



Cytotoxic Drugs and Related Waste

A Risk Management Guide for
South Australian Health Services

2015



Government
of South Australia

SA Health

Legislation

In July 2008, the Council of Australia Governments formally committed to the harmonisation of work health and safety laws by signing an Intergovernmental Agreement for Regulatory and Operational Reform in Occupational Health and Safety (IGA). The Commonwealth and each jurisdiction were to enact laws that reflected the model work health and safety laws. At the time of review and re-printing, South Australia Work Health and Safety (WHS) legislation has been enacted. When reading this publication you should always refer to current laws. Emerging developments will be available on the SA Health website.

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Table of Contents

| | | | | | |
|----------|---|-----------|----------|--|-----------|
| 1 | Scope | 5 | 3.7 | Monitor and review | 25 |
| | Preface | 5 | 3.8 | Other sources of information | 26 |
| | Acknowledgments | 5 | 4 | Staff Health | 27 |
| | Introduction | 6 | 4.1 | Health surveillance and monitoring | 27 |
| 1.1 | What are cytotoxic drugs? | 6 | | Health monitoring | 27 |
| 1.2 | What are hazardous drugs? | 7 | | Biological monitoring | 27 |
| 1.3 | BCG | 7 | | What type of health surveillance should be implemented? | 28 |
| 1.4 | Monoclonal Antibodies (MABs) | 7 | | Factors in implementing a health monitoring program | 28 |
| 1.5 | Who is at risk? | 8 | 4.2 | Special health considerations | 32 |
| 1.6 | Potential adverse effects | 8 | 4.3 | Hygiene | 32 |
| 2 | Legislation | 9 | 4.4 | Work flow | 33 |
| 2.1 | <i>Work Health and Safety Act 2012 (SA)</i> | 9 | 4.5 | Emergency procedures | 33 |
| 2.2 | Work Health and Safety Regulations 2012 (SA) | 10 | 4.6 | Reporting and keeping records | 33 |
| | Prohibited or restricted carcinogens and/or hazardous chemicals | 10 | 4.7 | Model Procedures | 33 |
| | Hazardous Chemicals Register | 10 | 5 | Training | 34 |
| 2.3 | Approved Codes of Practice | 11 | 5.1 | Who should be trained? | 34 |
| 2.4 | What is reasonably practicable? | 11 | 5.2 | Identify training requirements and resources | 35 |
| 2.5 | Risk management | 11 | | Patient training | 36 |
| 2.6 | Hazardous Chemicals | 12 | 5.3 | Evaluate the training program | 36 |
| 2.7 | Duties of manufacturers, importers and suppliers of Hazardous Chemicals | 12 | 5.4 | Training records | 36 |
| 2.8 | Safety data sheets (SDS) | 13 | 5.5 | Model Procedures and Associated Attachments | 36 |
| 2.9 | Summary of duties of persons conducting a business or undertaking (PBUs) who use hazardous chemicals and substances | 14 | 6 | Preparation and Dispensing | 37 |
| 2.10 | Transport of cytotoxic drugs as dangerous goods | 14 | 6.1 | Eliminate the hazard | 39 |
| 2.11 | Plant, structure and equipment | 14 | 6.2 | Isolate or substitute the hazard at the source | 39 |
| 2.12 | Other legislation, policies and measures | 15 | 6.3 | Reduce the risk through engineering controls | 41 |
| 3 | Managing the Risk | 16 | 6.4 | Reduce exposure to the hazard using administrative actions | 43 |
| 3.1 | What is required to manage the risk? | 16 | 6.5 | Personal Protective Equipment (PPE) | 46 |
| | The Risk Management Approach | 17 | 6.6 | Safe Work Procedures | 47 |
| 3.2 | Consultation and communication | 18 | 6.7 | Model Procedures | 47 |
| 3.3 | Hazard identification | 19 | 7 | Labelling | 48 |
| 3.4 | Risk assessment | 19 | 7.1 | All cytotoxic drugs | 48 |
| 3.5 | Controlling the risk | 23 | 7.2 | Supply of a cytotoxic drug to a patient | 49 |
| | Hierarchy of controls | 23 | | General Content Requirements for Cytotoxic Drug Labels | 49 |
| | Develop a risk control plan | 24 | | Ancillary labels | 49 |
| 3.6 | Trial and implementation | 24 | | | |

| | | | | |
|-----------|--|-----------|---|-----------|
| 7.3 | Cytotoxic drugs for transportation | 51 | 12 Cleaning and Laundry | 69 |
| 7.4 | Cytotoxic drugs provided to drug preparation facilities by a supplier for further processing | 51 | Cleaning | 69 |
| 7.5 | Model Procedures | 51 | 12.1 Standard cleaning procedures | 69 |
| 8 | Transport | 52 | 12.2 Cleaning agents | 70 |
| 8.1 | Transportation of cytotoxic drugs | 53 | Surfactants | 70 |
| | External transportation | 53 | Chlorine-based agents | 71 |
| | Additional considerations for manufacturers | 55 | Alcohol | 70 |
| | Transportation within a Health Service | 55 | 12.3 Guide to dilution of chlorine-based disinfectant solutions | 71 |
| 8.2 | Transport of cytotoxic waste | 56 | 12.4 Workplace monitoring | 72 |
| | On-site waste transport | 56 | 12.5 Cleaning staff | 72 |
| | Off-site waste transport | 56 | Laundry | 72 |
| | Transport licence and certificate | 57 | 12.6 Risk control measures in healthcare facilities | 72 |
| 8.3 | Model Procedures | 57 | 12.7 Contaminated personal protective equipment (PPE) | 72 |
| 9 | Administration | 58 | 12.8 Contaminated bedding | 73 |
| 9.1 | Key risk control measures | 58 | 12.9 Information sources | 73 |
| 9.2 | Establishing a drug administration area | 59 | 13 Personal Protective Equipment (PPE) | 74 |
| 9.3 | Cytotoxic drug administration | 60 | Recommended PPE for handling cytotoxic drugs and related waste | 74 |
| | Patient assessment | 60 | 13.1 Coveralls and gowns | 75 |
| | Parenteral administration | 61 | 13.2 Gloves | 75 |
| | Intravesical administration | 61 | 13.3 Protective eyewear | 75 |
| | Topical administration | 62 | 13.4 Shoe covers and overshoes | 76 |
| | Oral administration | 62 | 13.5 Respiratory Protective Equipment (RPE) | 76 |
| 9.4 | Model Procedures and Associated Attachments | 62 | 13.6 Head covering | 77 |
| 10 | Caring for Patients in the Community | 63 | 14 Spills | 78 |
| 10.1 | The role of the treating facility | 63 | 14.1 Sources of spills | 78 |
| 10.2 | Personnel management | 64 | 14.2 Spill kits | 79 |
| 10.3 | Safe work procedures for the community setting | 64 | 14.3 Spill containment | 80 |
| | | | Worker accidental exposure | 80 |
| 10.4 | Community dispensing | 64 | Managing cytotoxic spills in the community setting | 80 |
| 10.5 | Administration of cytotoxic drugs | 65 | 14.4 Reporting procedures | 81 |
| 10.6 | Managing cytotoxic waste | 65 | Notification of incidents | 81 |
| 10.7 | Emergency procedures | 65 | 14.5 Model Procedures and Associated Attachments | 81 |
| 11 | Caring for Patients at Home | 66 | | |
| 11.1 | Home care by nursing staff | 66 | | |
| | Setting up a patient care area | 67 | | |
| | Equipment | 67 | | |
| 11.2 | Home care by relatives and/or the patient | 68 | | |

| | | | |
|--|-----------|--|-----|
| 15 Waste Management | 82 | Model Procedures and Associated Attachments | |
| 15.1 What is cytotoxic waste? | 82 | 1. Health Surveillance for Workers Handling Cytotoxic Drugs and Related Waste | 123 |
| 15.2 Establishing waste management safe work procedures | 83 | <i>Attachment 1a Health Surveillance Questionnaire</i> | 125 |
| 15.3 Key risk control measures | 83 | <i>Attachment 1b Log of Exposure to Cytotoxic Drugs for Pharmacy Workers</i> | 131 |
| 15.4 Identification, containment and segregation | 84 | <i>Attachment 1c Log of Exposure to Cytotoxic Drugs for Nursing Workers</i> | 132 |
| Identification | 84 | 2. Staff Training for the Safe Handling of Cytotoxic Drugs and Related Waste | 133 |
| Containment | 84 | <i>Attachment 2a Training Matrix</i> | 136 |
| Segregation | 84 | 3. Preparation of Parenteral Cytotoxic Drugs Without a Closed System Drug Transfer Device in the Pharmacy Department | 137 |
| 15.5 Requirements and licensing for handling or storage of cytotoxic waste | 85 | 4. Transport of Cytotoxic Drugs External to the Health Service | 140 |
| 15.6 Waste disposal and treatment | 85 | <i>Attachment 4a Sample Labels</i> | 144 |
| 15.7 Contaminated body waste | 85 | <i>Attachment 4b Log of Cytotoxic Drug Parcels Sent to External Institutions</i> | 145 |
| 15.8 Precautions when handling cytotoxic contaminated body waste | 86 | 5. Transport of Cytotoxic Drugs Within the Health Service | 146 |
| 15.9 Model Procedures | 86 | <i>Attachment 5a Cancelled/Delayed Therapy form</i> | 149 |
| | | <i>Attachment 5b Sample – Distribution Book of Cytotoxic Drug Sent to Wards</i> | 150 |
| 16 Animal Research Facilities | 87 | 6. Safe Handling of Oral Cytotoxic Drugs in a Health Service | 151 |
| 16.1 Establishing an animal care area | 88 | <i>Attachment 6a Time Out Procedure</i> | 153 |
| 16.2 Equipment required | 88 | <i>Attachment 6b Time Out Procedure Checklist (example pro-forma)</i> | 154 |
| 16.3 Safe work procedures | 88 | 7. Accidental Exposure to Cytotoxic Drugs and Related Waste | 155 |
| | | 8. Spill Management of Cytotoxic Drugs | 157 |
| Appendices | 90 | <i>Attachment 8a Recommended Cytotoxic Drug Spill Kit Contents – Check List</i> | 161 |
| 1. Glossary | 91 | <i>Attachment 8b Cytotoxic Drug Spill Kit Register</i> | 162 |
| 2. References and Information Sources | 99 | 9. Managing Cytotoxic Waste | 163 |
| 3. Monoclonal Antibodies (MABs) | 102 | | |
| 4. Hazardous Chemicals (Cytotoxic Drugs) Register | 105 | | |
| 5. Risk Assessment Tool for Cytotoxic Drugs and Related Wastes | 106 | | |
| 5A. Safe Work Method Statement/Risk Treatment Plan | 109 | | |
| 5B. WHS Risk Matrix and Treatment Plan | 110 | | |
| 5C. Hierarchy of Risk Control Process | 114 | | |
| 5D. Decision Making Process for the Safe Handling of Cytotoxic Drugs | 115 | | |
| 6. Cytotoxic Drug Precautions (Example Alert Pro-Forma) | 116 | | |
| 7. Table of Cytotoxic Drugs and Excretion Rates | 117 | | |
| 8. Safe Handling Recommendations for BCG | 120 | | |

1. Scope

Preface

The second edition of the SA Health's *Safe Handling - Cytotoxic Drugs and Related Waste – A Risk Management Guide*, represents an update to the 2012 edition, primarily to reflect changes in nationally harmonised Work Health and Safety legislation. It is the aim of the guide to support SA Health Local Health Networks, Health Services, Business Units and workers to better understand safe handling and risk management requirements for cytotoxic drugs and related waste to enable the development and implementation of safe work procedures. This edition has been rebadged as A Risk Management Guide to more accurately convey its intent and purpose.

In addition to legislative updates, recommendations for the safe handling of monoclonal antibodies (MABs) and the Bacillus of Calmette and Guerin strain of *Mycobacterium bovis* (BCG) are included. While neither of these agents are cytotoxic drugs, SA Health healthcare services have sought guidance on the safe handling of these medicines that are increasingly used in cancer treatment and other medical interventions.

Feedback from healthcare services has been considered in this guide wherever possible to improve its utility, and to assist Health Services in the practical application and implementation of safe handling requirements. Some sections have been merged, for example the sections on cleaning and laundry given their relatedness and similarly the sections on waste management and patient waste. Additions include a Table of Cytotoxic Drugs and Excretion Rates to assist workers identify more common cytotoxic drugs and provide guidance, in particular when handling patient waste or body fluids following cytotoxic drug therapy.

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Consultation was undertaken via the Chairs of the SA Health Local Health Network Cytotoxic Advisory Committees and other interested parties in SA Health including SA Cancer Services, SA Pharmacy and Workforce. Acknowledgement and thanks also go to the individuals within SA Health who contributed their time and expertise in developing this document.

This guide was originally adapted from WorkCover NSW: Cytotoxic Drugs and Related Waste – Risk Management Guide 2008. A full list of references and information sources is available in **Appendix 2 – References and Information Sources**.

Introduction

This Risk Management Guide provides practical advice for SA Health healthcare services such as Local Health Networks, Health Services and related workers on how to prevent or minimise the occupational health risks associated with handling cytotoxic drugs and related waste. It is designed to provide general advice to assist in the development and implementation of safe work systems including processes and procedures that are consistent with the requirements of Work, Health and Safety laws. It does not claim to cover every eventuality in the handling of cytotoxic drugs and is not intended as an operational manual. Healthcare related services must establish safe work procedures that take into account new information and professional judgments of clinical staff in addition to these recommendations.

This guide should be made available to all workers involved in the handling of cytotoxic drugs and related wastes and applies primarily to the clinical handling of these in the provision of healthcare related services in:

- > hospital settings
- > pharmacy settings
- > patient homes
- > nursing homes, hostels and other residential care settings
- > paramedical or ambulance vehicles
- > analytical pathology and research laboratories
- > research, pathology or diagnostic services associated with veterinary science
- > domiciliary ambulatory clinics
- > doctors' surgeries and medical practice rooms
- > pharmacy courier services
- > other transport services
- > pathology courier services
- > mortuaries.

For the purposes of this guide, the scope of the use of cytotoxic drugs includes their preparation, administration, handling, storage, transportation, disposal and spills management. While the guide addresses primarily the handling of cytotoxic drugs, the risk management framework model provided will enable healthcare services to assess and evaluate site specific clinical and operational factors to be applied in the development of safe work procedures for the safe handling of other hazardous drugs.

While this document has specifically designed for use by SA Health healthcare services, the principles discussed and the risk management framework described may be applicable to private health care settings (such as private hospital facilities, veterinary facilities etc.) where cytotoxic drugs are handled and therefore may be used as a reference by these services.

1.1 What are cytotoxic drugs?

Cytotoxic drugs are highly toxic to cells mainly through their action on cell reproduction. Many are proven to be carcinogenic, mutagenic or teratogenic. Cytotoxic drugs are a subset of antineoplastic drugs; therapeutic agents intended for but not limited to the treatment of cancer. Handling cytotoxic drugs is an area of occupational risk to workers where the long term effects of prolonged or frequent exposure are not known. Exposure may potentially occur during preparation, administration, transportation, waste disposal and when handling patient waste (excreta) or in the event of a spill.

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



1.2 What are hazardous drugs?

In occupational terms a hazardous drug is defined as an agent that, due to its inherent toxicity, presents a danger to healthcare personnel. Hazardous drugs are identified as being carcinogenic, teratogenic, genotoxic or as having other developmental, reproductive or organ toxicity regardless of dose; or a similar profile to drugs already considered hazardous. As a class, hazardous drugs may include cytotoxic drugs, certain antiviral drugs and hormones, some bioengineered drugs and other miscellaneous drugs. While this guide addresses primarily the handling of cytotoxic drugs the risk management framework model provided will enable healthcare services to assess and evaluate site specific clinical and operational factors to be applied in the development of safe work procedures for the safe handling of other hazardous drugs.

1.3 BCG

BCG (the Bacillus of Calmette and Guerin strain of *Mycobacterium bovis*) is a hazardous drug (biohazard). It contains live, attenuated (reduced virulence) *Mycobacterium bovis* and therefore has the potential risk for transmission.

The potential occupational risks to health workers handling BCG are not well described in the literature. Infections have been reported in workers exposed primarily through needle-stick injuries and skin lacerations during the preparation of BCG for administration, while nosocomial infections have been reported in immunosuppressed patients receiving parenteral drugs that were prepared in areas in which BCG was prepared.

BCG used in the treatment of neoplastic diseases is a non-cytotoxic, antineoplastic, immunostimulant agent. While the scope of this guide does not specifically extend to hazardous drugs that are not cytotoxic, the risk management framework described can be applied in the development of local safe work procedures for handling BCG. SA Health healthcare services seeking guidance on the safe handling of this agent may be assisted by referring to the general recommendations for the safe handling of BCG in Appendix 8.

It must be noted that risks are to be assessed for hazardous drugs individually and considering their purpose; risk assessments should be based on current literature, safety data sheets, approved product information and other relevant information, taking into account molecular and cellular level mechanisms of action as well as published toxicity data. Depending on the individual agent and clinical setting, similar handling precautions to those used for cytotoxic drugs may be required.

For additional information see **Appendix 8 – Safe Handling Recommendations for BCG.**

1.4 Monoclonal Antibodies (MABs)

Monoclonal Antibodies (MABs) have been used in clinical practice for nearly 30 years during which time there have been no reported cases of occupational injury or harm to workers involved in their preparation or administration. Some confusion has existed as to the risk categorisation of MABs in part due to their wide ranging clinical application, which extends beyond various cancers to non-cancer diseases including chronic immune-mediated inflammatory conditions. While MABs used in cancer treatment may be antineoplastic, they are *not* cytotoxic drugs (except where conjugated to a cytotoxic drug). Due to their increasing and wide ranging clinical use, and the recent availability of national consensus guidelines, risk management and safe handling recommendations for MABs are included to assist healthcare services in the development of safe work procedures addressing the safe handling of these agents.

For additional information see **Appendix 3 – Monoclonal Antibodies (MABs).**



1.5 Who is at risk?

Occupational exposure to cytotoxic drugs and related waste may occur when:

- > preparing drugs
- > administering drugs
- > transporting drugs
- > storing drugs
- > handling cytotoxic waste
- > transporting and disposing of waste
- > cleaning up spills.

Exposure may occur through skin contact, skin absorption, inhalation of aerosols and drug particles, ingestion and sharps injuries.

1.6 Potential adverse effects

Where risk control measures have been inadequate, the health effects on those who prepare, administer and handle cytotoxic drugs have included:

- > alterations in complete blood picture (blood cell count, immunology variations, lipid variations, urine anomalies)
- > foetal loss and possible chromosomal aberration in offspring
- > fertility changes in both males and females
- > abdominal pain, hair loss, nasal sores and vomiting
- > liver damage
- > contact dermatitis.

Where appropriate risk control measures are in place and adhered to, the risk to health are greatly reduced.

2 Legislation

This section aims to provide practical advice to persons conducting business or undertakings (PCBUs), responsible agencies (SA Health and its Local Health Networks), WHS defined Officers, and workers about the legal requirements that must be met when handling cytotoxic drugs and related wastes. PCBUs and responsible agencies have obligations to ensure all workers (employees, contractors, agency staff, volunteers, students) and other persons (occupiers, visitors, carers, members of the public on SA Health sites) are not exposed to risks which may affect their health, safety and wellbeing.

This section should be read in conjunction with:

- > Section 8 – Transport
- > Section 15 – Waste Management
- > Appendix 4 – Hazardous Chemicals (Cytotoxic Drugs) Register

2.1 Work Health and Safety Act 2012 (SA)

The Work Health and Safety Act 2012 (SA) (the Act) places a primary duty of care on PCBUs and their responsible agencies to ensure, so far as is reasonably practicable, that the health and safety of workers and other persons are not put at risk from work carried out as part of the conduct of the business or undertaking. This includes ensuring the safe use, handling and storage of substances by:

- > the provision and maintenance of a work environment that is without risks to health and safety
- > the provision of maintenance of safe plant and structures
- > the provision of safe systems of work
- > information, instruction and training
- > monitoring of the workplace and the health of all workers.

All workers, contractors, self-employed people, agency staff, employees, designers, manufacturers, importers, suppliers, installers and commissioners of plant, equipment and substances also have an obligation to ensure workplace health and safety.

Persons who have the management or control of fixtures, fittings or plant at the workplace have the same duty of care.

Officers as defined in the Act must ensure that they meet their legal obligations and the elements of due diligence, via the provision of resources (physical and financial) and processes to eliminate or minimise risks that arise from hazardous chemicals at the workplace.

All workers, including contractors have a duty, as defined in the Act to take reasonable care for their own health and safety and must not adversely affect the health and safety of other persons.

Workers must comply with any reasonable instruction and cooperate with any reasonable SA Health policy or Health Services safe work procedure relating to the use, handling and storage of hazardous chemicals at the workplace, including cytotoxic drugs and related waste.

2.2 Work Health and Safety Regulations 2012 (SA)

The Work Health and Safety Regulations 2012 (the Regulations) make specific provisions for hazardous chemicals and/or substances when they meet the criteria of the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS); this includes the suite of cytotoxic drugs which present a potential risk to a worker health, safety and wellbeing.

Even when a chemical and/or substance is not classified as a hazardous chemical via GHS, information must be provided to all workers to ensure it is safe and without risks to health. Safety data sheets (SDS) and product information provide an additional source of information about safe use.

Cytotoxic drugs that are classified as dangerous goods (refer to SDS) under the *Australian Code for the Transport of Dangerous Goods by Road and Rail* (ADG Code) may also have specific WHS regulatory requirements for storage. Refer to **Section 7 – Transport** for both transport and storage requirements.

Cytotoxic drugs that are classified as Dangerous Goods and meet placarding quantity requirements (WHS Regulations 2012 (SA) Schedule 11 Hazardous Chemicals) are to be placarded as specified in the Regulations, Chapter 7 Part 1 Division 4 regulation 349.

A limited number of chemicals and/or substances are exempt from the Regulations. These include therapeutic goods at the point of administration or chemicals and substances that are brought into the workplace for personal use.

Persons conducting a business or undertaking (PCBUs) and their responsible agencies have specific duties specified in the Regulations to manage the risks to health and safety associated with using, handling, generating and storing hazardous chemicals at a workplace.

These duties include, but are not limited to:

- > correct labelling of containers, using warning placards/outer warning placards and displaying of safety signs, if placard quantities are met
- > maintaining a register of hazardous chemicals
- > maintaining a manifest (where relevant) of hazardous chemicals with emergency plans and regulator notification of quantities (as required)
- > identifying risks of physical/chemical reactions of hazardous chemicals and ensuring their stability
- > ensuring that available exposure standards are not exceeded
- > provision of health monitoring to workers (as required)
- > provision of information, training, instruction and supervision to workers
- > provision of spill containment and management
- > obtaining the current SDS from the manufacturer, importer or supplier of the chemical and ensuring they are readily accessible (see 2.8)
- > controlling ignition sources (as identified through SDS) and the provision of fire protection/emergency/ safety equipment.

Prohibited or restricted carcinogens and/or hazardous chemicals

Prohibitions and restrictions for hazardous chemicals and carcinogens are specified in Schedule 10 of the Regulations (i.e. cyclophosphamide) with specific requirements for authorisation of use and handling.

All SA Health Local Health Networks/Health Services/Business units that use or handle any form of cyclophosphamide or any other Schedule 10 identified carcinogen must have and maintain the authorisation from the regulator (Safework SA).

Hazardous Chemicals Register

Work Health and Safety Regulations 2012 (SA) R346 requires a register of all hazardous chemicals, including cytotoxic drugs, used, handled or stored at the workplace is prepared and kept. The register must be maintained to ensure it is up to date. A current SDS for each cytotoxic drug must also be listed and updated as new hazardous chemicals are introduced to the workplace or when the use of a particular hazardous chemical is discontinued.

2.3 Approved Codes of Practice

Safe Work Australia has developed model Codes of Practice as part of harmonised work health and safety laws.

Approved codes of practice are practical guides to achieving the standards of health, safety and welfare required under the Act and its Regulations.

The approved codes of practice relative to hazardous chemicals address particular issues and do not cover all hazards or risks which may arise. The health and safety duties require duty holders to consider all risks associated with working with hazardous chemicals, not only those for which regulations and codes of practice exist.

It must be noted that these approved codes of practice are admissible in court proceedings. Courts may regard an approved code of practice as evidence of what is known about a hazard, risk or control and may rely on the code in determining what is reasonably practicable in the circumstances to which the code relates.

Approved codes of practice are referred to throughout this guide, dependent on subject matter.

2.4 What is reasonably practicable?

In relation to a duty to ensure health and safety, 'reasonably practicable' means that which is, or was at a particular time, reasonably able to be done in relation to ensuring health and safety, taking into account and weighing up all relevant matters including:

- > the likelihood of the hazard or the risk concerned occurring; and
- > the degree of harm that might result from the hazard or the risk; and
- > what the person concerned knows, or ought to reasonably know about:
 - the hazard or the risk; and
 - ways of eliminating or minimising the risk; and
- > the availability and suitability of ways to eliminate or minimise the risk; and
- > After assessing the extent of the risk and the available ways of eliminating or minimising the risk, the cost associated with available ways of eliminating or minimising the risk, including whether the cost is grossly disproportionate to the risk.

2.5 Risk management

Even when a chemical and/or substance, including a cytotoxic drug, is not classified as a hazardous chemical by the manufacturer or importer, a PCBU including a responsible agency must still comply with the requirements of the Act and its Regulations in identifying the reasonably foreseeable hazard that may give rise to risks to health and safety, with respect to that chemical and/or substance and ensuring that each chemical and/or substance does not pose a health or safety risk to those at work. This obligation extends to not harming visitors or workers, for example contract waste collection personnel who enter the workplace.

In other words:

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

Refer to **Section 3 – Managing the Risk** for risk management processes.

2.6 Hazardous Chemicals

WHS Regulations Chapter 7 Part 1 aims to protect all persons against risks to their health and safety when hazardous chemicals are used, handled and stored at a workplace.

A hazardous chemical means a substance, mixture or article that satisfies the criteria for a hazard class in the Globalised Harmonised System (GHS) (including a classification referred to in Schedule 6 of the Regulations).

It must be noted that the Regulations, Chapter 7 Part 1 do not apply to in the following circumstances:

- > therapeutic goods within the meaning of the Therapeutic Goods Act 1989 of the Commonwealth at the point of intentional intake by or administration to humans;
- > veterinary chemical products within the meaning of the Agvet Code at the point of intentional administration to animal.

For example: this means that a hazardous chemical, such as the cytotoxic drug, methotrexate (which is TGA approved and administered for therapeutic reasons) is exempt from the requirements of this regulation at the point of intake; for example a SDS does not have to accompany the cytotoxic drug when it is being administered to a patient, but it must be made available to all workers in the ward involved in using, handling, storing of the drugs for reference should it be required.

When a cytotoxic drug is classified as a hazardous chemical, any waste generated may also be classified as a hazardous chemical and the Regulations apply.

The SA Environmental Protection Authority (EPA) regulates the transport of cytotoxic waste, particularly bulk transport. Refer to **Section 8 – Transport and Section 15 – Waste Management** for additional information.

2.7 Duties of manufacturers, importers and suppliers of Hazardous Chemicals

In addition to the general duties under the Act and Regulations, manufacturers, importers and suppliers of hazardous chemicals are required to provide information about their product to purchasers.

They are required to:

- > determine whether a chemical and/or substance is a hazardous chemical as per the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS)
- > classify the hazardous chemical correctly as it is this classification that determines what information is required on labels and SDS under the Regulations.
- > prepare and provide specific information in the form of SDS and labels to PCBUs and/or their responsible agencies who use their chemicals and / or substances as per the GHS (further reference can be made to the *Code of Practice for Labelling of Workplace Hazardous Chemicals*)
- > ensure that containers of chemicals and/or substances are correctly labelled with safety information as per the GHS
- > amend SDS every 5 years and whenever necessary to ensure it contains correct, current information.

In addition, suppliers (excluding retailers) are required to provide PCBU's and their responsible agencies with a copy of the manufacturer's or importer's SDS.

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

| Duty holder | Responsibilities |
|---|---|
| Manufacturer or importer | <ul style="list-style-type: none"> > determine whether a substance, mixture or article is a hazardous chemical > ensure the hazardous chemical is correctly classified > prepare and provide safety data sheets > ensure the hazardous chemical is correctly labelled > amend safety data sheets every 5 years and whenever necessary to ensure it contains correct, current information. |
| Supplier | <ul style="list-style-type: none"> > ensure the hazardous chemical is correctly labelled |
| Person conducting a business or undertaking | <ul style="list-style-type: none"> > ensure the hazardous chemical is correctly labelled |

Source: Safe Work Australia Model Code of Practice – Labelling of Workplace Hazardous Chemicals

2.8 Safety data sheets (SDS)

Cytotoxic drugs that are classified as hazardous chemicals may have the inherent properties of having the potential risk of causing a health or physicochemical hazard if not handled or stored correctly.

Health hazards are hazards like skin irritants, carcinogens or respiratory sensitisers that have the potential to cause an adverse effect on a worker's health as a result of direct contact with or exposure to the chemical and/ or substance, usually through inhalation, skin contact or ingestion.

Physicochemical hazards generally result from the physical or chemical properties, like flammable, corrosive, oxidising or explosive substances.

The inherent properties of a hazardous chemical are listed in its SDS.

The SDS is a document that describes the chemical, physical and toxicological properties of a chemical and / or substance. It provides precautionary advice on safe handling and use.

The SDS is a recognised source of information in the workplace and underpins the risk assessment to control the potential exposure to chemicals and / or substances.

Legal obligations in relation to SDS are specified in the Regulations and the code of practice for the *Preparation of Safety Data Sheets for Hazardous Chemicals*.

Manufacturers are required to classify chemicals and prepare SDS.

Importers must ensure that the manufacturer's responsibilities are met.

Suppliers are required to provide SDS for those chemicals classified as hazardous chemicals if they supply to workplaces. If a supplier fails to provide adequate information to develop a safe work method, other sources of information should be used to assist in the development of safe work procedures.

PCBUs and their responsible agencies must ensure that current safety data sheets and other sources of information are readily accessible to workers who may use, prepare, administer, transport or handle these chemicals and /or substances.

2.9 Summary of duties of persons conducting a business or undertaking (PBU) who use hazardous chemicals and substances

PCBUs and their responsible agencies, in consultation with workers, must use information provided by manufacturers, importers or suppliers to identify the hazardous chemicals used in the workplace and assess and control the risk to health associated with their use. In summary, the Regulations require PCBUs and their responsible agencies to:

- > obtain a copy of the manufacturer's or importer's SDS and ensure that it is accessible to workers
- > ensure all containers of hazardous chemicals are labelled according to GHS
- > set-up a Hazardous Chemicals register – **See Appendix 4.**

Furthermore, in consultation with workers:

- assess workers risk to health from potential exposure to hazardous chemicals and/ or substances
- eliminate or control the risk associated with the use, prepare, administer, transport or handle hazardous chemicals and / or substances
- provide workers with information, instruction and training.

2.10 Transport of cytotoxic drugs as dangerous goods

SafeWork SA is the authority responsible for regulating dangerous substances and transport of dangerous goods in South Australia. The South Australian Environmental Protection Authority is responsible for regulating the transport of hazardous waste in SA.

Cytotoxic drugs that are classified as dangerous goods and are being transported must comply with the *Australian Dangerous Goods Code and Dangerous Goods Transport Regulations 2008* requirements for road transport and the International Air Transport Association's (IATA) Dangerous Goods Regulations for air transport.

Refer to **Section 8 – Transport** for further information.

2.11 Plant, structure and equipment

Chapter 5 of the Regulations outlines specific obligations with respect to plant and structure. Plant and structure includes any machinery, equipment, appliance, container, implement or tool. With respect to cytotoxic drugs and related waste, plant may include cytotoxic drug safety cabinets, automated trolleys for carrying cytotoxic drugs, administration equipment, drug delivery services, washing machines, other laundry equipment, needles and syringes.

PCBUs and their responsible agencies, designers, manufacturers, suppliers and installers of plant, structure and equipment have obligations, which include but are not limited to:

- > management of risks associated with plant
- > installing, erecting, guarding, and commissioning/decommissioning plant
- > using plant and operational controls
- > maintenance, inspection and repairing plant
- > maintaining records
- > providing information.

A PCBU and its responsible agencies must use risk management processes to address potential risks to health and safety when using, handling, generating, storing a hazardous chemical at a workplace, (Refer to Regulation 351). This includes the consideration of:

- > the hazardous properties of the hazardous chemical;
- > any potentially hazardous chemical or physical reaction between the hazardous chemical and another substance or mixture, including a substance that may be generated by the reaction;
- > the nature of the work to be carried out with the hazardous chemical;
- > any structure, plant or system of work—
 - that is used in the use, handling, generation or storage of the hazardous chemical; or
 - that could interact with the hazardous chemical at the workplace.

2.12 Other legislation, policies and measures

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

- > *Controlled Substances Act 1984 (SA)*
- > Controlled Substances (Poisons) Regulations 2011(SA)
- > *Environment Protection Act 1993 (SA)*
- > Environment Protection Regulations 2009 (SA)
- > Environmental Protection (Waste to Resources) Policy 2010
- > Environment Protection (Movement of Controlled Waste) Policy 2014.

PCBUs and/or their responsible agencies must identify chemicals and/or substances used in the workplace, assess the risk to health and safety, and control the hazards associated with their use.

3 Managing the Risk

This section outlines the risk management processes based on hazard identification and risk management and is inclusive of the SA Health Risk Management Framework and *AS/NZS ISO 31000:2009 Risk Management – Principles and Guidelines*.

Cytotoxic drugs are known to be highly toxic to health and classified as hazardous chemicals by the Globally Harmonised System of Classification and Labelling of Chemicals (GHS). For this reason, Person(s) Conducting a Business or Undertaking (PCBU), their responsible agencies and all workers who handle cytotoxic drugs occupationally have an obligation to:

- > work to a risk management plan
- > keep up-to-date with current local safe work procedures, practices and standards
- > consult with workers at key stages of risk strategy development – at the planning stage, during implementation, monitoring and review
- > assess safe work and procedures on a regular basis.

The risk management approach is integral to the *Work Health and Safety Act 2012 (SA)* its regulations and relevant approved codes of practice, and is essential for every day sound risk management practice and good corporate and clinical governance (See *Figure 1 – The Risk Management Approach*).

PCBUs and their responsible agencies need to ensure that communication and consultation with external and internal key interested parties takes place during all stages of the risk management process.

3.1 What is required to manage the risk?

A PCBU and its responsible agency must manage risks associated with using, handling, generating or storing of hazardous chemicals at a workplace.

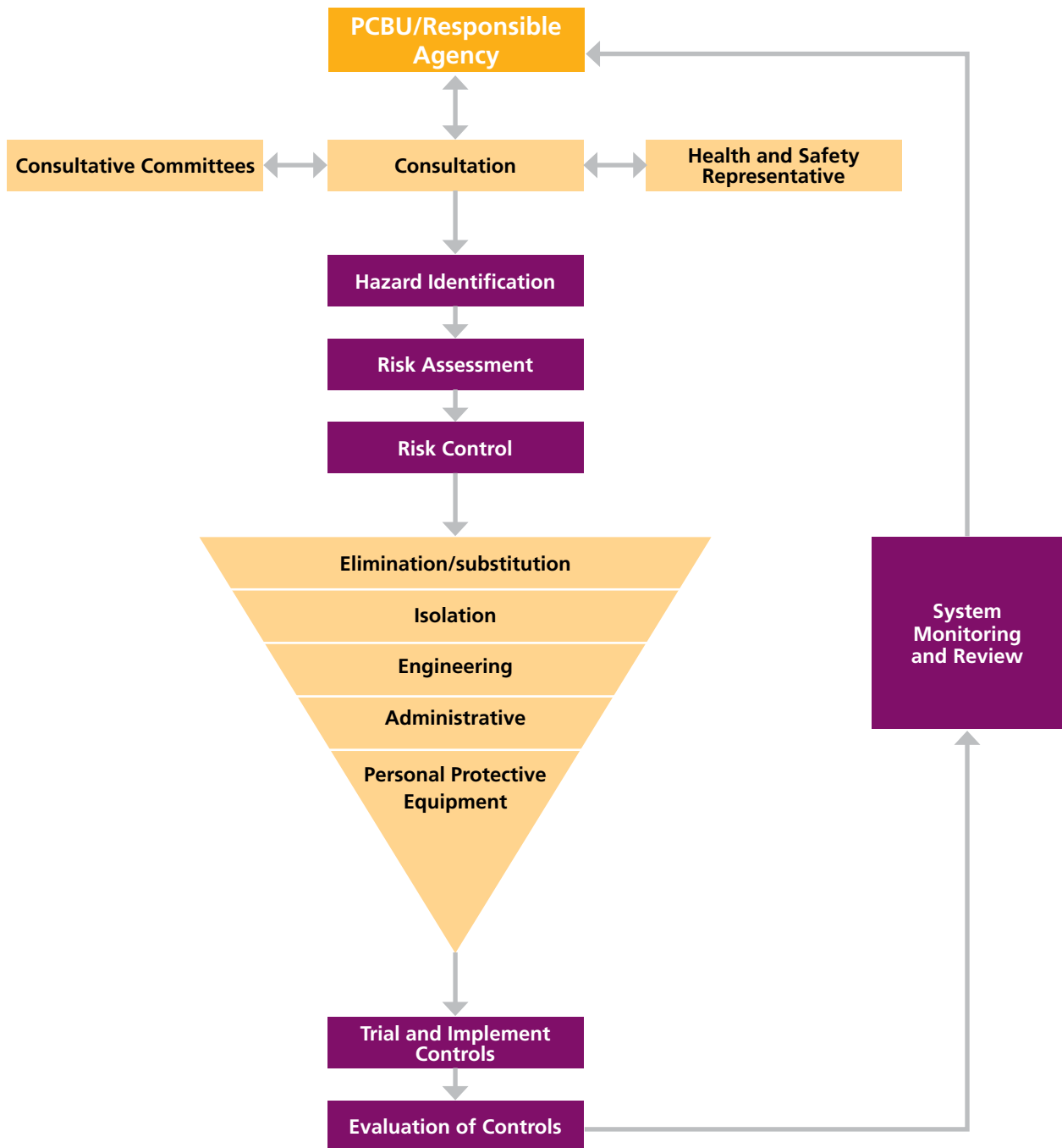
To manage this risk a duty holder must:

- > identify reasonably foreseeable hazards that could give rise to the risk
- > eliminate the risk so far as is reasonably practicable
- > if it is not reasonably practicable to eliminate the risk – minimise the risk so far as is reasonably practicable by implementing control measures in accordance with the hierarchy of risk control
- > maintain the implemented control measure so that it remains effective
- > review, and if necessary revise all risk control measures so as to maintain, so far as is reasonably practicable, a work environment that is without risks to health and safety.

When managing the risks associated with cytotoxic drugs the following must be considered:

- > the hazardous properties of the cytotoxic drug
- > any potentially hazardous reaction (chemical or physical) between the cytotoxic drug and another substance or mixture, including a substance that may be generated by the reaction
- > the nature of the work to be carried out with the cytotoxic drug
- > any structure, plant or system of work that:
 - is used in the use, handling, generation or storage of the hazardous chemical
 - could interact with the hazardous chemical at the workplace.

Figure 1. The Risk Management Approach



The aim of a risk management approach is to eliminate or minimise the risk of illness or injury associated with work. The process is outlined in the Work Health and Safety Regulations 2012 (SA) and the approved Safe Work Australia Codes of Practice entitled *Managing Risks of Hazardous Chemicals in the Workplace and How to Manage Work Health and Safety Risks*. **Generally, risk management is a process of:**

- > consultation and communication with workers
- > consultation, cooperation and coordination of activities with other duty holders i.e. waste management contractors, laundry/linen service providers
- > hazard identification
- > risk assessment
- > implementing risk control measures
- > evaluation of risk control measures
- > continuous improvement.

Effective management of health and safety involves:

- > induction and training
- > documentation of activities such as safe work procedures, worksite inspections, action plans, risk registers
- > regular review of the management system.

3.2 Consultation and communication

The *Work Health and Safety Act 2012* (SA) places a duty, so far as reasonably practicable, on the PCBU and its responsible agency, to consult with workers who carry out work or who are likely to be directly affected by the WHS matter. This enables workers and/or their health and safety representatives to contribute to making decisions that may affect their health, safety and wellbeing at work.

It is a legal obligation for health and safety representatives to have access to relevant information on matters that can affect the health and safety of workers, for example, hazardous chemicals register and data from monitoring airborne contaminants.

Duty holders may have dual responsibility for health and safety matters. In these situations communication and consultation with external and internal interested parties should take place during all stages of the risk management process. Therefore, plans for communication and consultation need to be developed from an early stage and should address issues related to the risk and the measures to control, treat and monitor the risk. This will ensure the exchange of information to determine roles and responsibilities and co-operation and co-ordination so that all risks are eliminated or minimised as far as reasonably practicable.

Consultation must occur:

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

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

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

3.3 Hazard identification

Hazard identification should establish who may be at risk, the cytotoxic drugs being used, the routes of exposure and the specific activities where there is a risk of exposure. Risk control measures currently in use and their effectiveness with future planned treatments should be identified and recorded in action plans.

The table below provides examples of how you can ascertain if the cytotoxic drugs that are used in your workplace pose a risk to staff health and safety.

| Identify which cytotoxic drugs are used and stored at the workplace | |
|---|--|
| Obtain a copy of the manufacturer's or importer's safety data sheet for all cytotoxic drugs. | Ways of achieving this include: <ul style="list-style-type: none"> > contact the supplier > if a 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 as per GHS classification and labelling of hazardous chemicals. | Ways of achieving this include: <ul style="list-style-type: none"> > check all containers for GHS labels and information. |
| Set up and maintain a cytotoxic drugs register. | Ways of achieving this include: <ul style="list-style-type: none"> > list the product names of all cytotoxic drugs used at the workplace > check the safety data sheet and the product label to identify cytotoxic drugs that are classified as hazardous chemicals. The safety data sheet will state whether the product is classified as hazardous as per GHS > work place inspection > indicate which products are classified as hazardous. |
| Additional useful information may be added to the register in Appendix 4 – Hazardous Chemicals (Cytotoxic Drugs) Register | |

3.4 Risk assessment

The purpose for the assessment is to enable decisions to be made about the appropriate risk control measures, induction and training, monitoring and health surveillance as may be required by legislation.

The assessment process enables a distinction to be made between 'hazard' and 'risk'. If a cytotoxic drug is classified as hazardous, it has the potential to be harmful to health. The risk is the likelihood that harm will be caused in the actual circumstances of use of the substance.

Decisions about appropriate action to protect workers will depend on the degree of health risk that arises from the use of cytotoxic drugs and related wastes in particular environments.

The risk assessment may be done for a work process (job safety analysis/safe work method statement) and may cover more than one cytotoxic drug. The following step-by-step procedure may be used to assist with the risk assessment process.

Risk assessment can be separated into two parts; assessing the hazard and evaluating the risk.

| Obtain and review information about cytotoxic drugs used | |
|---|--|
| Consult the safety data sheet (or other available information for each drug) for details of the properties and hazards associated with the substance. | <p>This may include:</p> <ul style="list-style-type: none"> > health hazard information > physicochemical properties > GHS Classification and labelling > precautionary statements > safe handling information. |
| Determine the physical, chemical properties and hazard classification of the substance. | <p>This may include:</p> <ul style="list-style-type: none"> > flammability > corrosiveness > oxidising agent > toxicity > carcinogenicity > sensitisation > acute toxicity. |
| Determine the physical form and the concentration of the substance. | <p>This may include:</p> <ul style="list-style-type: none"> > liquid > powder > solid tablet > creams, ointments and lotions for topical application. |
| Determine the routes of exposure. | <p>This 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. |
| Ascertain the potential harmful effects. | <p>This 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. |

Identify the nature of the work involving cytotoxic drugs

Divide up the workplace and determine where cytotoxic drugs are used and who may be at risk of potential exposure.

For example:

- > drug preparation in the pharmacy
- > drug administration in the ward or day care centre
- > handling, transport and disposal of cytotoxic waste on the premises
- > patient care after administration.

Examine the work tasks practices and conditions. (Involve workers who are working with the cytotoxic drugs.)

What to look for:

- > how the substance(s) is used in various jobs/tasks
- > the quantities and concentrations used
- > level of potential exposure
- > frequency and duration of use
- > the number of workers that may be exposed
- > risk control measures already in place and their effectiveness.

Review information relating to incidents or symptoms of exposure.

What to do:

- > review incident records via the WHS SLS reporting system
- > identify any problems associated with storage and transport of cytotoxic drugs
- > determine whether workers have suffered any adverse effects
- > ascertain whether there have been any spills
- > determine if incidents have been reported and followed up.



| Evaluate the risks | |
|---|--|
| <p>No likelihood of injury or illness. This means that duty holders have a high degree of confidence that safe work procedures and practices are sound and that workers are protected as reasonably practicable.</p> | <p>It may be reasonable to make such a conclusion where:</p> <ul style="list-style-type: none"> > risks have been eliminated/reduced so far as is reasonably practicable > work procedures and 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. |
| <p>Likelihood of injury or illness. This means it is apparent that safe work procedures and practices need improvement.</p> | <p>It may be reasonable to make such a conclusion where:</p> <ul style="list-style-type: none"> > safe work procedures and 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 worn as recommended > the workforce has not received appropriate training > control measures are not maintained or serviced > no spill management system exists. |
| <p>Likelihood of injury or illness is uncertain. This means that duty holders are not certain whether safe work procedures and practices are adequate to protect workers.</p> | <p>It may be reasonable to make such a conclusion where duty holders are not certain if there is a risk to health and may require workers to do more work, for example:</p> <ul style="list-style-type: none"> > conduct environmental wipe sampling (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 reasonably practicable. |

The Work Health and Safety legislation requires duty holders to demonstrate evidence of the risk assessment process. See **Appendix 5 – Risk Assessment Tool** as an example

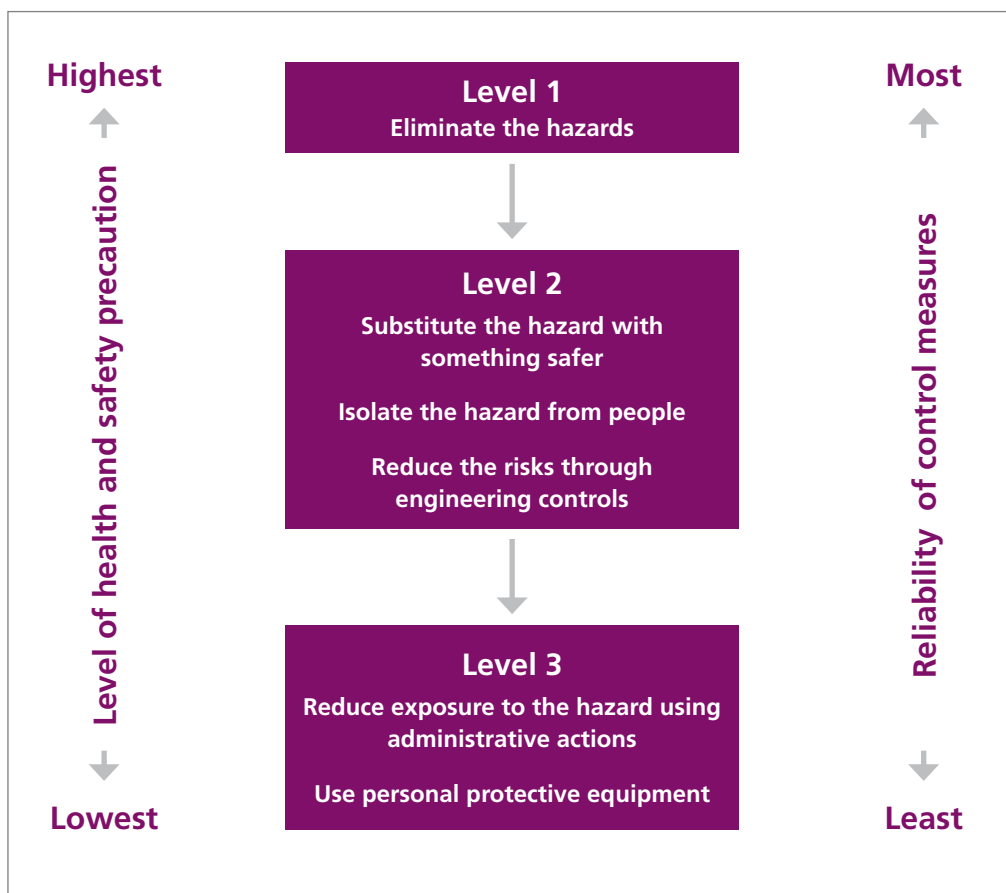
3.5 Controlling the Risk

The Work Health and Safety regulations set out a hierarchy of controls (or ranking of controls) that incorporates a best practice approach to managing risks. These controls are in order of greatest effectiveness to least effective as follows:

- > elimination – removing the hazard or hazardous work practice from the workplace
- > substitution – replacing the hazardous chemical with a chemical that is less hazardous
- > isolation – involves separating people from the chemicals or hazards by distance or barriers to prevent or minimise the risk of exposure
- > engineering controls – are physical in nature, including mechanical devices or processes that eliminate or minimise the generation of chemicals, suppress or contain chemicals, or limit the area of contamination in the event of spills and leaks
- > administrative controls- should only be considered when other higher order control measures are not practicable, or to supplement other control measures. For carcinogens, administrative controls should only be used to provide additional protection
- > personal protective equipment (PPE)-should not be relied on to control risk; It should be used only as a last resort when all other reasonably practicable control measures have been used and the risk has not been eliminated, or as interim protection until higher level controls are implemented. There may also be situations when the use of other controls is not practicable.

The hierarchy of control should be implemented from the most effective to the least.

Figure 2. Hierarchy of Controls



The duty holder's primary duty is to eliminate any risk to health arising from the use of hazardous chemicals. Where elimination of risk is not practicable, duty holders must reduce the risk, so far as is reasonably practicable.

PCBUs and their responsible agencies must first consider whether the risk can be eliminated. This is the most effective way of protecting the health of workers.

PCBUs and their responsible agencies need to ensure that all risk 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 workers to work safely in a hazardous work 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.

For strategies reflecting the hierarchy of controls refer to **Appendix 5C Hierarchy of Control Process**.

Develop a risk control plan

One way of tracking proposed and implemented risk controls measures and future treatments 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 basic structure for a risk control plan |
|--|---|
| <p>A risk control plan defines current risk control measures, future treatments and the actions required to implement It also provides a useful tool to effectively manage this process, defining responsibilities and timelines for implementation of actions required.</p> | <p>A risk control plan should:</p> <ul style="list-style-type: none"> > provide a history of health and safety activities for work involving cytotoxic drugs, including any current control measures, their effectiveness and future planned treatments. > specify immediate, interim and long-term treatments > set priorities for implementing risk control measures > indicate when risk control measures and treatments are to be are to be implemented > specify those responsible and accountable for the implementation > record the date of completion and 'sign off' by a person nominated and authorised by management > include or refer to relevant safe work procedures for work involving cytotoxic drugs > outline plans for the provision of training > involve worker and their health and safety representatives through consultation |

3.6 Trial and implementation

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

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

3.7 Monitor and review

Control measures should be regularly monitored, reviewed and, where necessary, improved, extended or replaced. The following table outlines the strategies to facilitate a robust monitoring and review process:

| Review and revise the risk analysis | |
|--|---|
| <p>Review and revise the risk assessment. This will help measure the effectiveness of risk controls and may reveal areas for improvement.</p> <p>The risk assessment should be reviewed and revised when work enrichment or safe work procedures change and every 2 years.</p> | <p>Ways of achieving this include:</p> <ul style="list-style-type: none"> > schedule regular reviews/audits to ensure 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 or concentrations used – availability of new information about the health hazards of 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. |
| <p>Record the documented review process.</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 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>Update control measures.</p> | <p>Ways of achieving this include, but not limited to:</p> <ul style="list-style-type: none"> > updating safe work procedures > (re)training. |
| <p>Make the results of the analysis accessible to any worker to which the record relates.</p> | <p>Ways of achieving this include:</p> <ul style="list-style-type: none"> > keep copies of the assessment in accessible/commonly used files. |

3.8 Other sources of information

Additional information regarding hazards and risks associated with the use, handling, generation and storage of hazardous chemicals can be obtained from the following sources:

- > Incident records
- > Previous risk assessments
- > Work Health and Safety professionals
- > Australian Dangerous Goods Code 7.3
- > European Chemical Substances Information System (ESIS)
- > Safe Work Australia – Hazardous Substance Information System
- > The Poisons Standard – The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)
- > National Industrial Chemical Notification and Assessment Scheme (NICNAS)
- > Regulatory authorities
- > Trade unions and employer associations

4 Staff Health

An essential part of the risk management strategy is dealing with issues of staff health surveillance, counselling, reporting and record keeping. This section provides a **risk management framework** to assist in the development of local procedures, and aims to provide practical advice to Persons Conducting a Business or Undertaking (PCBU) and their responsible agencies in the matters of staff health.

4.1 Health surveillance and monitoring

Health surveillance is part of a comprehensive prevention program that also minimises worker exposure through the implementation of control measures i.e engineering controls, good work practices, and personal protective equipment (PPE), and provides education about working with hazardous drugs.

Health surveillance is the monitoring of persons to identify changes (if any) in their health status due to the potential risk of occupational exposure to certain substances.

The Work Health and Safety Regulations 2012 (SA) have specific duties for a PCBU and its responsible agencies which include Local Health Networks and Health in the provision of health monitoring to workers if the worker is carrying out ongoing work at a workplace preparing and administering hazardous chemicals and / or substance.

This requirement is based on a risk management approach utilising risk assessments and the review of risk control measures that may be in place.

Health surveillance is the monitoring of a person to identify changes in the person's health status because of exposure to certain substances; this includes health and biological monitoring but does not include atmospheric or environmental monitoring.

The benefits of health surveillance for occupational exposure to cytotoxic drugs and related wastes have not been adequately addressed in the current literature, however health surveillance should be considered in conjunction with environmental monitoring where hazards, incidents or health effects have been highlighted in areas where cytotoxic drug preparation and administration is undertaken.

Exposure standards for acceptable levels of exposure to cytotoxic drugs have not been developed and are not available to date, therefore adoption of standard precautions and the principles of ALARA (as low as reasonably achievable) is recommended. National and State-wide agreed safe work procedures with sufficient initial and regular ongoing training in safe handling/administration are paramount to reducing the potential risk of exposure.

Health monitoring

This includes the implementation of a health surveillance program that monitors an individual's health status pre-employment/ pre-placement and on an ongoing basis to determine any adverse effects to health following exposure to cytotoxic drugs. The program must include counselling of workers on the potential risks to health and reproductive risks, how exposures might occur and risk control measures in place.

It is recommended that complete blood count with differential and liver function tests are completed at baseline for staff who are assessed to be at a greater risk of exposure following a risk assessment based on duties performed; for example pharmacy production staff and cytotoxic drug administration nurses.

Biological monitoring

Biological monitoring is the measurement and evaluation of a substance or its metabolites in the body tissue fluids or exhaled air of exposed persons. The need for biological monitoring to detect exposure to a scheduled carcinogenic substance or tests to detect health effects caused by exposure should be carefully considered when the risk assessment is carried out. In particular, information must be obtained about methods that can detect the early signs of health effects or disease.

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

Several cytotoxic drugs are known to cause bladder damage and blood in the urine of treated patients leading some international standards to recommend monitoring the urine of workers who handle hazardous drugs with a urine dipstick or a microscopic examination of the urine for blood. The robustness of this testing is unclear.

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 and/or metabolites. As a consequence, there is conflicting information and opinion about the value of routine biological tests in monitoring the health of workers handling cytotoxic drugs and related waste.

What type of health surveillance should be implemented?

Any health surveillance program must first and foremost meet the needs of the workers and must include:

- > security of personal information
- > supported care (such as the Employee Assistance Program)
- > authorised medical practitioners selected in consultation with workers
- > elimination of sex bias and/or other biases
- > privacy
- > continuation throughout the period of use of cytotoxic drugs.

The need for ongoing health surveillance and monitoring should be determined at the scheduled termination work health monitoring assessment.

Additional factors to consider in the development and implementation of a health surveillance program are summarised below.

| Factors in implementing a health monitoring program | Considerations | Outcome |
|--|--|--|
| <p>1 A medical practitioner is appointed to oversee the program. Appointment means that the Health Service has a formal arrangement with a medical practitioner. All workers must be made aware of this arrangement (ideally this practitioner would be accessible to staff on site).</p> | <ul style="list-style-type: none"> > The medical practitioner may be an occupational physician, oncologist, haematologist or local general practitioner. > The medical practitioner should be suitably qualified to provide health surveillance in accordance with NOHSC <i>Competencies for health surveillance</i> (1998 and make reference to Safe Work Australia's Health Monitoring for Exposures to Hazardous Chemicals – Guide for Medical Practitioners. | <p>Staff and the Health Service are in agreement on the facilitation of health monitoring.</p> |
| <p>2 Guidance is provided to the appointed medical practitioner.</p> | <p>General guidance is provided in accordance with Safe Work Australia's Health Monitoring for Exposures to Hazardous Chemicals – Guide for Medical Practitioners.</p> | <p>Guidelines and competencies are followed and made available to all relevant workers.</p> |
| <p>3 In regard to the issue of privacy in relation to medical practitioners providing reports to PCBU and/or the responsible agencies.</p> | <ul style="list-style-type: none"> > Reporting must comply with all privacy requirements and government policy. > Records that are not related to Work Health and Safety screening should not be used or stored with records relating to health surveillance. | |

| Factors in implementing a health monitoring program | Considerations | Outcome |
|--|--|--|
| <p>4 The health monitoring program is an integrated part of the Health Surveillance Program which incorporates a risk management approach.</p> | <ul style="list-style-type: none"> > Implementation of the program will involve both relevant workers and Health Service representatives. > Health Services will undertake regular monitoring of their workers' health. > The PCBU and /or responsible agency must ensure that the appointed medical practitioner is: <ul style="list-style-type: none"> – provided with access to the workplace and information required – involved in discussions relating to risk exposure to staff including mitigation strategies. | <ul style="list-style-type: none"> > All workers are provided with information and training in relation to the Health Surveillance Program. > Workers will receive a copy of the health monitoring assessment findings including the timing of the next recommended health monitoring review. |
| <p>5 Prospective workers are counselled and provided information about the potential risks of working with cytotoxic drugs. Exposure to cytotoxic drugs should form part of the relevant staffs' role description. All prospective workers are required to acknowledge this aspect of the role at application. Prior to appointment, prospective staff must agree to and be counselled on the approved health monitoring protocol. Upon appointment information regarding the potential risk of exposure, risk control measures and Safe work procedures must be provided and further enhanced by relevant training as identified for the role.</p> | <p>The counselling must include:</p> <ul style="list-style-type: none"> > the nature of work to be undertaken > potential risks to health > reproductive risks > how exposure may occur > the risk control measures in place > safe work procedures > any training requirements. | <ul style="list-style-type: none"> > Staff orientation handbooks should include orientation to cytotoxic drugs, risk control measures in place and health monitoring programs. > Staff inductions at the workplace must include information regarding safe work procedures and risk control measures. > Health monitoring reviews are documented and counter signed by the staff member. |
| <p>6 Pre-employment/pre-placement health monitoring to establish baseline health is conducted by the approved medical practitioner before the worker commences their work with cytotoxic drugs.</p> | <p>Baseline health monitoring includes:</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 the Health Service and prospective worker. | <p>Prospective workers identified as at greater risk of exposure must undertake baseline health monitoring with the approved medical practitioner(s) within 2 weeks of employment. The worker is provided with a copy of any report with respect to the baseline health assessment and is also to be afforded the opportunity to discuss any adverse outcomes in a timely manner.</p> |

| Factors in implementing a health monitoring program | Considerations | Outcome |
|--|--|--|
| <p>7 Health monitoring is conducted during the period that the worker handles or administers cytotoxic drugs. The worker shall be advised as to the advisability of having periodic health assessments following cessation of employment or work with cytotoxic drugs and details of the types of investigations/ testing that are relevant. The worker shall be provided with a copy of all health monitoring reports. Should a worker refuse participation in the recommended health surveillance, a statutory declaration indicating the refusal, for example a refusal form, must be completed and signed by the worker and provided to the Health Service.</p> | <p>Health monitoring is conducted:</p> <ul style="list-style-type: none"> > during the period the staff member works with cytotoxic drugs > as advised following cessation of employment or work with cytotoxic drugs. <p>Data collection should include details of: health advice and counselling</p> <ul style="list-style-type: none"> > health issues identified > medical review after a spill or sharps injury > review of risk control measures – e.g. needleless injection sets should be in place to eliminate the potential for sharps injuries > the name of carcinogenic substance(s) involved > the period of exposure or potential exposure. > be provided with copies of any exposure incident reports > recommendations as to the advisability. <p>The results of health monitoring shall be made available within clearly defined time frame with consideration given to delays involving further investigations.</p> | <p>Workers attends health monitoring assessment:</p> <ul style="list-style-type: none"> > signs off the record, and > is provided with a copy of the health record within agreed time frames. <p>On termination of placement/ employment the worker must sign the report of the final assessment to acknowledge that they understand the contents of the report and any implications to their health discovered during the scheduled final health monitoring assessment.</p> |
| <p>8 Any relevant worker may access advice and counselling from any approved medical officer(s) at any time outside of scheduled health monitoring.</p> | <p>Workers will be given access to contact details of approved medical officer(s) and released from duties to attend a consultation.</p> | <p>Information to relevant workers on how to contact approved medical officers is available at all times.</p> |
| <p>9 No person will be compelled to work with cytotoxic drugs if special health considerations apply (see Section 4.2).</p> | <p>Skill matched and appropriate alternative duties must be provided to workers that choose not to, or are unable to, work with cytotoxic drugs. Workers will not suffer disadvantage in relation to loss of pay and conditions, and continuity of service. All entitlements must be maintained.</p> | <p>A clear process to opt out of work involving cytotoxic drugs should be made available to new and existing staff through establishment of identified communication processes.</p> |
| <p>10 A workers medical records are confidential.</p> | <p>Where any form of health monitoring is undertaken, confidentiality of a workers health surveillance records must be ensured. Access to a worker's medical records can be obtained only with the written consent of the worker.</p> | <p>Worker health records will be secured separate to their human resource records and/ or hospital medical records. Review of a workers health monitoring record may only occur during scheduled health monitoring or to support health care of the worker.</p> |

| Factors in implementing a health monitoring program | Considerations | Outcome |
|---|---|---------|
| <p>11 Biological monitoring issues.</p> | <p>No one test can be used to detect the presence of all cytotoxic drugs and/or their metabolites.</p> <p>When choosing tests, the following requirements should be considered:</p> <ul style="list-style-type: none"> > specificity > sensitivity > availability > rapidity > reproducibility > cost. <p>Consult with workers on appropriate biological monitoring to be carried out.</p> <p>Obtain informed consent from workers to do tests.</p> | |
| <p>12 Consultation.</p> | <p>Health Services are to consult with workers including those of non-English speaking backgrounds about consultative arrangements.</p> <p>Consultation should occur:</p> <p>when identifying cytotoxic drugs and associated hazards</p> <ul style="list-style-type: none"> > during the risk assessment process > when determining which control strategies should be applied to eliminate or minimise risks associated with the handling of cytotoxic drugs > when reviewing the effectiveness of risk control measures > prior to changing premises, work environment, plant, systems of work or substances used for work, including safety data sheets > where appropriate, when a worker's circumstances change – e.g. pregnant women and immuno- compromised individuals. <p>Accurate and relevant safety information must be made available to all persons i.e. workers, visitors.</p> | |



4.2 Special health considerations

All personnel involved in any aspect of the handling of cytotoxic drugs should be informed about the risks of occupational exposure to hazardous drugs.

Workers required to perform duties associated with the preparation or administration of cytotoxic drugs or related waste may elect to not do so in the cases listed in the table below. In such cases, appropriate and suitable alternative duties must be provided.

| Consideration | Issue |
|--|--|
| Planning parenthood (male and female), pregnancy and lactation | Workers who are planning parenthood, or are pregnant or breast feeding and are involved in the preparation or administration of cytotoxic drugs and the handling of cytotoxic contaminated wastes should be informed of the reproductive risks and possible effects on foetal development. |
| Illness | Staff with infectious diseases such as upper respiratory, cutaneous infections etc. |
| Abnormal pathology results | Staff with abnormal pathology results should not prepare cytotoxic drugs until the abnormality has been investigated. |

4.3 Hygiene

Strict hygiene procedures must be developed and followed when handling cytotoxic drugs. Eating, drinking, chewing gum and the application of cosmetics is strictly prohibited. In addition, personnel in the preparation facility should not wear jewellery.

4.4 Work flow

A sufficient number of qualified workers must be available to provide for the expected workload in service provision.

The following considerations should also be taken into account in cytotoxic drug preparation areas when setting staff levels:

- > the workload during the busiest period
- > the complexity of products manufactured.

Staff allocation must be sufficient to allow for adequate breaks for those working in the cytotoxic cleanroom. It is recommended that no more than two hours be spent working at the cabinet or isolator without a break. As staff often work in isolation, sufficient breaks must be provided to maintain concentration.

4.5 Emergency procedures

Planning for emergencies is an essential part of risk management. Systems should therefore be in place to manage all incidents, including spills, sharps injuries and personal contamination. Any incident must be reported via the the WHS module of the Safety Learning System (SLS) so that the cause can be investigated and determined, and follow-up action taken if required. See **Model Procedure 7 – Accidental Exposure to Cytotoxic Drugs and Related Wastes**.

For exposure to cytotoxic drugs in the presence of blood or body fluids, refer to the SA Health and/or Local Health Network/Health Service/Business Unit Blood and Body Fluid Exposure (BBFE) Management procedure.

4.6 Reporting and keeping records

The Health Service must keep the following records:

- > a register of all hazardous chemicals (including cytotoxic drugs) that are used in the workplace, along with the current safety data sheet for each substance listed
- > risk assessment reports
- > health monitoring records (this record must be kept for at least 30 years)
- > training records, including any training on hazardous chemicals (these should be kept within the health monitoring record, even if a record is also kept with the workers' human resource training record)
- > individual worker records – medical records are to be kept confidential
- > details about drug preparation equipment, such as cytotoxic drug safety cabinets
- > details about spills, sharps injuries and contamination.

The worker should keep copies of their records.

4.7 Model Procedures

The following Model Procedures are associated with this section:

- > Model Procedure 1 – Health Surveillance for Staff Handling Cytotoxic Drugs and Related Wastes.
- > Model Procedure 7 – Accidental Exposure to Cytotoxic Drugs and Related Wastes.

5 Training

Persons conducting a business or undertaking and/or responsible agencies, have a duty of care to provide information, instruction, training and supervision to all workers handling cytotoxic drugs and related waste. This section provides a **risk management framework** to assist in the development of local safe work procedures and aims to provide practical advice on the development of training programs and associated record keeping.

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

Health Services must ensure that only workers who have received appropriate training, and have attained the required level of competency and proficiency, handle cytotoxic drugs and related waste.

Training should be undertaken:

- > at induction
- > prior to commencement of duties where cytotoxic drugs or related waste are involved
- > when new equipment or substances are introduced, or procedures change
- > on an ongoing basis with annual review via Performance Review and Development (PR&D) processes or similar.

5.1 Who should be trained?

The risk assessment results are used to identify all workers requiring specific training. Different levels of training are recommended, depending on the level of potential risk of exposure to cytotoxic drugs and related waste.

| Workers at greater risk of exposure to cytotoxic drugs (task dependent*) | Workers at lower risk of exposure to cytotoxic drugs |
|---|---|
| <ul style="list-style-type: none"> > pharmacy personnel > nursing personnel > laboratory staff > animal handlers (research) > medical personnel | <ul style="list-style-type: none"> > supervisors and managers (non-clinical) > maintenance personnel > stores/procurement personnel > cleaners > on-site waste transporters > couriers and porters > waste handlers > carers > ambulance officers > patient transport personnel > workers in diagnostic laboratories > community care workers > other allied health care workers. |

*Workers involved directly in the preparation or administration of cytotoxic drugs are considered at greater risk of exposure.

Refer to **Attachment 2a Training Matrix** for guidance on training requirements for various workers.

5.2 Identify training requirements and resources

Training requirements reflect the level of potential risk of exposure.

SA Health training and competency resources for health care professionals that address competencies for safe handling of cytotoxic drugs include:

- SA Health – Standards for Chemotherapy Services in South Australia, 2010
- > **Pharmacy**
 - SA Health Central Training Manual – Clinical Pharmacy Services – Cancer and Chemotherapy
 - SA Health Central Training Manual – Production Pharmacy Services – Cytotoxic and Other Hazardous Drugs
- > **Nursing**
 - SA Health; *State-wide Framework Chemotherapy Education and Assessment; An Integrated Model for South Australia*

Training competencies or other health industry association training resources available for cytotoxic drugs include:

- > eviQ Cancer Treatments Online Learning Resources, Cancer Institute NSW; www.eviq.org.au
- > Cancer Australia; Cancer Learning On-line; www.cancerlearning.gov.au
- > Cancer Nurses Society of Australia; *Position Statement on the Minimum Education Requirements for Nurses involved in the Administration of Anti-Cancer Drugs within the Oncology and Non-Oncology Setting 2010*
- > Clinical Oncological Society of Australia (COSA); *Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy 2008.*
- > The Society of Hospital Pharmacists of Australia (SHPA) *Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments 2004*

Written training competencies for handling cytotoxic drugs that are available for specialist professions should be reviewed regularly.

Training provided should be tailored to the needs of each individual after consideration of the:

- > role description
- > previous level of education
- > specific responsibilities relating to cytotoxic drugs.

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

- > work hazards and potential risks of exposure to cytotoxic drugs and related waste
- > the risk management process
- > risk control measures, safe work procedures and work practices to be adopted when handling cytotoxic drugs and related waste
- > legislative requirements for work health and safety
- > legislative requirements for cytotoxic waste management
- > safe preparation of cytotoxic drugs
- > safe administration of cytotoxic drugs
- > pre maintenance cleaning and maintenance of equipment
- > cleaning and laundering procedures
- > correct selection, use, cleaning and disposal of personal protective equipment (PPE)
- > procedures to be adopted in the event of incident, injury or spill, including reporting and recording
- > access to first aid resources
- > storage, transport, treatment and disposal of cytotoxic drugs and related waste
- > health surveillance and reporting
- > written safe work procedures.

Resource requirements need to be considered and adequate resources made available to enable training, which should be provided by competent academic, clinical or technical specialists. This requirement will vary depending on the specific training required.

Patient training

Patients, family and carers must be provided with education and information relevant to the environment in which the patient is being treated. General guidance on training and information content is provided in **Section 11 – Caring for Patients at Home**.

5.3 Evaluate the training program

Training programs should be evaluated to:

- > assess the effectiveness of the training, by monitoring how work is being performed and whether risk control measures are used correctly
- > incorporate review of reported incidents for continual practice improvement
- > regularly (annually) monitor workers' performance to ensure continued competency. Monitoring performance will determine if further training is required, for example through PR&D processes
- > ensure modules and topics included in training are applicable to the work being carried out; this should be done regularly and each time there is a relevant change such as change of equipment, chemical, safe work procedure, work practice or risk control measure.

Following all incidents and injury, the training program should be reviewed to ensure its adequacy.

5.4 Training records

Health Services must keep records of workers' training for at least five years after the date the record was created.

Training records should include:

- > date of training
- > topics covered
- > name of the person who conducted the training
- > names and attendance validation (e.g. signature) of the workers who attended the training
- > course evaluations
- > competencies and proficiencies assessed.

5.5 Model Procedures and Associated Attachments

The following Model Procedure and Attachment are associated with this section:

- > Model Procedure 2 – Training for the Safe Handling of Cytotoxic Drugs and Related Wastes.
- > Attachment 2a – Training Matrix

Training requirements reflect the level of potential risk of exposure.

6 Preparation and Dispensing

This section provides a **risk management framework** to assist in the development of local safe work procedures, and aims to provide practical advice on how to prevent or reduce the potential risk of occupational exposure associated with the preparation and dispensing of cytotoxic drugs.

This section should be read in conjunction with:

- > Section 3.5 – Managing the Risk (Hierarchy of Controls)
- > Section 4 – Staff Health
- > Section 5 – Training
- > Section 7 – Labelling
- > Section 8 – Transport
- > Section 12 – Cleaning and Laundry
- > Section 13 – Personal Protective Equipment (PPE)
- > Section 14 – Spills
- > Section 15 – Waste Management

Cytotoxic drug preparation poses the greatest risk of occupational exposure to workers. With adequate precautions, contamination of personnel and the work environment has been shown to be reduced. The risk of exposure may be reduced by ensuring that cytotoxic drugs are prepared by trained pharmacists or technicians in approved facilities.

Health services that are unable to provide the facilities, equipment and training as specified in this guide must not undertake the service of cytotoxic drug preparation.

Exposure may occur through:

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

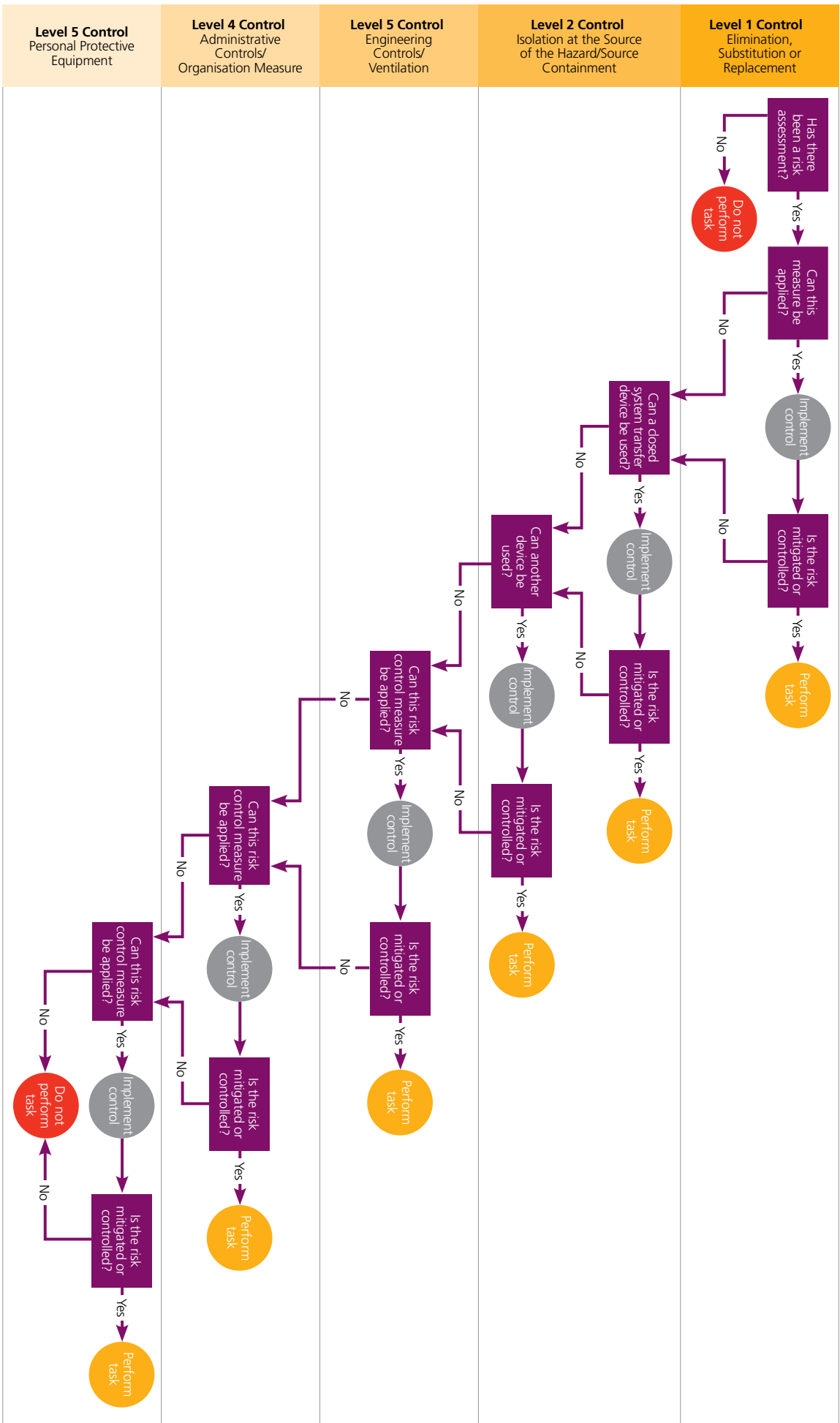
To facilitate the safe preparation of cytotoxic drugs, consideration should be given to:

- > workplace design, set-up and maintenance regimes
- > use of cleanrooms
- > cytotoxic drug safety cabinets
- > other specialised equipment.

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

Applying the hierarchy of risk control outlined in **Section 3 – Managing the Risk**, to the preparation of cytotoxic drugs is essential. Figure 2 summarises the decision making process when applying the hierarchy of risk control to the preparation of cytotoxic drugs.

Decision making process for the safe handling of cytotoxic drugs



6.1 Eliminate the hazard (Level 1 Risk Control Measure)

It is rarely possible to eliminate, substitute or replace a cytotoxic drug for a less toxic or non-toxic drug, therefore the most practical first level risk control measure is to identify an alternative supply of cytotoxic drugs.

| | |
|---------------------------------|---|
| Alternative supply arrangements | <p>Alternative arrangements could include:</p> <ul style="list-style-type: none"> > purchasing and supplying prepared cytotoxic drugs in a single-dose delivery unit from a commercial source – it is not safe for community pharmacies and community workers to reconstitute cytotoxic drugs as adequate risk control measures are not in place > establishing supply arrangements with a Health Service that has the required facilities, equipment and trained staff to provide prepared cytotoxic drug doses. |
|---------------------------------|---|

6.2 Isolate or substitute the hazard at the source (Level 2 Risk Control Measure)

It may be possible to prevent the potential risk of exposure of staff and the environment by containing the cytotoxic drug at its source. If possible, source containment should be continuous throughout the entire process of preparation.

| | |
|----------------------------|--|
| Drug preparation equipment | <p>Specific handling techniques and procedures incorporating suitable equipment (designed to reduce the risk of exposure) are to be implemented.</p> <p>Equipment used for preparing drugs would ideally incorporate closed system drug transfer devices (unless the preparation process does not allow it) and should also minimise the potential for preparing drugs under pressure.</p> <p>Closed system drug transfer devices</p> <p>A closed system drug transfer device prohibits the release of hazardous drug (regardless of its form, i.e. powder, vapour, liquid) and the transfer of environmental contaminants into the system.</p> <p>Recent studies have concluded that closed system drug transfer devices can reduce occupational contamination and exposure to cytotoxic drugs in the hospital work environment.</p> <ul style="list-style-type: none"> > When selecting an appropriate closed system drug transfer device, the following factors should be taken into consideration: <ul style="list-style-type: none"> – does the device cover all steps in the preparation? If not, then it is important to identify where the closed properties of the device are NOT retained – does the device retain its closed characteristics when more than one vial is used for a preparation? – are there any studies available showing that the device fulfils its intended purpose of eliminating or reducing environmental/operator contamination in daily practice and, if so, to what degree? <p>Closed system drug transfer devices should always be used in combination with a cytotoxic drug safety cabinet.</p> |
|----------------------------|--|

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|---|---|
| <p>Drug preparation equipment continued</p> | <p>Other devices</p> <p>In the absence of a closed system drug transfer device which covers all steps in preparation, consider the concomitant use of alternative devices with the closed system device.</p> <p>In the absence of any form of closed system device, use an alternative device.</p> <p>Numerous studies have shown that aseptic manipulation using a classic syringe and needle technique almost universally results in contamination. Droplets, leakage from vial stoppers after multiple punctures and aerosol generation resulting from increased pressure inside drug vials have also been observed.</p> <p>Alternative devices that have been implemented to protect workers using this classic technique include:</p> <ul style="list-style-type: none"> > luer-slip syringes (only if luer-lock connections are incompatible), such as intrathecal needles > syringe-to-syringe connectors when transferring solutions from one syringe to another > wide-bore needles, 18 G/1.2 mm, to reconstitute and draw-up cytotoxic drugs > filter needles, but only when the cytotoxic drug has been removed from a glass ampoule or if particulate matter is visible – e.g. if coring of vial rubber has occurred > air-venting devices, fitted with a 0.2 micron hydrophobic filter, to equalise pressures and to prevent the passage of powder aerosols and liquids. |
| <p>Drug storage</p> | <ul style="list-style-type: none"> > A dedicated storage area, including refrigeration, must be clearly marked and identifiable by all staff. > Use of a dedicated area offers quick and efficient containment and management of a spill. > A dedicated area should: <ul style="list-style-type: none"> – be designed to limit the chance of breakage – limit the extent of contamination if breakage occurs – be secured and access limited to authorised staff. > Current safety data sheet for each drug should be located in each dedicated storage area. > The quantity of cytotoxic drugs stored in pharmacy departments, wards, clinics and satellite pharmacies should be restricted to those required for short-term use. > A dedicated area should be provided for the unpacking of cytotoxic drugs. > Damaged packages should be handled with care. Badly damaged packages should be safely contained and destroyed as per cytotoxic waste management procedures. > In the drug preparation area: <ul style="list-style-type: none"> – competent staff wearing appropriate personal protective equipment (PPE) should open damaged packages – See Section 13 – Personal Protective Equipment) – contents should be examined for damage or leakage to determine whether they are safe for repackaging or must be disposed of as cytotoxic drug contaminated waste – institutional investigation and reporting should be followed when damaged packages are received and subsequent repackaging is required. > All staff involved in the receipt, distribution and storage of cytotoxic drugs must complete a low risk training module (or similar) covering the hazards, potential risks of exposure and risk control measures, followed by training in relevant local safe work procedures – See Model Procedure 2 – Training for the Safe Handling of Cytotoxic Drugs and Related Waste |

6.3 Reduce the risk through engineering controls (Level 2 Risk Control Measure)

Engineering controls use technological means to isolate or remove hazards from the work environment.

| | |
|-----------------------------|--|
| Drug preparation facilities | <p>Cytotoxic drugs should be prepared in a purpose-designed cleanroom suite that comprises:</p> <ul style="list-style-type: none"> > a primary barrier to provide drug containment and aseptic manipulation. All preparation of cytotoxic drugs must take place in either a cytotoxic drug safety cabinet (CDSC) or a pharmaceutical isolator for drug preparation > a secondary barrier to prevent cytotoxic drug contamination of the outside environment. This should be provided by high efficiency particulate air (HEPA) filters which supply filtered air to the cleanroom and the anteroom. Secondary containment is provided by maintaining the cleanroom at a pressure lower than that of the anteroom. <p>Note: Separate CDSC, biohazard cabinets or pharmaceutical isolators must be used for preparing cytotoxic drugs and BCG due to the risk of contamination of the cytotoxic drug preparation.</p> <p>The following technical standards are recommended. They describe suitable risk control measures for facilities and installation of those facilities</p> <ul style="list-style-type: none"> > AS/NZS ISO 14644.5.2006 <i>Cleanrooms and associated controlled environments - operations</i> > PIC/S Guide to “<i>Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE010-4)</i> 2014. <p>Standards for the provision of drug containment and aseptic manipulation include:</p> <ul style="list-style-type: none"> > a separate dedicated cytotoxic drug safety cabinet installed with a carbon filter that complies with AS 2567 – 2002 <i>Laminar flow cytotoxic drug safety cabinets</i>. Installation and use of cytotoxic laminar flow drug safety cabinets should be in accordance with the specifications of AS 2639-1994 <i>Laminar flow cytotoxic drug safety cabinets – installation and use</i>, or use of a pharmaceutical isolator that complies with AS 4273-1999 and AS 4273-1999/Amdt1-2000 <i>Guidelines for the design, installation and use of pharmaceutical isolators</i>. |
| Ventilation | <p>Any form of dilution will reduce the concentration of contamination. Ventilation as a risk control measure discussed here may have a number of features, such as HEPA filters, controlled air flow and protection shields however none of these features will prevent contamination once it has already occurred.</p> <p>Horizontal laminar flow hoods must never be used for preparing cytotoxic drugs due to the high risk of exposure to staff.</p> <p>Cytotoxic drugs are to be prepared in either a cytotoxic drug safety cabinet or a pharmaceutical isolator cabinet.</p> <p>Cytotoxic drug safety cabinets</p> <ul style="list-style-type: none"> > These cabinets are purpose built for the preparation of cytotoxic drugs and must comply with AS 2567- 2002 – <i>Laminar Flow Cytotoxic Drug Safety Cabinets</i>. <p>Pharmaceutical isolator cabinets</p> <p>An isolator is a completely enclosed system with an airflow which is either turbulent or laminar flow.</p> <p>Isolator specifications for the preparation of parenteral cytotoxic drugs are as follows:</p> <ul style="list-style-type: none"> > located in a room which should have limited access, be easily cleaned and well organised > can be positive or negative pressure, with the room design directly influenced by which type is used. |

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| Ventilation tools continued | <p>Biological safety cabinets (BSC)</p> <ul style="list-style-type: none"> > Class I and II – NOT appropriate for the preparation of cytotoxic drugs as they do not safe guard the product and/or the operator from contamination. > Class III – These are totally enclosed vented cabinets of gas tight construction. They have a physical barrier between the drug and the operator. These cabinets are an intermediate between a Class II and an isolator. Class III BSCs may be used for the preparation of cytotoxic drugs but should not be selected in preference to either a cytotoxic drug safety cabinet or a pharmaceutical isolator cabinet. |
| Organisation of the physical environment and work flow | <p>Attention to ergonomic design principles, equipment layout and work practices will minimise operator error and risk mitigate the potential of exposure. Factors to consider in the organisation of the physical environment and design include:</p> <ul style="list-style-type: none"> > provision of access for cleaning and replacement of equipment e.g. cytotoxic drug safety cabinet > incorporation of seam-free, 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 drug preparation cleanroom > temperature control > ensuring the anteroom provides: <ul style="list-style-type: none"> – the only access for staff to the cleanroom – access to only one cleanroom – facilities for donning personal protective equipment and checking that it fits correctly (full length mirror on wall) > ensuring the pass through hatch has: <ul style="list-style-type: none"> – no direct access to the external environment unless a HEPA filter(or equivalent) is used to control emissions – interlocking doors and is supplied with HEPA filtered air > provision of a means of communication between the cleanroom and other areas (preferably a telephone) > installation of a manometer to monitor the pressure differential within the cytotoxic drug preparation suite and record daily differential pressure readings > installation of a manometer alarm in case of inadequate pressure differentials > installation of a reverse airflow switch to minimise contamination to the external environment. |

6.4 Reduce exposure to the hazard using administrative actions (Level 3 Risk Control Measure)

| | |
|--|---|
| Safe work practices – staff considerations | <p>When people are working in isolation:</p> <ul style="list-style-type: none"> > remote and/or isolated work - working-alone arrangements should be in place – e.g. communications system, medical, first aid, emergency and rescue arrangements, > access should be controlled. <p>Staff numbers and staff contact rotation requires consideration (see also Section 4 – Staff Health).</p> |
| Handling techniques and procedures for preparation | <p>All preparations must be undertaken in cytotoxic drug safety cabinets or pharmaceutical isolators as specified in AS2567–1994 <i>Laminar flow cytotoxic drug safety cabinets</i> and AS4273-1999/Amdt1-2000 <i>Guidelines for the design, installation and use of pharmaceutical isolators</i>.</p> <ul style="list-style-type: none"> > To minimise the potential for dosing error, vial sizes closest to the actual dose should be selected. > Only one drug should be in the CDSC at any one time (or one drug per operator in a 2 person CDSC). > Opened/used vials should not be left in the CDSC for later use. <p>Parenteral preparations Safe work procedures should be documented and address the need to:</p> <ul style="list-style-type: none"> > 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. <p>Non-parenteral preparations If the preparation of creams, mixtures and ophthalmic preparations is required, they should be prepared under the same conditions as parenteral cytotoxic drugs. Additional safe work procedures include:</p> <ul style="list-style-type: none"> > using purpose-dedicated equipment > making mixtures by dispersing tablets in water (preferably inside a cytotoxic drug safety cabinet) > not crushing tablets in an open mortar > not counting tablets or capsules by machine. <p>Non-parenteral preparations – oral tablets and capsules Oral tablets and capsules must be handled in a manner so as to avoid or minimise skin contact and liberation of powdered drug. They must also be handled in a manner that avoids chemical cross-contamination with other drugs. Safe work procedures should be documented and address the need to:</p> <ul style="list-style-type: none"> > use gloves when handling tablet or capsule dosage forms > clean equipment immediately after use > use purpose-dedicated equipment > ensure tablets are not crushed or broken. |

Performance testing and inspection of facilities and equipment

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

The following frequency is recommended in the PIC/S *Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments for Physical Monitoring* PE010-4) 2014.

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

| Equipment | Test Parameter | Frequency |
|-----------------------|---|---------------------------------------|
| Laminar flow cabinets | <ul style="list-style-type: none"> > Pressure differentials between rooms. > Pressure differentials across HEPA filters (workstations) – note that most cabinets will have built in alarms that will activate if pressure differentials are outside limits. | Before beginning work, usually daily. |
| Isolators | Pressure differentials across HEPA filters. | Before beginning work, usually daily. |
| | Isolator glove integrity. | Visual checks every session. |
| | Isolator pressure hold test (glove attached). | Weekly. |

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

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

- > lockout or isolation devices
- > danger tags
- > permit-to-work systems
- > decontamination prior to maintenance (essential)

| | |
|--------------------------------------|---|
| Equipment maintenance | <p>Equipment commissioning/decommissioning, maintenance, testing and inspection must be carried out by a competent person, in accordance with manufactures recommendations.</p> <p>Equipment maintenance schedule must include:</p> <ul style="list-style-type: none"> > inspection of cytotoxic drug safety cabinets, isolators and suitable filters (as required by the Australian Standards and manufacturer's instructions) > inspection at regular intervals, and at least every 12 months > inspection after relocation, and after mechanical or electrical maintenance > test records and a summary of results in a place accessible to all workers > identification of faulty cabinets – e.g. attach a lock-out tag and do not use until repairs and clearance for use is authorised by a competent person > repair of faulty cabinet faults, and recertification/commissioning prior to use > routine performing and recording of microbial and air-particle testing. |
| Cleaning drug preparation facilities | <p>Daily and weekly routines should be established and all equipment used in the cleaning should be dedicated for the purpose.</p> <p>Cleaning should include bench tops and surfaces, grilles, filters, cabinets, floors, walls and ceilings.</p> <p>Written safe work procedures (including PPE requirements) should be developed for the cleaning of cytotoxic drug facilities and equipment and a cleaning log maintained.</p> <p>General cleaning staff (including contractors), who may be involved in cleaning cytotoxic drug preparation suites and associated equipment, must be informed of the potential hazards associated with cytotoxic drugs and be trained in safe cleaning procedures for low risk workers. They should also be educated on the extent of surface contamination involving cytotoxic drugs in areas both inside the preparation area and outside of it, and their important role in primarily the removal of this contamination or in the decontamination of these surfaces.</p> <p>A number of cleaning products /agents and combination of agents appear in the literature – See Section 12 – Cleaning and Laundry.</p> <p>Whichever cleaning agent is used, it must be validated for the particular facility based on the manufacturer recommendations and the cytotoxic drugs that are being prepared.</p> |
| Primary packaging labels | <ul style="list-style-type: none"> > Appropriate warning labels should be on cytotoxic drug containers, including syringes and IV bags, e.g. 'Caution – Cytotoxic Drug'. > Appropriate advisory labels as per latest edition of Australian Pharmaceutical Formulary and Handbook should be on cytotoxic drug containers. > Containers that carry cytotoxic drugs should identify the contents as cytotoxic drugs > Cytotoxic drugs prepared for intrathecal use must be labelled on both the syringe and outer container with the warning 'For Intrathecal Use Only'. Intrathecal drugs must be clearly identifiable and segregated from other preparations. > Vinca alkaloids should be labelled 'For intravenous use only – fatal if given by other routes' and be supplied in a mini-bag (50 mL or 100 mL), not in a syringe. > Oral medications should be labelled 'do not cut or crush'. > Topical cytotoxic medication e.g. fluorouracil cream should be labelled 'wear disposable gloves and use spatula to apply'. > Cytotoxic drugs that are vesicants should have an extravasation warning label. Additional information regarding labelling is included in Section 7 – Labelling. |

| | |
|---|--|
| Checking procedures | <ul style="list-style-type: none"> > Before preparation commences, all orders must undergo a full clinical check by a chemotherapy competent pharmacist. > Checks by a pharmacist should be made before components enter the cleanroom and when the product is finished. > Each step of the checking procedure should be documented. |
| Record keeping | <p>Authorised workers must maintain the following records:</p> <ul style="list-style-type: none"> > for all equipment: <ul style="list-style-type: none"> – maintenance schedules – testing dates for all equipment – test results – operating times – repairs and breakdowns – contamination monitoring – cabinet relocations. <p>In addition, for all staff preparing cytotoxic drugs, a log should be kept which includes:</p> <ul style="list-style-type: none"> > daily activities of each operator > if more than one cabinet/isolator is used, the actual cabinet/isolator that was used. <p>All records associated with health surveillance/monitoring must be retained by the Health Service for at least 30 years. The worker should be provided with a copy of their records upon cessation of work from the Health Service - See Section 4 – Staff Health.</p> <p>All worker incidents are to be reported via the WHS module of the Safety Learning System (SLS) – See Section 4 – Staff Health.</p> |
| Handling techniques and safe work procedures for dispensing | <p>Oral cytotoxic tablets and capsules must be handled in a manner that avoids or minimises skin contact and liberation of powdered drug. They must also be handled in a manner that avoids chemical cross-contamination with other drugs.</p> <p>Safe work procedures should be documented and address the need to:</p> <ul style="list-style-type: none"> > use gloves when handling tablet or capsule dosage forms > clean equipment immediately after use > ensure tablets are not crushed or broken > use purpose-dedicated equipment > ensure tablets are not crushed or broken. |

6.5 Personal Protective Equipment (PPE) (Level 3 Risk Control Measure)

The use of personal protective equipment (PPE) is the lowest control priority in the hierarchy of control measures. Higher levels of control options should be fully investigated before PPE is selected.

| | |
|-----|--|
| PPE | <p>PPE must be:</p> <ul style="list-style-type: none"> > appropriate for the individual and the task > readily available > clean and functional > correctly used when fitted > maintained and fitted by appropriately trained staff in keeping with relevant standards (i.e. fit testing) – See Section 13 – Personal Protective Equipment. |
|-----|--|



6.6 Safe Work Procedures

The following is a suggested list of tasks for which safe work procedures (SWPs) regarding the preparation and dispensing of cytotoxic drugs should be developed:

- > There should be individual safe work procedures for:
 - preparation of parenteral treatments
 - preparation of topical treatments
 - preparation of oral treatments
- > operation and maintenance of cleanrooms and ante-rooms used in the production of cytotoxic drugs
- > operation and maintenance of cytotoxic drug safety cabinets or pharmaceutical isolators used for the production of cytotoxic drugs
- > receipt and storage of cytotoxic drugs
- > selection and use of PPE – **See Section 13 – Personal Protective Equipment**
- > cytotoxic waste management – **See Section – 15 Waste Management**
- > management of cytotoxic drug spills – **See Section 14 – Spills**
- > transport of cytotoxic drugs – **See Section 8 – Transport**
- > staff management **See Section 4 – Staff Health**
- > staff training – **See Section 5 – Training**

6.7 Model Procedures

Noting that there are many possible parenteral preparation procedures that can be undertaken, two examples are presented to illustrate how the guidance in this section may be applied:

- > **Model Procedure 3 – Preparation of Parenteral Cytotoxic Drugs Without a Closed System Drug Transfer Device in the Pharmacy Department:**
 - Bolus injection in syringe requiring reconstitution of drug from powder form for parenteral treatment
 - Infusion requiring dilution of cytotoxic drug from a concentrated solution.

7 Labelling

This section provides a **risk management framework** to assist in the development of local safe work procedures, and aims to provide practical advice on labelling considerations incorporating state based and national legislation, standards and codes as well as pharmacy standards of practice recommendations.

7.1 All cytotoxic drugs

All containers should indicate that the drug is a cytotoxic.

The primary container label should include the wording 'cytotoxic'.

The secondary packaging as well as transport containers, should have the purple label with the cell in late teleophase and the warning 'CYTOTOXIC – HANDLE WITH CARE' prominently affixed.



Safety Data sheets must also be referred to, to determine if a cytotoxic drug is classified as a hazardous chemical as per the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS). If it meets the criteria of a hazardous chemical it must be appropriately labelled with the applicable GHS pictogram(s), **unless it is a therapeutic good and labelled as such**.

The requirements for labelling under Work Health and Safety Regulations 2012 (SA) have been met when a cytotoxic drug is classified as being a therapeutic good and labelled in accordance with the Therapeutic Goods Administration (TGA) requirements, and in a form that is:

- > intended for intake or administration to or by a patient or consumer, or
- > intended for use for therapeutic purposes.

Practically, as an example this means, that cyclophosphamide injection prepared in pharmacy intended for use by a patient does not require any GHS labels.

When not in a form intended for intake or administration to or by a patient, or for therapeutic purposes, workplace labelling (GHS) must be used.

For example cyclophosphamide purchased for research or diagnostic purposes does require additional GHS labels (as described under 7.3).

This also applies to veterinary chemical products within the meaning of the Agvet Code at the point of intentional administration to animals.

Reference can be made to Safe Work Australia – *Code of Practice for Labelling of Workplace Hazardous Chemicals*.

7.2 Supply of a cytotoxic drug to a patient

Supply of cytotoxic drugs to a patient is via a medication order or prescription. Labelling content requirements are listed in Table 1.

Table 1: General Content Requirements for Cytotoxic Drug Labels

| | |
|--------------------------|---|
| Health service details | > Name, address and telephone number of the Health Service/pharmacy dispensing the cytotoxic drug. |
| Patient details | > Patient name and other identifiers (e.g. date of birth record number). |
| Drug details | <ul style="list-style-type: none"> > Name of the cytotoxic drug. > The strength, the dose form and the quantity supplied; for extemporaneously prepared medicines and medicines not dispensed by count, the name and strength of each active ingredient, and the name and strength of any added preservatives or the name of the formula as described in a standard reference book > Directions for use including (where relevant) the route of administration. |
| Warnings | <ul style="list-style-type: none"> > The words 'KEEP OUT OF REACH OF CHILDREN' in red on a white background. > 'CYTOTOXIC – HANDLE WITH CARE' > If the cytotoxic drug is intended for external use only, the word 'POISON' or the words 'FOR EXTERNAL USE ONLY', in red on a white background. |
| Additional label content | <ul style="list-style-type: none"> > Storage directions (where important) > Expiry date (where applicable) > A unique identifier that enables the cytotoxic drug to be linked with the prescription > The date on which the cytotoxic drug is sold or supplied (unless the date is clear from the unique identifier). |
| for veterinary use | > The species of animal and the name of the animal's owner. |

For more information on labelling requirements refer to:

1. Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)
2. Controlled Substances Poisons Regulations 1996 (SA)
3. Pharmacy Board of Australia Guidelines for Dispensing of Medicines
4. Approved code of practice for labeling of workplace hazardous chemicals
5. Safe Work Australia: Globally Harmonised System for the Classification and Labelling of Chemicals
6. Safe Work Australia: Code of Practice for Labelling of Workplace Hazardous Chemicals
7. Australian Pharmaceutical Formulary and Handbook

Ancillary labels

The Australian Pharmaceutical Formulary and Handbook

The Australian Pharmaceutical Formulary and Handbook (APF) lists labelling recommendations (cautionary advisory labels) which apply to medicines dispensed for patient use to assist in pharmacists' counselling. They also provide information to carers or healthcare staff administering medications to patients.

The APF recommends that all cytotoxic drugs be labelled with the following ancillary label:



The APF may also stipulate additional labelling requirements for commonly used cytotoxic drugs. For details about additional labelling requirements, refer to the APF.

Following sentinel events associated with the inadvertent intrathecal administration of vincristine repeatedly reported in Australia and overseas, the Australian Commission on Safety and Quality in Health Care (The Commission) has issued the following recommendations:

- > **Vinca alkaloid products**, including outer wraps, should be labelled with a prominent warning label stating: 'FOR INTRAVENOUS USE ONLY – Fatal if given by other routes'.

FOR INTRAVENOUS USE ONLY
Fatal if given by other routes

- > **Medicines for intrathecal administration** should have a prominent warning label on the syringe and the outer wrap, stating 'For Intrathecal Use Only'.

For Intrathecal Use Only

National Standard for user-applied labelling of medicines, fluids and lines

The *National standard for user-applied labelling of medicines, fluids and lines* outlines labelling requirements for use in clinical settings to improve patient safety by assisting health care professionals to identify the correct medicine and/or fluid at all times and the correct route of administration of that injectable medicine.

These labelling requirements do not apply to manufacturers or hospital pharmacy production units. The labelling standards incorporate:

- all injectable medicines and fluids removed from the manufacturer's or hospital pharmacy's original packaging prior to administration
- all containers (for example infusion bags, syringes, jugs and basins) containing medicines which leave the hands of the person preparing the medicine prior to administration (including flushes)
- all conduits (for example catheters and burettes) and lines for parenteral administration.

For specific details about the labelling requirements refer to the *National standard for user-applied labelling of medicines, fluids and lines*.

Also refer to the SA Health Policy Directive: *User-applied Labelling of Injectable Medicines, Fluids and Lines* (2014).

7.3 Cytotoxic drugs for transportation

The following labels should be prominently displayed on the outer packaging and shipper:

- > the purple 'CYTOTOXIC – HANDLE WITH CARE' label
- > appropriate temperature and light conditions labels
- > instructions in case of an emergency, particularly in regards to a spill or breakage. There should be clear contact details to source advice should this be required
- > hazardous chemicals that are classified as dangerous goods and transported by road or rail must comply with the labelling or marking requirements that are specified in the Australian Dangerous Goods Code (ADG Code). Transport markings and class labels of the ADG Code are designed primarily to assist emergency services personnel in case of an accident or emergency
- > refer to the Safety Data Sheet to determine if the cytotoxic drug is classified as a dangerous good with an assigned United Nations (UN) number
- > for all cytotoxic drugs classified as dangerous goods attach the ADG label i.e. the Class 6 Toxic label.



- > the ADG Code also recognises the GHS as an appropriate labelling system for packages of dangerous goods during transport. The following pictograms from the GHS indicate chronic health hazard and acute toxicity respectively and may also be used.



- > If transporting a dangerous good by air, any additional requirements of the International Air Transport Association (IATA) should be adhered to.

7.4 Cytotoxic drugs provided to drug preparation facilities by a supplier for further processing

Cytotoxic drugs provided to SA Health and its Health Services by external suppliers should be received labelled in accordance with the ADG Code and contain shipping documentation and labelling on the outer package, if classified as a dangerous goods with a UN number.

7.5 Model procedures

The following model procedures are associated with this section:

- > Model Procedure 4 – Transport of Cytotoxic Drugs External to the Health Service
- > Model Procedure 5 – Transport of Cytotoxic Drugs Within the Health Service

8 Transport

This section provides a **risk management framework** to assist in the development of local safe work procedures, and aims to provide practical advice on considerations for the transportation of cytotoxic drugs and related wastes to, from and within a Health Service.

This section should be read in conjunction with the following sections:

- > Section 5 – Training
- > Section 7 – Labelling
- > Section 12 – Cleaning and Laundry
- > Section 13 – Personal Protective Equipment (PPE)
- > Section 14 – Spills
- > Section 15 – Waste Management

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

It is the responsibility of drug manufacturers and suppliers to provide cytotoxic drugs in containers that are free of contamination.

8.1 Transportation of cytotoxic drugs

External transportation

| General considerations | Recommendation |
|--------------------------|--|
| From suppliers | |
| Packaging | <p>Containers used for transporting the cytotoxic drugs should be:</p> <ul style="list-style-type: none"> > hard walled and robust > made from moulded foam or some other suitable packaging material that is capable of withstanding shock equivalent to a one-metre drop onto a concrete surface > securely closed and sealed. <p>The current safety data sheet must be supplied in the packaging, when the cytotoxic drug is being supplied for the first time to the workplace or where the safety data sheet has been updated since the last supply.</p> <p>Cytotoxic drugs packaged for transport outside the Health Service should be in accordance with state and federal requirements, such as the <i>Australian Dangerous Goods Code Ed.7</i> (ADG Code) and the International Air Transport Association's (IATA) <i>Dangerous Goods Regulations</i>, if classified as a dangerous goods with an assigned UN number.</p> |
| Labelling | See Section 7 – Labelling . |
| Transport considerations | <p>For cytotoxic drugs classified as dangerous goods with an assigned UN number:</p> <p>For air transport, compliance with the IATA's Dangerous Goods Regulations is required.</p> <p>For rail and road transport, compliance with the AGD is required.</p> |
| Spills | Cytotoxic drug spill kits should be readily available to all workers involved in the transportation and receipt of cytotoxic drugs. |
| Receipt of drugs | Workers involved in the receiving and inventory control should be informed of the possibility of surface contamination. |
| Controls | <p>All workers, including contractors involved in the packaging, transportation, receiving and inventory control of the cytotoxic drug must receive appropriate training, for example:</p> <ul style="list-style-type: none"> > how to use a spill kit > what to do with contaminated waste following a spill clean up > what to do with packages that appear to be damaged > health surveillance/monitoring (as per risk assessment identification) > due to the potential of surface contamination, safe handling procedures such as wearing gloves, washing hands and cleaning surfaces must be undertaken. |
| Documentation | <p>The supplier must provide the current safety data sheet when the cytotoxic drug is being supplied to the workplace for the first time or where the safety data sheet has been updated since the last supply.</p> <p>The following records should be kept by the supplier:</p> <ul style="list-style-type: none"> > date of transport > contents of the package > destination details > contact details of recipient > name and contact details of the courier company used. <p>The recipient of the drug (Health Service) must retain a compilation of the safety data sheets, ensure that they are current and reflect the actual products used within the Health Service, and must update the Hazardous Chemicals Register whenever purchased products change. These safety data sheets should be readily available in all areas where hazardous drugs are stored or used.</p> <p>Refer to the ADG Code and the IATA's Dangerous Goods Regulations for documentation required for the transport of cytotoxic drugs that are classified as dangerous goods with an assigned UN number.</p> |

| General considerations | Recommendation |
|--|--|
| <p>From the Health Service</p> <p>This section describes the transport of cytotoxic drugs from a pharmacy to off site and to third party organisations (such as residential care facilities).</p> | |
| Packaging | <p>Containers used for transporting the cytotoxic drugs must be:</p> <ul style="list-style-type: none"> > hard walled and robust > made from moulded foam or some other suitable packaging material that is capable of withstanding shock equivalent to a one-metre drop onto a concrete surface > securely closed and sealed. <p>Primary packaging:</p> <ul style="list-style-type: none"> > package in a sealed, leak-proof container, with outer bags heat-sealed where possible > ensure the container offers protection from light where required > protect the drugs from breakage in transit > contain leakage if breakage occurs > childproof packaging. <p>Refer to the ADG Code and the IATA's Dangerous Goods Regulations for the transport of cytotoxic drugs that are classified as dangerous goods with an assigned UN number.</p> |
| Labelling | Refer to Section 7 – Labelling . |
| Transport considerations | <p>For cytotoxic drugs classified as dangerous goods with an assigned UN number</p> <p>For air transport, compliance with the IATA's Dangerous Goods Regulations is required. For rail and road transport, compliance with the AGD is required.</p> |
| Spills | Cytotoxic drug spill kits must be readily available to all workers involved in the transportation and receipt of cytotoxic drugs. |
| Receipt of drugs | Workers involved in the receiving and inventory control should be informed of the possibility of surface contamination. |
| Controls | <p>All workers, including contractors involved in the packaging, transportation, receiving and inventory control of the cytotoxic drug must receive appropriate training, for example:</p> <ul style="list-style-type: none"> > how to use a spill kit > what to do with contaminated waste following a spill clean up > what to do with packages that appear to be damaged > health surveillance/monitoring (as per risk assessment identification) > due to the potential of surface contamination, safe handling procedures such as wearing gloves, washing hands and cleaning surfaces must be undertaken. |
| Documentation | <p>The supplier must provide the current safety data sheet when the cytotoxic drug is being supplied to the workplace for the first time or where the safety data sheet has been updated since the last supply.</p> <p>The following records should be kept by the supplier:</p> <ul style="list-style-type: none"> > date of transport > contents of the package > destination details > contact details of recipient > name and contact details of the courier company used. <p>The recipient of the drug (Health Service) must retain a compilation of the safety data sheets, ensure that they are current and reflect the actual products used within the Health Service, and must update the Hazardous Chemicals Register whenever purchased products change. These safety data sheets should be readily available in all areas where hazardous drugs are stored or used.</p> <p>Refer to the ADG Code and the IATA's Dangerous Goods Regulations for documentation required for the transport of cytotoxic drugs that are classified as dangerous goods with an assigned UN number.</p> |

Additional considerations - cytotoxic drugs received from manufacturers

It is the responsibility of drug manufacturers to supply cytotoxic drugs in containers that are free of contamination. It is highly desirable that manufacturers provide some form of certification that vials and primary packaging are not contaminated with cytotoxic drugs. This analysis should preferably be carried out by an independent laboratory.

Manufacturers must provide safety data sheets on all of their cytotoxic drug products with explicit details on decontamination and protection measures to be followed in the case of a spill or other incident.

Transportation within a Health Service

This section describes recommendations for the transportation of cytotoxic drugs from pharmacy departments to wards and clinics within the hospital grounds for in-house use.

| General considerations | Recommendation |
|--------------------------|---|
| Packaging | <ul style="list-style-type: none"> > Package in a sealed, leak-proof container, with outer bags heat-sealed where possible > Ensure the container offers protection from light where required > Protect the drugs from breakage in transit > Containers used for transport should be hard walled > Contain leakage if breakage occurs > Childproof packaging > Tablet containers should be labelled 'do not cut or crush' > Containers should be appropriately labelled for the specified use – e.g. intrathecal, oral or topical > Outer packaging to have 'Cytotoxic – Handle with care' label. |
| Labelling | <ul style="list-style-type: none"> > Tablet containers should be labelled 'do not cut or crush' > Containers should be appropriately labelled for the specified use – e.g. intrathecal, oral or topical > Packaging to have contains 'Cytotoxic – Handle with care' label. |
| Transport considerations | <ul style="list-style-type: none"> > consideration should be given to using an enclosed trolley or similar enclosed device for security, patient confidentiality and spill management. |
| Spills | Cytotoxic drug spill kits should be readily available to all workers involved in the transportation and receipt of cytotoxic drugs. |
| Controls | <p>All workers, including contractors involved in packaging, transporting and receiving the cytotoxic drug must receive appropriate training, for example:</p> <ul style="list-style-type: none"> > how to use a spill kit > what to do with contaminated waste following a spill clean up > what to do with packages that appear to be damaged > health surveillance/monitoring (as per risk assessment identification) > due to the potential of surface contamination, safe work procedures such as wearing gloves, washing hands and cleaning surfaces must be undertaken. |

| | |
|---------------|--|
| Documentation | <p>The supplier must provide the current safety data sheet when the cytotoxic drug is being supplied to the workplace for the first time or where the safety data sheet has been updated since the last supply.</p> <p>The following records should be kept by the supplier:</p> <ul style="list-style-type: none"> > date of transport > contents of the package > destination details > contact details of recipient > name and contact details of the courier company used. <p>The recipient of the drug (Health Service) must retain a compilation of the safety data sheets, ensure that they are current and reflect the actual products used within the Health Service, and must update the Hazardous Chemicals Register whenever purchased products change. These safety data sheets should be readily available in all areas where hazardous drugs are stored or used.</p> <p>Refer to the ADG Code and the IATA's Dangerous Goods Regulations for documentation required for the transport of cytotoxic drugs that are classified as dangerous goods with an assigned UN number.</p> |
|---------------|--|

8.2 Transport of cytotoxic waste

On-site waste transport

To minimise exposure, the following risk control measures should be implemented when transporting cytotoxic waste within a facility:

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

Off-site waste transport

The Environmental Protection Agency SA is responsible for ensuring the proper transport of cytotoxic waste in South Australia. The *Environment Protection Act 1993* (EP Act) and the Environment Protection Regulations 2009 (EP Regs) regulate the transport of cytotoxic waste.

Medical waste producers (such as SA Health, Local Health Networks and their Health services) have legal obligations for the cytotoxic drug waste they generate, and hence are licensed appropriately through the EPA. Legal obligations extend beyond the on-site handling of the waste and the maintenance of the Medical Waste Producers Certificate requirements and Health Services must also ensure that:

- > any Person Conducting a Business or Undertaking (PCBU) who transports waste for SA Health, Local Health Networks and Health Services has the required licence as per Schedule 1 of the EP Act
- > the waste is disposed at a facility licensed by the EPA to handle cytotoxic drug waste.

There are three principal statutory requirements for the transport of cytotoxic drug waste by a waste management organisation i.e. waste management contractors:

- > appropriate licences
- > transport certificates
- > vehicle signage.

Refer to the ADG Code for transport licensing and placarding requirements.

Transport licence and certificate

SA Health Local Health Networks (LHN) and Health Services are licensed through the Environment Protection Authority (EPA) as Medical Waste Producers and have a Medical Waste Producers Certificate. Medical waste (including cytotoxic waste) collected from a Medical Waste Producer must be collected and transported only by a person or company with a Waste Transport Certificate issued by the EPA. No government or private vehicle is to be used to transport cytotoxic waste generated by SA Health Local Health Networks (LHN) or the Health Services.

Community nurses who provide care to patients in their homes may collect minor quantities of patient related cytotoxic drug waste (e.g. empty packaging, absorbent pads) and transport it in work vehicles BACK to the LHN/HS for cytotoxic drug waste disposal. Government vehicles used for this service provision must carry the following to meet compliance requirements:

- > A copy of the LHN/HS Medical Waste Producers Certificate
- > A spill kit for the vehicle including personal protective equipment (PPE) and identifiable (purple) plastic waste bags.

8.3 Model procedures

The following model procedures are associated with this section:

- > Model Procedure 4 – Transport of Cytotoxic Drugs External to the Health Service
- > Model Procedure 5 – Transport of Cytotoxic Drugs Within the Health Service

9 Administration

This section provides a **risk management framework** to assist in the development of local safe work procedures and aims to provide practical advice on how to prevent or reduce the risks associated with the administration of cytotoxic drugs in the hospital environment. The principles discussed here can also be adapted to the community and home environment.

This section should be read in conjunction with the following sections:

- > Section 3 – Managing the Risk
- > Section 5 – Training
- > Section 10 – Caring for Patients in the Community
- > Section 11 – Caring for Patients at Home
- > Section 13 – Personal Protective Equipment (PPE)
- > Section 14 – Spills
- > Appendix 8 – Safe Handling Recommendations for BCG

To ensure that cytotoxic drugs are safely administered, workplace design, use of specially designed equipment, safe work practices and personal protective equipment (PPE) are essential. To ensure that risk control measures and safe work procedures and practices are developed, understood, implemented and maintained; education, training and supervision are crucial.

Exposure while administering drugs may occur through:

- > handling cytotoxic drugs
- > spills
- > splashes to the skin or eyes
- > inhalation of airborne contaminants (for example, which may be generated by the expulsion of air from a syringe containing medicine)
- > sharps injuries.

9.1 Key risk control measures

Applying the hierarchy of control measures outlined in **Section 3 – Managing the Risk**, to the administration of cytotoxic drugs is essential.

The following are examples of ways to ensure risk control measures implemented are 'best practice':

- > only undertake a drug administration service with risk control measures
- > use closed system drug administration devices where possible
- > follow LHN/Health Service procedures for administration where available
- > drugs intended for administration are appropriately packaged, labelled and ready to use
- > cytotoxic orders should be identified by using a specific cytotoxic medication chart or equivalent electronic order
- > provide secure and labelled storage of waste and sharps containers to minimise exposure to cytotoxic waste
- > provide information, training and education about side effects of cytotoxic drugs to the patient and carer
- > ensure that equipment used, such as infusion pumps, are well maintained and in good working order
- > ensure access to emergency equipment (or emergency procedures) is available at all times
- > correct PPE is used for administration of all cytotoxic drugs.

These best practice risk control options should be considered a priority.



9.2 Establishing a drug administration area

When establishing a designated drug administration area in a health care facility, consider the following:

- > sufficient room for movement of staff around the patient chair/bed during drug administration
- > secure storage for cytotoxic waste and sharps containers
- > secure storage for cytotoxic waste ready for disposal
- > a system for obtaining and updating health and safety information such as safety data sheets, in a place accessible to all workers
- > washable chairs and other furnishings
- > liquid resistant mattress covers
- > hand-washing facilities
- > facilities for storage and disposal of PPE
- > secure storage facilities for cytotoxic drugs
- > ensure there are pre-administration checklist strategies for nursing and medical staff.

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

When administering cytotoxic drugs in a community or home setting, apply these considerations also, as far as reasonably practicable (see **Sections 10 and 11** for further information about cytotoxic drug handling considerations in these settings).

9.3 Cytotoxic drug administration

Patient assessment

Prior to administration, it is essential that the patient be deemed fit for treatment.

Pre-treatment assessment, at baseline and prior to each cycle, should include:

- > full blood count, renal and liver function tests prior to each treatment cycle (as per individual treatment protocols), and between cycles or recovery phases as recommended. If blood parameters are abnormal notify a medical officer
- > symptom/side effect toxicity review
- > allergy and drug reaction history
- > performance status
- > weight, height, body surface area (BSA). Any changes in weight of more than 10% should be referred to a medical officer
- > psychosocial screening
- > patient or guardian consent obtained.

Equipment

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

- > closed administration devices:
 - Y infusion line or Y site adaptor
 - threaded locked cannula
- > other devices:
 - needleless administration systems
 - luer-lock syringes
- > portable trolleys to store administration equipment, allowing movement from patient to patient
- > disposable injection trays to contain and carry syringes
- > plastic-backed absorbent sheets or pads under the injection site
- > plastic, rigid walled, wide-necked, cytotoxic sharps disposal containers that are readily accessible
- > personal protective equipment as outlined in **Section 13 – Personal Protective Equipment (PPE)**
- > a spill kit as outlined in **Section 14 – Spills.**

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

Parenteral administration

Prior to administration, calculate the body surface area (or other parameters), then calculate the required dose and check against the medication order.

Safe work procedures for parenteral administration of cytotoxic drugs are to be clearly documented and emphasise the need to:

- > store all drugs appropriately prior to administration as directed by pharmacy
- > cross-check therapy with the pharmacist, medical practitioner or nurse
- > prepare any dose reductions in the pharmacy
- > follow administration procedures as recommended by the supplier and pharmacy
- > use cytotoxic labels to identify all intravenous infusion bags, syringes and pump cartridges
- > wear appropriate PPE at all times
- > check all syringes and infusion bags prior to use for any signs of leakage or contamination
- > use lines compatible with solutions and the cytotoxic drug
- > connect all drug administration bags and bottles at waist level
- > avoid contact with fluid from body cavities following administration – e.g. after intrapleural, intravesicular or intraperitoneal administrations
- > involve the patient and encourage them to alert administering staff to any problems
- > maintain close supervision of the patient
- > manage extravasation incidents promptly
- > dispose of empty bags and bottles – with the administration set attached – into a sealable bag before placing into a multi-use cytotoxic waste bin, or discard empty cytotoxic bags and bottles at the bedside or patient chair into a dedicated cytotoxic bin and close lid of cytotoxic bin immediately as per **Section 15 – Waste Management**
- > partially used bags/bottles/syringes or spiked but unused bags should be disposed of with other contaminated cytotoxic waste in the parenteral administration area
- > appropriately seal and return the unused cytotoxic drugs (i.e. unopened/unspiked bags) to the pharmacy, or to the source of referral
- > discard gloves and other PPE after use into the cytotoxic waste bin
- > wash hands following administration and disposal of cytotoxic drugs and related waste.

During drug administration, do not:

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

Intravesical administration

The intravesical route is used for the administration of chemotherapy drugs into the bladder to treat bladder cancer. A catheter inserted into the urethra carries the drug into the bladder where it remains for a predetermined length of time. Registered nurses and medical practitioners must be trained and assessed as competent in delivering intravesical treatment.

Due to the nature of this route of administration, additional risk control measures for consideration when preparing safe work procedures for intravesical administration include:

- > limit leakage and 'explosive' aerosol spray of unmetabolised cytotoxic drug from the site of insertion of the urinary catheter:
 - instruct the patient to limit fluid intake for 4 hours prior to administration
 - remind the patient to void prior to catheterisation
 - remove the catheter as soon as practicable after instillation.

- > to limit environmental contamination consider:
 - advising the patient to sit for each urination for 6 hours after treatment
 - where possible designating a toilet for these patients and double flushing the toilet, prior to decontamination with sodium hypochlorite solution.
- > advising the patient to wash their genitalia after each urination for 6 hours after treatment to limit patient exposure.

PPE must be worn by all workers handling or administering cytotoxic drugs; for the intravesical route this may include gloves, a face shield and P2 mask due to the high risk of aerosol formation.

For recommendations on the safe handling of BCG administered via the intravesical route see Appendix 8 – Safe Handling Recommendations for BCG.

Topical administration

Topical cytotoxic drugs are applied directly to the skin, eyes or ears and may be in the form of creams, pastes, ointments, lotions or eye drops. Additional risk control measures when using topical cytotoxic drugs include:

- > avoid unnecessary contact with the topical cytotoxic drug
- > minimise contact with a patient's clothing
- > apply ointments evenly with a disposable spatula
- > educate the patient about safe application of the medication
- > dispose of all contaminated equipment as cytotoxic waste
- > wear appropriate PPE.

Oral administration

Oral agents are generally given as tablets and capsules. Additional risk control measures when using oral agents include:

- > store cytotoxic tablets and capsules appropriately as directed by pharmacy
- > use a non-touch technique when transferring tablets or capsules from their container into a disposable medication cup, to avoid direct handling
- > do not crush or break tablets or capsules – e.g. for oral, nasogastric or PEG feed, or for any reason, outside the pharmacy's cytotoxic drug preparation area
- > isolate and discard damaged tablets or capsules as cytotoxic waste, and notify pharmacy
- > contact pharmacy if it is necessary to compound a cytotoxic drug mixture
- > discard contaminated medication cups as cytotoxic waste
- > provide appropriate information, education and training regarding safe handling and potential exposure risks to patients and their carers where oral cytotoxic drug treatment is to be administered in the community or home setting
- > wear appropriate PPE.

9.4 Model Procedures and Associated Attachments

The following Model Procedures and Attachments are associated with this section:

- > Model Procedure 6 – Administration of Oral Cytotoxic Drugs in the Health Service
 - Attachment 6a – Time Out Procedure
 - Attachment 6b – Time Out Procedure Checklist (example pro-forma)
- > Model Procedure 7 – Accidental Exposure to Cytotoxic Drugs and Related Wastes

10 Caring for Patients in the Community

This section provides a **risk management framework** to assist in the development of local safe work procedures, and aims to provide practical advice on how to prevent or reduce the potential risk of exposure associated with the handling of cytotoxic drugs and related waste, specifically in the community setting, which may include residential and aged care facilities. It also provides guidance to Health Services supervising treatment in the community about community specific considerations.

This section should be read in conjunction with the following sections:

- > Section 3 – Managing the Risk
- > Section 4 – Staff Health
- > Section 5 – Training
- > Section 6 – Preparation and Dispensing
- > Section 7 – Labelling
- > Section 9 – Administration
- > Section 11 – Caring for Patients at Home
- > Section 12 – Cleaning and Laundry
- > Appendix 7 – Table of Cytotoxic Drugs and Excretion Rates

While many patients undergoing cytotoxic drug therapy are treated in health care services such as hospitals, day hospitals and clinics, the number of patients being treated in community and residential settings is increasing. The potential risks associated with the handling of cytotoxic drugs and related waste in community settings may be somewhat different to those faced in health care services due to an often uncontrolled treatment environment where both the Health Service and worker have less influence over implementing risk control measures.

Nursing and medical staff in community and aged care facilities may be involved in administering cytotoxic drugs. 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 treatments. Other workers who may be at risk of exposure include waste collection workers and other contractors that may be working around the facility.

For advice on developing safe work procedures for handling cytotoxic drugs in the home environment see **Section 11 – Caring for Patients at Home**.

10.1 The role of the treating facility

The treating facility is the hospital, pharmacy or treating doctor overseeing the patient's treatment with cytotoxic drugs. Written information should be provided by the treating facility to residential care facility workers, community health care workers, general practitioners and where applicable, ambulance officers.

Relevant information may include:

- > the cytotoxic drug(s) being administered
- > any special care requirements
- > advice about precautionary time periods following cytotoxic drug treatment when handling patient waste (excreta) potentially contaminated with cytotoxic drugs or residue – See *Appendix 7 – Table of Cytotoxic Drugs and Excretion Rates*
- > disposal of cytotoxic waste including body waste (excreta)

- > use of personal protective equipment (PPE) and universal precautions as appropriate, such as hand washing for infection control
- > managing suspected personal contamination
- > spills management
- > safety precautions for those who are pregnant or breast feeding and dealing with cytotoxic drugs and related waste.

10.2 Personnel management

All community workers involved in the administration or transportation of cytotoxic drugs, or the transportation of patients receiving cytotoxic drugs require:

- > a risk management process enabling the identification of hazards and risk (**Section 3 – Managing the Risk**)
- > appropriate training (**Section 5 – Training**)
- > information about the potential risks of occupational exposure to cytotoxic drugs (**Section 4 – Staff Health**) including provision of precautionary information to community workers who are may be planning a family, are pregnant or breast feeding.

10.3 Safe work procedures for the community setting

With the assistance of the treating facility, safe work procedures should be developed which include:

- > identifying patients undergoing cytotoxic drug treatment
- > correct use of PPE
- > appropriate administration techniques
- > appropriate management of cytotoxic waste
- > a documented spill management strategy which includes:
 - advice to clean up spills immediately
 - written instructions on how to manage a spill in an ambulatory situation
 - information on the contents of a spill kit
- > laundering contaminated linen and clothing.

10.4 Community dispensing

Cytotoxic drugs may be dispensed by community pharmacies. Many oral cytotoxic formulations such as tablets and capsules are provided by the manufacturer in blister packs so the dispensing pharmacist will not in this case usually need to take extra precautions when dispensing, however the following precautions are recommended to avoid exposure if handling loose formulations such as tablets and capsules:

- > wear gloves
- > use separate counting trays
- > use separate, disposable counting spatulas
- > clean reusable equipment immediately after use with an appropriate cleaning agent (see **Section 12 – Cleaning and Laundry**) and rinse thoroughly with water
- > ensure tablets and capsules are not crushed, opened, broken or compounded - if required refer back to the treating facility – See **Section 6 Preparation and Dispensing**.

Labeling advice for community dispensed cytotoxic drugs is included in **Section 7 – Labelling**; see also Guidelines for Dispensing of Medicines (Pharmacy Board of Australia).

It is not safe for community pharmacies and community workers to prepare or reconstitute parenteral cytotoxic drugs or compound oral cytotoxic drugs as adequate risk control measures are not in place or available.

Parenteral cytotoxic drugs should not be prepared in the community setting. Health care workers preparing parenteral cytotoxic drugs without adequate precautions have been shown to contaminate themselves and their work environment. The risk of exposure may be eliminated or minimised by ensuring that parenteral cytotoxic drugs are prepared by trained pharmacists or technicians in approved facilities, such as a cytotoxic drug safety cabinet or a pharmaceutical isolator.

Alternative arrangements could include:

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

See Section 6 – Preparation and Dispensing for further information.

10.5 Administration of cytotoxic drugs

Nursing and medical personnel may be involved in administering cytotoxic drugs in community settings. When establishing a drug administration area in a community setting, care should be taken to apply the recommendations outlined in **Section 9 – Administration** as closely as practicable.

10.6 Managing cytotoxic waste

Cytotoxic waste to be considered includes:

- > any residual cytotoxic drug that remains following a patient's treatment and any materials or equipment contaminated with cytotoxic drugs
- > body waste (excreta) following cytotoxic drug treatment.

Cytotoxic waste generated must be disposed of safely to reduce the potential risk of exposure to waste management workers. This waste may include cytotoxic drug residue or dressings, nappies, incontinence aids, ostomy bags, catheters, catheter bags and the like contaminated with cytotoxic drug. Cytotoxic drug waste should be contained, secured and disposed of in a cytotoxic waste container and taken back to the health care facility, in the boot of a vehicle, for disposal in a cytotoxic waste bin.

10.7 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. Report any worker related incident through the WHS Safety Learning System (SLS) so that the cause can be investigated, determined and follow-up action taken if required.

For exposure to blood or body fluids, refer to the SA Health and/or Local Health Network/Health Service/Business Unit Blood and Body Fluid Exposure (BBFE) Management procedure.

Written information should be provided by the treating facility to relevant community workers including residential care facility staff, community health care workers, general practitioners and where applicable, ambulance officers.

11 Caring for Patients at Home

This section provides a **risk management framework** to assist in the development of safe work procedures, and aims to provide practical advice on how to prevent or reduce the risk of potential exposure associated with the handling of cytotoxic drugs and related waste in the home environment.

This section should be read in conjunction with the following sections:

- > Section 8 – Transport
- > Section 12 – Cleaning and Laundry
- > Section 14 – Spills
- > Section 15 – Waste Management
- > Appendix 7 – Table of Cytotoxic Drugs and Excretion Rates

For the purposes of this Guide, patient excreta is defined as body fluids and faeces from patients receiving cytotoxic drug therapy that may contain traces of cytotoxic drugs and/or their active metabolites. This may include, urine, vomit, blood, faeces, sweat, bile, plasma.

Regardless of where cytotoxic drugs are administered, cytotoxic safety precautions, especially those related to handling cytotoxic waste and patient excreta potentially contaminated with cytotoxic drugs or metabolites, are an ongoing concern in a patient's home.

An additional consideration in providing treatment with cytotoxic drugs in the patient's home is not only the potential presence of children but also for children to be undertaking the role of a carer. If children are present in the setting or will be undertaking administration activities, it is strongly recommended that the treating Health Service undertake a robust risk assessment of the patient's home and ensure appropriate storage, administration and disposal controls are in place and that the child, if undertaking administration activities, is able to understand and comply with safe handling procedures.

11.1 Home care by nursing staff

All nurses administering cytotoxic drug therapy in the patient's home must be adequately trained and competency assessed to do so.

It is the responsibility of the Health Service providing the home care service to ensure that all cytotoxic drugs taken into the patient's home are appropriately packaged and labelled, and that the facilities and equipment meet recommended standards. Cytotoxic drug therapy used in the home care situation must be prepared under the same conditions as all other cytotoxic drug therapies; specifically parenteral or compounded formulations must be prepared in the hospital pharmacy department or in a production facility complying with the same requirements.

Nursing staff must not reconstitute parenteral cytotoxic drugs in the patient's home.



Setting up a patient care area

Before proceeding with cytotoxic drug therapy in the home, the nurse must verify that the following facilities are available:

- > hand-washing facilities
- > laundry facilities
- > access to a flushable toilet
- > appropriate waste disposal
- > a patient administration area, preferably set up in a non-carpeted area of the home.

Equipment

The nursing staff must also verify that the following equipment is available:

- > spill kit (suitable for home use) and instructions (see **Section 14 – Spills**)
- > cleaning and decontaminating agent(s) (see **Section 12 – Cleaning and Laundry**)
- > approved container for sharps
- > cytotoxic waste container/bags
- > personal protective equipment (PPE)
- > extravasation kit.

The transport of cytotoxic drugs from the site of preparation to the patient's home must be in accordance with procedures described in **Section 8 – Transport**. Nursing staff transporting cytotoxic drug therapy should have the following available in their vehicles:

- > a spill kit
- > a safety data sheet relevant for the cytotoxic drug
- > details of whom to contact in case of an emergency
- > a copy of the Health Service's "Medical Waste Producers Certificate" - See **Section 15 – Waste Management**.

11.2 Home care by relatives and/or patient

If the home care is to be provided by either relatives or by the patient, it is important that this care is organised and coordinated in advance. In this way and with close cooperation between Health Service staff, all aspects of the treatment may be explained and education and training provided. Carers of patients receiving cytotoxic drug treatment should be provided with written information about safe cytotoxic drug handling and the precautions to be taken while caring for patients during the time the drug may be excreted. Carers should be advised about any special requirements for the particular cytotoxic drug used.

Patients, family and carers must be provided with education, including written health and safety information about:

- > the cytotoxic drugs to be administered
- > precautionary time period following cytotoxic drug treatment when handling excreta (**See Appendix 7 – Table of Cytotoxic Drugs and Excretion Rates**)
- > necessary equipment and instructions and training for use
- > safe and appropriate home storage requirements
- > correct administration
- > instructions and training in the use of necessary personal protective equipment (PPE)
- > cytotoxic waste management such as:
 - safe handling and disposal of waste including body waste (excreta)
 - items to be disposed of such as incontinence aids, syringes, disposable medicine cups
 - waste identification (such as the use of purple cytotoxic bags) and secure storage (seal or tie bags)
 - precautions when transporting waste (double bag where necessary)
 - disposal of cytotoxic drugs no longer required
- > how to deal with a spill, or leakage from administration sites and sets
- > laundering clothing and linen which is or may be contaminated with cytotoxic drug(s)
 - wash contaminated items as soon as possible using warm water and laundry detergent. Separate from other non-contaminated items, wash on a full cycle and dry.
- > instructions on how to proceed in the event of an emergency or other incident such as extravasation or accidental ingestion of a cytotoxic drug
- > contact details for care such as home care nurses and Health Service staff (including medical and pharmacy personnel)
- > precautions to be taken where a care giver is pregnant (or planning a pregnancy) or breast feeding.

12 Cleaning and Laundry

This section provides a **risk management framework** and practical information to assist in the development of local safe work procedures associated with general cleaning and decontamination of cytotoxic drug contaminated surfaces. It provides general advice on choice of cleaning and decontaminating agents, dilution of chlorine based agents, and addresses the safe handling of laundry and linen potentially contaminated with cytotoxic drugs and residues.

This section should be read in conjunction with the following sections:

- > Section 5 – Training
- > Section 6.4 – Preparation and Dispensing
- > Section 14 – Spills
- > Section 15 – Waste Management
- > Appendix 7 – Table of Cytotoxic Drugs and Excretion Rates

Cleaning

Given the wide use of cytotoxic drugs in medical therapies and their high toxicity, cytotoxic drugs represent a potential risk for workers at each step of the healthcare process. While preventing contamination of surfaces and equipment with cytotoxic drugs and their residues is the best strategy to minimise worker exposure, the handling of cytotoxic drugs may inevitably result in surface contamination that must be minimised and eliminated to negate potential handling risks.

12.1 Standard cleaning procedures

Effective cleaning procedures and practices to decontaminate the work area should be developed with documented safe work procedures including:

- > establishment of regular scheduled cleaning routines for all work surfaces and equipment used where cytotoxic drugs are prepared or administered
- > use of disposable cleaning materials where possible, that generate a low amount of particles; reusable cleaning materials should be decontaminated or discarded after use along with other cytotoxic waste
- > use of specially designed and dedicated cleaning equipment
- > treatment of all equipment used for cleaning as potentially contaminated
- > use suitable personal protective equipment (PPE) when cleaning:
 - use gloves that are chemically resistant to detergent, disinfection and decontaminating agents
 - wear face shield if splashing is possible
 - wash hands thoroughly with soap and water after removing gloves used for cleaning and decontaminating
- > appropriate cleaning techniques
- > consideration of appropriate cleaning agents
 - consider compatibility, effectiveness and potential for toxic residues.

Cleaning of Ventilation Tools

Written procedures for the cleaning, disinfection and decontamination of ventilation tools, safety cabinets and isolators is the responsibility of trained operators (such as pharmacists and pharmacy technicians) and must be in accordance with manufacturer recommendations – See **Section 6.4 Preparation and Dispensing** for more information.

12.2 Cleaning agents

This is a general guide to cleaning agents – refer to manufacturer’s instructions for the specific product being used and the relevant safety data sheet (SDS) for safety instructions when dealing with undiluted product.

Surfactants

Surfactants such as liquid detergents diluted in warm water, followed by rinsing will clean water are generally recommended for cleaning of all surfaces potentially contaminated with cytotoxic drugs and related waste. Detergent agents combined with decontaminating agents are available commercially.

Chlorine-based agents

Sodium hypochlorite (liquid bleach) of various concentrations has been found to be the most effective reagent for the chemical degradation of a variety of cytotoxic drugs and is often recommended for decontamination purposes.

The high decontamination potential of sodium hypochlorite solution makes it useful for the cleaning of cytotoxic drug spills and decontamination of material potentially contaminated with infectious agents, however its corrosive nature on metals like stainless steel are a major drawback and manufacturers of biosafety cabinets (BSCs) and barrier isolators do not recommend the use of sodium hypochlorite.

It is also known that sodium hypochlorite can degrade cytotoxic agents to mutagenic residues so a minimum one hour time gap is recommended between cleaning and preparation of cytotoxic drugs. This may not be feasible in pharmacy production routines in which case other cleaning agents should be used.

Milton® tablets or solution and granular chlorine are also forms of chlorine based disinfectant solutions that are effective decontaminating agents.

Alcohol

Agents such as isopropyl 70% and ethyl alcohol 60% may be effective for disinfecting surfaces potentially contaminated with biological/infectious agents however are generally only to be used for surfaces where sodium hypochlorite is unsuitable.

Do not use alcohol to clean cytotoxic drug spills as some drugs can bind to alcohol and increase the area of contamination.



12.3 Guide to dilution for chlorine-based disinfectant solutions

Source: Communicable Disease Control Branch Fact Sheet www.sahealth.sa.gov.au/infectionprevention

Refer to manufacturer's instructions for the specific product being used and the relevant safety data sheet (SDS) for safety instructions when dealing with undiluted product.

Liquid bleach (sodium hypochlorite)

| Available chlorine level* | Recommended dilution |
|---------------------------|--|
| 0.05% or 500 ppm | 1 part bleach to 99 parts water: e.g. 10ml bleach + 990ml H ₂ O = 1Litre |
| 0.1% or 1000 ppm | 1 part bleach to 49 parts water: e.g. 20ml bleach + 980ml H ₂ O = 1Litre |
| 1% or 10,000 ppm | 1 part bleach to 4 parts water: e.g. 200ml bleach + 800ml H ₂ O = 1Litre |

*Note: these calculations are based on using a 5% sodium hypochlorite product.

If using 4% sodium hypochlorite product, adjust accordingly.

Milton tablets

(320mg available chlorine per tablet)

| Available chlorine level* | Recommended dilution |
|---------------------------|--------------------------------|
| 0.06% or 640 ppm | 4 tablets in 2 litres of water |
| 1%(approx.) or 10,240 ppm | 8 tablets in 250 ml water |

Milton solution

(1% sodium hypochlorite with 10,000ppm available chlorine).

| Available chlorine level* | Recommended dilution |
|---------------------------|---|
| 500ppm | 50ml + 950ml H ₂ O = 1 Litre |

Granular hypochlorite products

These are also available in convenient sachet form and should be diluted according to manufacturer's instructions.

Precautions

When preparing sodium hypochlorite solutions the following precautions must be taken:

- > mix in a well-ventilated room
- > use appropriate PPE - eye wear, plastic apron and utility gloves
- > when handling and using undiluted bleach, it should not be used in spray bottles
- > do not mix with acids
- > corrosive to metals.

12.4 Work place monitoring

Regular and random monitoring of surfaces in areas where there is a risk of contamination from cytotoxic drugs, such as the pharmacy preparation and storage areas and patient administrations areas, is an important quality assurance measure to assess the effectiveness of the cleaning practices. This is known as environmental wipe sampling.

12.5 Cleaning staff

General cleaning staff who may be involved in cleaning areas where cytotoxic drugs are stored, prepared or administered, must be informed of the potential hazards associated with cytotoxic drugs and be trained in safe cleaning procedures. They should also be educated on the importance of their role in elimination and decontamination through cleaning. A low risk training module incorporating this information must be provided to these low risk workers (such as eViQ Module 1, or similar – see **Section 5 – Training**).

Laundry

Body fluids (excreta) from patients receiving cytotoxic drugs may contain traces of active cytotoxic drug or its metabolites. The excretion rates for cytotoxic drugs are variable, up to 7 days after treatment depending on the individual cytotoxic drug and route of excretion.

A table of excretion rates for some cytotoxic drugs is available – see **Appendix 7 Table of Cytotoxic Drugs and Excretion Rates**.

12.6 Risk control measures in healthcare facilities

Safe work procedures for handling contaminated laundry should be established in consultation with the Health Service laundry service provider or contractor. Healthcare facilities must have documented procedures for the collection, transport and storage of linen. Healthcare facilities that process or launder linen must have documented operating procedures consistent with AS/NZS 4146.

All used linen should be handled with care to avoid dispersal of microorganisms into the environment and to avoid contact with worker clothing. The following principles apply for linen used for all patients in healthcare facilities:

- appropriate PPE is worn during handling of soiled linen to prevent skin and mucous membrane exposure to blood and body substances and cytotoxic drugs or residues
- used linen is ‘bagged’ at the location of use into an appropriate laundry receptacle
- used linen must not be rinsed or sorted in patient-care areas or washed in domestic washing machines
- linen soiled with body substances should be placed into leak-proof laundry bags for safe transport
- hand hygiene is performed following the handling of used linen.

Clean linen must be stored in a clean dry place that prevents contamination by aerosols, dust, moisture and vermin and is separate from used linen.

Domestic-type washing machines must only be used for a patient’s personal items (not other linen). Washing must involve the use of an appropriate detergent and hot water. If hot water is not available, only individual patient loads can be washed at one time. Clothes dryers should be used for drying.

Grossly contaminated linen may be discarded into the appropriate cytotoxic/hazardous waste bin.

12.7 Contaminated personal protective equipment (PPE)

Special precautions are required for the laundering of non-disposable PPE that may be contaminated with cytotoxic drugs. The requirements of the manufacturer or supplier of the PPE should be followed.

PPE must be decontaminated and cleaned prior to sterilisation or reuse.

12.8 Contaminated bedding

Bed mattresses should be cleaned with a decontaminating solution. Consider use of vinyl covered and plastic backed mattresses, pillows and chairs for ease of cleaning where risk of contamination is greater.

12.9 Information sources

1. SA Health Infection Control Service, Communicable Disease Control Branch Fact Sheet: Guide to dilution of chlorine-based disinfectant solutions
2. eviQ Cancer Treatments On-line 2014; Cancer Institute of NSW www.eviQ.org.au
3. Lamerie T et al. *Evaluation of Decontamination Efficacy of Cleaning Solutions on Stainless Steel and Glass Surfaces Contaminated by 10 Antineoplastic Agents*. *Ann Occup Hyg*. 2012; 57(4):456-469.
4. International Society of Oncology Pharmacy Practitioners (ISOPP); *Standards of Practice: Cytotoxic spills, extravasation and other incidents*. *J Oncol Pharm Pract* 2007;14.
5. Fransman et al. *Inhalation and dermal exposure to eight antineoplastic drugs in an industrial laundry facility*. *Int. Arch Occup Environ Health*. 2007; 80(5):396-403.
6. Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010).

13 Personal Protective Equipment (PPE)

This section provides a risk management framework to assist in the development of local safe work procedures, and aims to provide practical advice on the selection of personal protective equipment (PPE).

This section should be read in conjunction with the following sections:

- > Section 5 – Training
- > Section 12 – Cleaning and Laundry
- > Section 15 – Waste Management

The correct selection and use of personal protective equipment (PPE) is required to both protect those who handle cytotoxic drugs and related waste, and ensure the sterility of the end product. Listed in Table 1 below are general recommendations. Before selecting PPE, a risk assessment should be performed for each activity within the particular setting and appropriate PPE selected.

Table 1. Recommended PPE for handling cytotoxic drugs and related waste

| | Coveralls and gowns | Gloves | Protective eyewear | Shoe covers or overshoes | Respiratory Protective Equipment (RPE) | Head covering |
|--|---------------------|--------|--------------------|--------------------------|--|---------------|
| Preparation of cytotoxic drugs – inside an isolated cytotoxic drug safety cabinet (CDSC) | ● | ● | ● | ● | ● | ● |
| Cleaning of cytotoxic drug preparation areas and equipment | ● | ● | | ● | ● | ● |
| Drug administration and patient care (parenteral treatment) | ● | ● | ● | | ● | |
| Cleaning spills | ● | ● | ● | ● | ● | ● |
| Laundry – handling cytotoxic contaminated linen bags | ● | ● | | | ● | |
| Handling cytotoxic drug contaminated waste | ● | ● | | | | |
| Handling contaminated body waste | ● | ● | ● | ● | ● | |
| Receiving and storing cytotoxic drugs | | ● | | | | |

*Safety glasses are strongly recommended for contact lens wearers, otherwise optional.

13.1 Coveralls and gowns

Selection considerations for coveralls or gowns include:

- > made of impermeable material, e.g. bonded polyethylene fibre
- > closed front and long sleeves with elastic cuff
- > disposable or reusable noting that reusable coveralls and gowns have a limited life span and are to be discarded when full protection can no longer be guaranteed by the manufacturer or supplier
- > hooded coveralls for cytotoxic drug preparation.

Gowns should not be shared. Take care in the removal of gowns to minimise the potential risk of personal contamination.

Gowns should be used for a maximum of one shift with contaminated garments removed immediately and disposed of or laundered as appropriate.

13.2 Gloves

Glove use is essential and gloves must be chosen to maximise protection by minimising permeability. Standard surgical gloves may not provide the required level of protection due to drug and/or carrier permeability in the case of liquid cytotoxic drugs.

Selection considerations for gloves include:

- > long enough to cover wrist cuffs of coveralls or gowns while arm is bent or stretched
- > purpose manufactured or manufacturer recommended
- > disposable
- > nitrile gloves are generally recommended for handling cytotoxic drugs
- > latex gloves used in drug preparation should be sterile and powder free
- > polyvinyl chloride (PVC) industrial gloves can be used for waste management activities.

Individuals handling cytotoxic drugs and related wastes should be double gloved if they are not wearing purpose manufactured gloves. This can be done with two pairs of powder-free latex gloves. Note: With double gloving, both pairs of gloves must be changed.

Gloves should be changed at:

- > intervals recommended by the manufacturer, or more regularly where stipulated in local safe work procedures, or
- > when punctured, torn or contaminated.

13.3 Protective eyewear

Protective eyewear should be provided to prevent exposure to the mucous membranes of the eye from liquid splashes. Eye protection can be provided by:

- > goggles or protective eyewear with side shields
- > a transparent full-face chemical splash shield
- > full eye protection provided by full-face respiratory protective equipment (RPE).

A risk assessment will assist to determine whether a worker wearing prescription glasses requires additional protection.

Reusable eyewear can be cleaned with a neutral detergent solution and rinsed thoroughly at the end of the shift or when contaminated.

Contaminated disposable eyewear is to be disposed of as cytotoxic waste.

13.4 Shoe covers and overshoes

Selection considerations for shoe covers and overshoes include:

- > shoe covers must be made of impervious material, e.g. bonded polyethylene fibre. Paper disposable shoe covers, such as used in operating rooms, do not provide sufficient protection from cytotoxic spills
- > overshoes should be high enough to cover the trouser cuff of the coverall and designed so they do not slip down
- > the soles should be made of a skid-resistant plastic or other suitable non-shedding material.

Contaminated, non-disposable footwear should be cleaned with a detergent solution and rinsed thoroughly after each use, and reusable overshoes stored for laundering.

Contaminated disposable shoe covers are to be disposed of as cytotoxic waste.

13.5 Respiratory Protective Equipment (RPE)

Suitable respiratory protective equipment (RPE) should be selected, used, stored and maintained as recommended in AS/NZS1715: 2009 – *Selection, use and maintenance of respiratory protective equipment* or comparable internationally accepted standard.

Selection considerations for RPE include:

- > reference must be made to the safety data sheet for manufacturers/supplier recommendations of RPE
- > a particulate filter P2 (N95) mask is recommended for situations in which aerosols may be generated
- > a requirement for a worker to wear prescription glasses should be taken into account in selection and fitting of RPE.

Staff required to wear RPE must be fit tested.

When using reusable RPE, an effective storage and regular maintenance program should be implemented with procedures covering:

- > cleaning and disinfection, noting that reusable face piece RPE requires the face piece washed after each daily use or following any contaminating incident
- > replacement of filter
- > inspection for defects
- > repair of equipment.

Contaminated replaceable filters are to be disposed of as cytotoxic waste at the end of service life.

Disposable RPE are to be disposed of as cytotoxic waste after each use or following any contamination incident.

Note: surgical respirators do not offer sufficient respiratory protection against exposure to powders, liquids or aerosols (particulates).

13.6 Head covering

Head coverings are worn to contain hair and minimise contamination. They should cover exposed hair, including beards and moustaches.

Selection considerations for head coverings include:

- > hoods fit snugly around the face (hooded coveralls are recommended for drug preparation)
- > caps fit snugly around the head
- > removable and separate facial covers may be available for use
- > hoods, caps and facial enclosures should not interfere with respiratory protection.

14 Spills

This section provides a **risk management framework** to assist in the development of local safe work procedures, and aims to provide practical advice on dealing with cytotoxic spills. Spill management requires the removal of as much of the spilt material as possible prior to decontamination of the surface.

This section should be read in conjunction with the following sections:

- > Section 4 – Staff Health
- > Section 5 - Training
- > Section 12 – Cleaning and Laundry
- > Section 15 – Waste Management

A cytotoxic drug and related waste spill requires immediate attention and must be effectively controlled so as not to promote any further unnecessary contamination of the environment. Health services should develop a spill management strategy which includes a cytotoxic drug spills register.

14.1 Sources of spills

Worksite inspections and risk assessments aim to identify areas of risk in a work environment, including the potential risk of a cytotoxic drug spill.

Spills may involve:

- > cytotoxic drugs in all forms – liquid, powder, broken tablets or capsules or creams
- > cytotoxic drugs spilt (or leaking) during preparation, storage or transport of packaged drugs
- > cytotoxic drugs spilt during administration or disposal
- > cytotoxic drugs leaking following disposal
- > cytotoxic drugs spilt or leaking during the transport of a patient receiving drug therapy
- > cytotoxic contaminated body waste/substances
- > cytotoxic contaminated waste.

Spills may result in the contamination of floors, work surfaces, equipment, bedding and clothing as well as the potential risk of exposure to patients and workers.

14.2 Spill kits

All areas where cytotoxic drugs are prepared and administered should have access to a spill kit. A risk assessment is to be completed for each area to determine the contents of the cytotoxic drug spill kit, with the contents listed in the table below.

Storage and access locations of the cytotoxic drug spill kit are to be clearly sign-posted.

Cytotoxic drug spill kit contents are to be reviewed regularly, for example via worksite inspections, to ensure contents are replenished, have not deteriorated and remain appropriate for the designated area.

| Contents to be included in a cytotoxic drug spill kit: | |
|--|--|
| 1 | Safe work procedures for the management of a cytotoxic drug and related waste spill (i.e. instructions for use) |
| 2 | Sign(s) to identify and isolate the spill (caution tape can be used to quarantine an area) |
| 3 | Personal protective equipment: <ul style="list-style-type: none"> > latex(double gloved) and/or nitrile gloves x 2 > head cover > impermeable gown or coverall > overshoes* > safety glasses or full-face chemical splash shield > P2** mask or other suitable respiratory protective device |
| 4 | Adequate quantities of absorbent materials such as. swabs, absorbent towels, chemical absorbent spill pillow, chemical absorbent granules, chemical absorbent mat |
| 5 | A small scoop to collect any glass fragments e.g. dedicated dustpan or disposable scoop |
| 6 | Plastic waste bags and ties, and bin or container (clearly labelled for cytotoxic use) |
| 7 | Suitable cleaning/decontaminating agent may also be included |
| 8 | Water for powder spills (to be used to reduce dust and particulate matter) |

* Shoe covers must be made of impervious material, e.g. bonded polyethylene fibre. Paper, disposable shoe covers, such as used in operating rooms, do not provide sufficient protection from cytotoxic spills.

** Trained spill management personnel would ideally use their own fit tested P2 mask for dealing with cytotoxic drug spills. A P2 mask should also be made available in the spill kit should no other be available.

Note that there are commercially available cytotoxic spill kits. Prior to purchase, these kits should be assessed for applicability to the particular clinical setting and validated before use.



14.3 Spill containment

Keep calm. Alert others to the spill and do not leave the spill unattended.

Spills may occur wherever cytotoxic drugs and waste are handled, stored, transported or disposed.

People in the immediate vicinity of a spill should be alerted to the incident forthwith and warned to keep clear, with the area being isolated.

Ancillary workers should assist only in the containment of a spill while alerting trained staff.

Responsibility for managing the cytotoxic drug spill cleanup must be allocated to a person that has not been contaminated and has received training in the handling of risks associated with cytotoxic drugs.

Refer to the cytotoxic drug safety data sheet (SDS) for specific information.

Worker accidental exposure

If staff exposure has occurred, seek immediate medical advice and attention as necessary Refer to **Section 4 – Staff Health** (Emergency Procedures).

Managing cytotoxic spills in the community setting

- > Patients treated at home or in the community are to be provided with cytotoxic spill kit which includes contents appropriate to the home or community care setting.
- > Clear instructions, information on replacement and disposal of used items is to be included.

14.4 Reporting procedures

Health Services must have a system in place for workers to report spills or exposure to management as soon as possible, and before the end of the working shift with incidents recorded via the WHS module of the Safety Learning System (SLS) – **See Section 4 – Staff Health**

Notification of incidents

It is a legal requirement of SA Health and its Health Services to notify SafeWork SA of any work related incident involving hazardous chemicals, including cytotoxic drugs - *WHS Act 2012 (SA) Part 3*.

14.5 Model Procedures and Associated Attachments

The following Model Procedure and Attachments are associated with this section:

- > Model Procedure 8 – Spill Management of Cytotoxic Drugs
- > Attachment 8a – Cytotoxic Drug Spill Kit Contents Checklist
- > Attachment 8b – Cytotoxic Drug Spill Register

15 Waste Management

This section provides a **risk management framework** to assist in the development of local safe work procedures, and aims to provide practical advice on managing cytotoxic waste including contaminated body waste or excreta. This section identifies the key elements for consideration when managing cytotoxic waste, taking into account the requirements of environmental protection legislation and industry standards from the Waste Management Association of Australia and Standards Australia.

This section should be read in conjunction with the following sections:

- > Section 14 – Spills
- > Section 12 – Cleaning and Laundry
- > Section 13 – Personal Protective Equipment (PPE)
- > Appendix 7 – Table of Cytotoxic Drugs and Excretion Rates

15.1 What is cytotoxic waste?

Cytotoxic waste is waste contaminated with cytotoxic drug(s) or metabolites – it includes any residual cytotoxic drug that remains following patient treatment and all materials that have come into contact with cytotoxic drugs during the reconstitution, preparation or administration of cytotoxic drug therapy. Cytotoxic waste may include:

- > unused cytotoxic pharmaceuticals
- > contaminated waste from preparation processes
- > used and contaminated sharps and syringes, ampoules and vials
- > contaminated intravenous infusion sets and containers
- > packaging that has been in contact with cytotoxic drugs
- > disposable drug administration aids and devices such as used medicine cups
- > contaminated personal protective equipment (PPE) such as gloves, gowns, shoe covers, respirators
- > materials used to clean cytotoxic contaminated equipment or spills
- > contaminated body substance receptacles such as disposable vomit bags
- > contaminated dressings and bandages
- > heavily contaminated linen that is unable to be cleaned
- > contaminated patient body waste (excreta) following treatment of the patient with cytotoxic drug
- > contaminated specimens from the laboratory.

As cytotoxic waste is hazardous to human health and the environment, it is a listed waste and is subject to the requirements of the *Environment Protection Act 1993* (EP Act) and gazetted updates and the *Environmental Protection (Waste to Resources) Policy* (EP Policy) (2010). These requirements cover the generation, storage and transportation of waste that is pre-classified as a listed waste.

In the situation where cytotoxic waste may be transported between South Australia and another state or territory, the requirements of *Environment Protection (Movement of Controlled Waste) Policy* (2014) and the National Environment Protection (Movement of Controlled Waste between States and Territories) Measure 2012 apply.

Effective separation and segregation of the different waste streams in a clinical setting are essential for compliance with the legal requirements of the EP Act and for protecting the health and safety of workers and the environment.

15.2 Establishing waste management safe work procedures (SWPs)

Health Services must develop and periodically review written safe work procedures to safely manage and dispose of cytotoxic waste. A comprehensive audit of all sections of the Health Service that generate or handle cytotoxic waste will assist in the development of SWPs.

Procedures must describe requirements for the segregation and identification, collection, transport and storage of cytotoxic waste and should be developed in consultation with those who generate cytotoxic waste and those responsible for the provision of support, transport and disposal services.

To streamline work activities and provide consistent safe practices for all those involved in waste management, SWP should be consistent across Health Services.

Cytotoxic waste should be managed separately from other types of waste generated in a clinical setting that are not assessed or classified as hazardous waste.

Key elements of waste management safe work procedures include:

- > designating a person with suitable experience and training to be responsible for ensuring an efficient waste disposal system
- > a clear chain of responsibility, and involvement of all levels in procedure development and implementation
- > compliance with legal requirements
- > use of a South Australian Environment Protection Authority (EPA) authorised facility able to accept cytotoxic waste
- > procedures and systems to avoid and minimise waste at the point of generation
- > consultation with all those who may be exposed, including those generating the waste, waste handlers and waste disposal workers
- > use of appropriate risk control measures
- > regular monitoring and reviewing of procedures.

Key references for the management of cytotoxic waste in clinical settings are:

- > South Australian *Environment Protection Authority's Waste Strategy 2011-2015*
- > South Australian Environment Protection Authority; *EPA Guidelines on Medical Waste – Storage, Transport and Disposal 2003*
- > Waste Management Association of Australia's (WMAA) *The Industry Code of Practice for the Management of Clinical and Related Wastes 6th Ed (2010)*
- > AS/NZ 3816:1998 *Management of clinical and related wastes*
- > HB 202:2000 *A management system for clinical and related wastes – guide to application of AS/NZ 3816: 1998, Management of clinical and related wastes.*

15.3 Key risk control measures

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

- > elimination, substitution or isolation of identified high risk activities
- > engineering or automated methods to minimise the amount of handling
- > safe systems of work for identified waste management activities – segregation, packaging, storage, transport, administration and disposal
- > identification of cytotoxic waste through designated labelling, and use of identifiable waste bags and containers
- > managing cytotoxic waste generated by Health Services' community based activities
- > training of supervisors, workers and all those who may be exposed to cytotoxic contaminated waste
- > maintaining records and tracking cytotoxic waste in accordance with the requirements of the EP Act and Health Service SWP
- > a transport and disposal flowchart covering internal and external activities from waste generation to treatment and destruction
- > use of appropriate PPE for waste management activities.

15.4 Identification, containment and segregation

Identification

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

All cytotoxic waste should be placed into suitable bags and/or bins/containers that are appropriately labelled. The following identification of cytotoxic waste is required:

- > bins/containers and bags are identified by colour coding – purple
- > bins/containers are marked with the words “Cytotoxic Waste” clearly displayed.



Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) the following labels/pictograms indicate a chronic health hazard, acute toxicity and environmental hazard respectively; they may all be applicable to signage for cytotoxic drug waste.



Cytotoxic waste storage areas in health care services should be appropriately dedicated, sign-posted, secure and well-lit and ventilated. Storage should be away from drains and other sensitive areas.

Containment

Risk control measures include:

- > package the waste in a hard walled bin/container for transport to the Health Service waste disposal facility
- > a leak proof labelled plastic bag may be sufficient for use in the home
- > the storage of sharps in a rigid walled container as per AS 4031-1992 and AS4031-1992/Amdt 1 – 1996 – *Non-reusable container for the collection of sharp medical items used in healthcare areas*
- > waste bins/containers should be sealed prior to collection by waste collectors.

Segregation

Risk control measures include:

- > segregation of cytotoxic drug waste at the point of generation
- > appropriate signage in collection and storage areas
- > separation of cytotoxic drug waste from general and clinical waste during internal transport and storage. Reference should be made to local safe work procedures – cytotoxic drug waste management
- > non-rigid receptacles should be placed in a rigid walled container, such as a wheelie bin (identifiable as containing cytotoxic waste), for transport to a collection area
- > containers/bins should be secured.

15.5 Requirements and licensing for handling or storage of cytotoxic waste

Medical waste is a listed waste under the EP Act.

Under the EP Act any person who carries on an activity in which medical waste is produced must be licensed.

Requirements for a licensed facility under the EP Policy include:

- > storing the medical waste in containers that:
 - are weatherproof, shatterproof, insect and vermin proof and leak proof
 - are cleaned and disinfected immediately after use
 - have a label clearly indicating the nature of the contents
 - are stored in a secure location
- > equipment on hand ready to clean up spills
- > storage of medical sharps in containers that comply with Australian Standards
- > disposal of medical waste as soon as practicable
- > advising the medical waste transporter of the nature and hazards of the medical waste and any precautions to be taken during collection, transport and disposal.

Note: A licence is not required if the medical waste is produced in the course of any of the following activities:

- > medical practice, not being the pathology service
- > retail pharmacy
- > domestic activity
- > dental practice
- > operation of a nursing home
- > veterinary practice
- > operation of a hospital with a capacity of **less than 40 beds**
- > operation of an immunisation clinic.

Local Health Networks and Health Services must have a medical waste producers licence from the EPA. This licence must be made readily available to waste management workers and community workers as it enables the return of cytotoxic drug waste from community residents to the Health Service for disposal.

15.6 Waste disposal and treatment

Incineration (at 1100°C) is the only approved technology for treating cytotoxic waste. All incinerators used for the treatment of cytotoxic waste must be licensed with the EPA and meet the prescribed standards. Patient excreta such as urine, faeces, vomit 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
- > the operation of on-site sewerage treatment systems such as septic tanks might be affected by cytotoxic drug waste. Further information can be obtained from the manufacturer or supplier of the system.

Note: If using a contractor to dispose of cytotoxic drug waste, the contractor must be a licensed waste transporter authorised to collect and transport medical waste by the EPA and/or a local council.

15.7 Contaminated body waste

Cytotoxic drug waste also includes contaminated body waste. Excreta or body fluids from patients who have recently received cytotoxic drug treatment should be handled as potentially contaminated as such waste may contain traces of cytotoxic drug and active metabolites.

Cytotoxic drugs are primarily eliminated from the patient in urine and faeces however all body substances including bile, sweat and saliva may be contaminated with the unchanged drug or with active drug metabolites.

15.8 Precautions when handling cytotoxic contaminated body waste

The time period during which patient excreta may be contaminated with cytotoxic drugs differs for individual drugs and patients. When developing safe work procedures for workers and carers of patients who have recently undergone cytotoxic drug therapy, consider the following:

- > cytotoxic drug treatment administered
- > dose
- > route of administration
- > route of excretion
- > type of body waste
- > time since drug administration

The majority of cytotoxic drugs will be excreted within 7 days following treatment however some may have longer excretion periods. Refer to Appendix 7 for specific drug excretion rates. Where the excretion period is not known, use precautions for at least 48 hours following treatment.

Workers and patient carers/relatives should be informed about the potential risks of handling contaminated patient excreta and appropriate precautions to take.

Information about the excretion rates for some cytotoxic drugs is included in **Appendix 7 – Table of Cytotoxic Drugs and Excretion Rates**.

Safe work procedures should address the potential risk of handling contaminated body waste during the cytotoxic drug excretion period and include:

- > prevent generating aerosols when handling body waste
- > avoid skin contact with body waste
- > contain and clean up spills immediately
- > use urine hats where possible to avoid sprays and aerosols
- > patient excreta such as urine, faeces, vomit and the contents of colostomy and urostomy bags may be disposed of in the normal sewerage system however disposable nappies, used colostomy, urostomy bags and dressing materials should be placed into a cytotoxic waste bag for disposal
- > consider use of indwelling catheters for incontinent patients
- > label all specimens sent to the laboratory with appropriate cytotoxic warning
- > consider soiled linen and clothing as potentially contaminated
- > use appropriate PPE when handling body waste.

15.9 Model Procedures

The following model procedures are associated with this section:

- > Model Procedure 9 – Managing Cytotoxic Waste

16 Animal Research Facilities

Research staff, veterinarians, veterinary nurses, animal attendants and cleaners may be involved with the handling of cytotoxic drugs and related wastes in dealing with animals held in animal research facilities.

This section should be read in conjunction with the following sections:

- > Section 12 – Cleaning and Laundry
- > Section 13 – Personal Protective Equipment (PPE)
- > Section 14 – Spills
- > Section 15 – Waste Management
- > Appendix 7 – Table of Cytotoxic Drugs and Excretion Rates

In animal research, exposure to cytotoxic drugs can occur when cytotoxic drugs and related waste are handled, stored, administered, transported or disposed.

In addition, exposure can also occur through contact with animal waste during treatment or cleaning procedures. Many of the recommendations, procedures and risk control measures used in human patient management can be applied in these research facilities to ensure the health and safety of all workers. Refer to other sections and appendices of this guide for related information.

The following information should be provided to research veterinary workers as a part of their cytotoxic drug handling training session:

- > work hazards and potential risks of exposure to cytotoxic drugs and related waste
- > the risk management process
- > risk control measures, safe work procedures and work practices to be adopted when handling cytotoxic drugs and related waste
- > legislative requirements for work health and safety
- > legislative requirements for cytotoxic waste management
- > safe preparation of cytotoxic drugs
- > safe administration of cytotoxic drugs (including labelling of animal cages)
- > pre maintenance cleaning and maintenance of equipment
- > cleaning and laundering procedures (including contaminated bedding)
- > correct selection, use, cleaning and disposal of personal protective equipment (PPE)
- > procedures to be adopted in the event of accident, injury or spill, including reporting and recording
- > access to first aid resources
- > storage, transport, treatment and disposal of cytotoxic drugs and related waste
- > health surveillance and reporting
- > written safe work procedures.

16.1 Establishing an animal care area

- > ensure a secure area accessible by authorised personnel only
- > ensure access to appropriate cytotoxic waste disposal (plastic bags and cytotoxic waste bin)
- > ensure ready access to a cytotoxic spill kit
- > have safety data sheets (SDS) available for workers to refer to.



16.2 Equipment required

Suitable equipment designed to reduce the risk of exposure should be employed.

Further animal care equipment which may be considered to minimise worker exposure may include:

The contents of the cytotoxic spill kit are outlined in **Section 14 – Spills**.

Further animal care equipment which may be considered to minimise personnel exposure may include:

- > animal cages designed to flush excreta directly into the waste sewerage system
- > disposable scoops or equivalent for faecal clean up
- > disposable bedding material/articles
- > disposable cage liners
- > filtered caging systems
- > use of cytotoxic cabinet for the cleaning of small animal cages to reduce aerosols created when removing contaminated bedding (if risk identified in risk assessment).

Animal cages and cleaning

- > Animal cages must be signed with “receiving cytotoxic drug therapy”.
- > Use purpose-designated or disposable equipment.
- > If equipment is non disposable, it must be cleaned. For guidance on cleaning agents refer to **Section 12 – Cleaning and Laundry**.
- > Dispose of cytotoxic waste as per **Section 15 – Waste Management**.

16.3 Safe work procedures

Safe work procedures should be developed with the assistance of the treating facility and include the following risk control measures:

- > avoid breaking or crushing tablets, or opening capsules when administering cytotoxic drugs
- > use appropriate PPE when preparing and administering cytotoxic drugs, particularly those for parenteral preparation and administration (such as eye protection, nitrile gloves, a P2 mask and gown – See **Section 13 – Personal Protective Equipment (PPE)**)
- > use appropriate PPE for cleaning tasks
- > cytotoxic drugs should only be reconstituted by trained personnel in an approved facility
- > contain the urinating habits of the animal where possible and dilute animal excretions by gently hosing down affected areas
- > animal patients should be adequately restrained by trained personnel when administering cytotoxic drugs
- > keep animals confined to their caged areas/bedding during periods when the drug may be excreted
- > clean up faeces by scooping with a disposable shovel and disposing appropriately
- > clean/decontaminate or discard soiled articles after use
- > minimizing aerosols when cleaning cages
- > wash hands following handling of cytotoxic drugs, animals receiving cytotoxic drug treatment, or related waste products
- > dispose of contaminated items (such as gloves) and other cytotoxic drug waste appropriately – See **Section 15 – Waste Management**
- > consider cytotoxic drug excretions rates and routes when handling animal excreta following cytotoxic drug treatment – See **Appendix 7 – Table of Cytotoxic Drugs and Excretion Rates**
- > attend to cytotoxic drug spills immediately – See **Section 14 – Spills.**

Appendix 1

Glossary

| A | |
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| administrative control | a risk control measure that involves minimising the risk through the use of procedures or instruction, for example, safe work procedures, labelling and training |
| ADG Code | the Australian Dangerous Goods Code 7th edition (7.3) is accessible at the National Transport Commission website: http://www.ntc.gov.au |
| ALARA | as low as reasonably achievable |
| alginate bag | bag made of artificial fibres spun from a constituent of kelp – the fibres become gelatinous when moist and so are biodegradable |
| approved codes of practice | practical guides to achieving the standards of both physical and psychological health and safety as per the <i>Work Health and Safety (WHS) Act 2012 (SA)</i> and the <i>Work Health and Safety Regulations 2012 (SA)</i> . |
| ASCC | Australian Safety and Compensation Council – national body that leads and coordinates national efforts to prevent workplace death, injury and disease in Australia, formerly known as National Occupational Health and Safety Commission (NOHSC) |
| aseptic manipulation | activity performed so as to exclude micro-organisms |
| aseptic suite | work space free from micro-organisms in the working area |
| B | |
| BCG | an attenuated, live culture preparation of the Bacillus of Calmette and Guerin strain of <i>Mycobacterium bovis</i> |
| biohazard | organic substances that pose a threat to the health of humans and other living organisms |
| biohazardous drug | a drug that has the potential to cause infections in human due to the presence of viable microorganisms |
| biological monitoring | measurement and evaluation of hazardous chemicals or their metabolites in the body tissue, fluids or exhaled air of a person |
| bodywaste (excreta) | body fluids and faeces from patients receiving cytotoxic drug therapy that may contain traces of cytotoxic drugs and/or their active metabolites. May include, urine, vomit, blood, faeces, sweat, bile, plasma |
| bunding | a constructed barrier designed to retain liquid |
| C | |
| carcinogen | substance or physical agent with the potential to cause cancer in certain circumstances or to make cancer more likely to occur |
| CDSB | cytotoxic drug safety cabinet; provides the primary barrier against exposure to aerosols that are produced in the preparation, manipulation, and dispensing of cytotoxic drugs |
| cleanroom | a room with environmental control of particulate contamination, temperature and humidity; constructed and used in such a way as to minimise the introduction, generation and retention of particles inside the room |
| closed system device | a device that does not exchange unfiltered air or contaminants with the adjacent environment |

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| closed system drug transfer device | a drug transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system |
| competent person | a person who is suitably qualified and considered competent to carry out the function |
| consultation | the sharing of information and exchange of views between and within PCBU's, Responsible Agency(s), WHS defined Officers and workers and their representatives, including volunteers, contractors, labour hire staff, students and occupiers. This includes the genuine opportunity for all parties to contribute, communicate, coordinate and cooperate |
| contractor | under the <i>Work Health and Safety Act 2012 (SA)</i> a contractor is a Person Conducting Business or Undertaking (PCBU); a contractor can be an entity or individual who is not a worker of SA Health but provides a service, facility or equipment to SA Health under a contract specifying the work or work materials, and the cost and schedule for completion of the work |
| consultative committee | work health and safety committee or committees established by the PBCU/ Responsible Agency and workers |
| cytogenic | pertaining to the formation of cells |
| cytotoxic | harmful to cells of the body, particularly those that reproduce rapidly |
| cytotoxic drug | a drug that affects cell growth and proliferation, usually by binding directly to genetic material in the cell nucleus or by affecting cellular protein synthesis. Cytotoxic drugs do not typically distinguish between normal and cancerous cells |
| cytotoxic spill | a spill of cytotoxic drugs or related wastes |
| cytotoxic waste | waste contaminated with cytotoxic drug or metabolites – it includes any residual cytotoxic drug that remains following patient treatment and any materials or equipment potentially contaminated with cytotoxic drugs |
| D | |
| dangerous goods | for the purposes of the definition of dangerous goods in Schedule 1 of the <i>Work Health Safety Act 2012 (SA)</i> , the following are prescribed: (a) anything that is a dangerous good within the meaning of the <i>Dangerous Substances (Dangerous Goods Transport) Regulations 2008</i> ; (b) a good of a kind that is described in column 2 of the table in WHS Regulation 328(3) |
| duty of care | The legal obligation every person and organisation has to another person and themselves to avoid acts or omissions that are likely to cause harm to others. Under the <i>Work Health Safety Act 2012 (SA)</i> the general duty of care describes duties that the Act places upon people to ensure their own safety at work and that of others who are in the workplace. These duties are aimed at preventing death, injury or incidents i.e. contracting an illness because of work or activities at a workplace |
| E | |
| elimination | a risk control measure in which the hazard is eliminated |
| engineering control | a risk control measure which uses technological means to isolate or remove hazards |
| exposure standards | exposure standards are the calculated airborne concentrations of an individual chemical, which according to current knowledge, should neither impair the health of, nor cause undue discomfort to workers. The exposure standards serve as a guide only and the risk control measures selected must ensure that the applicable exposure standard is not exceeded |
| excreta | see <i>body waste</i> |
| extravasation | unplanned escape of a liquid from a vessel or tube into surrounding body tissues |

G

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| GHS | <p>The Globally Harmonised System of Classification and Labelling of Chemicals (GHS) is a single internationally agreed system of chemical classification and hazard communication through labelling and Safety Data Sheets (SDS). The GHS is published by the United Nations and includes harmonised criteria for the classification of:</p> <ul style="list-style-type: none"> – Physical Hazards – Health Hazards and – Environmental Hazards |
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H

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| hazard | a hazard is the potential for a chemical or plant, equipment or structure to adversely affect the health and safety of persons in the workplace |
| hazardous drug | a drug that presents an occupational risk due to its inherent toxicity: identified as a demonstrated carcinogen or teratogen or drug that has other developmental, reproductive or organ toxicity at low doses, genotoxicity or similar profile to drugs already considered hazardous |
| hazardous chemical | a substance, mixture or article that satisfies the criteria for a hazard class in the GHS (including a classification referred to in Schedule 6 of the <i>WHS regulations 2012 (SA)</i>). |
| hazardous chemicals register | a register recording hazardous chemicals that are kept and maintained onsite; records how and where these chemicals are stored, how they should be used and safety data sheets |
| health | includes both physical and psychological health of an individual(s) |
| health monitoring | health monitoring means monitoring of a person to identify changes in the person's health status because of exposure to certain substances. There are different types of health monitoring procedures used to assess exposure to hazardous chemicals, including interviews, medical examinations, biological effect monitoring and biological exposure monitoring |
| health surveillance | systematic collection analysis and interpretation of occupational injuries, illnesses, hazards, and exposures |
| HEPA (high efficiency particulate air) filter | filter that is made to be at least 99.97 per cent efficient in removing an aerosol of particles with a diameter of 0.3 micrometres when tested with a standardised procedure |
| hierarchy of risk control | <p>used to determine the most appropriate risk control measure. The hierarchy of risk controls in order of preferred action is:</p> <ul style="list-style-type: none"> > elimination of the hazard or risk > substitution of the hazard or risk with something posing a lesser risk > engineering control e.g. a mechanical aid > administrative control e.g. a safe work procedure or training; and > personal protective equipment |

I

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| intravesical infusion | introduction of liquid through a urinary catheter into the bladder |
| isolation | a type of control measure that uses barriers to prevent exposure |

L

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| lyophilised cytotoxic drugs | cytotoxic drugs preserved during manufacture by being rapidly frozen and dehydrated in a vacuum – they do not require refrigeration, although sterile distilled water needs to be added before use |
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| M | |
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| MABs | see Monoclonal antibodies |
| manifest | a manifest is different to a Hazardous Chemical register, and is intended primarily for emergency services personnel to use where they are required to respond to an emergency situation at the workplace. A manifest is required to contain additional information about hazardous chemicals at the workplace than is in a register, including the hazard classes and categories of the hazardous chemicals and details of the type, size and locations of containers present at the workplace |
| manufacturer | an obligation holder as per the <i>Work Health and Safety Act 2012 (SA)</i> |
| Monoclonal antibodies | laboratory engineered immunoglobulin proteins with very specific cell binding properties. They are produced by cloning numerous identical cells from a single parent cell. A monoclonal antibody consists of a single type of protein (antibody). Monoclonal antibodies have numerous applications in the field of diagnostics, therapeutics and targeted drug delivery systems, including cancer, metabolic and hormonal disorders to name a few. |
| mutagen | substance with the potential to change DNA, the part of a body cell that controls its growth and multiplication – being a mutagen also gives a substance the potential to cause cancer |
| N | |
| non touch technique | known correctly as the ‘Aseptic Non Touch Technique”, a technique used during clinical procedures to identify and prevent contamination of key parts and sites by ensuring they are not touched either directly or indirectly |
| NOHSC | National Occupational Health and Safety Commission – see Safe Work Australia |
| O | |
| obligation | a legal requirement to take specified action as per the <i>Work Health and Safety Act 2012 (SA)</i> .or <i>Work Health and Safety Regulations 2012 (SA)</i> |
| occupational exposure | exposure to cytotoxic drugs during a work activity |
| ostomy | a surgically created artificial opening, usually created through the abdominal wall, to allow the discharge of bodily wastes |
| P | |
| parenteral | theoretically includes all routes of administration other than the oral route but in clinical usage typically refers to intravenous, subcutaneous, intramuscular or intradermal administration |
| patient waste | see <i>body waste (excreta)</i> |
| Person Conducting a Business or Undertaking (PCBU) | a PCBU may conduct a business or undertaking alone or with others. To meet the definition the business or undertaking can operate for profit or not-for-profit. The definition of a PCBU focuses on the work arrangements and the relationship to carry out the work. In addition to employer, a PCBU can be a corporation, an association or a sole trader. A volunteer organisation which employs any person to carry out work is considered a PCBU |
| PEG | percutaneous endoscopic gastrostomy |
| percutaneous injury | a route of exposure – taking in cytotoxic drug or waste through a puncture of the skin |

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| personal protective equipment | clothing and equipment worn to minimise exposure to serious workplace injuries and illnesses which may result from contact with chemical, radiological, physical, electrical, mechanical or other workplace hazards |
| pH | measure of how strongly acidic or basic a substance is when dissolved in water – acids have a pH less than 7; bases have a pH greater than 7 |
| place of work | premises where persons work |
| plant | includes— (a) any machinery, equipment, appliance, container, implement and tool; and (b) any component of any of those things; and (c) anything fitted or connected to any of those things |
| PPE | see personal protective equipment |
| premises | as per the WHS Act 2012 (SA), includes any place and, in particular, includes: <ul style="list-style-type: none"> > any land, building or part of any building > any vehicles, vessel or aircraft > any installation on land, on the bed of any waters or floating on any waters > any tent or movable structure |
| preparation (of drugs) | handling of cytotoxic drugs up to the stage of administration to a patient – includes manufacture, forming tablets and capsules, preparing a pre-measured single dose unit (e.g. drawing liquid cytotoxic drug into a syringe from a vial), and crushing or dissolving tablets or emptying capsules to prepare part doses |
| R | |
| reasonable care | workers and others at a workplace, including visitors/members of the public/carers, must take 'reasonable care' to ensure their own safety and wellbeing whilst in the workplace |
| reasonably practicable | in relation to a duty to ensure health and safety, 'reasonably practicable' means that which is, or was at a particular time, reasonably able to be done in relation to ensuring health and safety, taking into account and weighing up all relevant matters |
| research chemical | a substance or mixture that— (a) is manufactured in a laboratory for genuine research; and (b) is not for use or supply for a purpose other than analysis or genuine research |
| respirator | see respiratory protective equipment |
| respiratory protective equipment | equipment designed to prevent inhalation of contaminated air |
| restricted carcinogen | a substance— (a) listed in the <i>Work Health Safety Regulations 2012 - Schedule 10, table 10.2, column 2</i> for a use listed in column 3; and (b) present in a concentration of— (i) for a solid or liquid—0.1% or more, determined as a weight/weight (w/w) concentration; and (ii) for a gas—0.1% or more, determined as a volume/volume (v/v) concentration |
| risk | a risk is the likelihood that a hazard will cause illness or injury in the conditions of its use – the risk to health and safety usually increases with the severity of the hazard, the amount of hazardous chemical used and the duration and frequency of exposure |

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| risk assessment | evaluation of the probability that an adverse health effect may occur under the conditions that are likely to develop – a risk assessment of the use of a chemical will take account of its toxicity, the frequency and duration of exposure, risk control measures in use (engineering, administrative or personal protective equipment) and their effectiveness, and conditions of use |
| risk control measure | control of factors associated with an increase in the probability of a toxic effect occurring – there is an ordered priority for selection of the means to minimise the level of an occupational exposure, ranked from most desirable form of control to least desirable – elimination, substitution, isolation, engineering controls (e.g. local exhaust ventilation), administrative controls, personal protective equipment. The type of control measure to implement is determined as per the hierarchy of risk controls |
| risk management | analysis and judgment that uses the results of risk assessments to produce decisions about environmental actions to be initiated – i.e. the giving of priorities to various risks, the delivery of risk-averting outcomes and the continuing audit of outcomes and trends |
| RPE | see <i>respiratory protective equipment</i> |
| S | |
| safety data sheet (SDS) | <p>Safety Data Sheet means a safety data sheet prepared under WHS regulation 330 or 331. In addition:</p> <p>A Safety Data Sheet (SDS) is a document prepared by the manufacturer or importer of a chemical that describes the properties and uses of that chemical that is its, identity, chemical and physical properties, health hazard information, precautions for use and safe handling information. It will conform to the requirements of WHS Regulation 330 or 331.</p> <p>Other chemical management databases may provide a SDS for a particular chemical which can be used for reference but legislative requirements state that a supplier SDS is required before the first supply of that chemical..</p> |
| SHPA | Society of Hospital Pharmacists of Australia |
| specific test | diagnostic or screening test where a positive result rules in the disease with a high degree of confidence |
| safe work procedure(s) | a document that identifies the hazards and risk control measures associated with a task / activity and considers the best practice approach of completing it (e.g. the operation of plant or equipment and explains how to operate plant safely) |
| SLS | Safety Learning System – the electronic system for the reporting of both patient and worker Hazards, Incidents and Injuries affecting Work Health and Safety and Patient Safety are reported via the Safety: Safety Learning System (SLS) using the SLS web form |
| sterile | free from living organisms |
| structure | <p>means anything that is constructed, whether fixed or moveable, temporary or permanent, and includes—</p> <p>(a) buildings, masts, towers, framework, pipelines, transport infrastructure and underground works (shafts or tunnels); and</p> <p>(b) any component of a structure; and</p> <p>(c) part of a structure</p> |
| substitution | a risk control measure that substitutes a hazardous chemical or process with a less hazardous one |
| supplier | an obligation holder as per the WHS Act 2012 (SA) |

| T | |
|--------------------------|--|
| telophase | the last of four stages in the division of a single body cell into two identical cells |
| teratogen | agent capable of causing harm to an embryo or foetus to produce birth defects |
| U | |
| UN Number | <p>in relation to dangerous goods:</p> <ul style="list-style-type: none"> > the number assigned to the dangerous goods by the United Nations Committee of Experts on the Transport of Dangerous Goods > the substance identification serial number shown in the list of dangerous goods mentioned in appendix 2, column 1 of the ADG code (6th edition, 1998) – e.g. cytotoxic drugs that meet the classification criteria of Class 6.1 are listed in the ADG code as UN 2810 or UN 2811 |
| urostomy | diversion of urine away from a diseased or defective bladder through a surgically created opening in the skin of the abdominal wall |
| use (of cytotoxic drugs) | includes administration, preparation, handling, storage, movement and disposal of cytotoxic drugs and related waste |
| V | |
| vesicants | cytotoxic drugs that induce tissue damage and necrosis |
| W | |
| WHS representative | a work health and safety representative(s) elected by workers |
| work | a person completes for a PCBU and/or responsible agency |
| worker | a person carrying out work in any capacity for SA Health. Workers include, but not limited to, employees, contractors, subcontractors, employees of contractors / subcontractors, employees of labour hire companies that have been assigned to work in the business, an apprentice or trainee, police officers, students (including dental, medical, nursing students contributing to health service provision and students gaining work experience) and volunteers |
| workplace | an environment where work is carried out for business or undertaking and includes any place where a worker goes, or is likely to be, while at work. This includes a vehicle, vessel, aircraft or other mobile structure for conducting business or undertaking. Any area of attendance by a SA Health worker in the community becomes a workplace (e.g. paramedic, midwife, community nurse) |
| work injury | <p>an injury to a person that requires first aid or medical treatment if the injury was caused by work, a workplace, a work activity or specified high risk plant;</p> <p>the recurrence, aggravation, acceleration, exacerbation or deterioration of an existing injury in a person if first aid or medical treatment is required for the injury; and it was caused by work, a workplace, a work activity or specified high risk plant;</p> <p>any serious bodily injury, if the injury was caused by work, a workplace, a work activity or specified high risk plant</p> |
| workplace incident | an incident resulting in a person suffering a work injury or a work-related injury or an incident resulting in a dangerous event |
| worker representative | a person with or without managerial responsibilities, elected by members of a workgroup for representation in work health and safety matters |

Appendix 2

References and Information Sources

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

South Australian Acts and Regulations

- > *Controlled Substances Act 1984 (SA)*
- > Controlled Substances (Poisons) Regulations 2011
- > Dangerous Goods Transport Regulations 2008
- > *Dangerous Substances Act 1979*
- > Dangerous Substances Regulations 2002
- > *Environment Protection Act 1993 (SA)*
- > Environment Protection Regulations 2009
- > Environment Protection (Movement of Controlled Waste) Policy (2014)
- > Environment Protection (Waste to Resources) Policy 2010
- > *Work Health and Safety Act 2012 (SA)*
- > Work Health and Safety Regulations 2012 (SA)

Codes of Practice and Standards

- > Australian Commission on Safety and Quality in Health Care (2015); National Standard for User-applied Labelling of Injectable Medicines, Fluids and Lines,
- > International Air Transport Association (IATA); *Dangerous Goods Regulations 51st Edition*.
- > Safe Work Australia; Code of practice - Labelling of Workplace Hazardous Chemicals
- > Safe Work Australia; Code of practice – Managing risk of Hazardous Chemicals in the Workplace
- > Safe Work Australia; Code of Practice – How to Manage Work Health and Safety Risks
- > Safe Work Australia; Code of practice – Preparation of Safety Data Sheets for Hazardous Chemicals in the Workplace
- > Safe Work Australia; Hazardous Substances Information System - Guidance Material for Hazard Classifications
- > Safe Work Australia; Hazardous Substances Information System
- > Safe Work Australia; GHS Hazardous Chemical Information List
- > Safe Work Australia; GHS HSIS Consolidated Listing
- > Safe Work Australia; HSIS Guidance Material for Exposure Standards Data
- > Safe Work Australia; Workplace Exposure Standards for Airborne Contaminants
- > Safe Work Australia: Globally Harmonised System of Classification and Labelling of Chemicals (GHS)
- > Safe work Australia: Health Monitoring for Exposure to Hazardous Chemicals – Guide for Workers 2013
- > Safe Work Australia: Health Monitoring for Exposure to Hazardous Chemicals- Guide for Medical Practitioners 2013
- > Safe Work Australia: Hazardous Chemicals requiring Health Monitoring 2013
- > Society of Hospital Pharmacists of Australia; Standards of practice for the safe handling of cytotoxic drugs in pharmacy departments, *J Pharm Pract Res* 2005 35(1): 44-52
- > South Australian Environment Protection Authority; *Hazardous Waste Strategy*
- > South Australian Environment Protection Authority; *EPA Guidelines on Medical Waste – Storage, Transport and Disposal*
- > Society of Hospital Pharmacists of Australia; *Standards of practice for the transportation of cytotoxic drugs from pharmacy departments*. *Aust J Hosp Pharm* 2000 30(3): 116-17

- > Society of Hospital Pharmacists of Australia; Standards of Practice for the *Provision of Oral Chemotherapy for the Treatment of Cancer*. J Pharm Pract Res 2007 37(2): 149-52
- > The Australian Dangerous Goods Code Edition 7.3
- > The National Environment Protection (Movement of Controlled Waste between States and Territories) Measure 2012
- > The Poisons Standard – The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)

Australian Standards

- > AS/NZS 14644.5-2006 *Cleanrooms and associated controlled environments – operations*
- > AS/NZS 1715-2009 *Selection, use and maintenance of respiratory protective equipment*
- > AS/NZS 1716-2003/Amdt 1-2005 *Respiratory protective devices*
- > AS/NZS 2243.1-2005 *Safety in laboratories – Planning and operational aspects*
- > AS/NZS 2243.2-2006 *Safety in laboratories – Chemical aspects*
- > AS/NZS 2243.3-2010 *Safety in laboratories – Microbiological aspects and containment facilities*
- > AS/NZS 3816:1998 *Management of clinical and related wastes*
- > AS/NZS ISO 31000:2009 *Risk Management – Principles and Guidelines*
- > AS/NZS 2243.8:2006 *Safety in laboratories – Fume cupboards*
- > AS/NZS 3831-1998 *Waste management – Glossary of terms*
- > AS/NZS 2982.1-2010 *Laboratory design and construction – General requirements*
- > AS/NZS 4146 *Laundry Practice*
- > AS 1386-1989 *Cleanrooms and clean workstations*
- > AS 2243.4-1998 *Safety in laboratories – Ionizing radiations*
- > AS 2243.5-2004 *Safety in laboratories – Non-ionizing radiation – Electromagnetic, sound and ultrasound*
- > AS 2243.6-2010 *Safety in laboratories – Plant and equipment aspects*
- > AS 2243.7-1991 *Safety in laboratories – Electrical aspects*
- > AS 2243.9-2009 *Safety in laboratories – Recirculating fume cabinets*
- > AS 2243.10-2004 *Safety in laboratories – Storage of chemicals*
- > AS 2567-2002 *Laminar flow cytotoxic drug safety cabinets*
- > AS 2639-1994 *Laminar flow cytotoxic drug safety cabinet – Installation and use*
- > AS 4031-1992 *Non-reusable containers for the collection of sharp medical items used in health care areas*
- > AS 4031-1992/Amdt1-1996 *Non-reusable containers for the collection of sharp medical items used in health care areas*
- > AS 4273-1999 *Guidelines for the design, installation and use of pharmaceutical isolators*
- > AS 4273-1999/Amdt1-2000 *Guidelines for the design, installation and use of pharmaceutical isolators*
- > HB 202-2000 *A management system for clinical and related wastes – Guide to application of AS/NZS 3816-1998, Management of clinical and related wastes. Standards Australia*
- > HB 436-2005/Amdt 1-2005 *Risk management guidelines – Companion to AS/NZS 4360: 2004, Risk Management. Standards Australia*

SA Health Documents

- > SA Health; Standards for Chemotherapy Services in South Australia
- > SA Health; Central Training Manual – Clinical Pharmacy Services – Cancer and Chemotherapy
- > SA Health; Central Training Manual – Production Pharmacy Services – Cytotoxic and Other Hazardous Drugs
- > SA Health; Statewide Framework for Chemotherapy Education and Assessment; An Integrated Model for South Australia
- > SA Health; Risk Management Policy
- > SA Health; Work Health Safety and Injury Management Policy

- > SA Health; Performance Review and Development (PR&D) Policy
- > Management of the Healthcare Environment to Minimise the Risk of Transmission of Infection Policy
- > SA Health; Fact Sheet: Guide to dilution for chlorine-based disinfectant solutions; Communicable Disease Control Branch
- > SA Health; Blood and Body Fluid Exposure Management Procedure
- > SA Health; SA Pharmacy Recommendations (2014) Occupational Risk Assessment for the Clinical Use of Monoclonal Antibodies (MABS).

Additional Reference Materials

Australian

- > Australian Commission on Safety and Quality in Health Care; Medication Alert No. 2 December 2005
- > Australian Council for Safety and Quality in Health Care; Medication Alert No 2, December 2005
- > Australian Medicines Handbook July 2014 (online). Available at: <http://www.amh.net.au>
- > Cancer Australia; Cancer Learning On-line
- > Cancer Institute of NSW: eviQ Cancer Treatments On-Line 2014
- > Cancer Nurses Society of Australia; Position Statement on the Minimum Education Requirements for Nurses involved in the Administration of Anti-Cancer Drugs within the Oncology and Non-Oncology Setting 2010
- > Clinical Oncology Society of Australia; Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy 2008
- > Department of Health, Western Australia. *Guidelines for the administration of intravesical cytotoxic and immunotherapeutic drugs within the hospital setting*. Perth: Health Networks Branch
- > National Industrial Chemical Notification and Assessment Scheme (NICNAS) www.nicnas.gov.au
- > NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings 2014
- > National Occupational Health and Safety Commission; *Guidelines for Health Surveillance 1995*
- > National Occupational Health and Safety Commission; *Competencies for Health Surveillance 1998*
- > NHMRC Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010)
- > Pharmaceutical Society of Australia (PSA); *Australian Formulary and Handbook 21st Edition 2010*
- > Queensland Department of Industrial Relations; Guide for the Handling of Cytotoxic Drugs and Related Waste 2005
- > South Australian Environment Protection Authority's Waste Strategy 2011-2015
- > South Australian Environment Protection Authority; EPA Guidelines on Medical Waste – Storage, Transport and Disposal 2003
- > The Australian National Cancer Nursing Education Project; EdCaN On-line
- > The Australian Pharmaceutical Formulary and Handbook (APF)
- > Waste Management Association of Australia (WMAA); The Industry Code of Practice for the Management of Clinical and Related Wastes 6th Ed 2010
- > WorkCover NSW; Cytotoxic Drugs and Related Waste – Risk Management Guide 2008
- > WorkCover NSW; Improved guide to reduce safety risks with cytotoxic drugs
- > WorkSafe Victoria; Handling Cytotoxic Drugs in the Workplace: Managing Health and Safety Risks Associated with the Handling of Cytotoxic Drugs in the Healthcare Industry 2003
- > WorkCover Victoria; Training Competencies: Handling Cytotoxic Drugs in Health Care Establishments 1997

International

- > American Society of Health-System Pharmacists (ASHP); Guidelines on Handling Hazardous Drugs Am J Health-Syst Pharm 2006 63
- > International Society of Oncology Pharmacy Practitioners (ISOPP); *Standards of Practice: Safe Handling of Cytotoxics*, J Oncol Pharm Pract 2007, 13 Suppl:1-81
- > Cancer Drug Manual (Drug Index Professional). British Columbia Cancer Agency (BCCA). June 2012
- > PIC/S Guide to “Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE010-4) 2014

- > US CDC/NIOSH; *Guidelines on Occupational Exposure to Antineoplastic Agents*
- > World Health Organisation; *Safe Management of Wastes from Health Care Activities 1999*

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Appendix 3

Monoclonal Antibodies (MABs)

Minimum safe handling requirements to protect workers who prepare, administer and dispose of monoclonal antibodies (MABs) are available in *The Australian consensus guidelines for the safe handling of monoclonal antibodies for cancer treatment by healthcare personnel (2014)*. These provide risk management strategies for safely managing occupational exposure when handling MABs used to treat a range of conditions, and specific evidence-based recommendations for the safe handling of parenteral MABs used in cancer treatment. A summary of the *Australian consensus guidelines* recommendations is provided below.

Individual health facilities should assess clinical and operational factors taking into account the following recommendations:

I. The work health and safety risk to healthcare personnel handling MABs is dependent on the internal risk exposure and toxicity.

- > Dermal absorption is not considered to be a viable mechanism of internalisation during any phase of preparation of doses for administration or administration.
- > Inhalation of aerosolised MABs is a potentially viable route of internalisation during preparation of doses for administration (not during administration) as workers may be exposed to powdered or aerosolised liquid particles. Absorption via the nasal mucosal surface is considered to be the most likely potentially viable route.
- > Although oral absorption may occur via hand to mouth contamination with MABs, systemic absorption with occupational exposure via the oral route is considered highly unlikely.

II. From a work health and safety perspective, it would be prudent for MABs to require greater handling precautions than other non-hazardous injectable medications however they do not warrant full cytotoxic precautions, with exceptions only where sufficient evidence exists of safety concerns for a specific MAB

- > All currently available MABs have a similar low risk of internalisation with occupational exposure levels (class effect)
- > MAB admixtures should not be labelled as “cytotoxic” or “treat as cytotoxic” unless there is evidence to the contrary.
- > Safe handling procedures are recommended to mitigate potential work health and safety risks.

III. Safe handling procedures should be stratified according to

- i. Healthcare worker role (preparation, administration, transportation and disposal)
 - ii. Health considerations such as pregnancy
- > Workers involved in the preparation of doses for administration have the highest risk of occupational exposure
 - > Without evidence to demonstrate safety, workers with relevant health considerations (pregnancy, immunosuppression or other) should avoid the preparation of doses for administration where exposure risk is the greatest.

IV. Procedures for the handling of waste generated during the preparation or clinical use of MABs are as follows:

- i. Waste products generated during the preparation of MABs should be disposed as per safe work procedure for parenterally administered agents, i.e. not classified as cytotoxic waste
- ii. Waste products and/or bodily fluids of patients who have been administered MABs should be disposed as per safe work procedures for parenterally administered agents, i.e. not classified as cytotoxic waste

Exposure to waste products does not present work health and safety risk to workers beyond that of other parenterally administered agents.

Exposure to patient waste products and/or bodily fluids does not present work health and safety risk to workers beyond that of other patient waste products.

V. The range of available interventions/safeguards to minimise occupational exposure are:**i. Personal Protective Equipment (PPE)**

- Gloves
- Gowns
- Respirator mask
- Protective eyewear

ii. Discipline based aseptic technique**iii. Isolator cabinet****iv. Cytotoxic Drug Safety Cabinet (CDSC)****v. Closed System Drug Transfer Devices (CSDTDs)**

Use of these should be risk stratified according to risk of internal exposure and toxicity.

- > Gloves are not warranted for either the preparation of doses for administration or handling of MABs from an occupational exposure perspective; they may be considered as part of good aseptic technique.
- > Gowns/and or coveralls are not warranted for either the preparation of doses for administration or handling of MABs.
- > Respirator masks should be worn during the preparation of doses for administration where the risk of splashing and aerosolisation is greatest. Protective eyewear should be worn during the preparation of doses for administration where the risk of splashing is greatest.
- > Aseptic technique should be implemented for the preparation of injectable doses for administration, as per any other injectable medicines.
- > Isolator cabinets are not required for the preparation of doses for administration.
- > CDSCs are not required for the preparation of doses for administration.
- > CSDTDs are not required for the preparation of doses for administration.

VI. That the following factors (not related to occupational exposure risk) should be considered when determining preparation and handling recommendations**i. Vial sharing****ii. Complexity of preparation****iii. Medication error**

- > Sites should follow local procedures with regards to the practice of vial sharing of parental medicines.
- > Complex or multiple vial preparations (>3 vials) may be best undertaken by experienced and trained staff.
- > MABs need not be considered within the A-PINCH 'high risk' medication list.

VII. MAB handling recommendations consider work health and safety risks as well as operational and clinical factors.

To access the complete Australian consensus guidelines see

http://www.wcmics.org/guidelines/20140422_MABs_Guidelines.pdf

SA Pharmacy Recommendations

1. MABs are not classified as hazardous substances.
2. The potential for internalisation by staff during occupational handling is extremely low.
3. The potential for harm during the occupational handling of MABs in clinical settings is extremely low.
4. Preparation and administration of MABs should be in accordance with the approved product information for each product with precautions taken to protect the product and handler such as hand washing and the wearing of gloves, gowns and appropriately fitted face masks.
5. There is no justification or requirement for full cytotoxic precautions.
6. There is no justification or requirement for the use of closed preparation/administration systems when using MABS. If, for specific local reasons, closed systems are used for MAB or other product preparation, training in their use is essential to ensure safe and effective utilisation.

7. The general management of storage, transport and spills of MABs and the handling of body wastes from such treated patients does not require any deviation from that required for any non-hazardous drug.
8. The individual approved product information should be consulted for any product-specific requirements e.g. refrigeration. In particular the information for all new MABs should be reviewed to determine if they are a cytotoxic drug conjugate, e.g. Gemtuzumab.

The individual approved product information should be consulted for any product-specific requirements, in particular for new MABs to determine if they are a cytotoxic conjugate.

MABs conjugated to cytotoxic compounds drugs are considered cytotoxic and should be handled accordingly.

References

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- SA Health; SA Pharmacy Recommendations (2014) *Occupational Risk Assessment for the Clinical Use of Monoclonal Antibodies (MABS)*.

Appendix 5

Risk Assessment Tool for Cytotoxic Drugs and Related Wastes

Rationale:

This risk assessment is required to be completed, in consultation with the workgroup Health and Safety Representative (HSR) where appropriate, prior to introducing or trialling any cytotoxic drug, or

- > implementing risk control measures for safe preparation and administration
- > in ensuring appropriate processes are in place to manage related waste
- > to support the development of safe work procedures (SWPs).

Name of assessor: _____ Date of assessment: _____

Name of HSR (if involved in consultation): _____

Site/location: _____ Department: _____

Product name: _____ Supplier: _____

Safety Data Sheet (SDS) available? Yes No Date of SDS: _____

Current (Within 5 years of issue): Yes No

Describe how and where this cytotoxic drug will be used: _____

Please answer the following questions. Refer to the SDS for information









1. DANGEROUS GOODS CLASSIFICATION AND TRANSPORT CONSIDERATIONS

Is it a Dangerous Goods: Yes No

If yes,
Class: (Cytotoxic Drugs are normally classified as Class 6) _____ UN Number: _____

Are any special transport requirements required for transporting the cytotoxic drug? Yes No

If yes, name transport requirements: _____

| | | | | | | | | |
|---|--------------------------|---------------------------|---|--------------------------|----------------------|--|--------------------------|------------------------------------|
|  | <input type="checkbox"/> | Explosive |  | <input type="checkbox"/> | Gases |  | <input type="checkbox"/> | Flammable Liquid |
|  | <input type="checkbox"/> | Spontaneously Combustible |  | <input type="checkbox"/> | Oxidising Substances |  | <input type="checkbox"/> | Toxic & Infectious Substances |
|  | <input type="checkbox"/> | Radio active Material |  | <input type="checkbox"/> | Corrosive Substances |  | <input type="checkbox"/> | Miscellaneous (Incl Environmental) |

2. Is it a Hazardous Chemical? Yes No

(*Note: Treat all chemicals as being hazardous until otherwise defined)

Chemically active ingredient/s:

3. Globally Harmonised System of Classification and Labelling of Chemicals (GHS) CLASSIFICATION- Physical, Health and Environmental information

Physical Hazards:



Explosive



Gas under pressure



Flammable



Oxidising



Corrosive

Health Hazard:



Acute Toxicity



Health Hazard



Chronic Health Hazard

Environmental Hazard:



Environmental harm

Comments:

4. INCOMPATIBLE Products

Comments:

5. FORM OF THE Cytotoxic Drug

Liquid Solid tablet Powder Creams, ointments and lotions for topical application

6. Potential routes of EXPOSURE – During the preparation, administration and waste disposal

Can the cytotoxic drug enter the body via:

Ingestion: Yes No Inhalation: Yes No Skin absorption: Yes No

Eyes / Mucus Membrane absorption: Yes No

Comments:

IF THIS PRODUCT IS CURRENTLY USED, OR IS INTENDED TO BE USED, PLEASE CONTINUE WITH ASSESSMENT.

Note that the supplier SDS must provide information for the management of large quantities of the cytotoxic drug. When completing this assessment, please take into consideration:

- > the quantity to be used, handled and transported
- > the purpose

Risk Assessment

STEP 1

- > Is the facility required to be licensed under the Environmental Protection Act? Yes No
- > If 'yes', Name of Licence: _____ Licence Number: _____
- > Is the cytotoxic drug classified as a prohibited or restricted carcinogen requiring Safework SA authorisation? Yes No
Authorisation number: _____
- > Is a cytotoxic drug safety cabinet (CDSC) available, if drug preparation is required? Yes No NA
(Refer to Section 6.3 – Reduce the risk through engineering controls)
- > Is a secondary barrier (high efficiency particulate air – HEPA) filter available? Yes No NA
(Refer to Section 6.3 – Reduce the risk through engineering controls)
- > Is a closed system drug administration/transfer device, or similar in use/available? Yes No NA
- > Does the cytotoxic drug require any special storage (bundling/locked cupboard/placarding) Yes No
- > Is Personal Protective Equipment (PPE) required as per manufacturer's recommendations (SDS) Yes No
Name PPE in use/to be used _____
- > Is there an effective process for managing spills? Yes No
(Refer to Section 14 – Spills)
- > Can waste products be disposed of safely in accordance with waste management legislation? Yes No
(Refer to Section 15 – Waste Management)
- > Are any special transport requirements required for transporting the cytotoxic drug? Yes No
- > For new cytotoxic drugs, will workers require training in the following?
 - Safe and effective use of the cytotoxic drug Yes No
 - Proper, safe and effective use and maintenance of PPE Yes No
 - First aid, emergency, waste management procedures Yes No
- > Has environmental monitoring, where cytotoxic drugs are prepared, been previously conducted? Yes No

STEP 2

Complete Safe work method statement / Risk Treatment Plan – *Appendix 5A*, in conjunction with the following attachments, to identify actions required, to ensure the cytotoxic drug is safe for use:

- > *Appendix 5B* – WHS Risk Matrix
- > *Appendix 5C* – Hierarchy of Controls (use this information on safety controls to determine/or review current control measures)
- > *Attachment 5D* – Decision Making Process for the Safe Handling of Cytotoxic Drugs.

STEP 3 – Assessment Outcome

From the risk assessment process, is this cytotoxic drugs safe to use? Yes No

If determined to be not safe, can an alternative arrangements be organised? Yes No
(Refer to Section 6.1 – Eliminate the hazard).

STEP 4 – Sign Off

Name (Manager): _____ Name (HSR): _____

Signature: _____ Date: _____

Signature: _____ Date: _____

Review Date (Every 2 years with review of SWP or when SDS is due to be updated i.e. every 5 years): _____

STEP 5

- > Develop safe work procedure(s), or review established SWPs to determine suitability
- > Train workers in SWPs
- > Review Risk Assessment and SWP as per scheduled review date.

Appendix 5a

Safe Work Method Statement (Job Safety Analysis)/Risk Treatment Plan (Action Plan)

Use of Cytotoxic Drugs and Management of Related Wastes

Refer to the following information: Supplier Safety Data Sheet (SDS); Appendix 5 -Risk Assessment Tool for Cytotoxic Drugs and Related Wastes; Appendix 5B – WHS Risk Matrix and Treatment Plan; Appendix 5C – Safety Controls Management using Cytotoxic Drugs (Hierarchy of Controls Process); Appendix 5D – Decision Making Process for the Safe Handling of Cytotoxic Drugs.

STEP 1: Complete the following analysis to determine if the substance is safe to use for preparation of cytotoxic drugs, and handling of related wastes, and to provide a basis for developing the safe work procedures (SWP).

| Job/Process/Task: | | Department: | | Date: | |
|---------------------------------|--|--|---|--|--|
| Names – Assessment Team: | | | | | |
| Site/Location: | | | | | |
| SUBSTANCE(S) To be used | DESCRIPTION OF USE (Briefly describe tasks or situations where substance is used and/or exposure may occur) | ROUTES OF EXPOSURE/ TYPE OF RISK/ HAZARD CLASSIFICATION | EXISTING SAFETY MEASURES IN PLACE (Available/ in place e.g. laminar flow cabinet; SWPs, PPE) | RISK SCORE (Refer Appendix 5B) Take into consideration existing control measures | CONCLUSION ABOUT RISKS > Can risks be controlled? > Is there any alternative supply mechanisms? (Refer to Appendices 5C and 5D) |
| | | | | | |

FURTHER ACTION REQUIRED (Where risk assessment identifies that additional control measures are required):

Assessor's signature: _____ Date: _____ HSR's signature: _____ Date: _____
 Date of review: _____

STEP 2: If risks can be controlled, and process is considered safe to use, develop SWP and train staff in SWP prior to using products.

STEP 3: Attach Safe Work Method Statement (Job Safety Analysis)/Risk Treatment Plan to Risk Assessment Tool – Cytotoxic Drugs and Related Wastes for future review.

Appendix 5b

WHS Risk Matrix and Treatment Plan

Complete the RISK MATRIX to determine the severity of the risk and the appropriate control measure. Use the Hierarchy of Control to determine which level of risk control is suitable. Note a combination of risk control measures may also be appropriate to reduce the risk to acceptable levels.

Upon identification of a potential risk, through hazard identification and/or incident reported, this document will guide you in determining the likelihood and consequence of the risk and the level of action required to control the risk. Follow steps 1 – 4 for guidance in assessing the Risk Rating Priority. Please consider effectiveness of any current risk control measures, which may contribute to reducing the risk.

Enter the corresponding Consequence, Likelihood and Risk Rating and record actions to be undertaken to mitigate the risk to a controlled level of moderate or below, on the WHS Risk Treatment Plan.

When determining the rating, consider the effectiveness of any current risk controls, which may already contribute to reducing the risk.

Refer to SA Health Work Health, Safety and Injury Management (WHSIM) procedure CPR015 Mechanisms for Hazard Identification and Risk Management and SA Health Risk Management Framework.

Strategic and Operational Risk Assessment Matrix

STEP 1: CONSEQUENCE (Impact) RATING GUIDE

| Level | Category | Clinical | Financial | Our People | Legal, Policy and Regulatory | Organisation / Consumer | Corporate Reputation and Image |
|-------|---------------|---|--|--|---|--|--|
| 1 | Insignificant | Negligible clinical event resolved without impact on Consumer or organisation | Financial loss of either less than \$250,000 or 0.05% of budget | Negligible staff injury or near miss accident. Insignificant industrial grievance | Immaterial legal, regulatory or internal policy failure without penalty implication | Event with negligible impact on delivery of services to Consumers. Internal inconvenience only | One off negative media coverage only and no reputation impact |
| 2 | Minor | Clinical event resolved with minimal short term impact on Consumer or organisation | Financial loss of either between \$250,000 to \$1 million or between 0.05% to 0.2% of budget | Staff lost time injury. Local temporary poor engagement. Industrial grievance resolved internally | One-off minor legal, regulatory or internal policy failure resolved without penalty | Event with short term impact on delivery of services. Some impact on Consumers or Partners | Isolated adverse media exposure. Temporary minor negative impact on reputation |
| 3 | Medium | Clinical event resulting in temporary injury or impact with considerable effect on Consumer or organisation. Internal investigation required. May require external mediation | Financial loss of either between \$1 to \$5 million or between 0.2% to 1% of budget | Temporary injury to staff. Ongoing widespread engagement issues. Industrial disputation mediated with no major penalty | Repeated legal, regulatory or internal policy failure with penalty implications requiring internal investigation | Event requiring considerable remedial action with moderate impact on Consumers or Partners. Temporary loss of important information | Repeated isolated negative reporting in media. Temporary breakdown in key relationship. Short term reputation damage |
| 4 | Major | Clinical event resulting in serious permanent injury, requiring internal and medico legal investigation, external mediation, major penalties or compensation payments | Financial loss of either between \$5 to \$10 million or between 1% to 2% of budget | Serious permanent injury to staff. Entrenched engagement problems. Inability to recruit staff with necessary skills in key areas. Staff walkout and Industrial stoppages | Systemic legal, regulatory or internal policy failure with major penalty requiring extensive internal inquiry and external review | Event with major impact on delivery of services. Major impact on Consumers or Partners. Temporary loss of critical information | Widespread negative reporting in media leading to high-level independent investigation with adverse findings and longer term reputation damage. Premier or Ministerial involvement / intervention by Cabinet. Breakdown in key relationship(s) |
| 5 | Critical | Failure in clinical governance processes/ systems resulting in fatality requiring extensive internal and medico legal investigation, coroner's notification, significant penalties or compensation payments | Financial loss of either greater than \$10 million or 2% of budget | Staff fatality. Simultaneous loss of a number of critical staff (e.g. Executive) | Substantial failure in internal governance and control structures resulting in Royal Commission and significant penalty | Event with significant impact on delivery of services across SA Health for an extended period. Significant impact on Consumers or Partners. Permanent loss of critical information | Sustained adverse media exposure. Total loss of confidence within the community and with the Government. Parliamentary enquiry. Serious long term impact on reputation |

NB: Financial impact is assessed in context of your Unit/Division/Department/Health Network/Service budget (funding allocation); the highest financial impact must be applied.

Strategic and Operational Risk Assessment Matrix

STEP 2: LIKELIHOOD RATING GUIDE (Consider historical factors, such as whether the risk has happened before in the past and how frequently it has occurred)

| Level | Category | Probability Description |
|-------|----------------|---|
| 1 | Rare | Once in 10 YEARS < 1% probability of occurrence Event may only occur in exceptional circumstances in the long-term future |
| 2 | Unlikely | Once in 5 YEARS 1% - 20% probability of occurrence Event could occur but not anticipated in the foreseeable future |
| 3 | Possible | Once a YEAR 20% - 50% probability of occurrence Event could occur within short-term timeframe |
| 4 | Likely | Once a MONTH 50% - 99% probability of occurrence Event could occur in most circumstances |
| 5 | Almost Certain | Once a WEEK or DAILY >99% probability of occurrence Event is expected to occur in most circumstances, risk is occurring now |

ACTION REQUIRED*

Refer SA Health Risk Management Framework for details

STEP 4: RISK EVALUATION Risk rating priority related to hazard management (action required)

| Controlled Level of Risk (Current Risk) | Action Description |
|---|---|
| Extreme | Immediate action required and commitment of executive, Treatment Plan prepared and documented in < 2 weeks (if applicable), escalate to SA Health Chief Executive via Health Network or Service Chief Executive Officer / Department Executive if unable to be mitigated to a lower level and not already reported, active monitoring of controls |
| High | Executive attention required Treatment Plan documented in < 1 month, monitoring of controls at least quarterly |
| Moderate | Management responsibility must be specified & accountability defined, Treatment Plan optional based on benefit to business, periodic ongoing monitoring of controls |
| Low | Responsibility must be specified, Treatment Plan optional based on benefit to business (NB: requires control evaluation to be completed), monitoring by Management, consider excess or redundant controls |

STEP 3: RISK ASSESSMENT MATRIX (indicating priority & action)

Use the selected Likelihood and Consequence to determine the intersection of the relevant row and column; this will determine your risk rating.



Risk Control (Hierarchy of Risk Control Process)

Strategies to support development of Risk Treatment Plans; elimination is the most effective risk control measure.

| | | |
|-------|--------------------------------------|--|
| Best | Elimination | Complete removal of hazard, or risk of exposure to the hazard e.g. remove the problem / process |
| | Substitution | Replace hazardous plant, equipment, substance or work process with a less hazardous one |
| | Engineering Controls | May include: redesigning / re-engineering the workplace or maintenance, using a patient lifter, fixing guards |
| Least | Administration Controls | May include: introducing new work practices, placing signs, training in safe work procedures / safe work method statements. |
| | Personal Protective Equipment | Use safety shoes, goggles, splash glasses, gloves etc. The least effective method of control but may be required to protect workers from hazards in the workplace, in conjunction with other controls. |

Risk Treatment Plan

Complete the **Risk Treatment Plan** to facilitate the implementation of risk control measures, and to provide evidence of hazard management activity.

Record hazards identified and their description followed by the current risk control measures (if any), risk rating priority; planned actions to be taken; responsible person who will undertake the action; the timeframe that the activity is to be completed and outcome.

Department: _____

Date plan established: _____

Completed by: _____ Signature: _____ Date: _____

| Hazard Identified | Description | Current Risk Control Measures | Risk Rating Priority | Planned Treatment | Treatment Owner | Treatment Date | Outcome |
|-------------------|-------------|-------------------------------|----------------------|-------------------|-----------------|----------------|---------|
| | | | | | | | |
| | | | | | | | |
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Appendix 5c

Hierarchy of Risk Control Process

Risk Control Measures Involving Cytotoxic Drugs

ELIMINATION is the most effective control: apply the highest category possible.

| | Safety Measure | Explanation and Examples |
|----------------------|---|--|
| ↑ MOST EFFECTIVE | Elimination, Substitution or Replacement | Eliminate the use of the substance. Examples: <ul style="list-style-type: none"> > Total elimination of substance > Prevent exposure or minimise by elimination of certain processes. |
| | | Use a safer substance or a safer form of the substance. Examples: <p>Safer substance</p> <ul style="list-style-type: none"> > A safer alternative drug is identified. <p>Safer form or process</p> <ul style="list-style-type: none"> > Can alternative arrangements be made for purchase and supply of prepared cytotoxic drugs in a single dose delivery from a commercial source? > Outsource cytotoxic drug preparation work to a licensed manufacturer that specialises in this work > Establishing supply arrangements from a health service that has the required facilities, equipment and trained personnel to provide prepared cytotoxic drug doses. |
| | Isolation | Isolate the source of the hazard. Examples: <ul style="list-style-type: none"> > Use a closed system transfer device > Use of an alternative transfer device which is able to provide a closed system for at least some of the steps in preparation. |
| | Engineering | Physical controls (such as plant/equipment) that eliminate or reduce substances being produced; stop or contain substances; separate people or property from the substance by distance or barriers; or limit the area of contamination in the event of spills and leaks and meet recommended technical and safety standards. Examples: <ul style="list-style-type: none"> > Designing buildings that are compatible with the intended substances and designed to reduce contamination > Handling cytotoxic drugs in an enclosed area, such as a properly operational cleanroom with laminar cytotoxic drug safety cabinet (or closed system) > Drug packaging features in-built breakage prevention systems > Using a pharmaceutical isolator for drug preparation > Using bunding to reduce spillage > Using high efficiency particulate air (HEPA) filters which supply filtered air to the cleanroom and anteroom. Secondary containment is provided by maintaining the cleanroom at a pressure lower than that of the anteroom > Using needle-less drug administration systems or retractable needles. |
| | Administrative | Safe work procedures and methods employ best practice controls. Examples: <ul style="list-style-type: none"> > Drugs are stored in dedicated clearly marked storage areas, including refrigeration > Correct labelling of decanted solutions (same label as purchased product) > SDS are available at site of storage and use > Reducing the number of workers exposed > Reducing the duration and/or frequency of exposure > For dangerous goods, reducing the amount of goods stored and used > Ensuring safe interim storage of wastes > Effective work organisation layout and design > Cleaning up spills immediately > Ensuring no eating, drinking or smoking in areas where substances are used > Providing suitable washing facilities > Providing first aid facilities > Instructing staff on how to use substances/equipment safely > Testing competency of work in safe work processes > Ensuring working-alone processes are in place e.g. use of duress alarms > Controlled access to preparation areas > Effective management of contaminated laundry. |
| ↓ LEAST EFFECTIVE | Personal Protective Equipment (PPE) | Protective clothing and equipment for employees, supervisors, volunteers and visitors. Examples: <ul style="list-style-type: none"> > Coveralls and gowns > Gloves > Protective eyewear > Shoe covers or overshoes > Respiratory protective equipment (RPE) as recommended in AS/NZS 1715:1994 > Head covering. |

Appendix 5d

Decision Making Process for the Safe Handling of Cytotoxic Drugs

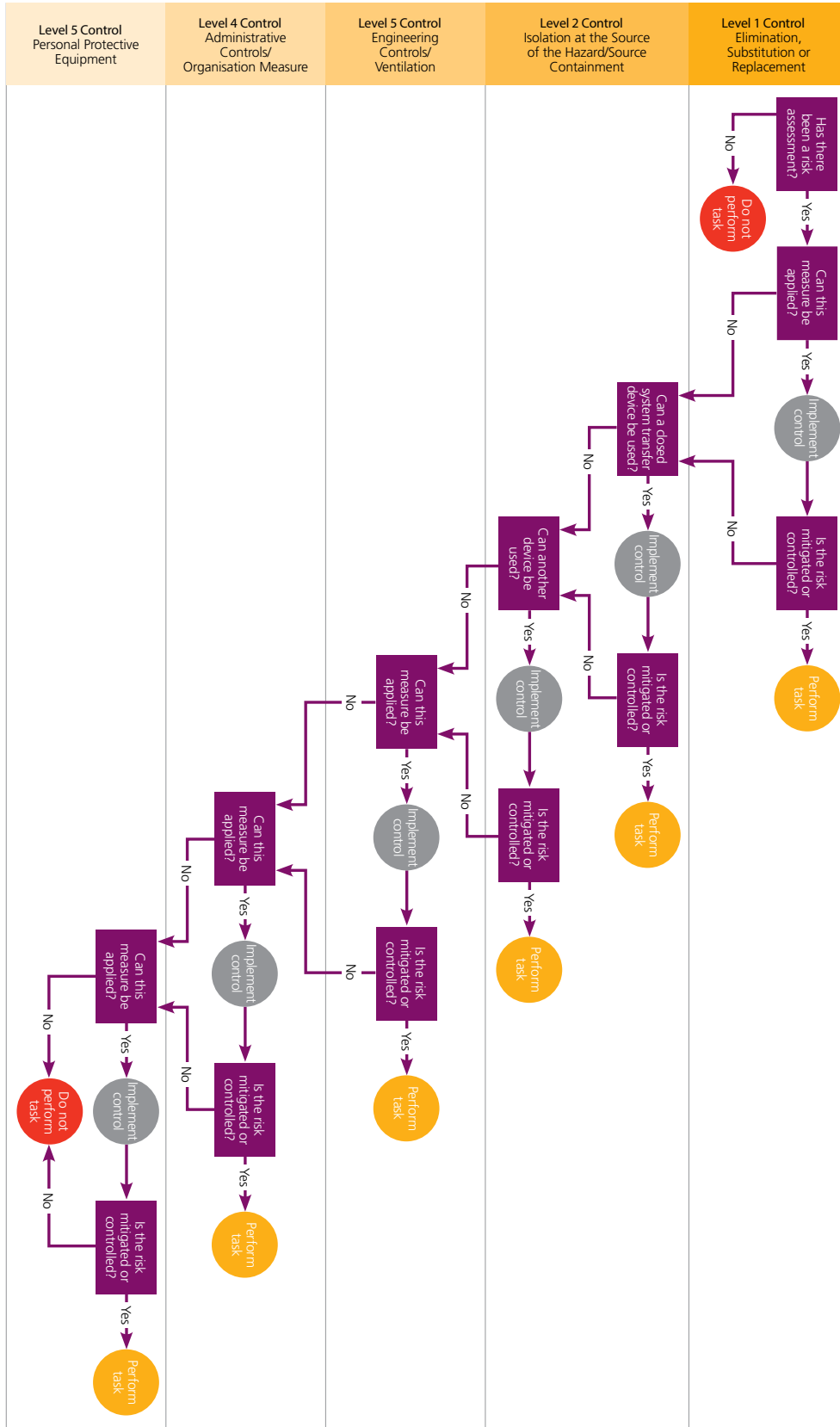


Figure 2: Decision making process for the safe handling of cytotoxic drugs

Appendix 6

Cytotoxic Drug Precautions Alert Proforma (example)

| | | |
|--|--|-----------------|
| <p style="text-align: center;">Cytotoxic Precautions Alert (Page 1 of 1)</p> | Affix Patient Identification Label Here | |
| | Surname | UR Number |
| | Given Name | DOB |
| | Address | Sex |
| | Suburb/Town | Post code |
| Precautions must be taken for up to 7 days after cytotoxic drug therapy | | |
| Therapy details | | |
| Cytotoxic drug given | Date | |
| | | |
| | | |
| | | |
| | | |
| | | |
| Cease cytotoxic precautions on: Date: / / Time: am / pm | | |
| Risk Control Measures: | | |
| Spill kit | Ensure access to a spill kit for spills management including spill of contaminated body fluids and waste | |
| Personal Protective Equipment (PPE) | Use correct PPE for handling potentially contaminated body waste, cytotoxic drug/ equipment disposal, spill clean-up and cytotoxic drug administration | |
| Waste management | Dispose of cytotoxic drug contaminated waste in cytotoxic bags and bins | |
| Cleaning contaminated equipment | Wash contaminated equipment and decontaminate surfaces with an appropriate agent | |
| Provision of precautionary information to community workers and carers/ relatives | Including provision of precautionary information to community workers who are may be planning a family, are pregnant or breast feeding | |
| Any special care requirements | | |
| Details of the worker (e.g. nurse) completing the alert: | | |
| Full name: | Signature | Date |
| For further information contact: Name of Health Service: | Client: | Contact Number: |

Appendix 7

Table of Cytotoxic Drugs and Excretion Rates

This table is intended as a guide for health care workers to assist in the safe handling of cytotoxic drugs. Compiled based on a drug's classification as "cytotoxic" according to the Australian Medicines Handbook¹, this is not a complete list of all cytotoxic drugs and generally cites only those approved for use in Australia. It does not include hazardous drugs that are not cytotoxic. Investigational drugs available via the Special Access Scheme or as part of clinical trials may be absent from this list. Reference should also be made to the drug's Safety Data Sheet when assessing handling risks.

Excretion rates are available only for selected cytotoxic agents based on guidelines from Cass and Musgrave².

| Drug name | Trade/Brand Name | Excretion Rate* | Precautionary time period following cytotoxic drug treatment when handling body waste (excreta)** | |
|------------------|--|--|---|--------|
| | | | Urine | Faeces |
| Azacitidine | <i>Vidaza</i> | | | |
| Azathioprine | <i>Imuran^{†a}</i> <i>Azathioprine^{†a}</i> <i>Thioprine^{†a}</i> <i>Azamun[†]</i> , <i>Azapin[†]</i> | | | |
| Bleomycin | <i>Bleo^a</i> | Urine: up to 68% in first 24 hours | 3 days | |
| Bortezomib | <i>Velcade</i> | | | |
| Busulfan | <i>Myleran[†]</i> , <i>Busulfex</i> | | | |
| Cabazitaxel | <i>Jevtana</i> | | | |
| Capecitabine | <i>Xeloda[†]</i> | | | |
| Carboplatin | <i>Carbaccord^b</i> | Urine: up to 60% in first 24 hours | 2 days | |
| Carmustine | <i>Gliadel</i> | Urine: up to 65% in first 24 hours | 4 days | |
| Chlorambucil | <i>Leukeran[†]</i> | | 2 days | |
| Cisplatin | <i>Cisplatin^a</i> | Urine: up to 75% in first 5 days | 7 days | |
| Cladribine | <i>Leustatin</i> | | | |
| Clofarabine | <i>Evoltra</i> | | | |
| Cyclophosphamide | <i>Endoxan[†]</i> , <i>Cycloblastin</i> | Urine: up to 62 % in first 48 hours | 3 days - in urine, sweat and saliva | 5 days |
| Cytarabine | <i>Cytarabine^a</i> | Urine: up to 90% in first 24 hours | 1 day | |
| Dacarbazine | | | 1 day | |
| Dactinomycin | <i>Cosmegen</i> | | | |
| Daunorubicin | <i>Daunorubicin</i> | | 7 days | 7 days |
| Docetaxel | <i>Docetaxel^b</i> , <i>Oncotaxel</i> , <i>Taxotere</i> | Urine: up to 60% in first 24 hours | 1 day | 2 days |
| Doxorubicin | <i>Doxorubicin^a</i> , <i>Adriamycin^a</i> , <i>Caelyx^a</i> | Urine: up to 15% in first 5 days Faeces: up to 85% | 6 days | 7 days |
| Epirubicin | <i>Epiccord^b</i> , <i>Pharmorubicin^a</i> | Urine: up to 11% in first 24 hours | 3 days | |

| | | | | |
|--|--|---|--------|--------|
| Etoposide | <i>Vepesid[†], Etoposide^ª</i> | Urine: up to 50% in first 24 hours Faeces: up to 15% in first 24 hours | 3 days | 5 days |
| Fludarabine | <i>Fludara[†], Fludarabine^ª, Farine^ª</i> | Urine: up to 60% in first 24 hours | 3 days | |
| Fluorouracil (5-FU, 5-Fluorouracil) | <i>Fluorouracil^ª</i> | Urine: up to 15% in first 24 hours | 2 days | 5 days |
| Fotemustine | <i>Muphoran</i> | | | |
| Gemcitabine | <i>Gemcitabine^ª, Gemaccord, Gemplan^ª Gemzar</i> | | 1 day | |
| Hydroxyurea | <i>Hydrea[†]</i> | | | |
| Hydroxydaunorubicin | <i>See Doxorubicin</i> | | | |
| Idarubicin | <i>Zavedos^{†ª}</i> | | 3 days | 2 days |
| Ifosfamide | <i>Holoxan</i> | | 2 days | |
| Irinotecan | <i>Irinoccord, Tecan^ª, Irinotecan^ª, Camptosar</i> | | | |
| Lomustine | <i>CeeNU[†]</i> | | | |
| Melphalan | <i>Alkeran[†]</i> | Urine: up to 60% over first 24 hours | 2 days | 7 days |
| Mercaptopurine | <i>Puri-Nethol[†]</i> | Up to 40% in first 24 hours | 2 days | 5 days |
| Methotrexate | <i>Methoblastin^{†ª}, Methotrexate^ª, Methaccord^ª</i> | Urine: up to 90% in first 48 hours Faeces: up to 9% | 3 days | 7 days |
| Mitomycin | <i>Mitomycin-C Kyowa</i> | | 1 day | |
| Mitozantrone | <i>Mitoxantrone, Onkotronea</i> | Urine: Up to 6.5% over first 5 days Faeces: up to 18% | 6 days | 7 days |
| Oxaliplatin | <i>Eloxatin^ª, Oxaliccord^ª, Xalox^ª</i> | Urine: up to 50% in first 24 hours | 3 days | |
| Paclitaxel | <i>Anzatax, Plaxel^ª, Abraxane</i> | Urine and faces: at least 13% in first 24 hours | 3 days | 5 days |
| Pemetrexed | <i>Alimta</i> | | | |
| Procarbazine | <i>Natulan[†]</i> | Urine: up to 70% in first 3 days | 3 days | |
| Raltitrexed | <i>Tomudex</i> | | | |
| Romidepsin | <i>Istodax</i> | | | |
| Temozolomide | <i>Astromide, Temizole, Temodal^{†ª}</i> | | | |
| Teniposide | <i>Vumon</i> | | 3 days | |
| Thioguanine | <i>Lanvis[†]</i> | | 1 day | |
| Topotecan | <i>Hycamtin, Topotecan^ª</i> | | 2 days | |
| Trastuzumab emtansine | <i>Kadcyla</i> | | | |

| | | | | |
|-------------|---|---|---------------|---------------|
| Vinblastine | <i>Vinblastine Sulphate</i> | <i>Urine: up to 33% in first 3 days</i> <i>Faeces: up to 41% in first 3 days</i> | <i>4 days</i> | <i>7 days</i> |
| Vincristine | <i>Vincristine sulphate^a</i> | <i>Urine: up to 8% in first 3 days</i> <i>Faeces: up to 40% in first 3 days</i> | <i>4 days</i> | <i>7 days</i> |
| Vinflunine | <i>Javlor</i> | | | |
| Vinorelbine | <i>Navelbine[†], Vinorelbine^a</i> | | <i>4 days</i> | <i>7 days</i> |

^a generic brands available

[†] oral formulation available

**May be unchanged drug or metabolite

*The majority of cytotoxic drugs will be excreted within 7 days however some may require longer precautionary periods. If the cytotoxic drug excretion rate is not known use precautions for at least 48 hours following treatment.

References:

1. Australian Medicines Handbook July 2014 (online). Available at: <http://www.amh.net.au>
2. Cass Y, Musgrave CF. Guidelines for the safe handling of excreta contaminated by cytotoxic agents. Am J Health Syst Pharm. 1992 Aug; 49:1957-1958

Appendix 8

Safe Handling Recommendations for BCG

These are occupational handling recommendations only; intended for workers who handle BCG (the Bacillus of Calmette and Guerin strain of *Mycobacterium bovis*) in the context of intravesical chemotherapy preparation and administration.

BCG is a hazardous drug (biohazard). Adequate risk controls must be in place to eliminate, or minimise as far as reasonably practicable, worker exposure to BCG when it is being prepared and administered.

An important consideration to promote safe handling is to minimise the areas within the healthcare facility that are exposed to BCG and the number of workers involved in the handling and transport of BCG. This may be achieved by reconstituting BCG for administration in the same area and by the same staff administering the BCG.

The following recommendations are adapted from the Cancer Institute of NSW; eviQ Cancer Treatments On-Line 2014:

- > Use appropriate personal protective equipment (PPE) including gloves, gown, P2 masks and goggles when reconstituting, administering and handling BCG.
- > BCG should not be handled by staff with immunologic deficiency.
- > BCG should be prepared in either a biological safety cabinet or using a closed system transfer device (CSTD).
- > BCG should only be prepared by an appropriately trained worker. The worker should wear appropriate PPE as stated above and avoid inadvertent exposure to broken skin or inhalation of BCG.
- > BCG should not be prepared in common treatment areas.
- > To avoid cross-contamination, parenteral drugs should not be prepared in areas where BCG has been prepared.
- > All equipment, supplies and receptacles in contact with BCG are to be handled and disposed of as biohazardous.
- > The preparation area should be thoroughly cleaned with detergent and water and disinfected with alcohol 70%, or a chlorine-based bleaching agent (e.g. sodium hypochlorite, Milton's solution).
- > Treatments should occur in an area with ensuite toilet facilities to minimise the risk of exposure to workers and other patients.
- > For six hours following administration, patients should urinate sitting on the toilet (to avoid splashing). Disinfect the toilet by adding 2 cups of undiluted bleach or 1 sachet of sodium hypochlorite and leave for 15 minutes before flushing.
- > BCG spills: wear appropriate PPE as described above when cleaning up spills. The spill should be covered with paper towel that is soaked with undiluted bleach, left for 10 minutes then collected and disposed of as biohazardous waste or placed in cytotoxic waste bin.
- > Workers sustaining an occupational exposure to BCG should attend first aid immediately:
 - for skin exposure, wash area thoroughly with soap and water, clean skin with alcohol
 - for eye exposure, wash with copious water
 - seek medical officer review
 - report in the WHS module of SLS
 - For exposure to blood or body fluids, refer to the SA Health and/or Local Health Network/Health Service/ Business Unit Blood and Body Fluid Exposure (BBFE) Management procedure.

References

1. Atiyeh BS1, Wazzan WC, Kaddoura IL, Saghir MB, Zaatari AM, Hamdan AM. 1996. Bacille Calmette-Guérin (BCG)-itis of the hand: a potential hazard for health workers. *Annals of Plastic Surgery*. Mar;36(3):325-9.
2. Australian Medicines Handbook 2014 (online). Adelaide: Australian Medicines Handbook Pty Ltd; 2014 July. Available from: <http://www.amh.net.au>
3. Cancer Drug Manual (Drug Index Professional). British Columbia Cancer Agency (BCCA). June 2012. Available from <http://www.bccancer.bc.ca/HPI/DrugDatabase/DrugIndexPro/BCG.htm>
4. Department of Health, Western Australia. Guidelines for the administration of intravesical cytotoxic and immunotherapeutic drugs within the hospital setting. Perth: Health Networks Branch.
5. eviQ Cancer Treatments Online 2014, Cancer Institute NSW, viewed July 2014, <https://www.eviq.org.au/>
6. Stone MM, Vannier AM, Storch SK, Nitta AT, Zhang Y. Brief Report: Meningitis Due to Iatrogenic BCG Infection in Two Immunocompromised Children. *NEJM* 1995: 333:561-563.

Model Procedures

How to use the Model Procedures

These Model Procedures are intended to be practical exemplar documents to assist with the development of safe work procedures. They are designed to assist practices in safety and quality improvement.

The Model Procedures are intended to guide Health Services in the process of creating or updating their own procedures related to the safe handling of cytotoxic drugs and related wastes in a manner that complies with the Guide. The Model Procedures do not represent legal advice, are not comprehensive and do not constitute a complete procedures manual for the safe handling of cytotoxic drugs and related wastes.

A Word version of the model procedures is available: www.sahealth.sa.gov.au/HazardousDrugs

Instructions for use:

1. Save the Model Procedure(s) to your computer or network.
2. Review the Model Procedure(s) to determine changes, additions or deletions that may be needed in your Health Service document(s).

Model Procedure 1

Health Surveillance for Workers Handling Cytotoxic Drugs and Related Waste

This Model Procedure applies to:

- > Health Networks and Services as the responsible agency for conducting a business or undertaking
- > Approved medical officers undertaking health surveillance of workers handling cytotoxic drugs
- > Workers where there is significant risk to their health due to potential workplace exposure to cytotoxic drugs.

The Work Health and Safety (WHS) Act 2012 (SA) and Regulations place a duty of care on responsible agencies conducting a business or undertaking:

- > to ensure so far as is reasonably practicable, the health of workers is monitored to prevent incident, injury or illness
- > to determine whether the potential risk to workers is significant and whether health monitoring is required and to provide health monitoring.

Abbreviations and definitions

| | |
|------------------------------|---|
| Biological monitoring | Biological monitoring is the measurement and evaluation of a chemical or its metabolites in the body tissue fluids or exhaled air of exposed persons. |
| Cytotoxic drug | A drug that affects cell growth and proliferation, usually by binding directly to genetic material in the cell nucleus or by affecting cellular protein synthesis. Cytotoxic drugs do not typically distinguish between normal and cancerous cells. |
| Cytotoxic waste | Waste contaminated with cytotoxic drug or metabolites – it includes any residual cytotoxic drug that remains following patient treatment and any materials or equipment potentially contaminated with cytotoxic drugs. |
| Health surveillance | Systematic collection, analysis and interpretation of occupational injuries, illnesses, hazards and exposures. |
| Health monitoring | Health monitoring means monitoring of a person to identify changes in the person's health status because of exposure to certain substances. |

General information

Prospective workers are to be counselled at interview, induction and as part of an ongoing health surveillance program (as required) about the potential risks to health and reproduction, how exposures might occur, and the risk control measures in place.

Health surveillance must be implemented and provided to all workers involved in the preparation and administration of cytotoxic drugs.

The health surveillance program is to be reviewed regularly to include any current developments in health monitoring and/or biological monitoring, and changes to legislation.

A health surveillance program may be extended to workers:

- > involved in the clean-up of spills, if required, based on risk assessment of the spill and risk control measures in place at the time
- > other workers who may not already be identified.

Health Networks and Services shall ensure workers are made aware of the health surveillance program and how to access it. The health surveillance program is to be available to all identified workers as detailed in the responsibilities on:

- > pre-employment/pre-placement
- > an ongoing basis when working with cytotoxic drugs
- > termination of employment or transfer to another area not involving work with cytotoxic drugs.

The WHS Regulations require that health monitoring is carried out, or supervised by, a registered medical practitioner with experience in health monitoring.

Health Networks and Services must ensure that the medical officer complies with the current competencies for health surveillance. The appointed medical officer shall:

- > comply with health surveillance/monitoring guidelines
- > plan, implement and evaluate the workers' health surveillance/monitoring program
- > recognise when it is appropriate to seek advice.

Reports of health and/or biological monitoring are to be provided to the worker after each consultation in an agreed time frame. The Health Network and Service that engages the work is accountable for expenses related to the workers' health monitoring. These expenses may include costs such as:

- > Doctor's fees
- > Testing and analysis costs
- > Travel costs.
- > Paid time off work to attend medical appointments/ testing that may be required.

Record keeping/WHS requirements

Health monitoring records must be kept:

- > for at least 30 years of date of last entry
- > separate from any Human Resource records
- > separate from hospital medical records
- > confidential.

Related Sections

- > Section 4 Staff Health

Related Attachments

- > 1a Health Surveillance Questionnaire
- > 1b Log of Exposure to Cytotoxic Drugs for Pharmacy Workers
- > 1c Log of Exposure to Cytotoxic Drugs for Nursing Workers

Resources and References

1. SA Health; *Safe Handling Cytotoxic Drugs and Related Wastes: A Risk Management Guide for South Australian Health Services 2015*, Section 4
2. *Work Health and Safety Act 2012 (SA)*
3. *Work Health and Safety Regulations 2012 (SA)*
4. National Occupational Health and Safety Commission; *Competencies for Health Surveillance 1998*.
5. National Occupational Health and Safety Commission; *Guidelines for Health Surveillance 1995*.
6. Safe Work Australia: Health Monitoring for Exposure to Hazardous Chemicals
7. Safe Work Australia: Health Monitoring for Exposure to Hazardous Chemicals – Guide for Workers 2013
8. Safe Work Australia: Health Monitoring for Exposure to Hazardous Chemicals- Guide for Medical Practitioners 2013
9. Safe Work Australia: Hazardous Chemicals requiring Health Monitoring 2013

Attachment 1a

Health Surveillance Questionnaire

Section 1: To be completed by Health Network/Health Service/Business Unit

| 1. Local Health Network / Health Service / Business Unit | | |
|---|---|---------------|
| LHN/ HS / BU name: | | |
| Site Address: | | |
| Suburb: | | Postcode: |
| Site Telephone: | Site Fax: | Contact Name: |
| 2. Labour Hire / Agency / Contractor (where applicable) | | |
| PCBU/ Organisation name: | | |
| Site Address: | | |
| Suburb: | | Postcode: |
| Site Telephone: | Site Fax: | Contact Name: |
| 2. Labour Hire / Agency / Contractor (where applicable) | | |
| Date of work environment assessment dd/mm/yyyy | | |
| <p>Cytotoxic Drug Work:</p> <p>Please tick response</p> <p>Work location of worker to be assessed</p> <p><input type="checkbox"/> Pharmacy Production</p> <p><input type="checkbox"/> Patient Administration</p> <p><input type="checkbox"/> Laboratory / Research</p> <p><input type="checkbox"/> Other (please specify)</p> <p>.....</p> | <p>Risk Controls:</p> <p>Please tick all risk controls in use</p> <p>All PPE:</p> <p><input type="checkbox"/> Readily accessible</p> <p><input type="checkbox"/> Clean and functional</p> <p><input type="checkbox"/> Gloves</p> <p style="margin-left: 20px;"><input type="checkbox"/> Nitrile</p> <p style="margin-left: 20px;"><input type="checkbox"/> Double latex</p> <p style="margin-left: 20px;"><input type="checkbox"/> Other</p> <p><input type="checkbox"/> Respirator use</p> <p style="margin-left: 20px;"><input type="checkbox"/> P2 /N95 disposable respirator</p> <p style="margin-left: 20px;"><input type="checkbox"/> P2 full or half face – non disposable respirator</p> <p><input type="checkbox"/> Gowns / coveralls</p> <p style="margin-left: 20px;"><input type="checkbox"/> Disposable gowns</p> <p style="margin-left: 20px;"><input type="checkbox"/> Disposable coveralls</p> <p><input type="checkbox"/> Eye wear</p> <p style="margin-left: 20px;"><input type="checkbox"/> Protective eye wear</p> <p style="margin-left: 20px;"><input type="checkbox"/> Goggles</p> <p style="margin-left: 20px;"><input type="checkbox"/> Full face chemical splash shield</p> <p style="margin-left: 20px;"><input type="checkbox"/> Shoe covers</p> <p>Engineering Controls / Ventilation:</p> <p><input type="checkbox"/> Local exhaust ventilation</p> <p><input type="checkbox"/> HEPA filter</p> <p><input type="checkbox"/> Pharmaceutical isolator cabinet</p> <p><input type="checkbox"/> Cytotoxic drug safety cabinets</p> | |

Isolation at the source:

- Closed system drug administration
- Drugs intended for administration appropriately packaged, labelled and ready to use

Training programs inclusive:
 please tick components included components

- Occupational hazards of exposure to cytotoxic drugs and waste
- Legislative requirements for Health and Safety
- Legislative requirements for waste management
- Risk management process
- Risk Control measures
- Safe Work Procedures/practices
- Maintenance of equipment
- Procedures in event of an incident, injury, spill
- Reporting recording procedures
- Maintenance of exposure logs
- How to use a spill kit
- Waste disposal

Risk Control Measures continued:
 Please tick all risk control measures in use

Administrative Controls:

- Documented work procedures
- Identification of cytotoxic waste through designated labelling

Spill kits:

- Spill kits available
- Spill kits readily accessible
- Worker allocation to allow adequate breaks when working at cabinet or isolator (recommendation no longer than 2 hours – before a break)
- Hand washing facilities

Other Risk Control measures please document

4. Exposure Logs (Worker to bring exposure logs to assessment)

Any exposures documented? Yes No
 Risk control measures implemented following any exposure/incident (please document)

5. Environmental Monitoring (please provide details of any environmental monitoring)

| Date | Monitoring Undertaken | Recommended Actions and or comment |
|------|-----------------------|------------------------------------|
| | | |
| | | |
| | | |

Questionnaire Section 2:

To be completed by Worker and assessing Medical Practitioner

| 6. Worker Information | | | | |
|--|--------------------------|---|--------------------------------|---------------------------------|
| <input type="checkbox"/> Staff <input type="checkbox"/> Labour Hire / Agency <input type="checkbox"/> Contractor <input type="checkbox"/> Volunteer <input type="checkbox"/> Other | | | | |
| Surname: | | Given Names: | | |
| Date of Birth: dd/mm/yyyy | | Gender: <input type="checkbox"/> Male <input type="checkbox"/> Female | | |
| Address: | | | | |
| Suburb: | | Postcode: | | |
| Telephone: (Work) | | (Mobile) | | |
| Current Position: | | | | |
| Date commenced with current Health Network/Service: dd/mm/yyyy | | | | |
| Date Started work with Cytotoxic Drugs: dd/mm/yyyy | | | | |
| 7. Employment – Working with Cytotoxic Drugs (•) tick all relevant boxes | | | | |
| <input type="checkbox"/> New to cytotoxic drug work. | | | | |
| <input type="checkbox"/> New worker but not new to work with cytotoxic drug work. | | | | |
| <input type="checkbox"/> Current worker continuing work with cytotoxic drugs. | | | | |
| <input type="checkbox"/> Worker termination of employment in SA Health. | | | | |
| <input type="checkbox"/> Termination of work with cytotoxic drugs. | | | | |
| 8. Personal Hygiene practices when working with Cytotoxic drugs (please tick all implemented and undertaken in your workplace) | | | | |
| <input type="checkbox"/> No eating or drinking when handling cytotoxic drugs | | | | |
| <input type="checkbox"/> No chewing gum | | | | |
| <input type="checkbox"/> No application of cosmetics | | | | |
| <input type="checkbox"/> No wearing of jewellery in preparation facility | | | | |
| <input type="checkbox"/> Any other hygiene measures, please document | | | | |
| 9. Medical History (to be completed by Worker and reviewed by Medical Officer) | | | | |
| Question | Yes | No | If yes, please provide details | Medical Practitioner's Comments |
| Have you ever smoked cigarettes? | <input type="checkbox"/> | <input type="checkbox"/> | | |
| If you still smoke how many cigarettes do you smoke a day? | <input type="checkbox"/> | <input type="checkbox"/> | | |
| Do you have a personal history of cancer? | <input type="checkbox"/> | <input type="checkbox"/> | | |
| Do you have a family history of cancer in first degree relatives? | <input type="checkbox"/> | <input type="checkbox"/> | | |
| Do you have an illness which lowers your immune system? | <input type="checkbox"/> | <input type="checkbox"/> | | |

| | | | | |
|--|--------------------------|--------------------------|--|--|
| Are you currently having any Immunosuppressive therapy? | <input type="checkbox"/> | <input type="checkbox"/> | | |
| Are you pregnant or breast feeding? | <input type="checkbox"/> | <input type="checkbox"/> | | |
| Are you planning parenthood or considering at some time in the future? | <input type="checkbox"/> | <input type="checkbox"/> | | |
| Do you have any respiratory condition(s) and or symptoms currently? | <input type="checkbox"/> | <input type="checkbox"/> | | |
| Do you have a history of any systemic allergic reactions? | <input type="checkbox"/> | <input type="checkbox"/> | | |
| Have you experienced any unexplained weight loss? | <input type="checkbox"/> | <input type="checkbox"/> | | |
| Do you have a history of dermatitis or any other skin disorders? | <input type="checkbox"/> | <input type="checkbox"/> | | |
| Do you have any other medical conditions? | <input type="checkbox"/> | <input type="checkbox"/> | | |
| Any other comments : | | | | |

Questionnaire Section 3:

Medical Practitioner to complete

| 6. Worker Information | | |
|--|------------------|--------------------------------|
| Date of Assessment: | | |
| | Result: | Comments: |
| Height: | | |
| Weight: | | |
| Blood Pressure: | | |
| Urinalysis: | | |
| 11. Biological Monitoring and Investigations (where indicated) Consideration to be given to, Full Blood examination with white cell differential, Biochemistry including (liver function tests, urea, creatinine and electrolytes. | | |
| Date: | Tests performed: | Results / actions recommended: |
| | | |
| | | |
| | | |
| 12. Physical Examination (where indicated) | | |
| Area Assessed: | Findings: | Results / actions recommended: |
| | | |
| | | |
| | | |

13. Exposure Logs (Medical review)Any exposures documented? Yes No

Risk controls implemented following any exposures (please document)

14. Health Advice and Counselling (Indicate what was provided) Information regarding the potential health effects associated with exposure to cytotoxic drugs. Information regarding potential risks to employees planning parenthood or those who are pregnant or breast feeding Any other advice provided. (please document)**Questionnaire Section 4:****Copy to Worker, Local Health Network / Health Service / Business Unit and Supervising Medical practitioner.****15. Worker Information****Local Health Network / Health Service / Business Unit /PCBU/Organisation**

Surname:

Given Names:

Date of Birth: dd/mm/yyyy

Gender: Male Female

Address:

Suburb:

Postcode:

Telephone: (Work)

(Mobile)

**16. Results and Recommendations (Completed by Medical Practitioner continued
(✓) tick all relevant boxes)** Suitable for work with Cytotoxic Drugs Counselling required and type Review Workplace Risk Control Measures Repeat Health Assessment in: years / months / week(s) Fit to resume work with Cytotoxic Drugs Remove from cytotoxic drug work

Referred to

 Medical Specialist General Medical Practitioner**17. Medical Practitioner undertaking assessment**

Name:

Signature:

Provider Number :

Date of Assessment dd/mm/yyyy

Medical Practice:

Address:

Telephone No:

Fax No:

18. Medical Practitioner (Responsible for supervising health monitoring)

Please provide copy to Medical practitioner responsible for oversight of Health Surveillance Program

| | |
|-------------------|-------------------------------|
| Name: | Signature: |
| Provider Number : | Date of Assessment dd/mm/yyyy |
| Medical Practice: | |
| Address: | |
| Telephone No: | Fax No: |
| Email: | |

Model Procedure 2

Training for the Safe Handling of Cytotoxic Drugs and Related Waste

Workers handling cytotoxic drugs must receive appropriate training about the potential occupational hazards and safe handling requirements prior to handling cytotoxic drugs and related waste. Appropriate and timely training will minimise risks to the health and safety of staff and patients, and contamination of the environment.

Abbreviations and definitions

| | |
|------------------------|---|
| Cytotoxic drug | A drug that affects cell growth and proliferation, usually by binding directly to genetic material in the cell nucleus or by affecting cellular protein synthesis. Cytotoxic drugs do not typically distinguish between normal and cancerous cells. |
| Cytotoxic waste | Waste contaminated with cytotoxic drug or metabolites – it includes any residual cytotoxic drug that remains following patient treatment and any materials or equipment potentially contaminated with cytotoxic drugs. |
| PR&D | Performance Review and Development. |
| TNA | Training needs assessment. |

General information

Workers must not handle (prepare, administer, transport and dispose) cytotoxic drugs and related waste unless they have completed specific skills and work practice training programs. For pharmacists preparing cytotoxic drugs and nurses administering cytotoxic drugs this includes competency and proficiency assessments.

The extent of the training program (including updates and specific instructions relative to changing practice and technology) should be based on measures necessary to protect the worker, other persons (such as occupants) and the environment from contamination. Health Service Unit managers are responsible for identifying workers involved (or potentially involved) in cytotoxic drug and related waste handling and ensuring that these individuals are recommended for training program entry.

Identification of training needs

1. A training needs assessment (TNA) may be conducted for each worker to identify specific training needs and to enhance technical skills and professional capabilities.
2. Training needs are identified through Performance Review and Development (PR&D) processes.
3. Recommendations for training topics by profession are provided in Appendix 2A.

Note: For pharmacists and nurses working with cytotoxic drugs, training competencies are outlined in the following documents:

- > Pharmacy:
 - SA Health; *Central Training Manual – Clinical Pharmacy Services – Cancer and Chemotherapy*
 - SA Health; *Central Training Manual – Production Pharmacy Services – Cytotoxic and Other Hazardous Drugs*
- > Nursing:
 - SA Health; *State-wide Framework Chemotherapy Education and Assessment; An Integrated Model for South Australia*
 - eviQ Cancer Treatments Online 2014; Cancer Institute NSW

Training plan

Based on TNA and the PR&D Process, an 'Annual Development Plan' should be prepared after consultation with the worker's line manager. In case of any change, the Annual Development Plan is updated. The former Annual Development Plan is cancelled by writing "Cancelled" otherwise it will be updated at the end of each year.

In-house and external training

- > This development plan covers in-house training of staff and external training
- > Internal trainers are selected considering their level of competency in the field of training
- > External trainers may be used considering their market reputation and cost of training.

Training records

1. An attendance record is to be completed for all training that may include:
 - > date and name of training
 - > summary of training content or topics covered
 - > details of the trainer (name, organisation, qualifications).
 - > attendance validation such as signature of trainee
 - > competencies and proficiencies assessed.
2. Training records should be maintained in a separate 'Training' folder or in the personnel file of the particular employee.

Validation of training

1. Line managers are to confirm that workers have a satisfactory level of knowledge or competency for duties.
2. Guidance on training competencies, which set out the knowledge and skills staff need in order to minimise occupational exposures to cytotoxic drugs and related waste, can be obtained from a number of internal and external sources (refer to *Information Resources* below)
3. The effectiveness of the training should be validated by regular review of content, professional performance review and quality evaluation of the program
4. Revalidation should occur on a regular basis. The frequency of revalidation will depend on the training element. For example, staff regularly reconstituting cytotoxics should undergo a validation test annually, at a minimum.

Re-training

1. Each profession has guidelines on annual competency and proficiency requirements.
2. Updates may be particularly necessary for:
 - > Workers in areas where handling of cytotoxic drugs is less frequent or on an intermittent basis
 - > Workers returning from prolonged leave or who have not handled cytotoxic drugs some time (12 months or greater)
3. To cover the introduction of new drugs and/or new technical innovations, annual training as part of the PR&D is recommended
4. Training should be repeated whenever any major change in practice occurs.

Related Sections

- > Section 5 Training

Related Attachments

- > 2a Training Matrix

Resources and References

SA Health

1. SA Health; *Safe Handling Cytotoxic Drugs and Related Wastes: A Risk Management Guide for South Australian Health Services 2015*, Section 5.
2. SA Health; *Performance Review And Development (PR&D)*
3. SA Health; *Standards for Chemotherapy Services in South Australia*
4. SA Health; *Central Training Manual – Clinical Pharmacy Services – Cancer and Chemotherapy*
5. SA Health; *Central Training Manual – Production Pharmacy Services – Cytotoxic and Other Hazardous Drugs*
6. SA Health; *State-wide Framework for Chemotherapy Education and Assessment; An Integrated Model for South Australia*

Other

- > eviQ Cancer Treatments Online 2014; Cancer Institute NSW www.eviQ.org.au
- > Cancer Australia; Cancer Learning On-line.
- > Cancer Nurses Society of Australia; *Position Statement on the Minimum Education Requirements for Nurses involved in the Administration of Anti-Cancer Drugs within the Oncology and Non-Oncology Setting 2010.*
- > Clinical Oncological Society of Australia (COSA); *Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy 2008.*

Attachment 2a

Training Matrix

This training matrix provides guidance on training that may be required for various workers who may handle cytotoxic drugs and related waste.

| | Pharmacists – production | Pharmacists – clinical | Pharmacy technicians | Nurses | Medical personnel | Workers involved with waste management | Laboratory workers | Stores personnel | Couriers and porters | Ambulance officers | Patient transport personnel | Cleaners | Animal handlers (research) | Maintenance personnel |
|---|--------------------------|------------------------|----------------------|--------|-------------------|--|--------------------|------------------|----------------------|--------------------|-----------------------------|----------|----------------------------|-----------------------|
| Potential risks of exposure to cytotoxic drugs and waste | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Basic pharmacology of cytotoxic drugs | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | | | | | | ✓ | |
| Theory and practice of aseptic technique | ✓ | | ✓ | | | | | | | | | | | |
| Legislative requirements for health and safety | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Legislative requirements for waste management | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| The risk management process | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Risk control measures to be adopted when handling cytotoxic drugs and related waste | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Maintenance of equipment | ✓ | ✓ | ✓ | ✓ | | | ✓ | | | | | | | |
| Correct selection, use, cleaning and disposal of PPE | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Procedures to be adopted in the event of incident, injury or spill, including reporting and recording | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Access to first aid resources | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Storage, transport, treatment and disposal of cytotoxic waste | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Health surveillance and reporting | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Working in a clean room | ✓ | | ✓ | ✓ | ✓ | | ✓ | | | | | | | |
| Any written safe work procedures. | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Correct storage | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ |
| Use of safety cabinet/isolator | ✓ | | ✓ | | | | ✓ | | | | | | | |
| Extravasation | ✓ | ✓ | | ✓ | ✓ | | | | | | | | | |
| Cleaning procedures | ✓ | | ✓ | ✓ | ✓ | ✓ | ✓ | ✓ | | ✓ | | ✓ | ✓ | |

Model Procedure 3

Preparation of Parenteral Cytotoxic Drugs Without a Closed System Drug Transfer Device in the Pharmacy Department

This Model Procedure applies to staff preparing cytotoxic drugs in hospital pharmacy departments. It aims to ensure that cytotoxic drugs are prepared in a manner that minimises the potential risk of occupational exposure to staff and contamination of the environment. It addresses the preparation of cytotoxic drugs for parenteral administration including:

- > bolus injection in syringe requiring reconstitution of the cytotoxic drug from powder form.
- > infusion requiring dilution of cytotoxic drug from a concentrated solution

Abbreviations and definitions

| | |
|------------------------|---|
| CDSC | Cytotoxic drug safety cabinets. |
| Cytotoxic drug | A drug that affects cell growth and proliferation, usually by binding directly to genetic material in the cell nucleus or by affecting cellular protein synthesis. Cytotoxic drugs do not typically distinguish between normal and cancerous cells. |
| Cytotoxic waste | Waste contaminated with cytotoxic drug or metabolites – it includes any residual cytotoxic drug that remains following patient treatment and any materials or equipment potentially contaminated with cytotoxic drugs. |
| Intrathecal | Injection into the fluid-filled space that surrounds the spinal cord. |
| ISOPP | International Society of Oncology Pharmacy Practitioners. |
| PIC/S | Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme – jointly referred to as PIC/S. |
| PPE | Personal Protective Equipment. |
| SHPA | Society of Hospital Pharmacists of Australia. |

General information

All pharmacy staff shall adopt work procedures that are in accordance with the PIC/S *Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE010-4)* 2014 and SHPA Standards of Practice for the Safe Handling of Cytotoxic Drugs in Pharmacy Departments.

These activities must be performed in the Cytotoxic Drug Safety Cabinet (CDSC) or Isolator Cabinet.

Separate CDSC or isolator cabinets should be used for preparing cytotoxic drugs and BCG (the Bacillus of Calmette and Guerin strain of *Mycobacterium bovis*) due to the risk of contamination of the cytotoxic drug preparation.

All staff undertaking preparation of cytotoxic drugs must wear personal protective equipment (PPE).

Only one patient's treatment should be prepared at a time and only one drug should be in the cabinet at any one time (or one drug per operator in a two person CDSC).

Luer-locking syringes and fittings must be used, both in preparation and handling of these drugs. Large bore needles should be selected to ensure that high-pressure syringing of the solutions is avoided. Alternatively 0.2 micron hydrophobic air-venting filter needles may be used to minimise risks associated with the manipulation of aqueous solutions (hydrophobic filters are not suitable for non-aqueous cytotoxic solutions).

Syringe to syringe connectors must be used to minimise the risk of spill when transferring from one syringe to another. Engineering control measures that are specifically designed, such as closed system devices that prohibit the transfer of environmental contaminants into the system and the escape of hazardous drug or vapour concentrations outside the system, may be considered for the preparation of parenteral cytotoxics.

Cytotoxic drugs in glass ampoules should be avoided whenever possible. Care must be exercised when using liquid filled ampoules of cytotoxic drugs as they produce aerosols of drug solution when opened. Ampoules should be opened away from the operator, and to avoid injury or damage to gloves an ampoule breaker should be used. Filter needles (5 micron) must be used when dispensing from glass ampoules. Any excess solution should be discarded in a sealed syringe for later safe destruction.

Contain excess drug or prevent air contamination when priming syringes and other devices. Excess drug should be returned to the original container or introduced into a closed container to be discarded. Opened/used vials should not be left in the cabinet for later use.

Procedures

1. Bolus injection in syringe requiring reconstitution of drug from powder

The negative pressure technique is used to add or withdraw solutions from a vial using a hypodermic needle.

It is important to perform this technique carefully to prevent the formation of aerosols. Also use caution to avoid the needle coming out of the bung which could lead to a needle-stick injury.

Note: If the cytotoxic drug is for intrathecal use it must not be prepared during preparation of any other agents.

Adding diluent solution to the vial

- > Withdraw required volume of diluent solution into luer lock syringe and attach 18G needle.
Note: refer to institution's specific drug procedure or manufacturer's product information leaflet for type of diluent and volume to use.
- > Insert needle into bung of cytotoxic drug vial.
- > Withdraw a few millilitres of air from vial, creating a negative pressure inside vial and then allow solution to flow from syringe into vial until pressure has equalised. Repeat until all of the solution has been added to vial.
- > Some vials containing powder are supplied with negative pressure in the vial and so it is not necessary to withdraw air from the vial initially. This may vary from batch to batch.
- > Swirl vial gently until the cytotoxic drug is dissolved. Do not shake vigorously.

Withdrawing solution from vial

- > Check the cytotoxic drug is completely dissolved.
- > Draw air into syringe equivalent to volume of solution to be withdrawn.
- > Attach syringe to needle in vial.
- > Invert vial and aspirate a few millilitres of solution into syringe creating a negative pressure in the vial and then allow air in the syringe to flow back into the vial.
- > Repeat until required volume is withdrawn.
- > Stand vial on workbench and use forceps to disconnect syringe from needle, leaving needle in vial. Seal syringe with sterile syringe cap.

Note: syringes must never be sent with a needle attached.

- > Discard all cytotoxic waste appropriately.

Note: if an air-venting device is used instead of a needle then it is not necessary to use the negative pressure technique.

2. Infusion requiring dilution of drug from a concentrated solution

- > Withdraw required volume of cytotoxic drug from vial(s) using luer lock syringe and 18G needle(s) and negative pressure technique or air venting device.
- > Prior to addition to infusion bag, all volumes drawn up by a pharmacy assistant must be checked by a pharmacist. Keep the original ampoules/vials and show to pharmacist at same time.

- > Thoroughly clean additive port of infusion bag/bottle with 70% sterile alcohol.
- > Using 21G needle, make the addition. If more than one syringe is to be added to an infusion container, an injection site cap is attached to a 21G needle and inserted into the additive port of the infusion container. The additions are made into the bung of the injection site cap.
Note: for certain non-PVC bags an 18G needle can be used to add to the bag. Refer to manufacturer's product information.
- > Thoroughly agitate to ensure mixing and check for leakage before removing from CDSC.
- > Clean additive port with 70% sterile alcohol and remove from CDSC.
- > Discard all cytotoxic waste appropriately.

Labelling

The cytotoxic drug must be labelled immediately upon preparation, including:

Primary container/syringe/bag

- > Drug name
- > Dose and volume
- > Infusion solution, if required/appropriate
- > Intended route of administration
- > Expiry date and time, if appropriate
- > Storage conditions
- > Other supplementary, cautionary instructions if required
Note 1: If the cytotoxic drug is for intrathecal use it must be clearly labelled 'For Intrathecal Use Only'.
Note 2: Vinca alkaloids must be labelled 'for intravenous use only – fatal if given by other routes'.
- > Patient's full name and a second patient identifier (e.g. medical record number, dob)
- > Prominent cytotoxic drug warning label e.g. 'Cytotoxic, Handle With Care'
- > Name and address of the pharmacy

Outer container

- > Labelled in the same manner as the individual items.

Packaging

- > Seal the prepared drug in two layers of plastic (this packaging may also offer protection from light).
- > The sealed cytotoxic drug should then be placed in a dedicated, secure area, ready for transport.
Note: If the cytotoxic drug is for **intrathecal** use it must be packaged and delivered separately from doses to be administered by other routes.

Related Sections

- > Section 6 Preparation and Dispensing

Resources and References

1. SA Health; *Safe Handling Cytotoxic Drugs and Related Wastes: A Risk Management Guide South Australian Health Services 2015, Sections 6 and 7*
2. SHPA; *Standards of Practice for the Safe Handling of Cytotoxic Drugs 2004*
3. PIC/S; *Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments (PE010-4) 20141*. Australian Standard AS 2639-1994 *Laminar flow cytotoxic drug safety cabinet – installation and use*
4. AS/NZS ISO 14644.5-2006 *Cleanrooms and associated controlled environments Part 5: Operations*
5. ISOPP; *Standards of Practice: Safe Handling of Cytotoxics 2007*
6. Australian Council for Safety and Quality in Health Care; *Medication Alert No 2, December 2005*

Model Procedure 4

Transport of Cytotoxic Drugs External to the Health Service

This Model Procedure addresses labelling and transport of cytotoxic drugs external to the Health Service.

Abbreviations and definitions

| | |
|-----------------------|---|
| Cytotoxic drug | A drug that affects cell growth and proliferation, usually by binding directly to genetic material in the cell nucleus or by affecting cellular protein synthesis. Cytotoxic drugs do not typically distinguish between normal and cancerous cells. |
| GHS | Globally Harmonised System of Classification and Labelling of Chemicals (GHS) |
| ADG Code | Australian Dangerous Goods Code 7.3 |
| UN Number | The number assigned to dangerous goods by the United Nations Committee of Experts on the Transport of Dangerous Goods. Cytotoxic drugs that meet the classification criteria of Class 6.1 are listed in the ADG code as UN 2810 or UN 2811. |
| SDS | Safety data sheet prepared under WHS regulation 330 or 331. In addition: A Safety Data Sheet (SDS) is a document prepared by the manufacturer or importer of a chemical that describes the properties and uses of that chemical that is its, identity, chemical and physical properties, health hazard information, precautions for use and safe handling information |

Codes and legislation

- > The Globalised Harmonised System of Classification and Labelling of Chemicals (GHS) places safety requirements on the handling of cytotoxic drugs in the workplace as relevant to their level of toxicity. The GHS classification is not relevant for transport.
- > *Work Health and Safety Regulations 2012 (SA)*.
- > The Dangerous Goods Transport Regulations 2008 and the Australian Dangerous Goods Code 7.3 place transport requirements on those cytotoxic drugs which are classified as dangerous goods. The safety data sheet of a cytotoxic drug includes whether it is classified as a dangerous good through the assignment of a UN number in section 14 Transport Information.
- > Most TGA approved cytotoxic drugs, for example, cyclophosphamide and methotrexate solution for Injection, are not currently classified as dangerous goods and hence the Australian Dangerous Goods Code labeling and documentation requirements for transport DO NOT APPLY.

Packaging

1. Place sealed syringes or infusion containers of prepared cytotoxic solutions into separate plastic bags, double wrapped and heat sealed as per standard practice.
2. **Room temperature transport:** wrap the prepared and labelled cytotoxic drugs in foil bubble wrap and tape closed.
Note: Room temperature is considered to be 25°C. If transporting drugs during hot summer days or to regional and remote areas (such as Roxby Downs or Ceduna), consideration must be given to ambient temperatures exceeding 40°C.
3. **Cold chain transportation:** At least one ice pack should be included in the packaging. Place the ice brick inside a folded section of the foil bubble wrap, then add the cytotoxic drugs ensuring that the drugs are not in direct contact with the ice brick. Tape the foil bubble wrap closed.
Note: When regularly transporting drugs to regional and remote areas under cold chain conditions, consideration should be given to validating the cold chain measures using a temperature data tracking device wrapped in the foil with the drugs.
Note: Drugs requiring different storage conditions, i.e. room temperature items and refrigerated items, must be placed into separate cartons. When there are refrigerate and room temperature drugs for the same patient it is necessary to send two parcels unless the room temperature drugs can safely be refrigerated (see **Exceptions**).

4. Attach the 'CYTOTOXIC – HANDLE WITH CARE' label below to the bubble wrapped package.



5. Package in an appropriately sized, hard walled carton made from moulded foam or some other suitable packaging material that is capable of withstanding shock equivalent to a one-metre drop onto a concrete surface.
6. Include the administration chart in the carton if the delivery is for the first date of administration on the order.
7. Include a safety data sheet in the carton if supplying the cytotoxic drug to the workplace for the first time or if the safety data sheet has been updated since the last supply.
8. Seal the carton securely with packaging tape.

Exceptions:

- > **Calcium folinate injection** requires cold chain transportation, however if it is sent with other drugs not requiring refrigeration it may be sent at room temperature.
- > Print a bag label. Place the calcium folinate into a brown paper bag with bag label attached. Also attach calcium folinate label.

**PLEASE REFRIGERATE
CALCIUM FOLINATE INJECTION
ON ARRIVAL**

- > **Carboplatin and gemcitabine:** if sending together, send them both in cold chain packaging but attach the label below to the outside of the carton. This instructs staff receiving the carton to store the gemcitabine at room temperature and to store the carboplatin in the refrigerator. Attach the carboplatin and gemcitabine label.

PLEASE NOTE:

This package contains Gemcitabine which can be stored at room temperature.

On arrival:

- > Remove the Gemcitabine and store at room temperature
- > Store carboplatin in the refrigerator

Labelling cartons for transport

- > The 'Cytotoxic – Handle with Care' label must be attached to the carton.



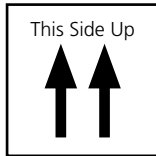
- > **IF** the cytotoxic is classified as a dangerous good with an assigned UN number, also affix Australian Dangerous Goods Code, class 6.1 label to the carton.



- > A large 'Refrigerate' label on each side of the carton (if refrigeration required)



- > Place 'This Side Up' labels on two opposite sides of carton (see Attachment 4a, sample 8)



Additional information

The following information must be included on the carton

- > Instructions in the event of spillage (see Attachment 4a, sample 7).

This item has been packaged in accordance with approved guidelines and is safe for transport.

In the event of accidental breakage or spillage

- > Do not touch spill contents or contaminated item
- > Avoid any contact with skin or clothes
- > If spillage has occurred on to unprotected skin or in the eye. Immediately wash the area with a large amount of water.
- > Remove any contaminated clothing

Contact Jane Smith on (08) XXX XXXX or on 04XX XXX XXX after hours

Name of Institution

Address of Institution

- > The name and address of the Hospital/Health Service and a direct contact to the pharmacy department in case of an emergency must be attached to the carton.
- > A separate piece of paper with the receiver's name and address plus contact telephone number (or pre-printed label) should also be taped to the top of the carton.

Transport and documentation for cytotoxic drugs classified as dangerous goods

A consignment note is ONLY required if the cytotoxic drug is classified as a dangerous goods with an assigned UN number. Reference must be to the safety data sheet Section 14: transport Information for this information.

- Complete the model transport consignment note or similar (electronic or in paper format as per Australian Dangerous Goods Version 7.3 Multimodal Dangerous Goods. Information must include:
 - > Consignor: Sender – SA Pharmacy - the name of the cytotoxic drug preparation pharmacist, their telephone number and address
 - > Consignee: Receiver – the doctor's name, delivery address and contact telephone number.
 - > Description of goods including:
 - If liquid, "UN2810 TOXIC LIQUID, ORGANIC (CYTOTOXIC DRUG)"
 - If solid, "UN2811 TOXIC SOLID, ORGANIC (CYTOTOXIC DRUG)"
 - Number of and kind of packages
 - Description of goods
 - > Shippers declaration: to be signed by SA Pharmacy authorised delegate
- This consignment note must be placed on top of the carton.

Logs

- > Complete the 'Log of Chemotherapy Parcels Sent to External Institutions' (see Appendix 4b).

Related Section

- > Section 8 Transport
- > Section 7 Labelling






Related Attachments

- > 4a Sample Labels
- > 4b Log of Chemotherapy Parcels Sent to External Institutions.

Resources and References

1. SA Health; Safe Handling Cytotoxic Drugs and Related Wastes: A Risk Management Guide for South Australian Health Services 2015, Sections 7 and 8.
2. *Work Health and Safety Regulations 2012*.(SA)
3. SHPA; Standards of Practice for the Transportation of Cytotoxic Drugs from Pharmacy Departments 2007.
4. Australian Council for Safety and Quality in Health Care; Medication Alert No. 2, December 2005
5. The Australian Dangerous Goods Code Edition 7.3
6. The International Air Transport Association's (IATA) Dangerous Goods Regulations
7. Safe Work Australia - Code of Practice for Labelling of Workplace Hazardous Chemicals
8. Chief Officer, Dangerous Substances SafeWork SA

Attachment 4a – Sample Labels

| Sample no. | Example |
|------------|---|
| 1 | <div style="border: 1px solid black; border-radius: 15px; padding: 10px; text-align: center;"> <p>PLEASE REFRIGERATE CALCIUM FOLINATE INJECTION ON ARRIVAL</p> </div> |
| 2 | <div style="border: 1px solid black; border-radius: 15px; padding: 10px;"> <p>PLEASE NOTE: This package contains Gemcitabine which can be stored at room temperature. On arrival: > Remove the Gemcitabine and store at room temperature > Store carboplatin in the refrigerator</p> </div> |
| 3 | <div style="border: 1px solid black; padding: 10px; text-align: center;"> <p>CYTOTOXIC</p>  <p>HANDLE WITH CARE</p> </div> |
| 4 | <div style="border: 2px solid blue; border-radius: 15px; padding: 10px; text-align: center;"> <p>REFRIGERATE Do not freeze</p> </div> |
| 5 | <div style="border: 1px solid black; padding: 10px;"> <p>CYTOTOXIC DRUG HANDLE WITH CARE</p> <p>Avoid contact with skin</p> <p>This item has been packaged in accordance with approved guidelines and is safe for transport.</p> <p>In the event of accidental breakage or spillage:</p> <ul style="list-style-type: none"> > do not touch spilt contents or contaminated item > avoid any contact with skin or clothes > if spillage has occurred onto unprotected skin or in the eye, immediately wash the area with large amounts of water > remove any contaminated clothing > contact Jane Smith on (08) 8XXX XXXX during business hours or on 04XX XXX XXX after hours. <p style="text-align: center; font-size: small;">Name of Institution Address of Institution</p> </div> |
| 6 | <div style="border: 1px solid black; padding: 10px; text-align: center;"> <p>This Side Up</p>  </div> |
| 7 | <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="text-align: center;">  <p>A</p> </div> <div style="text-align: center;">  <p>B</p> </div> <div style="text-align: center;">  <p>C</p> </div> </div> |

- ** A – GHS pictogram/label indicates acute toxicity; may be applicable under workplace (GHS) labelling requirements
- B – ADG Code pictogram/label indicates Class 6.1 toxic hazard; applicable to outer packaging for transport for Cytotoxic Drugs classified as dangerous goods with an assigned UN number only.
- C – GHS pictogram/label indicates chronic health hazard; may be applicable under workplace (GHS) labelling requirements

Attachment 4b – Log of Cytotoxic Drug Parcels Sent to External Institutions

| Month: | | Year: | | | | |
|-----------|---------------------------|-------------|---------------------------------------|-------------|--|--|
| Date sent | Patient name and U.R. no. | Destination | Name and batch number of drug(s) sent | Con. note # | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| | | | | | | |

Model Procedure 5

Transport of Cytotoxic Drugs Within the Health Service

This Model Procedure addresses labelling and transport of cytotoxic drugs within the Health Service.

Abbreviations and definitions

| | |
|-----------------------|---|
| Cytotoxic drug | A drug that affects cell growth and proliferation, usually by binding directly to genetic material in the cell nucleus or by affecting cellular protein synthesis. Cytotoxic drugs do not typically distinguish between normal and cancerous cells. |
| GHS | Globally Harmonised System of Classification and Labelling of Chemicals (GHS). |

Labelling

Primary packaging

| Cytotoxic drug | Label requirement | Sample |
|-----------------------------|--|--------|
| All | Primary label drugs has: <ul style="list-style-type: none"> > name of the drug > the dose > expiry date > batch number > patient name and URN > 'protect from light' if drug is light sensitive > 'keep out of reach of children' warning in red text > name, address and phone number of health service > date of supply. | |
| All | | |
| Cytotoxic drugs in solution | Name of fluid in which it is diluted | |
| Intrathecal | | |
| Vinca alkaloids | | |

| Cytotoxic drug | Label requirement | Sample |
|---|-------------------|---|
| Bortezomib | | FOR INTRAVENOUS OR SUBCUTANEOUS USE ONLY FATAL IF GIVEN BY OTHER ROUTES |
| Fluorouracil (infusion) | | WARNING Fluorouracil infusion may cause cardiac effects including chest pain (+/-ECG changes) and possibly arrhythmias or worse. If symptoms occur, STOP the infusion and contact RAH Medical Oncology. |
| Oral medications | | Do Not Cut or Crush |
| Topical cytotoxic medications e.g. fluorouracil cream | | Wear Disposable Gloves Use Spatula to Apply |
| Vesicants | | Warning Do not extravate |
| Requiring refrigeration | | Refrigerate Do not freeze |

Containers

Cytotoxic transport plastic eskies that may be used to carry cytotoxic drugs to the wards must identify the contents as cytotoxic drugs (purple 'CYTOTOXIC – Handle with Care' label as above).

Packaging

- Place sealed luer lock syringes or infusion containers of prepared cytotoxic solutions into separate plastic bags (double wrapped) and seal with heat sealer.
- If drug requires protection from light, first seal inside a clear plastic bag and then this package is sealed inside a black plastic bag.

Note: The black bag must have all the same labelling as the primary container.

Main delivery each day (example procedure)

- The pharmacist/assistant will check the distribution book for patient's name, ward and drug(s) ordered.
- Take appropriate drugs for that date from storage location (refrigerator/room temperature).
- Cross-check patient's name and drug with distribution list as:
 - there may be more than one patient with the same name
 - a patient may need different drugs delivered on different days.
- Check the number of containers required (sometimes two or more infusion containers may be required).
- The pharmacy assistant will assemble the delivery.
- The pharmacy assistant will initial the distribution book next to each patient entry whose items are included in the delivery.
- The pharmacist will then check all items are correct and initial the distribution book for each patient. This check may be waived at the discretion of the pharmacist.

8. Place drugs into cytotoxic transport plastic esky or onto cytotoxic transport trolley. These containers are designed to protect the cytotoxic drugs during delivery and also to contain a spill if it occurs. All personnel involved in the delivery of cytotoxic drugs must be aware of the potential hazards and the care required in handling, as well the procedure to follow in the event of a spill.
9. On arrival in the ward, the pharmacy assistant shall:
 - a. ask the Registered Nurse-in-charge (or delegate) to check the chemotherapy being delivered;
the nurse shall check that all drugs for each patient are correct and still required. The pharmacy assistant shall return those not required to the Pharmacy.
 - b. if drugs are not to be given, return them to the Cytotoxic Production Office and **notify the pharmacist**.
 - c. check also whether there is any 'Cancelled/Delayed' forms to be returned to Pharmacy.
 - d. ensure that form is attached to drug packaging for return to Pharmacy.

Subsequent deliveries

Pharmacist/assistant to complete documentation and pharmacy assistant to proceed as steps 8 and 9 above.

Deliveries on weekends and public holidays

Drugs for administration during the weekend/public holidays are delivered on Friday afternoon. If a new order is written on the weekend, it is prepared and delivered on the appropriate day(s).

Documentation

Logs: complete the Distribution Book – see Attachment 5b.

Related Sections

- > Section 7 Labelling
- > Section 8 Transport

Related Attachments

- > 5a Cancelled/Delayed Therapy form
- > 5b Sample – Distribution Book of Cytotoxic Drug Sent to Wards

Resources and References

1. SA Health; *Safe Handling Cytotoxic Drugs and Related Wastes: A Risk Management Guide for South Australian Health Services 2015, Section 7 and 8.*
2. Pharmaceutical Society of Australia; *Australian Formulary and Handbook 21st Edition 2010.*
3. ASHP; *Guidelines on Handling Hazardous Drugs Am J Health-Syst Pharm 2006, 63*
4. SHPA; *Standards of Practice for the Transportation of Cytotoxic Drugs from Pharmacy Departments 2007.*
5. *Controlled Substances Act 1984 (SA)*
6. *Controlled Substances (Poisons) Regulations 1996*
7. *The Poisons Standard – The Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)*
8. *Australian Council for Safety and Quality in Health Care; Medication Alert No. 2, December 2005*
9. *Safe Work Australia - Code of Practice for Labelling of Workplace Hazardous*

Model Procedure 6

Safe Handling of Oral Cytotoxic Drugs in a Health Service

Cytotoxic drugs in oral form are associated with ease of administration however they carry the same risk of potential exposure to health care workers, patients and carers as other forms of cytotoxic drugs.

Oral cytotoxic drugs must be administered to patients in a manner that minimises this potential risk to the health and safety of workers, patients and visitors, and contamination of the environment.

This Model Procedure refers to the safe handling of oral cytotoxic drugs from a work health and safety perspective and may form part of a greater overarching procedure for administration of cytotoxic drugs in in-patient and out-patient settings.

Abbreviations and definitions

| | |
|------------------------|--|
| Cytotoxic drug | A drug that affects cell growth and proliferation, usually by binding directly to genetic material in the cell nucleus or by affecting cellular protein synthesis. Cytotoxic drugs do not typically distinguish between normal and cancerous cells. See Appendix 7 – Table of Cytotoxic Drugs and Excretion Rates. |
| Cytotoxic waste | Waste contaminated with cytotoxic drug or metabolites – it includes any residual cytotoxic drug that remains following patient treatment and any materials or equipment potentially contaminated with cytotoxic drugs. |
| PPE | Personal Protective Equipment |

General information

- > Cytotoxic drugs must be identifiable by all workers and stored safely as directed by pharmacy or the manufacturer.
- > Proper storage and handling of oral cytotoxic drugs should be ensured by health care workers in order to prevent accidental exposure and to ensure the integrity of these medicines.
- > Appropriate use of personal protective equipment (PPE) is to be instituted.
- > Access to a spill kit and other necessary emergency equipment should be available in the event of a spill or accidental exposure.
- > If tablets/capsules are to be counted using a device (e.g. forceps, triangle), the device is to be clearly marked and dedicated for cytotoxic drugs only. The device should be thoroughly washed after each use.

Patients and carers are to be advised on all matters related to safe handling and proper administration of oral cytotoxic drugs including safe storage, dispensing and disposal requirements.

Staff training

Cytotoxic drugs must only be administered by medical practitioners and nurses who have undertaken appropriate training and competency assessment in cytotoxic drug administration and who have a complete understanding of the potential hazards and risks associated with cytotoxic drug handling.

Contaminated waste

Contaminated waste such as PPE, disposable medicine cups etc, must be placed into an approved container/bin for cytotoxic waste.

Handle patient excreta that may be contaminated with cytotoxic drugs or their metabolites as cytotoxic waste. Information on cytotoxic drug excretion rates and precautionary periods may be found in **Appendix 7 – Table of Cytotoxic Drugs and Excretion Rates**.

Safe handling for cytotoxic drugs administered orally

Oral cytotoxic drugs, generally available as capsules or tablets, must be handled in a manner so as to avoid skin contact, cross contamination with other medicines and the formation of particulates which may be inhaled.

- > All cytotoxic drugs prepared for administration are to be marked with a prominent label warning of the cytotoxic nature of the drug
- > A 'non touch technique' should be used by workers administering oral cytotoxic drugs to the patient
- > Medication should not be broken, crushed or otherwise further manipulated at administration. If compounding of the tablet or capsule is required this should be performed in pharmacy using a cytotoxic safety cabinet
- > Wear appropriate PPE (e.g. nitrile gloves or double gloves) when administering cytotoxic drugs
- > Patient to be deemed fit for treatment by their medical officer
- > Patient consent is to be obtained prior to treatment
- > Ensure that the patient can swallow the medication(s) and that there are no risk factors for aspiration
- > Perform the Time Out Procedure immediately prior to administration
- > Patients are to be observed during administration of the oral medication. Do not leave medication at the bedside and assist administration if necessary
- > If the patient experiences emesis immediately after ingestion a further dose must not be administered. Inform the treating medical practitioner of the episode for further guidance
- > Written information should be provided to the patient and their carer if they are returning home with oral cytotoxic drugs
- > Return unused cytotoxic tablets/capsules to the pharmacy, in an appropriately labelled sealed container.

Related Sections

- > Section 9 – Administration

Related Attachments

- > 6a Time Out Procedure
- > 6b Time Out Procedure Checklist (example pro-forma)

Related Appendices

- > Appendix 7 – Table of Cytotoxic Drugs and Excretion Rates

Resources and References

1. SA Health; *Safe Handling Cytotoxic Drugs and Related Wastes: A Risk Management Guide for South Australian Health Services 2015, Section 9*
2. Goodin S, Griffith N, Chen B, Chuk K, Daouphars M, Doreau C, Patel RA, Schwartz R, Tamés MJ, Terkola R, Vadnais B, Wright D, Meier K. *Safe handling of oral chemotherapeutic agents in clinical practice: recommendations from an international pharmacy panel. J Oncol Pract. 2011 Jan;7(1):7-12.*
3. SHPA; Standards of Practice for the Provision of Oral Chemotherapy for the Treatment of Cancer 2007.
4. Clinical Oncological Society of Australia (COSA); *Guidelines for the Safe Prescribing, Dispensing and Administration of Cancer Chemotherapy 2008.*
5. eviQ Cancer Treatments Online 2014; Cancer Institute NSW www.eviQ.org.au

Attachment 6a

Time Out Procedure

A “Time out” is taken to verify all critical information before medication is administered including:

All cytotoxic drugs must be checked at administration by two appropriately trained and skilled registered nurses. Where a second nurse is not available, an appropriately trained pharmacist or medical officer can perform this function.

The Time Out Procedure includes verification of:

- > right patient (patient name, date of birth, medical record number)
- > right drug (drug name, strength and volume)
- > right dose (including body surface area (BSA) check)
- > right route
- > right time

Performance of these checks is to be recorded, for example by signing and dating the medication chart or the Time Out Procedure checklist.

An example pro-forma is provided – see **Attachment 6b - Time Out Procedure Checklist**

This Time Out Procedure has been adapted from eviQ Cancer Treatments Online 2014; Cancer Institute NSW
www.eviQ.org.au

Model Procedure 7

Accidental Exposure to Cytotoxic Drugs and Related Waste

This Model Procedure addresses accidental exposure of workers to cytotoxic drugs and related waste.

Abbreviations and definitions

| | |
|------------------------|---|
| Cytotoxic drug | A drug that affects cell growth and proliferation, usually by binding directly to genetic material in the cell nucleus or by affecting cellular protein synthesis. Cytotoxic drugs do not typically distinguish between normal and cancerous cells. |
| Cytotoxic waste | Waste contaminated with cytotoxic drug or metabolites – it includes any residual cytotoxic drug that remains following patient treatment and any materials or equipment potentially contaminated with cytotoxic drugs. |
| Extravasation | Unplanned escape of a liquid from a vessel or tube into surrounding body tissues. |

Clothing and personal protective equipment (PPE)

1. Immediately remove outer gloves, gown and any contaminated clothing
2. Place disposable personal protective equipment in the cytotoxic waste container
3. Contaminated clothing should be bagged separately, machine washed separately and line dried
4. Remove and dispose of inner gloves into the cytotoxic waste disposal container

Penetrating injuries, skin and other body contact

Skin exposure

1. Remove contaminated clothing as above
2. Wash the affected skin with soap and clean thoroughly with copious amounts of water
3. Report to supervisor immediately
4. Seek immediate medical advice and further medical attention as necessary

Needle-stick injuries

1. Wash thoroughly as per skin exposure
2. If the needle-stick injury results in the injection of cytotoxic drug, refer to the Health Service's extravasation procedure
3. Do not administer anaesthetic drops or ointments
4. Refer to the Health Service's extravasation procedure where appropriate
5. Report to supervisor immediately
6. Seek immediate medical advice and further medical attention as necessary

Mucosal exposure e.g. eyes:

1. Immediately flush the affected area – the eyes – with an isotonic saline solution for at least 15 minutes – continuous irrigation may be facilitated with an intravenous infusion set connected to a bag of intravenous normal saline
2. Report to supervisor immediately
3. Seek immediate medical advice and further medical attention as necessary

Record keeping

Document occurrence of the incident via the WHS Safety Learning System - See **Section 4 – Staff Health**.

For exposure to cytotoxic drugs in the presence of blood or body fluids, refer to the SA Health and/or Local Health Network/Health Service/Business Unit Blood and Body Fluid Exposure (BBFE) Management procedure.

Related Section

- > Section 4 Staff Health

Resources and References

- 1 SA Health; *Safe Handling Cytotoxic Drugs and Related Wastes: A Risk Management Guide for South Australian Health Services 2015, Section 4*
- 2 SHPA; Standards of Practice for the Safe Handling of Cytotoxic Drugs 2004
- 3 SA Health; Blood and Body Fluid Exposure (BBFE) Management Procedure

Model Procedure 8

Spill Management of Cytotoxic Drugs

Cytotoxic spills must be managed and attended to in a manner that minimises the potential risk of exposure to personnel and contamination of the surrounding environment.

Abbreviations and definitions

| | |
|------------------------|--|
| Cytotoxic spill | A spill of cytotoxic drugs or related wastes. |
| Cytotoxic waste | Waste contaminated with cytotoxic drug or metabolites – it includes any residual cytotoxic drug that remains following patient treatment and any materials or equipment potentially contaminated with cytotoxic drugs. |
| PPE | Person protective equipment. |
| Cleaning agent | Use a locally approved cleaning agent for cytotoxic spills. |

General information

- > All cytotoxic drug spills must be attended to immediately. Stay calm, alert others to the spill and do not leave the spill unattended.
- > Attend to yourself first: remove any contaminated clothing and wash skin that has been contaminated with soap and water then obtain the nearest spill kit.
- > Ancillary workers should assist only in the containment of a spill while alerting trained staff.
- > Cleaning of cytotoxic spills should begin from the outside of the spill area and work towards the centre.
- > Cytotoxic drug spill procedures are to be followed in the event of a cytotoxic spill and must be available to all workers handling cytotoxic drugs.
- > Refer to the cytotoxic drug safety data sheet for specific information.

Spills during cytotoxic drug preparation (within a cytotoxic drug safety cabinet)

All workers 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*.

Note: within a pharmacy clean room, all workers must wear personal protective equipment (PPE).

Spills during cytotoxic drug preparation (within a cytotoxic drug safety cabinet)

1. Keep the cabinet operating.
2. Access the nearest spill kit as required.
3. Clean immediately using available absorbent material.
4. For a spill on a cytotoxic spill mat:
 - > cytotoxic solution: wait for the liquid to be absorbed then carefully fold the mat containing the spill, avoiding contact with the contaminated area.
 - > cytotoxic powder, carefully place an absorbent pad over the powder ensuring minimal dust production, then carefully wet the pad so that the powder dissolves and is absorbed.
5. For a spill* on the cabinet floor:
 - > cytotoxic solution: mop up the spill with an absorbent wipe or swab and place in plastic bag. Clean the area with a suitable cleaning agent working from outside in, rinse using sterile water and dry with fresh towlettes or cloths
 - > cytotoxic powder: cover with a dampened sterile wipe ensuring minimal dust production, fold absorbent sheet being careful to collect any broken glass.
6. Dispose absorbed and collected waste in plastic bag then place sealed plastic bag into cytotoxic waste bin.
7. Clean the area with a suitable cleaning agent working from outside in.
8. Rinse area thoroughly with purified water.
9. Dry the affected area with absorbent towels or swabs.
10. Wipe the affected area with sterile alcohol 70% to assist with drying of the surface.
11. Discard the waste into the cytotoxic waste bin (inside sealed plastic bag where required).
12. If personal protective equipment is contaminated, discard it into a cytotoxic waste bin and don new personal protective equipment.
13. Change gloves.
14. As soon as practicable or at the end of the shift:
 - > complete an incident report via the WHS Safety Learning System (SLS)
 - > enter details into the cytotoxic spills register (**Attachment 8b**)
 - > ensure that the spill kit is replenished and maintained.

* 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.

Drug spills in a pharmacy clean room but outside a cytotoxic drug safety cabinet

1. If in a cytotoxic suite – activate spill switch.
2. Alert others in the immediate vicinity that a cytotoxic spill has occurred, isolating the area and informing people to stay clear.
3. Personnel within the cytotoxic suite will already be wearing PPE.
4. Display the “Caution Hazardous Drugs Spill” signs as required.
5. Contain the spill by placing towelettes or cloths around the spill and gently place a chemosorb pad over the spill.
6. Clean the spill – if a powder spill, gently pour water onto chemosorb pad to that it saturates (without flooding) the area. Wait for the water to soak through to the powder.
7. Scoop up broken glass and/or powder slurry using the plastic scoop and scraper and dispose of it in a plastic bag.
8. Using towelettes or cloths moistened with water, start from the spill’s outside edge to carefully wipe towards the centre and dispose of this waste in the plastic bag. Use a fresh wipe each time.
9. Dry the area with the remaining towelettes or cloths and dispose of in a plastic.
10. Cover the area with suitable cleaning agent and absorb the solution with fresh towelettes or cloths and dispose of in plastic bag.
11. Rinse the area thoroughly with water, disposing clean up absorbent towels into plastic bag. Dry the area with absorbent towels or other suitable material.
12. If in cytotoxic suite – return air flow to normal.
13. Remove PPE in the following sequence and dispose of in plastic bag:
 - > overshoes
 - > outer gloves
 - > chemo-gown
 - > safety glasses.
14. Seal plastic bag with collected waste. Do not press down on the bag as broken glass may puncture the bag.
15. Place the plastic bag inside a purple or second waste bag without touching its exterior then remove the second pair of gloves, mask and hair net and place them in the purple waste bag.
16. Seal purple bag and dispose of the bag in the cytotoxic bin.
17. Wash your hands thoroughly with soap and water.
18. As soon as practicable or by the end of the shift:
 - > complete an incident report via the WHS Safety Learning System (SLS)
 - > enter details into the cytotoxic spills register (**Attachment 8b**)
 - > ensure that the spill kit is replenished and maintained.

Spills during drug transport, dispensing, administration and patient care areas

1. Secure the area and alert those in the immediate area to the potential hazard:
 - access the spill kit
 - place signs around the area where the spill has occurred
 - call for assistance if required.
2. The person to carry out the spill clean-up must be trained in the cytotoxic spill management procedure.
3. Appropriate PPE must be used for the cytotoxic drug spill clean-up including nitrile gloves/double latex glove and particulate respirator/mask.
4. Carefully collect any broken glass then cover the spill with absorbent mat or pad. If powder is spilt, carefully place the absorbent pad over the spill and wet with water so the powder dissolves and is absorbed.
5. Carefully collect the absorbent or mat and place in plastic waste bag.
6. Clean the area with strong alkaline cleaning/decontaminating agent, absorb the solution with absorbent towels and dispose of in plastic bag.

For a spill on carpet:

- Absorb as much of the spill as possible with absorbent pads or granules then clean with detergent and water minimising the seepage into unaffected areas of the carpet. (Note that the carpet may be bleached if sodium hypochlorite solution is used)
 - It may be necessary to have the carpet professionally cleaned with a commercial carpet cleaner. Decontamination of the carpet cleaning machines is not considered necessary due to the dilution effect.
7. Rinse area thoroughly with water, disposing clean up absorbent towels in plastic waste bag.
 8. Discard contaminated PPE and gloves into waste bag.
 9. Place the collected and sealed waste in the cytotoxic waste bin.
 10. Wash hands thoroughly with soap and water.
 11. Remove signs.
 12. As soon as practicable or by the end of the shift:
 - > complete an incident report via the WHS Safety Learning System (SLS)
 - > enter details into the cytotoxic spills register
 - > ensure that the spill kit is replenished.

Related Sections

- > Section 14 Spills

Related Attachments

- > 8a Recommended Cytotoxic Drug Spill Kit Contents – Check List
- > 8b Cytotoxic Drug Spill Kit Register

Resources and References

1. SA Health; *Safe Handling Cytotoxic Drugs and Related Wastes: A Risk Management Guide for South Australian Health Services 2015, Section 14*
2. ISOPP; *Standards of Practice: Safe Handling of Cytotoxics 2007*

Attachment 8a

Recommended Cytotoxic Drug Spill Kit Contents –
Check List

| Check | Item |
|-------|--|
| | Instructions for use (preferably laminated) |
| | Warning signs to identify and isolate the spill (caution tape can be used to quarantine an area) |
| | Personal protective equipment: |
| | > latex (double gloved) and/or nitrile gloves x 2 |
| | > head cover |
| | > impermeable gown or coveralls |
| | > bonded polyethylene fibre overshoes |
| | > safety glasses or full-faced chemical splash shield |
| | > P2 mask or other suitable respiratory protective device [#] |
| | Absorbent materials: |
| | – swabs (generous quantity) |
| | – absorbent towels/towelettes |
| | – spill mat |
| | – chemical absorbent granules/powder |
| | – spill pillow – may be supplied separately when required |
| | Disposable scoop or dedicated dustpan |
| | Cytotoxic waste container and cytotoxic waste bags and ties |
| | Suitable cleaning/decontaminating agent may also be included |
| | Water for powder spills (to be used to reduce dust and particulate matter) |

[#] Trained spill management personnel would ideally use their own fit tested P2 mask for dealing with cytotoxic drug spills. A P2 mask should also be made available in the spill kit should no other be available.

Spill kit for home use

Spill kits for home use will not necessarily include all of the above items but should be cytotoxic drug specific. Clear instructions for use, a list of contents and information on replacement and appropriate disposal of used items should be included.

Model Procedure 9

Managing Cytotoxic Waste

This Model Procedure refers to the safe handling of cytotoxic waste

Abbreviations and definitions

| | |
|------------------------|--|
| Cytotoxic drug | A drug that affects cell growth and proliferation, usually by binding directly to genetic material in the cell nucleus or by affecting cellular protein synthesis. Cytotoxic drugs do not typically distinguish between normal and cancerous cells. |
| Cytotoxic waste | <p>Waste contaminated with cytotoxic drug or metabolites – it includes any residual cytotoxic drug that remains following patient treatment and any materials or equipment potentially contaminated with cytotoxic drugs.</p> <p>Cytotoxic waste may include:</p> <ul style="list-style-type: none"> > expired cytotoxic drugs, or those returned from patients > unused cytotoxic pharmaceuticals > contaminated waste from preparation processes > used and contaminated sharps and syringes, ampoules and vials > contaminated intravenous infusion sets and containers > packaging that has been in contact with cytotoxic drugs > disposable drug administration aids and devices such as used medicine cups > contaminated personal protective equipment (PPE) such as gloves, gowns, shoe covers, respirators > materials used to clean cytotoxic contaminated equipment or spills > contaminated body substance receptacles such as disposable vomit bags > contaminated dressings and bandages > contaminated patient body waste (excreta) following treatment of the patient with cytotoxic drug, including specimen samples for pathology > contaminated specimens from the laboratory > contaminated animal excreta in research facilities > body waste (excreta) from patients receiving cytotoxic drug therapy that may contain traces of cytotoxic drugs and/or their active metabolites. May include urine, vomit, blood, faeces, sweat, bile, other body fluids and substances. |

Procedures must describe requirements for the segregation and identification, collection, transport and storage of cytotoxic waste, and be developed in consultation with those who generate cytotoxic waste and those responsible for the provision of support, transport and disposal services.

Identification

1. All cytotoxic waste is to be placed into suitable bags or bins that are readily identifiable (purple colour)
2. The bins must be clearly identified with the words 'CYTOTOXIC WASTE' clearly displayed.



Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) the following labels/pictograms indicate a chronic health hazard, acute toxicity and environmental hazard respectively; they may all be applicable to signage for cytotoxic drug waste.



Segregation

1. Cytotoxic waste must be separated from other types of waste at the point of generation*. Bags shall be removed from the initial collection containers and sealed before transferring to the contractor supplied identifiable wheellie bins for collection from a dedicated storage area.
2. Consideration should be given to wrapping glass bottles containing liquid waste in bubble-wrap and/or absorbent material to avoid breakages.
3. Sharps containers can be placed inside the cytotoxic waste bins for disposal.
4. Cytotoxic waste bins should be located as close as practicable to the site of generation to minimise the handling and transport of cytotoxic waste from the site of generation.
5. Bins should be emptied at least weekly or before the volume in the bin exceeds two thirds the volume of the liner or the weight capacity of the liner, whichever is the lesser, and kept in a secured and signed area.

* Pathology laboratories should take into consideration biohazard risks when implementing segregation recommendations.

Collection for disposal

Cytotoxic waste should be:

1. Collected in purple liners and transferred to readily identifiable bins.
2. Put out for collection within 7 days of being generated. Cytotoxic waste shall be held for as long as possible (without exceeding the 7 day limit) to fill the bin.
3. A bin need not be full if the contents of the bin require immediate disposal and the volume cannot be made up. For perishable waste, try to prolong the disposal time (for example by refrigerating) then transfer to fill a bin for disposal.
4. Waste should be sealed prior to collection by waste collectors; when bins are placed in public areas they must be locked at all times.

Storage

> All waste bins used to store cytotoxic waste must be:

1. Placed in such a manner as to reduce the risk of spill and/or contamination. Health Services should ensure that a cytotoxic waste collection area is:
 - a dedicated storage area with adequate lighting and ventilation. This may be situated within the main waste storage area, provided there is adequate room to separate cytotoxic waste material from the other waste streams
 - secured
 - located away from stormwater drains and other sensitive areas
 - appropriately signed for the type of waste stored.
2. Cytotoxic waste should be stored in bins identified as containing cytotoxic waste and capable of being secured. These bins are not to be re-opened on-site once they have been secured.

Spills

Spills must be attended to immediately with incidents recorded via the WHS module of the Safety Learning System (SLS) – See **Section 14 Spills and Model Procedure 8 – Spill Management of Cytotoxic Drugs**.

Transporters of cytotoxic waste

3. SA Health Local Health Networks (LHN) and Health Services (HS) are licensed through the Environment Protection Authority (EPA) as Medical Waste Producers and have a Medical Waste Producers Certificate.
4. Medical waste (including cytotoxic waste) collected from a Medical Waste Producer must be collected and transported only by a person or company with a Waste Transport Certificate (WTC) issued by the EPA.
5. A copy of the Waste Transport Certificate must be supplied by the waste collection contractor to the Health Service before any waste is removed from any site.
6. No government or private vehicle is to be used to transport cytotoxic waste generated by SA Health Local Health Network or the health service.
7. Community nurses who provide care to patients in their homes may collect minor quantities of patient related cytotoxic drug waste (e.g. empty packaging, absorbent pads) and transport it in work vehicles BACK to the LHN/HS for cytotoxic drug waste disposal. Government vehicles used for this service provision must carry the following to meet compliance requirements:
 - A copy of the LHN/HS Medical Waste Producers Certificate
 - A spill kit for the vehicle including personal protective equipment (PPE) and identifiable (purple) plastic waste bags.
8. Transportation shall be in accordance with:
 - *Environment Protection Act 1993 (SA)*
 - Environment Protection (Prescribed Waste) Regulations 1998
 - *Dangerous Substances Act 1979*
 - Dangerous Substances Transport Regulations 2008
 - The Australian Dangerous Goods Code 7.3

Record keeping

Work Health and Safety Act 2012 (SA) and its regulations specify that records must be kept for a period of 5 years – see **Section 4.6 Staff Health** for an exception to this requirement.

Related Sections

- > Section 15 Waste Management

Resources and References

1. SA Health; *Safe Handling Cytotoxic Drugs and Related Wastes: A Risk Management Guide for South Australian Health Services 2015*, Section 15
2. Waste Management Associate of Australia (WMAA); *Industry Code of Practice for the Management of Clinical and Related Wastes 6th Ed 2010*
3. AS/NZS 3816-1998 *Management of clinical and related wastes*
4. HB 202 *A management system for clinical and related wastes – guide to application of AS/NZ 3816-1998*
5. *Environment Protection Act 1993 (SA)*
6. Environment Protection Regulations 2009 (SA)
7. Environment Protection (Waste to Resources) Policy 2010
8. Environment Protection (Waste Management) Policy 1994
9. *Dangerous Substances Act 1979*
10. Dangerous Substances Transport Regulations 2008 (SA)
11. *Work Health and Safety Act 2012 (SA)*
12. Work Health and Safety Regulations 2012 (SA)
13. The Australian Dangerous Goods Code Edition 7.3

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For more information

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