certificates are to be completed, even where the transporter is exempt from permit requirements.

Vehicle signage

Permitted vehicles used to transport any volume of cytotoxic waste are subject to special requirements to display information, as set out in Schedule 3 of the *Environment Protection (Prescribed Waste) Regulation 1998*. The vehicle must display both a 'dangerous goods' label and the cytotoxic waste symbol.

WASTE TREATMENT AND DISPOSAL

Waste treatment must render the waste non-infectious and unrecognisable, and must meet standards to protect the environment. At the time of writing this guide, incineration is the only acceptable technology for treating cytotoxic waste. All incinerators used for the treatment of cytotoxic waste must be licensed with EPA Victoria and meet the prescribed standards.

Patient waste such as urine, faeces, vomitus and the contents of colostomy and urostomy bags may be disposed of in the normal sewage system. The following limitations should be noted:

- sewerage authorities do not allow disposal of incontinence aids to sewer. Further information can be obtained from the relevant sewerage authority
- where materials such as incontinence aids are contaminated with visible blood, or originate from patients with communicable diseases, they are classified as clinical waste and must be handled accordingly
- the operation of on-site sewerage treatment systems such as septic tanks might be affected by cytotoxic waste. Further information should be obtained from the manufacturer or supplier of the system.

SECTION 10: WASTE MANAGEMENT

PERSONAL PROTECTIVE EQUIPMENT

Personnel engaged in the routine handling (i.e. excluding spill situations) of cytotoxic waste for on-site transport should wear the following:

- industrial work-wear
- polyvinyl chloride (PVC) industrial gloves
- safety boots.

Protective clothing should be used whether the waste appears to be properly packaged or not, and should be removed as soon as possible if it becomes contaminated.

For further information on personal protective equipment refer to Appendix 9 - Personal Protective Equipment.

LAUNDERING

Laundrying contaminated personal protective equipment

Special precautions are required for the laundrying of non-disposable personal protective equipment that may be contaminated with cytotoxic drugs. The requirements of the manufacturer or supplier of the personal protective equipment should be followed. Systems should be established to:

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

Laundrying contaminated linen

Linen contaminated with cytotoxic drugs or related waste should be placed in plastic bags at the point of contamination for subsequent laundrying. Bed mattresses should be cleaned with decontaminating solution.

Personal protective equipment

The following personal protective equipment should be used when handling soiled linen that is contaminated with unchanged drug or active metabolites:

- gown
- protective gloves.

SUMMARY OF CONTROL MEASURES

<i>Controls covered in this section</i>	<i>Completed</i>
• <i>establishing a waste management strategy</i>	<input type="checkbox"/>
• <i>identifying, containing and segregating waste</i>	<input type="checkbox"/>
• <i>waste transport</i>	<input type="checkbox"/>
• <i>waste storage</i>	<input type="checkbox"/>
• <i>waste treatment and disposal</i>	<input type="checkbox"/>
• <i>personal protective equipment</i>	<input type="checkbox"/>

Further information about managing cytotoxic waste can be obtained from:

- EPA Victoria
- *Environment Protection (Prescribed Waste) Regulations 1998*
- *The Manual for the Management and Disposal of Biomedical Wastes in Victoria.*

APPENDIX 1: GLOSSARY OF TERMS

TERM	EXPLANATION
<i>alginate bag</i>	bag made of artificial fibres spun from a constituent of kelp. The fibres become gelatinous when moist and so are biodegradable.
<i>alkaline detergent</i>	detergent that has basic properties (ie with a pH ≥ 10).
<i>aseptic manipulation</i>	activity performed so as to exclude micro-organisms.
<i>aseptic suite</i>	work space free from micro-organisms in the working area.
<i>auto-immune disease</i>	alteration of the function of the immune system causing it to attack the body's own cells.
<i>biological monitoring</i>	measurement and evaluation of a substance or its metabolites in the body tissue, fluids or exhaled air of an exposed person.
<i>carcinogen</i>	substance or physical agent with the potential to cause cancer in certain circumstances or to make cancer more likely to occur.
<i>cradle-to-grave</i>	a method for managing waste to minimise risks to the environment and human health through the development of waste minimisation plans. For hazardous waste it also involves the identification of the generator and nature of the waste; tracking of the waste to the disposal facility by manifest; the requiring of permits for generators, storage facilities, and disposal sites; and the enforcement of regulations to ensure compliance.
<i>cytogenic</i>	to do with the formation of cells.
<i>cytotoxic</i>	harmful to cells of the body, particularly those that reproduce rapidly.
<i>hazardous substance</i>	substance listed in the <i>List of Designated Hazardous Substances</i> produced by the National Occupational Health and Safety Commission, or a substance that meets the criteria for a hazardous substance, set out in the <i>Approved, Criteria for Classifying Hazardous Substances</i> declared by the National Occupational Health and Safety Commission.
<i>hazardous substances register</i>	regularly maintained list of the product names of all hazardous substances used in a workplace, accompanied by an up-to-date Material Safety Data Sheet for each substance.
<i>health monitoring</i>	monitoring of individuals for the purpose of identifying changes to health status due to occupational exposure to a substance.
HEPA <i>[High Efficiency Particulate Air] filter</i>	filter that is made to be at least 99.97 percent efficient in removing an aerosol of particles with a diameter of 0.3 micrometres when tested with a standardised procedure.

APPENDIX 1: GLOSSARY OF TERMS

TERM	EXPLANATION
<i>lyophilised cytotoxic drugs</i>	cytotoxic drugs preserved during manufacture by being rapidly frozen and dehydrated in a vacuum.
<i>Material Safety Data Sheet (MSDS)</i>	a document that describes the properties and uses of a substance, including identity, chemical and physical properties, health hazard information, precautions for use, and safe handling information.
<i>mutagen</i>	substance with the potential to change DNA, the part of a body cell that controls its growth and multiplication. Being a mutagen also gives a substance the potential to cause cancer.
<i>oncology</i>	relating to cancer.
<i>parenteral</i>	not through the alimentary canal but instead by injection through some other route (e.g. intravenously).
<i>pH</i>	measure of how strongly acidic or basic a substance is when dissolved in water. Acids have a pH less than 7; bases have a pH greater than 7.
<i>PPE</i>	abbreviation for personal protective equipment.
<i>renal excretion</i>	removal of a substance from the blood by the kidneys. From the kidneys, the excreted substance passes into the urine.
<i>reproducible test result</i>	extent to which multiple measurements of a characteristic by a particular test are likely to be in agreement.
<i>respirable</i>	aerosol whose particle size and density enables it to reach the alveoli of a person's lungs by traversing the body's narrowest air tubes.
<i>risk assessment</i>	evaluation of the probability that an adverse health effect may occur under the conditions that are likely to develop. Risk assessment of the use of a substance will take account of its toxicity, the frequency and duration of exposure, control measures in use (engineering, administrative, or personal protective equipment) and their effectiveness, and conditions of use.
<i>risk control</i>	control of factors associated with an increase in the probability of a toxic effect occurring. There is an ordered priority for selection of the means to reduce the level of an occupational exposure. Following is a list of risk controls, ranked from the most desirable form of control to the least desirable: elimination, substitution, isolation, engineering controls (e.g. local exhaust ventilation), administrative controls, personal protective equipment (PPE).
<i>risk management</i>	analysis and judgment that uses the results of risk assessments to produce decisions about environmental actions to be initiated, ie the giving of priorities to various risks, the delivery of risk-averting outcomes and the continuing audit of outcomes and trends.
<i>systemic</i>	affecting a person's inner organs.
<i>telophase</i>	last stage in the division of a single body cell into two identical cells.
<i>teratogen</i>	agent capable of causing harm to an embryo or foetus to produce birth defects.
<i>workplace</i>	any place, whether or not in a building or structure, where employees or self-employed persons work.

APPENDIX 2: LEGISLATIVE REQUIREMENTS

A range of State and Federal laws and regulations aim to provide people with safe and healthy work environments.

OCCUPATIONAL HEALTH AND SAFETY ACT 1985

Under the Victorian *Occupational Health and Safety Act 1985* employers have a legal obligation to provide and maintain for employees, so far as is practicable, a working environment that is safe and without risks to health. Under the law, the qualification of duties with the term "so far as is practicable" is used to place some reasonable limits on a duty. It should not be seen as an excuse to avoid taking measures to control a risk.

For further information on the *Occupational Health and Safety Act 1985*, or to obtain a copy of *A Guide to the Occupational Health and Safety Act 1985* contact your local WorkSafe Victoria office.

OCCUPATIONAL HEALTH AND SAFETY (HAZARDOUS SUBSTANCES) REGULATIONS 1999

Work involving the handling of cytotoxic drugs falls within the scope of the *Occupational Health and Safety (Hazardous Substances) Regulations 1999* when the substance meets the criteria set out in the National Occupational Health and Safety Commission publication entitled *Approved Criteria for Classifying Hazardous Substances*.

The aim of the *Occupational Health and Safety (Hazardous Substances) Regulations 1999* is to protect people at work against risks to health from using hazardous substances. While many cytotoxic drugs are classified as hazardous substances by their manufacturer, there are some cytotoxic drugs that the manufacturer considers do not meet the Approved Criteria. In such circumstances, the work involving the cytotoxic drug is not specifically covered by the *Occupational Health and Safety (Hazardous Substances) Regulations 1999*. However, the employer is still required to provide and maintain a safe and healthy workplace under the *Occupational Health and Safety Act 1985*.

In addition to the employer obligations outlined in the Regulations mentioned above, manufacturers, importers and suppliers who supply hazardous substances to workplaces are required to provide certain information about their product.

The *Code of Practice for Hazardous Substances (2000)* gives practical guidance on how to comply with the *Occupational Health and Safety (Hazardous Substances) Regulations 1999*. This publication can be obtained from any WorkSafe Victoria office.

OTHER LEGISLATION AND STANDARDS

Other legislation and standards covering the handling and storage of cytotoxic drugs (and related waste) also need to be considered when implementing safe work systems. For example:

- Drugs and poisons legislation administered by the Department of Human Services
- Health legislation administered by the Department of Human Services
- Waste management legislation administered by the Environment Protection Authority Victoria
- Legislation covering the storage and transport of dangerous goods, administered by WorkSafe Victoria
- *Professional Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments (1997)* endorsed by the Society of Hospital Pharmacists of Australia.

Further information about other relevant legislation is provided in Appendix 3 - Information Sources.

APPENDIX 3: INFORMATION SOURCES

STATUTES, STANDARDS, CODES AND GUIDANCE NOTES

The following Acts, Regulations, Standards, Codes of Practice and Guidance Notes apply to work involving handling of cytotoxic drugs and cytotoxic waste.

Acts and Regulations

- *Occupational Health and Safety Act 1985*
- *Occupational Health and Safety (Hazardous Substances) Regulations 1999*
- *Dangerous Goods Act 1985*
- *Dangerous Goods (Storage and Handling) Regulations 2000*
- *Drugs, Poisons and Controlled Substances Act 1981*
- *Drugs, Poisons and Controlled Substances Regulations 1995*
- *Environment Protection Act 1970*
- *Environment Protection (Prescribed Waste) Regulations 1998*
- *Environment Protection (Scheduled Premises and Exemptions) Regulations 1996*

Australian Standards

- *Australian Standard AS 1386-1989, Cleanrooms and clean workstations*
- *Australian/New Zealand Standard AS/NZS 1715-1994, Selection, use and maintenance of respiratory protection devices*
- *Australian/New Zealand Standard AS/NZS 1716-1994, Respiratory protective devices*
- *Australian/New Zealand Standard AS/NZS 1716-1994/Amdt1-1996, Respiratory protective devices*
- *Australian Standard AS 2013-1989, Cleanroom garments - Product requirements*
- *Australian/New Zealand Standard AS/NZS 2243.1:1997/Amdt 1-2000, Safety in laboratories*
- *Australian/New Zealand Standard AS/NZS 2243.2:1997, Safety in laboratories – Chemical aspects*
- *Australian/New Zealand Standard AS/NZS 2243.3:2002, Safety in laboratories – Microbiological aspects and containment facilities*
- *Australian Standard AS 2243.4:1998, Safety in laboratories – Ionizing radiations*
- *Australian Standard AS 2243.5:1993/Amdt 1-1994, Safety in laboratories – Non-ionizing radiations*
- *Australian Standard AS 2243.6:1990, Safety in laboratories – Mechanical aspects*
- *Australian Standard AS 2243.7:1991, Safety in laboratories – Electrical aspects*
- *Australian/New Zealand Standard AS/NZS 2243.8:2001, Safety in laboratories – Fume cupboards*
- *Australian Standard AS 2243.9:1991, Safety in laboratories – Recirculating fume cabinets*
- *Australian Standard AS 2243.10:1993, Safety in laboratories – Storage of chemicals*
- *Australian Standard AS 2567-2002, Laminar flow cytotoxic drug safety cabinets*
- *Australian Standard AS 2639-1994, Laminar flow cytotoxic drug safety cabinets - installation and use*
- *Australian Standard AS 4031-1992, Non-reusable containers for the collection of sharp medical items used in healthcare areas*
- *Australian Standard AS 4031-1992/Amdt1-1996, Non-reusable containers for the collection of sharp medical items used in health care areas*
- *Australian Standard AS 4273-1999, Guidelines for the design, installation and use of pharmaceutical isolators*
- *Australian Standard AS 4273-1999/Amdt1-2000, Guidelines for the design, installation and use of pharmaceutical isolators*

Codes of Practice

- *Australian Code for the Transport of Dangerous Goods by Road and Rail (ADG Code)*. Federal Office of Road Safety, Federal Department of Transport and Communications, Australian Government Publishing Service, Canberra, 6th edition, September 1992
- *Code of Practice for Hazardous Substances*
- *Code of Practice for Manual Handling*

Guidance Material

- Society of Hospital Pharmacists of Australia *Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments*. March 1997, *Australian Journal of Hospital Pharmacy* 1999; 29(2): 108-16
- Society of Hospital Pharmacists of Australia *Standards of Practice for the Transportation of Cytotoxic Drugs from Pharmacy Departments*, March 1999, *Australian Journal of Hospital Pharmacy* 2000; 30(3): 116-17

APPENDIX 3: INFORMATION SOURCES

- National Health and Medical Research Council (NHMRC) *Guidelines for Laboratory Personnel Working with Carcinogenic or Highly Toxic Chemicals*, Australian Government Publishing Service, Canberra, 1990.
- National Health and Medical Research Council, *National Guidelines for the Management of Clinical and Related Wastes*, Australian Government Publishing Service, Canberra, 1988.
- National Health and Medical Research Council (NHMRC), *Occupational Health Record Keeping*. Australian Government Publishing Service, Canberra, June 1985.
- National Health and Medical Research Council (NHMRC), *Reports on Ethics in Epidemiological Research*, National Health and Medical Research Council Medical Research Ethics Committee, Australian Government Publishing Service, Canberra, 1985.
- Worksafe Australia, *Guide for the Prevention of Eye Damage*, Australian Government Publishing Service, Canberra, December 1989.
- WorkCover Authority of New South Wales *Guidelines for handling cytotoxic drugs and related waste in health care establishments (2nd edition)*. 1995, New South Wales Government.
- Department of Training and Industrial Relations, *Guide for Handling Cytotoxic (Anti neoplastic) Drugs and Related Waste*. November 1997, Queensland Government.
- Environment Protection Authority Victoria Publication 268, *Manual for the Management and Disposal of Biomedical Wastes in Victoria* (2nd edition), November 1993.
- WorkSafe Victoria, *A Guide to Risk Control Plans*. September 2001, Victorian Government.

Technical Reports

- Baker ES and Connor TH. (1996) *Monitoring occupational exposure to cancer chemotherapy drugs*. Review Article. *American Journal of Health-System Pharmacists* 53:2713-2723.
- Sessink PJM and Bos RP. (1999) *Drugs Hazardous to Healthcare Workers – Evaluation of Methods for Monitoring Occupational Exposure to Cytostatic Drugs*. Aids International Limited.

APPENDIX 4: LIST OF 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 sulfate
Busulfan	Myleran
Capecitabine	Xeloda
Carboplatin	Carboplatin
Carmustine	Bicnu
Chlorambucil	Leukeran
Cisplatin	Cisplatin
Cladribine	Leustatin
Colaspase	Leunase
Cyclophosphamide	Cycloblastin Endoxan
Cytarabine	Cytarabine
Dacarbazine	Dacarbazine D.T.I.C.
Dactinomycin	Cosmegen
Daunorubicin	Daunorubicin
Daunorubicin liposomal	Dauno Xome
Docetaxel	Taxotere
Doxorubicin	Adriamycin solution Doxorubin Doxorubicin
Doxorubicin liposomal	Caelyx
Epirubicin	Pharmorubicin
Etoposide Phosphate	Etopophos
Etoposide	Etoposide Vepesid
Fluorouracil (5-FU)	Efudix Fluorouracil
Fludarabine	Fludara
Fotemustine	Muphoran
Gemcitabine	Gemzar
Hydroxyurea	Hydrea
Idarubicin	Zavedos

APPENDIX 4: LIST OF COMMONLY USED CYTOTOXIC DRUGS

DRUG	TRADE NAMES
Ifosfamide	Holoxan
Irinotecan	Camptosar
Lomustine	Cee Nu
Melphalan	Alkeran
Mercaptopurine	Puri-nethol
Methotrexate (MTX)	Ledertrexate Methoblastin Methotrexate
Mitozantrone	Novantrone Mitozantrone Onkotrone
Mitomycin-C	Mitomycin C
Oxaliplatin	Eloxatin
Paclitaxel	Anzatax Taxol
Procarbazine	Natulan
Raltitrexed	Tomudex
Temozolomide	Temodal
Teniposide	Vumon
Thioguanine	Lanvis
Thiotepa	Thiotepa
Topotecan	Hycamtin
Vinblastine	Velbe Vinblastine sulfate
Vincristine	Oncovin Vincristine sulfate
Vindesine	Eldisine
Vinorelbine	Navelbine

APPENDIX 5: EXAMPLE OF A MATERIAL SAFETY DATA SHEET (MSDS)

Page x of y (Shows the page number and the total number of pages in the MSDS).
Date of Issue (Indicates the date of issue or review of the MSDS. A MSDS must be reviewed at least every five years – so it should not be more than five years old).
Statement of Hazardous Nature (It must contain a statement that the substance is hazardous).

Company Details

Company:
Address:
Telephone number:
Emergency telephone number:

(Details, name and contact number of the manufacturer or importer. Important for seeking further information about the substance or its use).

Identification

Product name: (Identifies the substance by product name).
Poisons schedule number:
Use: Describes its use, appearance and form (ie. whether the substance is a solid, liquid or gas).

Physical description/properties:

Appearance: Indicates the properties of the substance, or its ingredients. The properties that are commonly described include: volatility (boiling point, vapour pressure and if known, evaporation rate), solubility (in water and/or other substances or solvents) and odour (level at which substance is detectable by smell). This information is useful in assessing the potential hazards associated with exposure to the substance.

Boiling point/melting point:

Vapour pressure:

Specific gravity:

Flammability limits:

Solubility in water:

Other properties:

Ingredients: Identifies the ingredients contained in the substance and their proportions.

Chemical name:

Proportion:

Health Hazard Information

Health effects: Describes the immediate and long-term health hazards of the substance for each of the different ways it can enter the human body (routes of exposure). If known, the level of exposure that may give rise to a particular health effect should be indicated. Employers need to be aware of the health effects and be able to recognise the symptoms of exposure.

Acute:
 Swallowed:
 Eye:
 Skin:
 Inhaled:

Chronic:

First Aid: Provides first-aid information for employers and medical practitioners. Be familiar with these procedures, so that prompt action can be taken if an incident occurs.
 Swallowed:
 Eye:
 Skin:
 Inhaled:
 First aid facilities:
 Advice to doctors:

APPENDIX 5: EXAMPLE OF A MATERIAL SAFETY DATA SHEET (MSDS)

<i>Precautions for Use</i>	
Exposure standards:	States NOHSC exposure standard(s), if any, for the substance or its ingredients. Employers need to know this and ensure that employees' exposure does not exceed the standard.
Engineering controls:	Provides information about appropriate risk controls for the substance. Advice on controls should relate to the range of tasks that are normally performed using the substance (eg. decanting or spraying the substance).
Personal protection:	This information should not be limited to controls that rely on safe worker behaviour or the use of personal protective equipment; guidance on engineering controls such as ventilation should also be given. Where personal protective equipment is recommended, it should specify the exact type. For example, if gloves are recommended, the type of gloves that are suitable [Viton, Nitrile, Rubber or polyvinyl chloride (PVC)] should be specified, instead of just "impervious gloves".
<i>Safe Handling Information</i>	
Storage and transport:	Provides information on storage, dealing with spills, and methods of disposal.
Spills and disposal:	



APPENDIX 7: RISK ASSESSMENT TEMPLATE FOR CYTOTOXIC DRUGS

PROCESS DESCRIPTION:				
CYTOTOXIC DRUGS USED:		NAME OF PERSON PERFORMING ASSESSMENT: DATE:		
Possible health effects	Routes of exposure	Current control measures	Are additional control measures required? (if yes, state what & reason)	Actions

APPENDIX 8: GUIDELINES FOR MEDICAL PRACTITIONERS IN HEALTH MONITORING FOR CYTOTOXIC DRUGS

1. PRE-EMPLOYMENT AND BASELINE HEALTH MONITORING BEFORE THE EMPLOYEE COMMENCES WORK WITH CYTOTOXIC DRUGS

<p>1. Collection of demographic data</p>	<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 Standard Classification of Occupations (ASCO) and Australian Standard Industrial Classification (ASIC) • places of previous employment.
<p>2. Occupational history</p>	<ul style="list-style-type: none"> • past work history, including previous work with cytotoxic drugs • potential current exposure • whether suitable control measures are in place for handling cytotoxic drugs.
<p>3. Medical history</p>	<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) • is the employee taking immuno-suppressive therapy? • is the employee pregnant or breast-feeding?
<p>4. Physical examination</p>	<ul style="list-style-type: none"> • general physical examination.
<p>5. Investigation</p>	<ul style="list-style-type: none"> • no diagnostic test currently gives a sensitive, specific and interpretable indication of early or likely health effects arising from occupational exposure to cytotoxic drugs or their metabolites • the medical practitioner should focus on the risk factors outlined in the occupational history, and the outcome of the physical examination • the medical practitioner should perform any investigations that may be appropriate as a result of the examination.
<p>6. Health advice and counselling</p>	<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 • 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 employees planning parenthood, or those who are breast-feeding or pregnant.
<p>7. Report</p>	<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.

APPENDIX 8: GUIDELINES FOR MEDICAL PRACTITIONERS IN HEALTH MONITORING FOR CYTOTOXIC DRUGS

2. DURING THE PERIOD THAT THE EMPLOYEE WORKS WITH CYTOTOXIC DRUGS

8. <i>Data for inclusion in health records</i>	<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 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. <i>Health advice and counselling</i>	<ul style="list-style-type: none"> • as described in point 6 • this should be offered by the employer annually and may be initiated at any time by the employee.
10. <i>Medical review</i>	<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 sharps injury occurs - if an employee advises she is pregnant, or is breast-feeding • the review should take account of the previous medical examination and include: <ul style="list-style-type: none"> - health advice and counselling - report - follow-up the review in one month.
11. <i>Control measures</i>	<p>Monitor the availability, type, maintenance and frequency-of-use of control measures (for example, needleless injection sets should be in place to eliminate the potential for sharps injuries).</p>

3. ON TERMINATION OF EMPLOYMENT WHERE CYTOTOXIC DRUGS ARE USED

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

APPENDIX 9: PERSONAL PROTECTIVE EQUIPMENT

TYPE OF PERSONAL PROTECTIVE EQUIPMENT	DESCRIPTION	STANDARDS
Coverall or gown	<ul style="list-style-type: none"> • long-sleeved coverall or gown of impermeable material, eg. made from bonded polyethylene fibre (Tyvek ®) • gowns and coveralls may incorporate head covering • coveralls and gowns should have a closed front and elasticised cuffs • may be disposable or can be processed through a laundry facility capable of handling garments contaminated with cytotoxic drugs • coveralls should be changed at least daily, or if overt contamination results. Coveralls have a limited life span and should be discarded when full protection can no longer be guaranteed. • oversleeves can give added protection to the forearms (a vulnerable area of exposure). 	<ul style="list-style-type: none"> • Australian Standard AS 2013.1 1989 Cleanroom garments - Product requirements
Head covering	<ul style="list-style-type: none"> • if coveralls without hoods are worn, caps must be worn to contain hair and reduce contamination. They should fit snugly around the head and in the case of a coverall, also around the face. 	<ul style="list-style-type: none"> • Australian Standard AS 2013.1 1989 Cleanroom garments - Product requirements
Closed footwear	<ul style="list-style-type: none"> • closed footwear with soles made of a skid-resistant plastic or other suitable non-shedding material. 	<ul style="list-style-type: none"> • Australian Standard AS 2013.1 1989 Cleanroom garments - Product requirements
Overshoes	<ul style="list-style-type: none"> • overshoes of a similar impermeable material as the coverall or gown • overshoes should be high enough to cover the trouser cuff of the coverall • the soles should be made of a skid-resistant plastic or other suitable non-shedding material. 	<ul style="list-style-type: none"> • Australian Standard AS 2013.1 1989 Cleanroom garments - Product requirements
Protective gloves	<ul style="list-style-type: none"> • long polyvinyl chloride (PVC), surgical latex, or purpose-manufactured gloves • operators not wearing special-purpose gloves should be double gloved, and the outer glove should be replaced at regular intervals or after overt contamination • should be long enough to cover wrist cuffs of the coveralls while the arm is being bent or stretched • should be changed at regular intervals, or whenever contamination is apparent or perforation occurs. 	<ul style="list-style-type: none"> • Australian Standard AS 2013.1 1989 Cleanroom garments - Product requirements
Protective eyewear	<ul style="list-style-type: none"> • goggles or protective glasses with side shields. 	<ul style="list-style-type: none"> • Australian Standard AS 2013.1 1989 Cleanroom garments - Product requirements
Respiratory protective device (where an inhalation risk exists)	<ul style="list-style-type: none"> • suitable respiratory protection of a standard recommended in Australian/New Zealand Standard AS/NZS 1715-1994 • surgical masks should not be used, as they do not provide respiratory protection • when containing liquid spills, respiratory protective equipment with a combined organic vapour and particulate filter (A1P2) is recommended • if respiratory protective equipment is required when handling cytotoxic drugs outside a cytotoxic drug safety cabinet, a full-face chemical splash shield with P2 disposable respirator is recommended. 	<ul style="list-style-type: none"> • Australian/New Zealand Standard AS/NZS 1715-1994 Selection use and maintenance of respiratory protective devices.

APPENDIX 10: PROCEDURES FOR DEALING WITH SPILLS

CONTENTS OF A SPILL KIT

Spills should be handled using a "spill kit". A commercially prepared spill kit will effectively control spills of up to one litre. A spill kit should be accessible to employees and contain the following:

Personal protective equipment

- coverall or gown
- head covering
- closed footwear or overshoes
- protective gloves
- protective eyewear
- respiratory protective device (where an inhalation risk exists)

For further information on personal protective equipment refer to Appendix 9 - Personal Protective Equipment.

OTHER EQUIPMENT	
Type of equipment	Additional information
Instructions for use	
Safety signs	to assist in isolating and identifying the spill
Absorbent material	generous quantities of swabs, absorbent towels, alginate-impregnated mats, spill pillow and/or other purpose-designed absorbent material
Dustpan and broom	to collect glass fragments
Plastic waste bag	clearly labelled with cytotoxic telophase symbol
Waste container	clearly labelled with cytotoxic telophase symbol
Strong alkaline detergent	with a pH \geq 10 (for example, Decon-90 or Extran)
A supply of clean water	

PROCEDURES FOR DEALING WITH SPILLS

Spills during drug administration, patient care and transport

1. Secure the area and place signs if required.
2. Assess the situation and determine how to deal with the spill.
3. Access the nearest spill kit.
4. Allocate responsibility for managing the spill.
5. Use the personal protective equipment provided in the spill kit.
6. Contain and cover the spill with appropriate absorbent material provided in the spill kit.
7. If the spill involves a powder, carefully place a mat over the powder, ensuring minimal dust production, then carefully wet the mat so that the powder dissolves and is absorbed by the mat.
8. Gather absorbed material, being careful to collect any broken glass.
9. Discard collected waste into the cytotoxic waste container.
10. Wash area with alkaline detergent.
11. Rinse area thoroughly.
12. Dry the affected area with absorbent towels or swabs.
13. Discard the waste into the cytotoxic waste container.
14. Wash hands thoroughly with soap and water.
15. Complete an incident report.
16. Inform management.
17. Ensure that the spill kit is replenished and maintained.

APPENDIX 10: PROCEDURES FOR DEALING WITH SPILLS

Spills within a cytotoxic drug safety cabinet and a cleanroom

All personnel handling cytotoxic drugs in cytotoxic drug safety cabinets and cleanrooms must be familiar with the procedures to follow in the event of a spill. They must be familiar with *Appendix C* of Australian Standard AS 2639-1994 *Laminar flow cytotoxic drug safety cabinets – installation and use*.

NB. Within a clean room, all personnel are wearing personal protective equipment.

Small Spills

1. Clean immediately using available absorbent material.
2. If the spill involves a powder, carefully place a mat over the powder ensuring minimal dust production, then carefully wet the mat so that the powder dissolves and is absorbed by the mat.
3. Gather absorbed material being careful to collect any broken glass.
4. Discard collected waste into the cytotoxic waste container.
5. Wash area with alkaline detergent.
6. Rinse area thoroughly with purified water.
7. Dry the affected area with absorbent towels or swabs.
8. Wipe the affected area with sterile alcohol 70%.
9. Discard the waste into the cytotoxic waste container.
10. Change gloves.

Large Spills

1. Access the nearest spill kit.
2. For large spills, a spill pillow to absorb the fluid may be used, this may be placed on the floor of the cabinet or in the sump area as needed.
3. Follow items 2. – 9. above (ie. same as for small spills).
4. If personal protective equipment is contaminated, discard it into a cytotoxic waste container and don new personal protective equipment.
5. Change gloves.
6. At the end of the shift, complete an incident report.
7. Ensure that the spill kit is replenished and maintained.

Spills outside a cytotoxic drug safety cabinet but within in a cleanroom

Treat as already described with the following additional step:

1. Activate the spill switch.

APPENDIX 11: PROCEDURE FOR DEALING WITH CONTAMINATION OF EMPLOYEES

Procedure for dealing with contaminated clothing and personal protective equipment

1. Immediately remove gloves or gown and any contaminated clothing and dispose of in the cytotoxic waste bin.
2. Package and launder clothing that is not overtly contaminated.
3. Complete an incident report.
4. Inform management.

Procedure for dealing with direct skin, eye and other body contact of employees

1. Wash the affected skin and flush thoroughly with copious amounts of water.
2. For eye exposure, immediately flood the affected eye with clean water by continuous irrigation for a period of 15 minutes.
3. Do not administer antiseptic or anaesthetic drops or ointments.
4. Report to supervisor immediately.
5. Seek immediate medical advice and seek medical attention as necessary.
6. Complete an incident report.
7. Inform management.
8. Seek medical review with the appointed medical practitioner as outlined in point 10 of Appendix 8 – Guidelines for medical practitioners in health monitoring for cytotoxic drugs.

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ACKNOWLEDGMENTS

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