



HSE Guideline on the Safe Handling of Cytotoxic Drugs 2022

Policy

Procedure

Protocol

Guideline


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PART A:

1.0 Introduction

Cytotoxic drugs are used in hospital settings and the community in the treatment of cancers and non-malignant diseases (e.g. rheumatoid arthritis and multiple sclerosis).

Cytotoxic drugs (sometimes known as antineoplastics) describe a group of medicines that contain chemicals which are toxic to cells, preventing their replication or growth. The toxicity of cytotoxic drugs means that they can present significant risks of damage to health to those who handle them. Occupational exposure can occur when control measures are inadequate. Exposure to cytotoxic drugs may be through skin contact, skin absorption, inhalation of aerosols or dusts, ingestion and needle stick injuries resulting from a number of activities to include:

- Drug receipt/storage/preparation
- Drug administration
- Patient care activities
- Handling patient waste and contaminated laundry
- Transport and waste disposal
- Cleaning spills

By assessing the risk of exposure, implementing control measures and ensuring that appropriate advice and training is provided to employees the risk of exposure to cytotoxic drugs can be reduced to levels 'as low as technically possible'.

All risk assessments must be documented and must include the necessary control measures to eliminate or minimise the risks. The Cytotoxic Drugs Risk Assessment Form is available to download [here](#).

2.0 Risk Assessment Process

The hazard identification and risk assessment process will establish the cytotoxic drugs in use, who is at risk, the route of exposure, the specific activities where there is a risk of exposure and the control measures required.

The risk assessment process comprises of the following **four steps**:

- 1. Hazard Identification** - includes identifying the hazardous properties of the drug
- 2. Identification of the risk associated with the hazard** – decide who might be harmed and how
- 3. Assess (Rate) the risks** – assess how likely it is that cytotoxic drugs could cause ill health and decide if existing precautions are adequate or whether more should be done
- 4. Identify additional control measures (if required)** - identify and implement the most effective control measures

Communication and consultation with relevant stakeholders (e.g. employees, contractors, service users) at each stage of the risk assessment process is essential and will help achieve better health and safety outcomes. This should occur throughout the process.

To support line managers in meeting their legal obligations, to carry out workplace occupational safety and health risk assessments, please undertake the programme "[Risk Assessment Webinar](#)" available on HSEland.

Step 1 Hazard Identification - This requires identifying the hazardous properties (to include both health hazards and physical hazards) of the cytotoxic drugs in use.

NOTE - This step has been completed as outlined below. For the purpose of the risk assessment, cytotoxic drugs (to include all those deemed carcinogenic, mutagenic or reprotoxins (including teratogens¹); (CMRs)) are assigned to Hazard Group E and are subject to the measures outlined under the Safety, Health and Welfare at Work (Carcinogens) Regulations 2001 to 2019.

(A) Health Hazard Identification & Assignment to Hazard Groups

Identifying the health hazardous properties is carried out by the allocation of cytotoxic drugs to particular hazard classes² based on their hazardous properties under Classification, Labelling, Packaging (CLP) Regulations. This information may be obtained from the Safety Data Sheets (SDS) (if available for either the drug product or the active pharmaceutical ingredient) or the Summary of Product Characteristics (SPC) Information leaflet, particularly Section 4.6 Fertility, pregnancy and lactation and Section 5.3 preclinical safety data.

Under CLP, the potentially adverse properties of substance are represented by [hazard pictograms](#), signal words (Warning / Danger) and Hazard statements (H Statements). The H statements representative of health hazards are allocated to one of five groups A – E. Group A being the least hazardous and Group E being the most hazardous. (See Appendix IA for further information on Hazard Statements for Groups A-E and Hazard Classifications for CMRs).

For some health effects (e.g. genetic damage and cancer arising from it, and respiratory sensitisation) the available data and current state of knowledge do not allow confident identification of exposure levels that present no significant risk hence they have been assigned to Hazard Group E (most hazardous).

For the purpose of this risk assessment, and using the above rationale, a worst case approach is being adopted and all cytotoxic drugs (to include all those deemed carcinogenic, mutagenic or reprotoxins) are assigned to Hazard Group E.

Note: With reference to identifying other health hazards as required by legislation, there is a practical difficulty due to the absence of a legal requirement to supply SDSs or apply CLP labelling. Furthermore, by assigning Cytotoxic drugs to Hazard Group E and consequently adopting the highest level control measures, protection against any additional health hazards is automatically afforded.

(B) Physical Hazard Identification

A limited number of cytotoxic drugs may also pose a flammability hazard and these must also be considered in the context of the risk assessment.

Identify the physical form of cytotoxic drugs in use and stored to include drugs purchased 'in a ready to administer form'

Draw up a list of cytotoxic drugs dividing the list into:

- Solids i.e. powders (prior to reconstitution); coated tablets/capsules
- Liquids and solutions

¹Teratogenic effects (which cause human birth defects) constitute a health hazard for which a separate classification is no longer provided in the recent EU classification legislation (CLP Regulation 2008). Instead, they are seen as developmental toxicants, with developmental toxicity falling within the hazard class of reproductive toxicity (*European Agency for Safety and Health at Work (2016)*)

²Hazard Class is a group of hazardous chemical substances that share similar properties

Step 2- Identify the Risks Associated with the Hazard i.e. Identify the work activities / tasks where there is a risk of occupational exposure to cytotoxic drugs, identify who is at risk and how, examine the work environment and work practices.

<p>Identify the work activities/tasks which may expose employees to cytotoxic drugs</p>	<p>For example:</p> <p>Drug preparation in the pharmacy to include:</p> <ul style="list-style-type: none"> • Delivering, unpacking and pre-preparation storage • Drug preparation • Cleaning the drug preparation facilities • Cytotoxic waste management to include unused cytotoxic preparations • Spills management • Handling contaminated uniforms • Maintenance activities • Internal transport to ward / day care centre <p>Drug administration on the ward / day care centre</p> <ul style="list-style-type: none"> • Drug administration • Patient care after administration • Cytotoxic waste management • Spills management • Handling contaminated laundry • Maintenance work <p>Drug administration in a community setting /home</p> <ul style="list-style-type: none"> • Transport to the community setting /home • Drug administration • Disconnecting chemotherapy infusions in the home • Patient care after administration e.g. toileting • Spills management • Handling, transport and management of waste
<p>Identify the categories of personnel who may be directly or indirectly exposed</p>	<p>These may include:</p> <ul style="list-style-type: none"> • Pharmacy staff • Nursing / Medical staff / Healthcare Assistants • Support service staff • Maintenance staff • Allied Health Professionals • Sensitive risk groups e.g. pregnant employee, inexperienced employees young workers • Patients, visitors, family members • Contractors <p>Note: With reference to the employment of Young Persons Regulation 145 of the Safety, Health and Welfare at Work (General Application) Regulations 2007 prohibits the employment of a young person where a risk assessment reveals that the work involves harmful exposure to agents which are toxic, carcinogenic, cause heritable genetic damage, or harm to the unborn child or which in any other way chronically affects human health.</p>

<p>Examine the work activities, work conditions and work area design</p> <p>Involve employees who are at risk of exposure to cytotoxic drugs and related waste.</p> <p>For healthcare personnel the potential of exposure exists during tasks such as drug reconstitution and preparation, administration and disposal of waste equipment or patient waste</p>	<p>What to look for:</p> <ul style="list-style-type: none"> • How the substance is used in various tasks • The quantities and concentrations used • The number of employees that may be exposed • Risk control measures already in place and their effectiveness
<p>Determine the routes of exposure</p> <p>The more common routes of exposure are contact with skin or mucous membranes (e.g. spillage and splashing), inhalation (e.g. over-pressurising vials), and ingestion (e.g. through eating, drinking or smoking in contaminated areas or from poor hygiene)</p>	<p>Identify the routes of exposure for cytotoxic drugs in:</p> <ul style="list-style-type: none"> • Solids i.e. powders (prior to reconstitution), coated tablets/capsules • Liquids and solutions <p>Common routes of exposure include:</p> <ul style="list-style-type: none"> • Inhalation of aerosols or dusts containing drug droplets • Ingestion • Dermal absorption • Mucosal absorption • Percutaneous injuries
<p>Ascertain the potential harmful effects of exposure</p>	<ul style="list-style-type: none"> • For Hazard Statements representative of health hazards please refer to Appendix IA • Consider any potential for harmful interactions with other drugs, chemicals etc. in the pharmacy.
<p>Identify the characteristics of an exposure</p> <p>As a sufficient number of cytotoxic drugs fall into Hazard Group E, the control approach adopted must be reduced to as low a level as is technically possible</p>	<p>Identify:</p> <ul style="list-style-type: none"> • Frequency and duration of exposure (i.e. how often and for how long the exposure occurs during a task) <p>Note: where the level of exposure has been reduced to as low a level as is technically possible, it is envisaged that exposure may only occur in the event of an incident e.g. bag leaking, damaged syringes etc.</p>

Step 3-Assess the Risk

The next step is to:

- (1) Identify and document the existing control measures and
- (2) Assess and rate the risk associated with the hazard taking into account any existing control measures (Refer to [Risk Assessment Tool](#))

The likelihood and impact will depend on the control measures already in place, how effective they are, the experience, knowledge and skill of the employee(s) undertaking the task, the system of work and the available resources. In addition consideration should be given to the review of information relating to incidents or symptoms of exposure, monitoring and health surveillance.

Examples:

- Employee reports of any adverse effects related to the administration of cytotoxic drugs
- Records of any spills and near misses
- Reported incidents and follow up
- Health surveillance records

Based on a consideration of the above factors, a numerical likelihood rating and impact rating should be selected from the [Risk Assessment Tool](#).

Step 4- Identify any additional control measures required

If the risk is not adequately controlled further measures must be considered utilising the *Hierarchy of Controls* outlined below. These controls are set out in descending order of effectiveness.

1. Elimination

In general it is not possible to eliminate cytotoxic drugs from the workplace

Consider the following examples (supported by a risk benefit analysis):

- Eliminate or discontinue a dangerous activity that exposes workers to risk
- Minimise the preparation of drugs outside a controlled environment³ where possible
- Consideration to be given to the compatibility of outsourced products and closed system transfer devices
- Purchase of cytotoxic drugs in liquid form where possible to minimise pharmacy preparation steps

2. Substitution

Substitution involves using a less hazardous substance or a substance in a less hazardous form, or substituting techniques or processes with less hazardous ones

Consider the following examples:

- Use of a less hazardous drug where possible
- Using single-dose preparations
- Using cytotoxic drugs in a liquid form rather than in a powder form
- Incorporate handling techniques that minimise aerosol generation (in exceptional circumstances if crushing of tablets or capsule opening is deemed essential at patient's bedside refer to Pharmacy Department for advice)

³A controlled environment is a dedicated area that is clean, well ventilated, free from clutter, easy to maintain and is free of interruptions.

	<ul style="list-style-type: none"> • Using drugs in vials, not ampoules • Using drugs in plastic vials, or vials reinforced with plastic casings • Using needleless /needle safe systems • Using tablets in a foil/blister pack
3. Engineering controls	
<p>Engineering controls consist of the facility, equipment and the heating and air ventilation system. There are varying levels of engineering controls which are utilised to provide protection to the operator from exposure to hazardous drugs as well as ensuring a quality product. These vary from stand-alone equipment in a controlled environment* to aseptic compounding units.**</p> <p>*A controlled environment minimises risk of the cytotoxic exposure by implementing precautionary measures. It is a dedicated area that is clean, well ventilated, free from clutter, easy to maintain and is free of interruptions.</p> <p>**An aseptic compounding unit is a specialised suite of graded rooms with engineering controls such as HEPA filtration that contains specialised equipment such as isolators.”</p>	<p>Consider the following examples:</p> <ul style="list-style-type: none"> • Conducting drug preparation work in an appropriately designed and secure clean room • Installation of pharmaceutical isolators (Ref: (2015) Handling Cytotoxic Drugs in Isolators in NHS Pharmacies) • Using high efficiency particulate air (HEPA) filters • Placing dispensed drugs in impermeable packaging for delivery to administration areas • Designating a cytotoxic drug administration area, which only permits entry to authorised people • Adopting a closed transfer system • Using needleless /needle safe injection sets for drug administration⁴ • Use of an opaque bag to protect from light and an additional clear bag for storage and handling.
4. Administrative controls	
<p>If a risk remains, administrative controls should be implemented to further reduce the risk. Administrative controls include work practices that help to reduce employee exposure to cytotoxic drugs and related waste. The effective use of administrative controls relies on the full cooperation of employees, and therefore, consultation is important during their development. Adequate supervision and training are</p>	<p>Consider the following examples:</p> <ul style="list-style-type: none"> • Purchasing controls/supply chain controls • Delivery of cytotoxic drugs products in leak-proof packaging where possible • Delivery containers to be labelled with cytotoxic warning labels • Restricting the number of employees who work with cytotoxic drugs • Reduce the duration and/or frequency of exposure • Effective work organisation layout and design • Drugs are stored in dedicated clearly marked storage areas • Summary Product Characteristics (SPC) are available at site of storage and use and Safety Data Sheets where available • Documented procedures for the regular decontamination, cleaning and disinfection of work areas

⁴ European Union (Prevention of Sharps Injuries in the Healthcare Sector) Regulations, 2014

<p>paramount if work practices are to play an effective part in reducing employee exposure to cytotoxic drugs and related waste.</p> <p>Employees must be provided with appropriate information on the cytotoxic drug and why and how exposures are kept as low as is technically possible.</p>	<ul style="list-style-type: none"> • Keeping containers of cytotoxic drugs secure • Ensuring all containers of cytotoxic drugs are labelled with the manufacturer's or importer's label • Use of safe systems for internal transport of cytotoxic drugs • Prohibit eating, drinking and smoking in work areas • Hand hygiene • Developing and implementing standard operating procedures for all work activities to include activities in the homecare setting where there is a risk of exposure to cytotoxic drugs • Ensuring robust communication channels between hospital and community health care settings • Based on training needs assessment providing appropriate information, education and training to employees to include how to use substances and equipment safely, how to manage spills • Using cytotoxic signs and labels to clearly identify all cytotoxic drugs • Storing cytotoxic waste in specific, clearly identified areas, separate from other waste • Disposing of cytotoxic waste in accordance with <i>Healthcare Risk Waste Management Segregation Packaging and Storage for Healthcare Risk Waste, November 2010</i> • Disposing of contaminated nappies • Developing and implementing emergency procedures to deal with spills and exposure • Adequate supervision and follow up • Effective management of contaminated laundry • Providing suitable washing facilities • Providing first aid facilities • Equipment commissioning / decommissioning, maintenance, testing and inspection must be carried out by a competent person in accordance with manufacturer's instructions and documented safe systems of work • Incorporate secure storage facilities • Procedures for the management of foreseeable and unforeseeable exposures (See section 8.0) • Training (See section 5.0) • Health Surveillance and Record Keeping (See section 6.0) • Health monitoring (See section 7.0) • Incident Management (See section 8.0) • SOP for the preparation and packaging of cytotoxic drugs for transport to other facilities to include engagement with couriers
<p>5. Personal protective equipment (PPE)</p>	
<p>Where a risk remains, the risk should be controlled by providing PPE to employees at risk. PPE, as the last line of defense, is any device or appliance designed to be worn or held by an individual</p>	<p>This may include:</p> <ul style="list-style-type: none"> • Impermeable coveralls and gowns • Head covering • Closed footwear • Overshoes • Gloves of appropriate material and thickness (EN374-3:2003)

<p>for protection against one or more health and safety hazards⁵. Effective protection will only be obtained if the PPE chosen is:</p> <ul style="list-style-type: none"> • Suitable for the task • Meets the relevant technical standard • Suited to the wearer and environment • Compatible with other PPE in use • In good condition • Readily available • Worn correctly and changed appropriately • Maintained in accordance with the manufacture's recommendations and relevant standards 	<ul style="list-style-type: none"> • Safety glasses • Respiratory protective equipment⁶ <p>Note: Employees must be consulted with regard to the selection of PPE and provided with instruction, information and training in its correct use, maintenance, storage and also in correct donning and doffing</p>
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There is a requirement to do all that is technically possible to minimise the risk of harm to staff, service users and visitors. Therefore, once a hazard is identified and the risk assessed, any additional control measures must be implemented.

An action plan inclusive of time frames and named responsible persons should be devised for each risk where the assessment completed indicates that further control measures are required. Actions must be realistic and timely.

3.0 Communication and Notification of Risk

Where additional resources are required for the control of risks associated with handling of cytotoxic drugs and such resources are not immediately available, the risks associated with this hazard should be incorporated onto the relevant risk register and prioritised for action or notified to the next level. In the interim the risk will continue to be managed and monitored so far as is reasonably practicable at local level and the relevant manager informed of any changing circumstances⁷.

4.0 Monitoring and Periodic Review

The risk assessment must be documented and reviewed annually or more often in light of changes to work practices or when new equipment is introduced.

Steps must be taken to periodically review the effectiveness of current control measures in place. This should include the review of incidents and the auditing of safe systems of work. Performance indicators should be agreed locally and regularly analysed to measure progress.

⁵ HSA(2015) A guide to Non-Respiratory PPE for use with Chemical Agents in the Workplace

⁶ HSE UK (2010) A guide to Respiratory Protective Equipment HSG53, The selection, use and maintenance of respiratory protective equipment - a practical guide. HSE Books ISBN 978 0 7176 2904 6

⁷ HSE, (2017), Integrated Risk Management Policy (Part 3, Managing and Monitoring Risk Registers) – Guidance for Managers

REVIEW CONTROL MEASURES	
<p>Review the risk control measures to ensure they perform as originally intended and continue to provide adequate control</p>	<p>This may include:</p> <ul style="list-style-type: none"> • Auditing compliance with safe work practices and safe systems of work • Frequent inspections • Testing of equipment and relevant test reports • Preventative maintenance • Remedial work • Review of employee competencies • Monitoring health surveillance results • Review data from near misses, incidents, injuries or reports of work related illness

5.0 Training

Employers have a duty:

- To provide information, instruction, training and supervision to employees who handle cytotoxic drugs and related waste and
- To ensure that only employees who have received appropriate training and instruction carry out work involving the handling of cytotoxic drugs and related waste.

The outcome of the risk assessment should be used to identify staff requiring specific training. Different levels of training are required depending on the level of potential risk of exposure to cytotoxic drugs and related waste.

Employees at greater risk of exposure to cytotoxic drugs	Employees at lower risk of exposure to cytotoxic drugs
<ul style="list-style-type: none"> • Pharmacy personnel • Nursing personnel • Medical personnel • Laboratory personnel 	<ul style="list-style-type: none"> • Stores personnel • Cleaning personnel • On-site waste porters • Porters • Ambulance personnel • Waste handlers • Laundry personnel • Supervisors and managers (non-clinical) • Waste generators • Maintenance personnel to include external contractors • Other Allied Healthcare professionals

Training is required:

- At induction
- Prior to commencement of duties where cytotoxic drugs and related waste are involved
- In the event of the transfer of an employee or change of task assigned to an employee
- On the introduction of new work equipment, new systems of work, or changes in existing work equipment or systems of work
- On the introduction of new technology

- In the event of legislative changes
- To maintain employee competency.

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

- Legislative requirements for health and safety to include the provision of the Pregnant Employee Regulations
- Occupational hazards of exposure to cytotoxic drugs and waste / potential risks to health including the additional risks due to smoking
- The risk management process
- Control measures and work practices to be adopted when handling cytotoxic drugs and waste
- Maintenance of equipment
- Cleaning and laundering procedures
- Correct selection, use, cleaning and disposal of personal protective equipment
- Procedures to be adopted in the event of an accident, injury or spill
- Access to first aid resources
- Storage, transport, treatment and disposal of cytotoxic waste
- Hygiene requirements
- Labelling, warning and hazard signs.

All training programmes should be reviewed to ensure they are applicable to the work activities being undertaken.

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

- Date of the session
- Topics dealt with at the session
- The name of the person who conducted the session
- The names of the employees who attended the session
- Course evaluations
- The competencies assessed.

In addition, employers should evaluate the effectiveness of training provided.

6.0 Health Surveillance and Record Keeping

The Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001 and amendment Regulations require the employer to provide health surveillance for employees when the risk assessment reveals a risk to their health or safety. Following health surveillance the responsible Medical Practitioner may indicate that health surveillance must continue after the end of exposure for as long as he/she considers it necessary to safeguard the health of the employee concerned.

Employers have a responsibility to ensure that they remain aware of and apply current developments for monitoring the health of employees involved in the handling of cytotoxic drugs.

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 or incidents 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 for pharmaceutical products, therefore adoption of standard precautions and the principles of ALARA (as low as reasonably achievable) is recommended. Standard operating procedures with

sufficient initial and regular ongoing training in safe handling/administration are central to reducing potential for exposure and risk.

Health surveillance is appropriate where:

- Exposure to a hazardous substance is such that an identifiable disease or adverse health effect may be related to exposure
- There is a reasonable likelihood that the disease or effect may occur under the particular conditions of the work undertaken
- There are valid techniques for detecting indications of the disease or effect, and
- The technique of investigation is of low risk to the employee.

The results of the risk assessment for staff potentially exposed to cytotoxic drugs should be used to determine whether health surveillance is necessary. Where this has shown that exposure is most unlikely to result in any disease or adverse health effect, surveillance is not required.

In practice, the criteria for health surveillance are unlikely to be met for employees handling cytotoxic drugs. However, employers should keep a health record on all staff potentially exposed to these compounds. The health record should contain at least the following: surname, forenames, gender, date of birth, permanent address, date when present employment started and a historical record of jobs in this employment involving exposure to cytotoxic drugs.

A number of published studies have used biological monitoring and biological effect monitoring (measurement and assessment of early biological effects caused by absorption of handling cytotoxic drugs and chemicals) to try and draw inferences about the health of workers exposed to cytotoxic drugs. However, data from using these techniques are difficult to interpret in the context of the health of an individual and are therefore not recommended for routine use in health surveillance.

Furthermore the London Cancer Alliance (LCA) cite 'there is currently no form of biological monitoring or health assessment technique that is sensitive or specific enough to adequately predict the effect of chronic long-term exposure. It is therefore recommended that staff monitoring (e.g. blood or urine testing) is not routinely undertaken until improved methodology and means to interpret the data are available. Hence, the primary focus of safety during the preparation and administration of cytotoxic drugs must be on control of the working environment, minimising exposure and safe practice.

7.0 Health monitoring

This includes the implementation of a health programme which monitors an individual's health status pre-employment/pre-placement on an ongoing basis (if necessary) to determine any adverse effects to health following exposure to cytotoxic drugs.

A responsible medical practitioner should be appointed to oversee the programme. 'Appointed' means that the employer has a formal arrangement with a medical practitioner. All employees must be made aware of this arrangement.

7.1 Pre – employment and baseline health monitoring before the employee commences work with cytotoxic drugs involves:

7.1.1 Pre-Placement Health Assessment Form

- Manager indicates that required duties include exposure to cytotoxic drugs
- Prospective employee provides details including previous employment and aspects

- of past medical history and current treatment
- See “Health Service Executive Pre-Placement Health Assessment Form” for further information
- Forms are reviewed by Occupational Health staff. Where necessary, further contact is made with the prospective employee, or an in-person assessment is arranged.

7.1.2 Employers

- If health concerns are raised by an employee who is commencing work with cytotoxic drugs, the employer should carry out a risk assessment and refer the employee to their local Occupational Health Department as necessary.

8.0 Incident Management

8.1 Unforeseen Exposure (e.g. unforeseeable event or accident)

In the event of an unforeseen event e.g. accident which is likely to result in an abnormal exposure the employer must inform his/her employees.

The employer must also ensure that until the situation is restored to normal and the cause of abnormal exposure has been eliminated:

- (a) Only employees who are essential to the carrying out of repairs and other necessary work are permitted to work in an area of abnormal exposure
- (b) Employees are provided with protective clothing and individual respiratory protection equipment based on Risk Assessment
- (c) Such exposure is not permanent and is kept to the minimum time necessary, and
- (d) Unprotected employees are not permitted to work in an area of abnormal exposure.

There is a reciprocal legal duty on the employee to wear personal protective equipment provided by the employer and follow local protocols.

8.2 Foreseeable Exposure (any activity for which there is a foreseeable risk of exposure)

Where there is a potential for a significant increase in exposure of employees to cytotoxic drugs, and in respect of which all scope for further technical preventive measures for limiting exposure has already been exhausted, the employer must consult with the employees or their representatives on measures for limiting exposure to include:

- Reducing the duration of the exposure
- Providing individual respiratory equipment and PPE
- Ensuring that exposure is not permanent and is kept to a minimum
- Clearly demarcating the affected areas and limiting access to authorised personnel.

There is a reciprocal legal duty on the employee to wear personal protective equipment provided by the employer.

Any incident should be reported in accordance with the [HSE Incident Management Framework](#). The cause of the incident reviewed and determined, and follow up action(s) taken. The control measures developed during the risk assessment process should be reviewed and amended if required to prevent recurrence.

All incidents must be reported to the State Claims Agency via National Incident Management System (NIMS).

8.3 Emergency Procedures

Planning for emergencies is an essential part of risk management. Local protocols must be in place for the management of cytotoxic drug and related waste exposure, skin penetrating injury or spill to include rapid access to medical attention for the potentially exposed individual if necessary.

8.4 Information and notification to the HSA

When requested, the employer is required to provide the HSA with the findings of any assessment where the risk assessment identifies a risk to any employee's health or safety, with information relating to:

- Activities carried out including the reasons for which cytotoxic drugs are used
- Quantities of substances or preparations manufactured or used
- Number of employees exposed
- Preventive measures taken to prevent or reduce exposure
- Type of personal protective equipment used
- Nature and degree of exposure of employees, and
- Replacement substances or preparations used to reduce exposure.

9.0 Roles & Responsibilities

9.1 Chief Executive Officer (CEO)

The CEO has overarching responsibility to ensure, so far as is reasonably practicable the safety, health and welfare at work of all employees and others affected by HSE activities.

The CEO delegates operational responsibility for the day-to-day discharge of statutory duties under the Safety, Health and Welfare at Work Act, 2005 to the Executive Management Team, Senior Management Team, Extended Senior Management Team, Senior Managers and Line Managers for all matters within their control.

9.2 Local Senior Managers e.g. Hospital GM/CEO, Heads of Pharmacy, Directors of Nursing are responsible to:

- 9.2.1 Ensure that all employees are aware of this Guideline
- 9.2.2 Ensure the measures specified in Schedule 3 of the Carcinogens Regulations (S.I. 78 Of 2001 as amended by S.I. No. 622 of 2015 and S.I. No. 592 of 2019) (Refer to [Risk Assessment Tool](#)) are applied
- 9.2.3 Ensure that risk assessments are undertaken, regularly reviewed, communicated, in a written format and form part of the site or service Safety Statement
- 9.2.4 Reduce the use of cytotoxic drugs (in so far as is technically possible) by replacing them with substances, preparations or processes which eliminates or reduces the risk to an employee's health or safety
- 9.2.5 Give particular attention to any effects concerning the health or safety of employees at particular risk and to take account of the desirability of not having such employees present in areas where they may be exposed
- 9.2.6 Ensure when cytotoxic drugs are in use they are (in so far as is technically possible) used in a closed system
- 9.2.7 Ensure that the level of exposure of employees is reduced to as low a level as is technically possible where it is not technically possible to use a closed system
- 9.2.8 Ensure employees are provided with appropriate protective or other appropriate

- special clothing
- 9.2.9 Provide separate storage places for working or protective clothing and for ordinary clothes
- 9.2.10 Provide health surveillance for employees when the risk assessment reveals a risk to their health or safety
- 9.2.11 Ensure that employees are provided with appropriate information, instruction, supervision and training
- 9.2.12 Ensure an emergency plan is in place to prevent or mitigate the potential for emergency situations
- 9.2.13 Keep an up to date list of employees where the results of the risk assessment reveal a risk to their health and safety, indicating where possible the exposure. This list must be available for inspection at the request of the responsible medical practitioner or the HSA
- 9.2.14 Ensure that each employee has access to the information on the list which relates to him/her personally, and
- 9.2.15 Ensure that employees or their Safety Representative, or both, have access to anonymous collective information
- 9.2.16 Ensure the exposure record, the health surveillance and the medical record are kept for at least 40 years following the end of the relevant exposure and forward to the HSA if an employer ceases to be an employer for the purposes of the 2001 Regulations
- 9.2.17 Ensure all incidents are reported and managed in accordance with the [HSE Incident Management Framework](#)
- 9.2.18 Monitor and review the effectiveness of preventative procedures and measures
- 9.2.19 Audit implementation of the Guideline

9.3 Line Manager Responsibilities

- 9.3.1 Assess any risk to any employee's health or safety resulting from any activity likely to involve a risk of exposure to a cytotoxic drug, and to determine the nature, degree, routes of exposure and duration of any employee's exposure, and to implement the identified control measures
- 9.3.2 Review the risk assessment regularly and in any event whenever there is a change in conditions at the place of work
- 9.3.3 Prevent exposure of employees where the results of the risk assessment reveal a risk to their health or safety
- 9.3.4 Ensure in the case of areas where the risk assessment reveals a risk to employees' safety and health, that access is restricted to those employees performing their work or duties, and ensure that all containers, packages and installations containing cytotoxic drugs are labelled clearly and legibly and display clearly visible warning and hazard signs
- 9.3.5 Ensure employees do not eat, drink or smoke in any working area where there is a risk of exposure
- 9.3.6 Ensure that employees wear personal protective equipment provided
- 9.3.7 Ensure personal protective equipment is properly stored in a designated place, and cleaned where possible and checked before use and in any case after each use
- 9.3.8 Ensure personal protective equipment found to be defective is repaired or replaced, as may be appropriate
- 9.3.9 Implement appropriate responses for possible emergencies e.g. spill management, the management of cytotoxic drug and related waste exposure, skin penetrating injury
- 9.3.10 Carry out a training needs assessment (informed by risk assessment) to identify appropriate employee training

- 9.3.11 Ensure employees are adequately supervised in the performance of their work activities
- 9.3.12 On receiving notification that an employee is pregnant, carry out a pregnant employee risk assessment to assess the specific risks of exposure to cytotoxic drugs and take action to ensure her safety and that of her unborn child
- 9.3.13 Implement, monitor and review work practices, SOPs, procedures, control measures and the findings of incident reviews as are necessary to prevent or reduce exposure to levels as low as technically possible

9.4 Employee Responsibilities

- 9.4.1 Take reasonable care to protect their safety, health and welfare and that of others
- 9.4.2 Adhere to and apply this guideline, local procedures and safe systems of work and any associated risk assessments and risk controls
- 9.4.3 Work in a safe and responsible manner and co-operate with their Line Manager
- 9.4.4 Co-operating in the regular review of risk assessments and control measures
- 9.4.5 Attending relevant training as appropriate
- 9.4.6 Wear Personal Protective Equipment (PPE) provided as instructed
- 9.4.7 Reporting any defects in equipment or the place of work and any unsafe systems of work to the Line Manager
- 9.4.8 Reporting incidents to the Line Manager in accordance with the [HSE Incident Management Framework](#)

Appendix IA - Hazard Statements for Groups A-E and Hazard Classifications for CMRs

Hazard Statements for Groups A- E

A	B	C	D	E
Skin / Eye Irritant or not hazardous	Harmful on single exposure	Severely irritating, corrosive or toxic	Very toxic on single exposure	Risk of cancer or genetic damage
H304, H315, H319, H336 and all H numbers not otherwise listed	H302, H312, H332, H371	H301, H311, H314, H317, H318, H331, H335, H370, H373	H300, H310, H330, H351, H360, H361, H362, H372	H334, H340, H341, H350
Least Hazardous			More Hazardous Substances	Special Cases

Ref: Science and Technology Facilities Council (2019), COSHH Risk Assessment Procedure Rev. 1.5

Hazard Classification for Carcinogens, Mutagens and Reprotoxins (CMRs)

Carcinogens (Category 1)

- Category 1A (Carc.1A) carcinogen substances known to have carcinogenic potential for humans, classification is largely based on human evidence
- Category 1B (Carc.1B) substances which are presumed to have carcinogenic potential for humans, classification is largely based on animal evidence.

Mutagens (Category 1)

- Category 1A mutagen (Muta.1A) substances which are known to induce heritable mutations in the germ cells of humans; classification is based on positive evidence from human studies
- Category 1B mutagen (Muta.1B) substances which should be regarded as if they induce heritable mutations in the germ cells of humans; classification is based on evidence from mutagenicity tests in mammals or humans.

Classification	Code	Hazard Statement
• Carc. 1A, 1B	H350	May cause cancer
• Muta. 1A, 1B	H340	May cause genetic defects

A **third category** of carcinogen/mutagen exists and while these fall outside the specific scope of the carcinogen regulations they must still be risk assessed under the Chemical Agents Regulations and the Safety, Health and Welfare at Work Act, 2005

- Category 2 carcinogens are suspected human carcinogens. This is based on evidence obtained from human and/or animal studies but which is not sufficient for a Category 1 classification
- Category 2 mutagens cause concern for human owing to the possibility that they may induce heritable mutations in the germ cells of humans.

Classification	Code	Hazard Statement
• Carc. 2	H351	Suspected of causing cancer
• Muta 2	H341	Suspected of causing genetic defects

Reprotoxins

Reprotoxin is a hazard associated with some chemical substances, which interfere in some way with normal reproduction. They may adversely affect sexual function and fertility in adult males and females, as well as causing developmental toxicity in the offspring.

Repr.1A - substances which are known human reproductive toxicants, largely based on evidence from human studies

Repr.1B - substances which are presumed human reproductive toxicants, largely based on data from animal studies

Classification	Code	Hazard Statement
Repro. Tox. 1A /1B	H360:	May damage fertility or the unborn child
Repro. Tox. 2	H361:	Suspected of damaging fertility or the unborn child

Appendix II A

Schedule 3 Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001

- Limitations of the quantities of a carcinogen or mutagen at the place of work
- The keeping as low as possible of the number of employees exposed or likely to be exposed to a carcinogen or mutagen
- Design of work processes and engineering control measures so as to avoid or minimise the release of carcinogens or mutagens into the place of work
- The use of appropriate systems for the extraction of carcinogens or mutagens at source compatible with the need to protect health and the environment
- The use of appropriate procedures for the measurement of carcinogens or mutagens, in particular for the early detection of abnormal exposures resulting from an accident or other unforeseen event
- The use of suitable working procedures and methods
- The use of collective protection measures and where exposure cannot be avoided by other means, individual protection measures
- The use of hygiene measures, in particular cleaning of floors, walls and other surfaces
- The provision of information for employees
- The demarcation of risk areas and the use of adequate warning and safety signs, including “no smoking” signs, in areas where employees are exposed or are likely to be exposed to carcinogens or mutagens
- The drawing up of plans to deal with emergencies likely to result in abnormally high exposure
- The means for safe storage, handling and transportation, in particular by using sealed containers which are clearly and visibly labelled
- The means for safe collection, storage and disposal of carcinogenic or mutagenic waste by employees, including the use of sealed containers which are clearly and visibly labelled

Part B:

1.1 Purpose

This Guideline is intended to raise awareness among employers and employees of the occupational hazards associated with cytotoxic drugs and will assist in the development of the necessary risk assessments, protocols and procedures to ensure the safety, health and welfare of employees and others who may be exposed, and to provide information about legislative requirements.

Note: This Guideline supersedes the HSE Guideline on the Safe Management of Cytotoxic Drugs, 2021 (GD:002:01) and must be implemented with immediate effect.

1.2 Policy Statement

It is the policy of the HSE to ensure the protection of employees from the potential risks related to the exposure to cytotoxic drugs. For the purpose of this Guideline, the term cytotoxic drug is used to refer to all drugs with direct anti-tumor activity including conventional anticancer drugs, antibody drug conjugates and partially targeted treatments (for example imatinib, sunitinib) and drugs such as thalidomide.

The handling and administration of cytotoxic drugs are potentially hazardous to the healthcare professionals involved in their preparation and administration, patient care activities, spill management, waste disposal, handling patients' bodily fluids and handling contaminated laundry and to the patients receiving them. While the risks to patients are, in the main, well documented and can be balanced against the clinical benefit little is known of the specific long term effects of occupational exposure to cytotoxic drugs and related waste.

In general cytotoxic drugs are considered to be hazardous chemical agents, as defined by the Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2001. Some cytotoxic drugs are considered carcinogenic (Cat. 1A and 1B) and/or mutagenic (Cat. 1A and 1B) and are therefore subject to the restrictions of the Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001 and amendment Regulations

For the purpose of this Guideline all cytotoxic drugs (to include Cat. 2 carcinogens, Cat. 2 mutagens, reprotoxins. Category R1A and 1B and Category R2) will be considered as subject to the Safety Health and Welfare at Work (Carcinogens) Regulations, 2001 to 2019.

Central to the Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001 and amendment regulations, is a requirement to assess the risk from any work activity likely to involve a risk of exposure to carcinogens or mutagens and hence, all risks to an employee's health or safety must be assessed to determine the nature, degree and duration of exposure and to identify the necessary control measures taking into account the legislative requirements.

In addition, the Safety, Health and Welfare at Work (General Applications) Regulations, Chapter 2 of Part 6: Protection of Pregnant, Post Natal and Breastfeeding, requires the employer to assess the specific risks to their employee and take action to ensure that she is not exposed to anything, which would damage either her health or that of her developing child.

Employees should notify their Line Manager as soon as possible if they are pregnant, trying to conceive or breast feeding. This is particularly important as the greatest risk is during the first three months of pregnancy, when rapid cell division and differentiation occurs.

At this point where an employee discloses her pregnancy, a risk assessment specific to the individual must be carried out and any appropriate action taken.

Please refer to the attached link for the [Pregnant Employee Risk Assessment Form](#).

1.3 Scope

The Guideline applies to *all employees whose* work activities may involve risk of occupational exposure to cytotoxic drugs.

In line with the HSE Code of Governance (2015) Section 38 and Section 39 Organisations are required to adopt the HSE Guideline on the Safe Handling of Cytotoxic Drugs or develop a Guideline of their own which is consistent with the HSE Guideline and provide a statement of assurance to the HSE regarding same.

1.3.1 Out of scope

The Guideline does not deal with patient care, except in the context of workplace health and safety, and hence does not provide information on the clinical/patient treatment aspects of prescribing, preparing, and administering of oral treatment cytotoxic drugs.

1.4 Objective(s)

- To update the Guideline in line with legislative changes and evidence based practice
- To outline the clear roles and responsibilities of all responsible persons
- To provide advice on the risk assessment process and guidance on risk reduction measures and evidence based practice which is aimed at minimising the risks of exposure to cytotoxic drugs
- To provide advice on health surveillance and health monitoring
- To outline the requirements for incident management and emergency procedures
- To outline the information and notification requirements to the HSA.

1.5 Outcome(s)

- A safer working environment for employees and others who fall under the scope of this guideline
- Clear roles and responsibilities of responsible persons are clearly outlined
- A simplified approach to risk assessment with clear guidance on risk reduction measures and evidence based practice which will minimise the risk of exposure
- Clarity on the requirements for incident management, emergency procedures, information and notification to the HSA

1.6 PPPG Development Group

Members of the Cytotoxic Guideline Development Group can be found in Appendix IIB of this Guideline. Conflict of Interest Declaration Forms were signed by members of the Guideline Development Group and are retained on file by the National Health and Safety Function (NHSF), Policy Team.

1.7 PPPG Governance Group

Members of the Guideline Governance Group can be found in Appendix IIIB of this Guideline.

1.8 Supporting Evidence

1.8.1 The following legislation is pertinent and was referred to during the development of this guideline.

- Safety, Health and Welfare at Work Act, 2005
- Safety, Health and Welfare at Work (Reporting of Accidents and Dangerous Occurrences) Regulations, 2016
- Safety, Health and Welfare at Work (General Application) Regulations, 2007 with particular reference to:
 - Chapter 1 of Part 2 – Workplace
 - Chapter 2 of Part 2 Use of Work Equipment
 - Chapter 3 of Part 2 - Personal Protective Equipment
 - Chapter 1 of Part 6: Protection of Children and Young Persons
 - Chapter 2 of Part 6 - Protection of Pregnant, Post Natal and Breastfeeding Employees
- Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001 and amendment 2015 and 2019 Regulations
- 2020 Code of Practice for the Safety, Health and Welfare at Work (Chemical Agents) Regulations (2001-2015) and the Safety, Health and Welfare at Work (Carcinogens) Regulations (2001-2019)
- CLP Regulation (EC) No 1272/2008 on Classification, Labelling and Packaging of Substances and Mixtures and amendment Regulations
- Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001 and amendment Regulations
- The European Communities (Carriage of Dangerous Goods by Road and Use of Transportable Pressure Equipment) Regulations 2011 to 2019

1.9 Glossary of Terms/Definitions/Abbreviations

Refer to Appendix IV

2.0 Development of PPPG

2.1 Literature Review Question

The objective of the literature review was to determine the legal requirements, establish current evidence and best practice aimed at minimising the risk of occupational exposure to cytotoxic drugs.

2.2 Literature Search Strategy

A literature review was undertaken. The search terms used were “carcinogen regulations”, “cytotoxic drugs”, “hierarchy of controls”, “safe handling of cytotoxic drugs in the workplace”, “reducing the likelihood of accidental exposure to cytotoxic agents”, “cytotoxic drugs and related waste”, “classification labelling and packaging”, “occupational exposure banding”, “control banding”. Search dates were confined to 2001 to date.

Websites accessed included the following: Health and Safety Authority (HSA); Health and Safety Executive (HSE UK); Workplace Health and Safety Electrical Safety Office Workers' Compensation Regulator; US National Library of Medicine National Institutes of Health; European Biosafety Network and European Chemicals Agency (ECHA), Canadian Centre for Occupational Health and Safety (CCOHS), National Institute for Occupational Safety and Health (NIOSH).

The literature accessed was predominately legislation, articles, systematic reviews, commentaries or health organisation policies and guidance.

2.3 Method of appraising evidence

The process outlined in this document is based on a review of the relevant legislation, codes of practice and relevant publications as documented in section 1.8.

The following questions were considered:

- Legislative requirements
- Definition of cytotoxic drugs
- Reference standards for environmental exposure
- Methods and criteria for control banding
- Control measures to be taken to prevent exposure to cytotoxic agents
- Requirement for health surveillance and health monitoring

Information which was deemed relevant for the purpose of developing this Guideline was extracted from these sources and deemed appropriate for use in various settings throughout the Irish Health and Social Care Setting.

2.4 Recommendations

The results from the literature were reviewed and the evidence supported the objectives as outlined in Section 1.4.

Key recommendations from the literature review are to:

1. Adopt the generic risk assessment scheme by:
 - a. Allocating substances to particular hazard groups based on their toxicological classification and labelling under Classification Labelling Packaging (CLP)
 - b. The anticipated exposures based on
 - i. Physical properties of the substance
 - ii. The amounts used
 - iii. Potential control options chosen
2. Adopt a risk management approach to minimise occupational exposure to cytotoxic drugs
3. Implement control measures to reduce exposure to levels as low as technically possible

These recommendations informed the revision of this Guideline as set out in Part A of this document.

2.5 Resources necessary to implement the PPPG Recommendations

This Guideline revision requires Service Managers to review existing practices and procedures to ensure they are aligned with the requirements as set out in this Guideline.

3.0 Governance and Approval

Formal governance for this Guideline is provided by the National Director of Human Resources (see Appendix IIIB). The PPPG Checklist for developing Non-Clinical PPPGs was signed prior to approval and is retained on file by the NHSF, Policy Team.

4.0 Communication and Dissemination

The Guideline will be disseminated by the National HR Directorate for immediate implementation by relevant Services, in line with the agreed HSE protocol and is available on <https://healthservice.hse.ie/staff/benefits-services/health-and-safety/health-and-safety-helpdesk.html>

5.0 Implementation

5.1 Managers (Responsible Persons) are responsible for implementation of this Guideline to include the identification of responsible person(s), specifying the necessary actions and timeframes for implementation within their areas of responsibility (Please refer to Part A Section 9.0 for detailed roles and responsibilities)

5.2 Education & Training

To support implementation of this Guideline, any queries and or requests for training can be made through the National Health and Safety Function, Helpdesk <https://healthservice.hse.ie/staff/benefits-services/health-and-safety/health-and-safety-helpdesk.html>

6.0 Monitoring, Audit and Evaluation

6.1 Managers are required to monitor and audit the implementation of this Guideline within their area of responsibility using the checklist in Appendix VB and maintain evidence of same

6.2 Implementation of this Guideline shall be audited periodically at national level and by the National Health and Safety Function.

7.0 Revision / Update

This Guideline shall be reviewed at national level every three years or earlier if circumstances require it

8.0 References:

- Safety, Health and Welfare at Work (Chemical Agents) Regulations 2001 to 2021
- HSE, UK (undated) COSHH essentials, controlling exposure to chemicals – a simple control banding approach, available at <https://www.hse.gov.uk/pubns/guidance/coshh-technical-basis.pdf>
- HSE, UK (2015), Handling Cytotoxic drugs in isolators in NHS Pharmacies
- NHS Pharmaceutical Quality Assurance Committee, Edition 1(2018), Guidance on Handling of Injectable Cytotoxic Drugs in Clinical Areas in NHS Hospitals in the UK
- Government of South Australia, (2015), Cytotoxic Drugs and Related Waste – A Risk Management Guide for South Australian Health Services
- Office of Industrial Relations, Workplace Health and Safety Queensland, (2017), Version 4, last updated Feb 2017, Guide for handling cytotoxic drugs and related waste
- European Biosafety Network (2019) Amendments to the carcinogens and mutagens directive on hazardous drugs and implications for change to the healthcare system in Europe to ensure compliance with its requirements
- PLOS ONE (May 2018) Guidelines for safe handling of hazardous drugs: A systematic review
- Current Oncology (2015), Safe handling of cytotoxic: guideline recommendations, available at <https://current-oncology.com/index.php/oncology/article/view/2151/1710>
- JCO Oncology Practice (Jan 2011), Safe Handling of Oral Chemotherapeutic Agents in Clinical Practice: Recommendations From an International Pharmacy Panel available at <https://ascopubs.org/doi/10.1200/JOP.2010.000068>
- Ferguson, A., (2020) A look at control banding, Safety and Health available at <https://www.safetyandhealthmagazine.com/articles/19704-a-look-at-control-banding>
- Centre for Disease Control and Prevention, NIOSH Control banding, accessed September, 2020 available at [https://www.cdc.gov/niosh/topics/ctrlbanding/default.html#:~:text=Control%20banding%20\(CB\)%20is%20a,controls%2C%20containment%2C%20etc](https://www.cdc.gov/niosh/topics/ctrlbanding/default.html#:~:text=Control%20banding%20(CB)%20is%20a,controls%2C%20containment%2C%20etc)
- Canadian Centre for Occupational Health and Safety (CCOSH), OSH Answers Fact Sheets, Control Banding, accessed September, 2020 available at https://www.ccohs.ca/oshanswers/chemicals/control_banding.html
- [London Cancer Alliance \(2015\)](#) London Integrated Care Systems (ICSs) Guidelines for Safe Prescribing, Handling and Administration of Systemic Anti-Cancer Therapy

- HSG53 The selection, use and maintenance of respiratory protective equipment - a practical guide. HSE Books ISBN 978 0 7176 2904 6, available at <https://www.hse.gov.uk/pubns/books/hsg53.htm>
- European Agency for Safety and Health at Work (2016), State of the art report on reproductive toxicants Literature Review European Risk Observatory Summary, ISBN: 978-92-9496-224-9 doi:10.2802/87916 , available at https://www.hsa.ie/eng/topics/biological_agents/biological_agents_introduction/biological_agents_and_reproductive_health/state_of_the_art_report_on_reproductive_toxicants.pdf

9.0 Supports

HSE LanD Programmes

- Risk Assessment Webinar
- Managing Health and Safety in Healthcare Setting

10.0 Appendices

Appendix IB	Signature Sheet
Appendix IIB	Membership of the PPPG Development Group
Appendix IIIB	Membership of Approval Governance Group
Appendix IVB	Glossary of Terms/Definitions/Abbreviations
Appendix VB	Appendix V Checklist for the implementation of the HSE Guideline on the Safe Handling of Cytotoxic Drugs 2021

Appendix IIB Membership of the PPPG Cytotoxic Development Group

Brid Cooney National Health and Safety Advisor (Policy Team)
Patricia Heckmann Chief Pharmacist/AND National Network Lead - Systemic Therapy Programme, National Cancer Control Programme
Elizabeth Breen Chief Pharmacist II National Cancer Control Programme
Breda Bourke Senior Pharmacist St James's Hospital
Dr. Lynda Sisson HR Lead - Staff Health and Wellbeing and Occupational Health, Diversity and Inclusion Lead
Chairperson: Ms. Margo Leddy National Health and Safety Manager (Policy)

Acknowledgements:

The Guideline Development Subgroup would like to acknowledge the contribution of:

- Dr. Patricia Ennis, Lecturer, College of Sciences and Health, TU Dublin
- Dr. JJ Tobin, National Strategic Dangerous Goods Advisor to the HSE

Appendix IIIB Membership of the Approval Governance Group

Anne Marie Hoey, National Director HR	Signature:  Date: 6 th December 2021
Nicholas Parkinson Head of National Health and Safety Function	Signature: Date:

Appendix IV Glossary of Terms

Term	Definition
Carcinogen	Is a substance mixture or process (note: the processes referenced do not apply to the healthcare setting) which induce cancer or increase its incidence ⁸
Carcinogen (Category 1A) (Carc.1A)	Substances known to have carcinogenic potential for humans, classification is largely based on human evidence
Carcinogen (Category 1B) (Carc.1B)	Substances which are presumed to have carcinogenic potential for humans, classification is largely based on animal evidence
CMRs	Carcinogens, Mutagens and Reprotoxins
Cytotoxic drugs	Are therapeutic agents intended for, but not limited to, the treatment of cancer. Cytotoxic drugs are hazardous drugs that exhibit one or more of the following characteristics in humans or animals: <ul style="list-style-type: none"> • Carcinogenicity • Mutagenicity (genotoxicity) • Teratogenicity • Reproductive or developmental toxicity • Organ toxicity at low doses
Employee	Means any person who works for an employer under a contract of employment. This contract may be expressed or implied, and be oral or in writing. An employee may be employed fulltime or part-time, or in a temporary capacity ⁹ .
Employer	Means, in the context of the Safety, Health and Welfare at Work (Carcinogens) Regulations 2001, an employer of employees who are, or who are likely to be, exposed to carcinogens or mutagens as a result of their work ¹⁰ . In the context of the Safety, Health and Welfare at Work Act, 2005; (a) The person with whom the employee has entered into or for whom the employee works under (or, where the employment has ceased, entered into or worked under) a contract of employment, (b) Includes a person (other than an employee of that person) under whose control and direction an employee works, And (c) Includes where appropriate, the successor of the employer or an associated employer of the employer ¹¹
Exposure	Means an exposure to a cytotoxic drug(s)
Guideline	A guideline is defined as a principle or criterion that guides or directs action. Guideline development emphasis's using clear evidence from the existing literature, rather than expert opinion alone (HSE, 2011)
Mutagen	The term 'mutagenic' and 'mutagen' are used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms
Mutagen (Category 1A) (Muta.1A)	Substances which are known to induce heritable mutations in the germ cells of humans; classification is based on positive evidence from human studies

⁸ CLP Regulation 1272/2008 on the Classification, labelling and packaging of substances and mixtures

⁹ HSE Corporate Safety Statement, 2014

¹⁰ Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001

¹¹ Safety, Health and Welfare at Work Act, 2005

Mutagen (Category 1B) (Muta.1B)	Substances which should be regarded as if they induce heritable mutations in the germ cells of humans; classification is based on evidence from mutagenicity tests in mammals or humans
Responsible Medical Practitioner	Means the registered medical practitioner employed, or otherwise engaged, by an employer to be responsible for health surveillance of employees covered by the Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001
Reprotoxin	Is a hazard associated with some chemical substances, which interfere in some way with normal reproduction. They may adversely affect sexual function and fertility in adult males and females, as well as causing developmental toxicity in the offspring
Repr.1A	Substances which are known human reproductive toxicants, largely based on evidence from human studies
Repr.1B	Substances which are presumed human reproductive toxicants, largely based on data from animal studies
Young Worker	Means a person who has reached 16 years of age but is less than 18 years of age

Appendix VB Checklist for the implementation of the HSE Guideline on the Safe Handling of Cytotoxic Drugs 2022

	Checklist for the implementation of the HSE Guideline on the Safe Handling of Cytotoxic Drugs 2022	Yes	No	NA	Comment
1	Is there a system in place for the appropriate circulation/communication of this Guideline to all relevant employees?				
2	Does each relevant department / unit have access to this Guideline?				
3	Have risk assessments been completed in line with the risk assessment process as outlined in Part A – section 2.0?				
4	Where the risk is not adequately controlled have additional measures been identified utilising the hierarchy of control outlined in Part A - Step 4 to reduce the risk to levels as low as is technically possible?				
5	Have the control measures identified been implemented?				
6	Have control measures been evaluated (proactively and reactively) to determine their effectiveness?				
7	Where identified risks cannot be managed are they communicated and notified onto the relevant risk register for action? Note; in the interim the risk should continue to be managed and monitored so far as is reasonably practicable at local level				
8	Has appropriate information, awareness and training been provided based on an assessment of training needs?				
9	Is health surveillance provided to employees where the risk assessment reveals a risk to their health or safety? See 6.0				
10	Are health records maintained for employees who may be potentially exposed to cytotoxic drugs?				
11	Is there a programme of health monitoring in place as detailed in section 7.0?				
12	Are documented management procedures in place to deal with: <ol style="list-style-type: none"> 1. Unforeseen exposure 2. Foreseeable exposure 				
13	In the event of an exposure is there a procedure in place for the immediate and follow up care of the employee?				
14	Is there a procedure in place for reporting incidents in line with the HSE Incident Management Framework?				
15	Is there a system in place to ensure the requisite information is readily available, if required by the HSA? (reference Part A- Section 8.4)				

Action Plan: Each criterion that scored ‘no’ must have a comment placed in the comment column – this comment will form the basis of your Quality Improvement Plan (QIP)/Action Plan