GUIDELINES FOR THE SAFE HANDLING OF CYTOTOXIC DRUGS AND RELATED WASTE
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1. Summary

The Health and Safety in Employment Act (HSE Act) 1992 puts the primary responsibility on the employer to provide a safe and healthy work environment by effectively managing any hazards associated with the work.

Although there is currently no evidence to suggest that small quantities of cytotoxic drugs absorbed over a period of time can cause cancer in normal individuals, clinical studies indicate that the latency period following exposure to cytotoxic drugs may be several years. Therefore, it may be many years before the carcinogenic risk associated with occupational exposure to these drugs is fully understood. Under these circumstances, it is not appropriate to wait for indisputable evidence of harm.

Special precautions are required in the handling of cytotoxic drugs. Unless suitable protective measures are in place, contamination of the workplace and the worker is likely to occur and may result in exposure to and absorption of the drugs by health care personnel and others.

Two elements are essential to ensure a safe and healthy working environment:

- Adequate education and training of all staff involved in any aspect of handling of cytotoxic drugs and related waste, including the provision and use of personal protective equipment.
- A biological safety cabinet or its equivalent for the preparation and reconstitution of cytotoxic drugs.

There is currently no form of biological monitoring or health assessment technique which is sensitive or specific enough to adequately predict the effects of chronic long-term exposure to cytotoxic drugs. Therefore, the primary focus of safety during use of cytotoxic drugs must be on the control of the working environment and safe work practices.

2. Introduction

Cytotoxic drugs may also be known as anti-neoplastic drugs or cancer chemotherapy drugs. The names refer to a category of drugs which have the ability to kill or arrest the growth of living cells. They play an important part in the treatment of cancer but are also finding a wider role as immunosuppressive agents in transplantation and various diseases with an immunological basis.

There has been increasing concern among healthcare workers about the exposure to cytotoxic drugs during reconstitution, preparation, administration, and disposal of these drugs. While evidence from the administration of therapeutic doses of cytotoxic drugs to cancer patients is not directly applicable to the low level exposure of healthcare workers preparing or administering cytotoxic drugs, this evidence does indicate that those involved in occupational handling of cytotoxic drugs may be at risk from chronic long-term exposure to these drugs.
The main risk is during preparation and administration of the drugs. There is also some risk from exposure to urine, vomit, and excreta from patients being treated with cytotoxic drugs, and spillages or accidents of various kinds.

It is therefore necessary to establish techniques and procedures to prevent exposure in the workplace. The hazard can be further controlled and the risks minimised by ensuring that staff are both properly trained and using the appropriate protective equipment provided.

### 3. Scope and Application of these Guidelines

These guidelines have been prepared to provide practical guidance aimed at reducing the exposure of healthcare personnel, such as pharmacists, nurses and doctors, to cytotoxic drugs during reconstitution, preparation, administration, and disposal of related waste. While it is specific to healthcare establishments, it may be used by those involved in the handling of cytotoxic drugs and related waste in the community and other settings.

These guidelines are not intended to be used as an operational manual or a technical reference or to provide complete occupational health advice on any particular situation. The aim is to give general advice on the topic which can be used to develop the appropriate policies and safety procedures. When establishing such procedures, hospitals and healthcare facilities must consider any new information and the professional judgments of their staff as well as the recommendations contained in these guidelines. Keeping current with evolving knowledge and appropriately adjusting policies and procedures is an on-going responsibility.

These guidelines should be made readily available to all employees involved or likely to be involved in the handling of cytotoxic drugs and related waste.

### 4. Responsibilities

The Health and Safety in Employment Act 1992, which came into force on 1 April 1993, puts the primary responsibility on the employer to provide a safe and healthy work environment by identifying and effectively managing any hazards associated with the work.

#### 4.1 Duties of Employers

The employers’ overall responsibilities are to identify potential or actual hazards, evaluate the health risks, and to institute effective controls over the hazard.

The Act requires that, where possible, significant hazards must be eliminated; and where a hazard cannot be eliminated, isolation should be considered.
When the hazard cannot be practicably eliminated or isolated, the effects of the hazard must be minimised by various means, such as engineering controls or by personal protection.

Employees should be instructed in safe working practices for handling of cytotoxic drugs and, where necessary, correct procedures for the selection, wearing and maintenance of personal protective clothing and equipment. The extent of instruction and training should be appropriate to the duties of the individual and be sufficiently detailed to ensure that the individual understands not only the procedural and safety requirements, but also the reasons for these requirements.

The HSE Act 1992 requires the taking of all practicable steps to prevent harm to employees. Such steps can include, but are not limited to:

- Regular consultation with employees, including keeping employees up to date with any new developments in this field;
- Developing written safe working policies and procedures in consultation with employees, health and safety representatives, and the health and safety committee;
- Providing job instruction, information and training in the occupational health aspects of the handling of cytotoxic drugs and related waste to new and existing staff;
- Regular evaluation of work practices to ensure that safe working procedures are followed at all times. In general, supervision should not be required if staff are adequately trained and suitable procedures are developed and documented;
- Inspecting work areas, on a frequent and organised basis, for hazards relating to cytotoxic drugs, and the documentation of the findings;
- Analysing and monitoring work practices, procedures and systems to identify hazards which may otherwise be overlooked;
- Responding to employees' concerns and enquiries on cytotoxic drugs; and
- Ensuring that proper procedures are in place for the management of emergency spillages, including documentation of exposure following the investigation of any spills, accidents or injury.

### 4.2 Duties of Employees

While at work, employees should take care to protect their own health and safety, and the health and safety of any other person who may be affected by their acts in the workplace.

Employees' responsibilities may include, but are not limited to:

- Taking part in any training and instruction programme provided, and ensuring that work is carried out in accordance with the practices in which they have been instructed;
- Reporting potential cytotoxic hazards to supervisors;
- Reporting to supervisors any cytotoxic spill, accident or injury as soon as possible after the event;
- Reporting the need for maintenance of equipment, etc.;
- Assisting accident or hazard investigators;
- The proper use of any protective equipment provided for occupational health, safety and welfare purposes while dealing with cytotoxic drugs and the maintenance of such equipment in a satisfactory operational condition;
- Following any reasonable instruction that supervisors/managers give in relation to occupational health, safety and welfare at work in relation to cytotoxic drugs;
- Complying with any agreed cytotoxic drug policies, procedures and safe work practices;
- Ensuring that they do not endanger their own health or safety, or the health and safety of any other person while at work; and
- Assisting health and safety representatives by keeping them informed about issues of concern with cytotoxic drugs.

5. Potential Effects of Exposure to Cytotoxic Drugs

The main routes of exposure to cytotoxic drugs are through the inhalation of the drug dusts or aerosols, skin absorption, inadvertent ingestion through contact with contaminated food or cigarettes, and needle stick injuries.

Opportunities for exposure can occur during preparation and administration of the drugs, handling of body fluids from patients receiving cytotoxic drugs, handling and disposal of cytotoxic wastes and related trace contaminated material, and transportation of cytotoxic drugs.

The risks to workers handling cytotoxic drugs are a combined result of the drugs’ inherent toxicity and the extent to which workers are directly exposed. Other factors include the susceptibility of the individual to the drugs’ toxic effects, and co-factors such as dietary habits, smoking, and man-made or natural environmental contaminants.

5.1 Acute Effects

Some cytotoxic drugs have a direct irritant effect on the mucous membranes, eyes and skin. Spills onto skin surfaces that have cuts or abrasions and punctures of the skin with a contaminated needle or broken glass can lead to severe soft tissue injury and should be treated immediately and observed for potential problems.
Symptoms such as dizziness, light-headedness, and nausea have also been reported, possibly as a result of working in poorly ventilated areas.

5.2 Chronic Effects

The greatest cause for concern among health care workers is not the acute but the long-term effects of occupational exposure to cytotoxic drugs. Many published studies are inconclusive and little is known of the long-term effects of exposure to small quantities of cytotoxic drugs over an extended period of time.

The possibility that the carcinogenic threshold may be a cumulative one, indicates that any exposure to cytotoxic drugs should be minimised.

5.3 Employees who are Pregnant, Breast Feeding or Planning Parenthood

It is recommended that employees who are pregnant, breast feeding, or planning pregnancy and who are involved in the preparation and/or administration of cytotoxic drugs, should be made aware of the potential risks to the embryo or foetus from absorbed drug, and where possible, be offered alternative duties.

6. Procedures for Handling Cytotoxic Drugs and Related Wastes

6.1 Drug Preparation and Reconstitution

6.1.1 General

The primary focus of safety during the use of cytotoxic drugs must be on:

- Control of the working environment;
- Safe work practices; and
- Education and training of personnel.

The preparation and reconstitution of cytotoxic drugs should only be undertaken by specially trained nominated personnel, working under appropriate conditions which protect workers and the environment as well as protecting the integrity of the product.

6.1.2 Minimising Exposure

It is not possible to completely eliminate the risk involved in the preparation and reconstitution of cytotoxic drugs. However, occupational exposure to cytotoxic drugs can be minimised by:

- The use of detailed, written procedures and safe work practices for all aspects of handling cytotoxic drugs (including the management of spills);
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- Adequate education and training of all persons involved in handling cytotoxic drugs and related waste to ensure compliance with the procedures;
- Periodic evaluation and validation of the training given;
- The provision and correct use of protective equipment, facilities (e.g. biological safety cabinets) and clothing (e.g. gowns, gloves, etc.); and
- Adherence to universal safety precautions.

**Universal safety precautions** are based on the concept that all blood, blood products and body fluids of all persons are potential sources of infection, independent of diagnosis or perceived risk. Therefore, all staff must adhere rigorously to protective measures which minimise exposure to these agents. The use of universal precautions involves placing a barrier between staff and all blood and body fluids.

6.1.3 Alternative Arrangements for Supply

Facilities which are unable to provide facilities, equipment and training to ensure a safe working environment or who use the drugs infrequently should consider alternative arrangements for supply. Such arrangements could include:

- A delivery service from a facility which has the required equipment and personnel trained in the preparation of cytotoxic drug doses; or
- The purchase of commercially prepared cytotoxic drugs in a form which makes it unnecessary to conduct reconstitution or which permits reconstitution to be completed without opening a sealed packaging system.

If it is necessary to prepare the drugs in domestic premises or health centres (because of the need to use a freshly reconstituted agent), this should be done by adequately trained nominated personnel.

Once prepared, the drug should be clearly labelled and packaged in such a way that it will not spill or leak (especially if dropped) when transported to the area where it will be administered. (Refer to the section on Packaging, Labeling, and Transportation of Cytotoxic Drugs.)

6.1.4 Personal Protective Clothing and Equipment

Protective clothing should be provided for all personnel involved in the preparation and reconstitution of cytotoxic drugs. It should be considered mandatory during training and during circumstances where technique may not be sufficient to prevent exposure, e.g. when dealing with a spillage.

The minimum requirements for protective clothing for personnel preparing sterile solutions of cytotoxic drugs should include the following — a protective gown, shoe or boot covers, headwear, mask, and gloves. Goggles or a visor may be worn.
Gowns
Gowns should be made of disposable, lint-free fabric with low permeability to cytotoxic drugs. They must also be sterile. Protective gowns should have a closed front, long sleeves, and elastic or knit-closed cuffs that can be tucked under the gloves. All seams should be double stitched, bound and sealed to ensure that no needle holes exist and therefore seams are impervious to large particles and cytotoxic drug solutions.

Headwear
Headwear should fit snugly around the head and be made of disposable, low linting material.

Footwear
Footwear covers should be disposable and made of fabric with low permeability to cytotoxic drugs.

Gloves
Gloves are essential and should be worn during the handling of all cytotoxic drug products and related waste. No gloves are completely impermeable to all cytotoxic drugs. Double gloving is recommended — a double layer offers better protection than a single layer of gloves.

Gloves should be removed immediately after overt contamination, or if punctured. They should also be changed routinely after no more than 30 minutes of drug preparation or administration.

Masks
While normal surgical masks offer protection against the inhalation of powder, they do not necessarily protect against the inhalation of liquids and aerosols.

Employers should be aware of any developments in this field and adjust their procedures accordingly.

Eye protection
It is advisable to wear eye protection (protective goggles or visors) at all times when processing cytotoxic drugs or cleaning up spills containing cytotoxic drugs. These should fully enclose the eyes to protect against dust and splashes, and should be washed thoroughly with water after use.

When preparing cytotoxic drugs in a proper biological safety cabinet behind the glass shield, safety goggles or visors may be unnecessary.

Respiratory protective equipment
Use of respiratory protective equipment of a suitable type to protect against toxic chemicals in pharmacies is not recommended.

Biological Safety Cabinet
The only acceptable means of reducing operator exposure is by the use of a proper biological safety cabinet. Australian Standard, AS 2567—1994 Laminar flow cytotoxic drug safety cabinets, together with its companion document, AS 2639—1994 Laminar flow cytotoxic drug safety cabinets —
**Installation and use**, specifies means of providing both product and personnel protection in the preparation, manipulation and dispensing of cytotoxic drugs.

At the same time this standard permits the safe internal maintenance of the cabinet. Installations which provide a lesser degree of environmental and containment control than that specified in AS 2639 may not provide an adequate level of protection for personnel and drug products.

Alternatively the use of a pharmaceutical isolator which complies with the joint Australian and New Zealand Standard — *AS/NZ 4273: 1995 Guidelines for the design, installation and use of pharmaceutical isolators* is also recommended.

Cleaning and maintenance personnel servicing these cabinets or changing the high efficiency particulate air (HEPA) filters should be warned of the nature of the cytotoxic drugs and the potential health risks. Personal protective equipment appropriate to the circumstances and need should be used.

Performance checks and maintenance of cytotoxic drug biological safety cabinets should be undertaken at least every 6 months, along with testing and validation of performance. A written record of the testing and validation procedures and results should be kept.

*Protective equipment should not be worn outside the work area.*

### 6.1.5 Laundering of Contaminated Personal Protective Clothing

Policies and procedures should be established for the laundering of personal protective clothing which may be contaminated with cytotoxic drugs.

Laundry personnel handling the contaminated garments should wear protective gloves and gowns and be trained in the special precautions required.

Contaminated laundry should be placed in specially marked laundry bags and separately pre-washed before being added to other laundry for an additional wash.

### 6.1.6 Storage of Cytotoxic Drugs

All stocks of cytotoxic drugs should be kept in a secure area, with access limited to specified authorised personnel.

Warning labels should be applied to all cytotoxic drug containers, as well as shelves and bins where these containers are permanently stored.

A register should be kept of all drugs stored and the quantity of each drug stored. The register should contain information on the safe use of each drug and the details of treatment for extravasation. This information should be compiled from manufacturers’ data sheets and other sources of information.
6.2 Drug Administration

6.2.1 General

The administration of drugs to patients is commonly carried out by injection or infusion, but some are given by mouth in tablet, capsule, or suspension form. It is important that personnel administering the drugs are aware of the potential risks involved and use appropriate work practices and personal protective equipment to minimise that risk.

Injecting the drug into the IV line, clearing air from the syringe or infusion line, and leakage at the tubing, syringe, or stopcock connection present opportunities for both skin contact and aerosol generation leading to respiratory exposure. Clipping used needles and crushing used syringes, standard practice in some work situations, may also produce a considerable aerosol.

Unco-operative patients may also increase the difficulty of administration of the cytotoxic drugs.

6.2.2 Personal Protective Clothing

Precautions should be taken to prevent normal skin contact during the administration of cytotoxic drugs. Normal nursing practices involving the use of a mask, gloves and gowns or aprons and strict adherence to safe work practices should provide sufficient protection.

Such recommendations must be considered in the light in which they are proffered; health professionals must walk the narrow line between alarming their patients unnecessarily and protecting their own health.

6.3 Care of Patients Receiving Cytotoxic Drugs

6.3.1 General

Personnel providing direct patient care should be familiar with drug excretion patterns to guide safe behaviour practices while handling body fluids and linen contaminated with cytotoxic drugs or related waste.

Prior to caring for patients receiving certain cytotoxic drug therapy, nursing staff and other caregivers should be aware of the following details:

- The name of the drug administered.
- The route of administration.
- The route of excretion.
- The duration after administration that unchanged drug or active metabolites may be excreted.
- Handling precautions for urine, vomit, and excreta.
- Management of small spills likely to occur at home.
6.3.2 Personal Protective Clothing

Personnel dealing with blood, vomit, or excreta from patients who have received cytotoxic drugs in the last 48 hours should wear surgical latex gloves and disposable gowns, to be discarded after each use as described in the section on waste disposal. Hands should be thoroughly washed after removal of gloves or after contact with the above substances.

6.3.3 Patient Wastes

Excreta from patients who have received certain anti-neoplastic drugs may contain high concentrations of the drug or hazardous metabolites. Particular care should be taken with the urine of patients who have received intravesical treatment with cytotoxic drugs or who have received high doses of drugs that are excreted unchanged or as active metabolites in the urine. Strict adherence to universal safety precautions should be considered.

6.3.4 Contaminated Linen

Linen contaminated with cytotoxic drugs, blood, vomit, or excreta from a patient who has received cytotoxic drugs up to 48 hours before should be placed in a specially marked laundry bag. This laundry bag and its contents should be pre-washed, and then added to other laundry for an additional wash.

Laundry personnel handling the linen should wear protective gloves and gowns when handling this material and be trained in the special precautions required.

6.3.5 Care of Patients in the Home

Occasions may arise where drug administration is performed in the patient’s home, or in the doctor’s surgery by a community health professional or a medical practitioner, patient, or caregiver.

Personnel caring for patients at home or in the community should be informed of the potential adverse health effects of unprotected exposure to cytotoxic drugs and related waste. They should be provided with the information required for safe work practices, including necessary personal protective equipment, administration techniques, waste containment and disposal and management of spills. Patients or caregivers should also be given information on how to manage small spills which are likely to occur at home.

In the community setting, double flushing of the toilet is recommended to ensure complete and thorough disposal of the waste and any of its cytotoxic drug residues.

All materials used in home chemotherapy administration should be placed in an appropriate leak-proof container, and removed from the home to the designated area for appropriate disposal. This can be done by a nurse or a properly instructed patient or family member. Arrangements should be made with either a hospital or private waste management firm for proper disposal.
6.4 Spills and Contamination

6.4.1 Strategy for the Management of Spills and Contamination

In addition to adopting and following safe work practices which aim to prevent accidental spills of cytotoxic drugs, a written strategy must be developed and maintained for the management of the spills that may occur when preventative strategies fail.

Spills and breakages must be cleaned up immediately by a properly protected person trained in the appropriate procedures.

All personnel likely to be involved in a cytotoxic spill should be trained in:

- The correct procedures for handling cytotoxic drugs or waste in order to prevent and minimise the risk of spills;
- The location of the spill kit in their area (see Appendix 3 for contents);
- The arrangements for the medical treatment of any affected personnel;
- The procedure for the containment of the spill and decontamination of personnel and the environment;
- The procedure for waste disposal according to the nature and extent of the spill; and
- The procedure for the safe handling of packages of cytotoxic drugs which may be damaged or leaking.

A spill should be identified with a warning sign so that other persons in the area will not be contaminated.

6.4.2 Incident Report Forms

The circumstances and handling of all spillages should be documented on an incident report form. One copy should be kept on the departmental file for the staff member(s) involved. Another copy of this form should be sent to the person responsible for the occupational health of staff working within the hospital.

Information recorded on this report form should include:

- Date and time of the incident;
- Location of the incident;
- Name of the drug involved;
- Form of the drug;
- Approximate concentration and quantity spilled;
- Names of personnel involved, including any person in the area who might have been exposed;
- A description of any direct skin or eye contamination;
Absorption may have occurred; and

A description of what action was taken.

6.4.3 Emergency Procedures

Small spills that occur on-site and during transportation should be managed by the healthcare establishment. Procedures should specify under what conditions emergency services should become involved.

Consideration should be given to the establishment of an emergency spill management team which includes pharmacy and cleaning personnel. All personnel likely to be involved in the handling of cytotoxic drugs and waste should have training in spill management.

6.5 Waste Management and Disposal of Drugs and Contaminated Material

6.5.1 General

All waste generated during the preparation and use of cytotoxic drugs and the cleaning up of spills must be segregated, packaged, and disposed of in accordance with specifications outlined in the NZS 4304:1990 Healthcare waste management.

All containers for cytotoxic waste should be colour coded purple and marked with a symbol indicating cytotoxic waste. (See Appendix 2: Symbols for Waste Classification.)

6.5.2 Personal Protective Clothing

All personnel involved in the routine handling of cytotoxic waste should wear appropriate protective clothing, whether the waste appears properly packaged or not. This should be removed immediately if contamination is suspected and disposed of accordingly.

6.5.3 Waste Identification, Segregation and Containment

All staff should be familiar with, and follow the procedures established for, the collection, segregation, and disposal of cytotoxic drug waste.

Materials that have been used in the preparation and administration of cytotoxic drugs, such as gloves, gowns, syringes or vials, present a possible source of exposure or injury to support and housekeeping staff, as well as other healthcare workers not involved with their preparation and administration. The use of properly labelled, sealed, and covered containers, handled only by trained and protected personnel should be routine.

Solid waste should be double bagged and sent for incineration. “Sharps” (including contaminated glass vials and plastic syringes) should be placed in an impenetrable container specified for the purpose and sent for incineration.
Contaminated laundry should be placed in specially marked laundry bags and treated as for contaminated linen. (See the section on Care of Patients Receiving Cytotoxic Drugs — Contaminated Linen.)

6.5.4 Waste Storage
- Storage of cytotoxic waste in healthcare establishments should be in a dedicated, secure area which can also be easily cleaned and maintained.
- Waste bins should be sealable.

6.5.5 On-Site Waste Transport
Each facility should develop a safe internal collection system for its cytotoxic waste which ensures that personnel, other people, and the environment are not contaminated.
- To prevent operator contact, handcarts or trolleys specifically for the internal transport of waste should be used whenever possible.
- The use of waste disposal chutes should be avoided.
- The collection of waste should be undertaken on a regular basis to avoid accumulation.

6.5.6 Off-Site Waste Transport
- Small quantities (e.g. needles and syringes generated from drug administration) should be disposed of in appropriate waste containers.
- Large quantities of cytotoxic waste should be treated and transported in such a way as to meet the requirements of NZS 4304:1990 Health care waste management.

(Refer also to the section — Labelling, Packaging and Transport of Cytotoxic Drugs.)

6.5.7 Waste Disposal
It is the responsibility of the waste collection contractors to instruct, train and direct their personnel in the safe handling of cytotoxic waste, including while operating on the premises or property of a health facility or service.
- The disposal of cytotoxic wastes should be by incineration.
- Waste with low concentrations of cytotoxic wastes such as patient excreta, may be disposed of safely in the normal sewage system.

6.6 Labelling, Packaging, and Transport of Cytotoxic Drugs

6.6.1 General
Personnel involved in the transport of cytotoxic drugs within and between medical facilities should receive instruction on procedures for safe transport and for dealing with spills.
6.6.2 Labelling

All cytotoxic preparations should be clearly labelled with detailed, accurate, and legible information.

Labels should be specifically designed and should state that there is a cytotoxic substance in the preparation. The label should also state the total amount and volume of the preparation, the time and date after which it should not be used, and storage recommendations.

Other special labels should also be attached, where appropriate, to convey additional information or advice (e.g. do not extravasate).

All safety labels should be applied to both the immediate container and any outer safety packaging (e.g. bags containing syringes).

Cytotoxic drug preparations being transported to other hospitals should be labelled according to the requirements of NZS 5433:1988 *Transport of hazardous substances on land*.

This standard requires that all packaging, containers, and vehicles carrying hazardous substances shall be marked as to the hazard classification of the goods.

6.6.3 Packaging and Transport of Cytotoxic Drugs within the Facility

Procedures for the packaging and safe transport of cytotoxic drug preparations within the facility should be developed and maintained.

Sealed, rigid impervious containers with appropriate leak-proof packaging and labelling should be used to transport liquid cytotoxic drug preparations to wards, clinics, between health units and services, and to hospices, nursing homes and domestic premises in the community. This packaging must also offer protection from light if required. There should be sufficient adsorbent packaging to absorb the contents, and the outer packaging should ensure that breakage will not result in spillage.

Luer-lock syringes must be capped using standard luer caps to avoid spillage during transport.

Packages should be clearly labelled as cytotoxic drugs.

Transport methods that produce stress on contents such as pneumatic tubes should not be used to transport cytotoxic drugs.

Personnel involved in the transport of cytotoxic drugs should be cautioned and trained in the necessary precautions should a spill occur.

6.6.4 Packaging and Transport to Other Facilities

For transport between facilities, compliance with relevant packaging standards is essential. Cytotoxic drugs should be packaged in such a way as to prevent breakage and subsequent contamination due to accidental damage during handling and transportation.
Drivers of transport vehicles should be informed of the potential hazards associated with handling cytotoxic drugs and related waste. They should be instructed in safe handling procedures and in procedures for dealing with any spillage or leakages.

6.7 Provision of Information, Training and Supervision

6.7.1 New and Existing Employees

- A competent person should be appointed in writing to undertake responsibility for safety arrangements connected with the use of cytotoxic drugs in the areas controlled by the employer.

- Written procedures should be drawn up specifying a safe working method to cover each process which is being carried out within the employee's sphere of responsibility.

- Information on possible hazards associated with the materials in use should be included. The procedures should also cater for emergency action, e.g. in the event of a spillage in a non-designated area.

- All personnel involved in any aspect of the handling of cytotoxic drugs must receive an orientation to cytotoxic drugs, including their known potential risks, relevant techniques and procedures for their handling, the proper use of personal protective equipment and materials, spill procedures, medical policies, and first aid procedures in the event of accidental skin or eye contact with cytotoxic drugs. An evaluation of an individual's work practice and technique should be carried out before a person is assigned to prepare cytotoxic drugs.

- Prospective temporary and permanent employees who will be required to work with cytotoxic drugs should receive notice of this requirement.

- A complete policy and procedures manual should be made available to all employees.

- Knowledge and competence of validated staff should be periodically evaluated and documented, and updated if necessary.

- Training programmes should include both theoretical and practical components.

6.7.2 Other Staff

- Staff who are not employees (such as students, residents, or other medical staff) should be informed through customary channels that they will be expected to comply with established procedures for preparing, administering, and disposing of cytotoxic drugs and their associated waste.

- Administration of cytotoxic drugs and care of patients in the home or the community is outside the scope of these guidelines.
However, nurses, patients, and families should be adequately informed of the risks associated with handling these drugs and associated wastes.

7. Health Evaluation and Monitoring

7.1 General

A variety of methods have been used to investigate potential effects of exposure to cytotoxic drugs. The workplace can be monitored using environmental measurements, or the workers themselves can be monitored by studying levels of the cytotoxic drug or its breakdown products in the blood or urine, or effects on body cells. In general, these methods have given either negative results or results which are difficult to interpret. An increased awareness of the potential hazards associated with occupational exposure to these drugs has led to the adoption of improved hygiene standards and safety procedures for healthcare workers handling cytotoxic drugs. Protective gowns, gloves, and vertical laminar-flow biological safety cabinets are now widely used for the preparation of cytotoxic drugs, resulting in very low level exposure.

7.2 Environmental Monitoring

No reliable measures of environmental exposure are currently available, although some work has been published on environmental contamination of specific chemicals in limited workspaces and the detection of specific drugs in the urine of healthcare workers.

7.3 Biological Monitoring

The ideal assay for monitoring exposure to cytotoxic drugs should meet several important requirements.

It should be sensitive, specific, and quantitative, so that exposure to a particular agent can be related to biological effect. It should also be rapid, reproducible, and inexpensive to perform. In addition, the procedure used to obtain samples for the assay should be non-invasive.

There is currently no assay that meets all these requirements. Neither is there one assay that can be used to detect the presence of all cytotoxic drugs.

Conflicting information (and opinion) exists regarding the value of routine biological tests in the health surveillance of personnel handling cytotoxic drugs. Nevertheless, employers and employees have a responsibility to ensure that they remain aware of, and apply, current developments for monitoring the health of personnel involved in the handling of cytotoxic drugs. Of the techniques currently available, cytogenetic techniques (such as sister chromatid exchange (SCE) in peripheral lymphocytes, cytokinesis blocked micronuclei) have the potential to assess exposures and risks, but have some drawbacks when used for biological monitoring. These tests have a place in research projects assessing particular occupational groups, but are not gener-
ally recommended in routine health surveillance. The biggest problem is the lack of specificity and cost.

Routine blood counts, which have been used in the past, have no value here and can lead to a false sense of security.

7.4 Biological Monitoring within New Zealand

A biological monitoring programme would provide a means of assessing whether there is a relationship between consistent detection of abnormalities and occupational exposure to cytotoxic drugs.

Although monitoring is not routinely performed at New Zealand hospitals, some monitoring facilities are available at the Centre for Mutagen Testing, which has been established at the Cancer Research Laboratory in Auckland.

Further information regarding the testing facilities can be obtained by contacting:

Prof. L. R. Ferguson
Cancer Research Laboratory
Auckland Medical School
Private Bag 92 019
Auckland
New Zealand

7.5 National Register of Personnel involved in the Preparation and Administration of Cytotoxic Drugs

The hospital community should consider the advisability and feasibility of establishing a national registry of hospital personnel who prepare and administer chemotherapy agents routinely, with a record of the number of drugs prepared or administered by each employee.

All pharmacy departments should develop a system that provides accurate records of all cytotoxic drugs handled by individual staff members involved in the preparation of cytotoxic drug solutions.

These records may be used to provide an indication of the degree to which an individual may potentially have been exposed to cytotoxic drugs.

Ideally this information should be recorded on specially designed cytotoxic drug exposure files.

Information recorded on these files should include the following details:

- Full name of the individual
- Smoking habits (number/day)
- Total amount of each drug handled
- Number of solutions (of each drug) prepared
- Total amount of time spent in contact with cytotoxic drugs.
The maintenance of cytotoxic drug exposure files serves several important functions:

- A requirement to complete daily exposure files serves to remind staff of the hazardous nature of cytotoxic drugs, and the need to take special precautions when handling these drugs.
- The records provide the pharmacist-in-charge with a log of total contact time of each individual with cytotoxic drugs. This information is useful in developing strategies for operation of a safe cytotoxic drug dispensing service.
- Information on the types and quantities of drugs handled by individuals may be useful for conducting epidemiological studies to assess the long-term effects of occupational exposure to cytotoxic drugs.

**Appendix 1: Glossary of Terms**

**Acute toxicity:** where a toxic effect occurs immediately or shortly after a single exposure.

**Antineoplastic:** anti cancer.

**Aseptic:** sterile, free from germs.

**Biohazard:** hazardous to life.

**Cancer:** a malignant tumour which can spread to other organs of the body, distinct from a benign tumour which cannot. (Although leukaemia and some other malignant diseases are not solid tumours, they meet other criteria for cancer and can be, and often are, included under this definition.)

**Carcinogen:** an agent which is responsible for the formation of cancer.

**Carcinogenic:** capable of causing cancer.

**Chemotherapy:** the treatment of disease by chemical substances.

**Chronic toxicity:** harmful effects of a chemical which occur after repeated or prolonged exposure. Chronic effects may also occur some time after exposure has ceased.

**Cytogenetics:** the study of the structure and functions of the cells of the body, with particular reference to the chromosomes.

**Cytotoxic:** destructive to living cells.

**Excreta:** any waste matter eliminated from the body.
Extravasation: leakage of cytotoxic drug from the vein into the surrounding tissue.

Immunology: the study of immunity and an individual's response to antigens.

Immunosuppressive drug: a drug that is administered to reduce the tendency of the living organism to reject tissues or an organ, e.g. kidney or heart from a donor.

Immunotherapy: the stimulation of the body's immune system as a means of treating cancer.

Infusion: the term applied to the injection of a solution into blood vessels or tissue underlying the skin.

Ingestion: swallowing, by the oral route.

Inhalation: breathing in.

Irritant: a substance that will produce local irritation or inflammation on contact with tissues and membranes such as skin or eyes, or will, after inhalation, produce local irritation to nasal or lung tissue.

Laminar flow: an essentially uni-directional airflow with minimum turbulence.

Metabolite: in physiology, any product yielded by or taking part in the chemical processes essential to life.

Mutagenic: able to cause mutations.

Neoplasm: another word for tumour.

Oncogenic: causing or encouraging the growth of tumours.

Oncology: the science of new growth. It is that part of medical science which is concerned with the management of malignant disease such as cancer.

Teratogenic: able to produce abnormalities in a developing embryo or foetus, that is, causing birth defects.

Tumour: a swelling, enlargement, or an abnormal mass of tissue in which the growth of cells is uncontrolled. A tumour can either be benign (not malignant) or malignant (cancerous).
Appendix 2: Symbols for Waste Classification

**Special Wastes**

The symbol for these wastes is the internationally recognised biological hazard symbol in black:

![Special Wastes Symbol](image)

**Radioactive Wastes**

The symbol for these wastes is the internationally recognised ionising radiation symbol in black:

![Radioactive Wastes Symbol](image)

**Cytotoxic Wastes**

The symbol for these wastes is the telophase symbol in black:

![Cytotoxic Wastes Symbol](image)

Source: NZS 4304: 1990
Appendix 3: Contents of Cytotoxic Drug Spill Kit

1. Gown with cuffs and back closure, made of water impermeable fabric
2. Pair shoe covers
2. Pairs gloves
1. Pair goggles
1. Mask
1. Disposable dust pan (to collect any broken glass)
1. Plastic scraper (to scoop materials into dust pan)
2. Plastic backed or absorbable towels
1. Container of desiccant powder or granules to absorb wet contents
2. Disposable sponges (one to clean up spill, one to clean up floor after removal of spill)
1. Puncture-proof, leak-proof container (to place all contents in), clearly marked with a biological hazard waste label
1. Container of 70% alcohol for cleaning spill area
2. Large cytotoxic waste disposal bags

Appendix 4: Selected Reading and Bibliography

References

4. AS/NZ 4273:1995 Guidelines for the design, installation and use of pharmaceutical isolators.
5. NZS 4304:1990 Health care waste management.
Bibliography


