Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Guideline on the Safe Handling & Use of Cytotoxic Drugs

Date Approved: August 2016

Feidhmeannacht na Seirbhíse Sláinte Health Service Executive	**Guideline Document**		
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Note:	*The information provided in this Guideline Document is for general guidance only, should you require more specific advice please contact the Health & Safety Helpdesk. The management of any occupational safety and health issue(s) remains the responsibility of local management.*		

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1.0 Policy Statement

It is the policy of the HSE to ensure protection of employees from the 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-tumour activity including conventional anticancer drugs, monoclonal antibodies 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, and to the patients receiving them. While the risks to patients are, in the main, well documented and can be balanced against the clinical benefits, the risks to healthcare staff are largely theoretical. It is therefore prudent, with the present state of knowledge, to take every reasonable precaution to protect staff from unnecessary exposure.

2.0 Purpose

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

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 cytotoxic drugs.*

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

For the purpose of this guideline all cytotoxic drugs will be considered as subject to the Safety Health and Welfare at Work (Carcinogens) Regulations, 2001.

This guideline is not intended to be a legal interpretation of the Regulations.

3.0 Scope

The guideline applies to *all employees working in hospital departments* where work activities may involve risk of exposure of any employee to a cytotoxic drug.

4.0 Legislation

- Safety, Health and Welfare at Work Act, 2005
- Part X, Safety, Health and Welfare at Work (General Application) Regulations, 1993.
- 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 2 of Part 6 – Sensitive Risk Groups
- Safety, Health and Welfare at Work (Chemical Agents) Regulations, 2001
- Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001
- Classification, Packaging, and Labelling (CPL) Regulations 2003, 2004, 2006
  - Expires for substances put on market (December 2010) or if already in stock (Dec 2012)
  - Expires for preparations put on the market (June 2015) or if on the shelf (June 2017)
- Classification, Labelling & Packaging (CLP) Regulation 2008
  - Applies to substances put on market (December 2010) or if already in stock (Dec 2012)
  - Applies to mixtures put on the market (June 2015) or if on the shelf (June 2017)

5.0 Glossary of Terms and Definitions

Carcinogen	is a substance that is suspected to cause cancer and in the context of the legislation is defined as a substance or preparation which either: (a) is classified under CPL for labelling purposes as carcinogenic category 1 or 2 carrying the risk phrases R45 'May cause cancer', or R49 'May cause cancer by inhalation'; or (b) is classified under CLP for labelling purposes as carcinogenic category 1A or 1B carrying the Hazard statements H350 'May cause cancer', or H350i 'May cause cancer by inhalation'; or (c) would be so classified if the European system for classifying substances and preparations dangerous for supply was applied (even if the law does not require this, as with certain pharmaceutical products or by-products such as medicines)
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: 1. Carcinogenicity 2. Mutagenicity (genotoxicity)

	3. Teratogenicity 4. Reproductive or developmental toxicity 5. 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[1]
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[2] means**,** in the context of the Safety, Health and Welfare at Work Act, 2005 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[3]
Exposure	means an exposure to a cytotoxic drug(s)
Mutagen	is a substance that is suspected to cause mutation in cellular DNA and in the context of the legislation is defined as a substance or preparation which either: (a) is classified for labeling purposes under CPL as mutagenic category 1 or 2 carrying the risk phrase R46 'May cause heritable genetic damage'; or (b) is classified for labeling purposes under CLP as mutagenic category 1A or 1B carrying the Hazard Statement H340 'May cause genetic defects' ; or (c) would be so classified if the European system for classifying substances and preparations dangerous for supply was applied (even if the law does not require this)[4]
Reproductive Hazard	is a toxic substance that targets reproductive organs and cells
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

[1] HSE Corporate Safety Statement, 2014
[2] Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001
[3] Safety, Health and Welfare at Work Act, 2005
[4] Health and Safety Executive, (2008) Control of Substances Hazardous to Health 5th Edition, Approved Code of Practice and Guidance,

Safety Data Sheets	a document that describes the chemical and physical properties of a substance and provides precautionary advice on safe handling and use
Teratogen	is an agent that can disturb the development of the embryo or foetus. Teratogens halt the pregnancy or produce a congenital malformation (birth defect)

6.0 Roles & Responsibilities

6.1 Manager Responsibilities

6.1.1 Apply the measures specified in Schedule 3 of the Carcinogens Regulations (S.I. 78 OF 2001) (refer to Appendix II) wherever cytotoxic drugs are used

6.1.2 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

6.1.3 Renew the assessment regularly and in any event whenever there is a change in conditions at the place of work

6.1.4 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

6.1.5 Prevent exposure of employees where the results of the assessment reveal a risk to their health or safety

6.1.6 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

6.1.7 Ensure when cytotoxic drugs are in use they are (in so far as is technically possible) used in a closed system

6.1.8 Ensure that the level of exposure of employees is reduced to as low a level as is technically possible, and where it is not technically possible to use a closed system

6.1.9 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

6.1.10 Ensure employees do not eat, drink or smoke in any working area where there is a risk of exposure

6.1.11 Ensure employees are provided with appropriate protective or other appropriate special clothing

6.1.12 Provide separate storage places for working or protective clothing and for ordinary clothes

6.1.13 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, and

6.1.14 Ensure personal protective equipment found to be defective is repaired or replaced, as may be appropriate

6.1.15 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

6.1.16 Ensure all accidents, incidents and near misses are reported and managed in accordance with the *HSE Safety Incident Management Policy, 2014*

6.1.17 Ensure that each employee has access to the information on the list which relates to him/her personally, and

6.1.18 Ensure that employees or their Safety Representative, or both, have access to anonymous collective information

6.1.19 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 these Regulations.

6.2 Employee Responsibilities

In the context of the legislation it is the responsibility of all employees to comply with safety and health legislation and local guidelines.

Pertinent to these guidelines employees must:

6.2.1 Co-operate with the employer
6.2.2 Make full and proper use of control measures in place by the employer
6.2.3 Attend training
6.2.4 Wear Personal Protective Equipment (PPE) provided
6.2.5 Report any accident or incident of which they become aware involving the exposure or release of a cytotoxic agent
6.2.6 Not endanger one's own health or safety or the health and safety of any other person while at work
6.2.7 Report potential cytotoxic hazards to line manager
6.2.8 Comply with any agreed cytotoxic drug policies, procedures and safe work practices.

7.0 Guidance

7.1 Risk Assessment Process

Central to the Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001 is a requirement to identify the hazards and conduct a written assessment of the risks arising from the work activities. The hazard identification and risk assessment process will establish the cytotoxic drug 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.

Further guidance on the risk assessment process is provided in Appendix III.

7.2 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

(a) activities carried out including the reasons for which cytotoxic drugs are used
(b) quantities of substances or preparations manufactured or used
(c) number of employees exposed
(d) preventive measures taken to prevent or reduce exposure
(e) type of personal protective equipment used
(f) nature and degree of exposure of employees, and
(g) replacement substances or preparations used to reduce exposure.

7.3 Arrangements to deal with accidents / incidents / emergencies

7.3.1 Unforeseen Exposure

In the event of an accident/incident 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 ensure

(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
(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.

7.3.2 Foreseeable 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.

7.3.3 Emergency Procedures

Planning for emergencies is an essential part of risk management. Protocols must be in place for the management of cytotoxic drug exposure to include rapid access to medical attention for the potentially exposed individual if necessary. Any incident or near miss should be reported immediately in accordance with the *HSE Safety Incident Management Policy, 2014*. The cause of the incident or near miss should be investigated and determined, and follow up action taken. The control measures developed during the risk assessment process should be reviewed and amended if required to prevent reoccurrence.

7.4 Health Surveillance and Record Keeping

The Safety Health and Welfare at Work (Carcinogens) Regulations, 2001 require the employer to provide health surveillance for employees when the risk assessment reveals a risk to their health or safety. 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 procedures in place for the safe disposal of waste.

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, PPSN, 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.

7.5 Health monitoring

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

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.
The responsible medical practitioner should be suitably qualified to provide health surveillance in accordance with statutory framework and c*ompetencies for health surveillance.*

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

7.5.1.1 Collection of demographic data
- name and unique company identification number
- date of birth
- gender
- address
- date commencing employment

- descriptive job title to include the Standard Classification of Occupations (SCO) and Standard Industrial Classification (SIC)
- places of previous employment

7.5.1.2 Occupational history

- past work history, including previous work with cytotoxic drugs
- potential current exposure
- whether suitable control measures are in place for handling cytotoxic drugs

7.5.1.3 Medical history

- presence of symptoms
- general health
- smoking history
- personal history of cancer
- family history of cancer in first relatives
- history of asthma or other systemic allergic reactions or states (examples include systemic reaction to bee sting or allergic skin disorders)
- is the employee taking immuno-suppressive therapy?
- is the employee pregnant or breast-feeding?

7.5.1.4 Physical examination

- general physical examination

7.5.1.5 Investigation

- no diagnostic test currently gives a sensitive, specific and interpretable indication of early or likely health effects arising from occupational exposure to cytotoxic drugs or their metabolites
- the occupational health practitioner should focus on the risk factors outlined in the occupational history, and the outcome of the physical examination
- the medical practitioner should perform any investigations that may be appropriate as a result of the examination

7.5.1.6 Health advice and counselling

The appointed responsible medical practitioner should provide medical advice and counselling to the employee, including:

- the potential health effects associated with exposure to cytotoxic drugs and related waste
- the optimum standard of control measures to expect in the workplace
- the results of the health monitoring, including any abnormal findings
- the potential risks to employees planning parenthood, or those who are breast-feeding or pregnant

7.5.1.7 Report

- the appointed occupational health practitioner should provide a report to the employer and prospective employee advising that the employee has received assessment and health advice. Confidentiality of medical records is to be maintained. Access to medical records is to be only by written consent of the employee concerned.

7.6 Training

Employers have a duty

- to provide information, instruction, training and supervision to employees who handle cytotoxic drugs and related waste
- 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.

These staff may include:

- pharmacy personnel
- stores personnel
- nursing and medical personnel
- cleaners
- on-site waste transporters
- porters
- ambulance personnel
- waste handlers
- supervisors and managers
- waste generators
- maintenance personnel.

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
- 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
- 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
- labeling, warning and hazard signs.

In addition, 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.

8.0 Implementation

Implementation of this guideline forms an integral part of the Safety Management System and is underpinned by effective consultation, communication, supervision, monitoring, audit and review.

9.0 Revision and Audit

This guideline will be reviewed every three years, or when legislation or best practice dictates. Implementation of this guideline shall be audited periodically at national level.

Appendix I

Classification of Carcinogenic and mutagenic substances are classified in the Regulations into a number of categories:

Under the CPL Regulations 2003, 2004, 2006

- A category 1 (C1) carcinogen is a substance known to cause cancer in humans
- A category 2 (C2) is a substance which should be regarded as if it can cause cancer in humans
- A category 1 mutagen(Mut1) is a substance known to be mutagenic to humans
- A category 2 mutagen (Mut 2) should be regarded as if it is mutagenic to humans

Under the CLP Regulations 2008

- A category 1A (C1) carcinogen is a substance known to cause cancer in humans
- A category 1B (C2) is a substance which should be regarded as if it can cause cancer in humans
- A category 1A mutagen(Mut1A) is a substance known to be mutagenic to humans
- A category 1B mutagen (Mut 1B) should be regarded as if it is mutagenic to humans

In the regulations the following risk phrases apply to Categories 1 & 2 carcinogens/mutagens:

Under the **CPL Regulations 2003, 2004, 2006**

R45 May cause cancer
R49 May cause cancer by inhalation
R46 May cause heritable genetic damage

The equivalent Hazard (H) statements under the CLP **Regulations 2008**

H350 May cause cancer

H350i May cause cancer by inhalation

H340 May cause genetic defects

A **third Category (Category 3)** of carcinogen/mutagen exists and while these fall outside the specific scope of the Carcinogen Regulations they must still be assessed under the Chemical Agents Regulations, 2001 and the Safety Health and Welfare at Work Act, 2005

Under the **CPL Regulations 2003, 2004, 2006** category 3 carcinogens/mutagens are defined as substances which cause concern owing to possible carcinogenic effects but the available information is not adequate. There is some evidence from animal studies but this is insufficient to place the substance in category 2.

Under **CLP Regulations 2008** category 3 carcinogens/mutagens are defined as substances which cause concern owing to possible carcinogenic effects but the available information is not adequate. There is some evidence from animal studies but this is insufficient to place the substance in category 1B.

In the regulations the following risk phrases apply to Category 3 substances:

Under the **CPL Regulations 2003, 2004, 2006**

R40 Limited evidence of carcinogenic effect

R68 Possible risk of irreversible effects

Under the **CLP Regulations 2008**

H351 Suspected of causing cancer

H341 Suspected of causing genetic defects

In the regulations the following risk phrases apply to reproductive toxins:

Under the **CPL Regulations 2003, 2004, 2006**

R60 May impair fertility

R61 May cause harm to the unborn child

R62 Possible risk of impaired fertility

R63 Possible risk of harm to the unborn child

R64 May cause harm to breast-fed babies

Under the **CLP Regulations 2008**

H360 May damage fertility or the unborn child

H361 Suspected of damaging fertility or the unborn child

H362 May cause harm to breast-fed children

In the regulations the following risk phrases apply to substances that can cause organ toxicity:

Under the **CPL Regulations 2003, 2004, 2006**

There is specific reference to organ toxicity only general risk phrases e.g.

R48: Danger of serious damage to health by prolonged exposure

Under the CLP Regulations 2008

H370	Causes damage to organs (single exposure)
H372	Causes damage to organs (repeated exposure)
H371	May cause damage to organs (single exposure)
H373	May cause damage to organs (repeated exposure)

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

- Limitation 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 minimize 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 regular 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 labeled
- 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 labeled

Appendix III Risk Assessment Process

The risk assessment process comprises of the following four steps

1. Hazard identification
2. Identification of the risk associated with the hazard
3. Assess (Rate) the risks
4. Identify additional control measures.

Step 1 Hazard Identification and identification of factors that may lead to exposure

(1.) Identify the cytotoxic drugs which are in use

(2.) Obtain and review information about each cytotoxic drug in use:

(1) Identify cytotoxic drugs in use	
Set up and maintain a cytotoxic drug register. This should also include all cytotoxic drugs purchased "in a ready to administer form". Please refer to Appendix IV for Sample Drugs Register.	**Ways of achieving this include**: • list the product names of all cytotoxic drugs used at the workplace • obtain a copy of the manufacturer's or importer's Safety Data Sheet (SDS) for all cytotoxic drugs (the SDS should be current) • check the Safety Data Sheet and the product label to identify cytotoxic drugs that are classified as hazardous substances • request data from supplier / manufacturer on the potential level of contamination on the packaging

(2) Obtain and review information regarding the cytotoxic drug(s) in use	
Consult the label and Safety Data Sheet (or other available information for each drug) for details of the properties and hazards associated with the drug	**This may include**: • regulatory information • precautions for use • safe handling information (risk / hazard statements & safety phrases / precautionary statements)
Determine the routes of exposure	**These may include**: • inhalation of aerosols and drug particles or droplets • ingestion through poor hand hygiene, resulting in contaminated food or cigarettes • dermal absorption through splashes, spills or contact with cytotoxic contaminated laundry • mucosal absorption through splashes into the eye or mouth • percutaneous injuries
Identify the characteristics of an exposure	**This includes**: • frequency and duration • volume of cytotoxic drug or cytotoxic contaminated waste • the categories of employees and others who may be exposed
Determine the form of the substance	**This may include**: • liquid • aerosol • powder • solid tablet • creams, ointments and lotions for topical application
Ascertain the potential harmful effects following exposure	**These may include**: • carcinogenic, mutagenic or teratogenic potential • alterations to normal blood cell count • foetal loss in pregnant women and malformations in the offspring of pregnant women • abdominal pain, hair loss, nasal sores, vomiting, • liver damage • contact dermatitis, local toxic or allergic reaction, (nitrosoureas), urticaria due to amsacrine • irritation to the skin

Step 2 Identify the Risks Associated with the Hazard

Identity who is at risk of exposure, examine the work environment and the nature of the work activity / task being undertaken and identify existing control measures:

Identify the categories of staff who may be exposed	**These may include:** • Pharmacy staff • Nursing / Medical Staff • Support Service Staff • Maintenance Staff • Allied Health Professionals • Sensitive risk groups e.g. pregnant employee, inexperienced employees • Patients, visitors • Contractors
Identify the tasks which may expose employees to cytotoxic drugs	**For example**: • Delivering, unpacking and pre-preparation storage • drug preparation in the pharmacy • drug administration in the ward or daycare centre • handling, transport and disposal of cytotoxic waste on the premises • handling contaminated laundry • patient care after administration • cleaning up spillages • maintenance work
Examine the work environment and work practices (Involve employees who are at risk of exposure to cytotoxic drugs and related waste).	**What to look for**: • how the substance(s) is used in various activities • the quantities used • level of potential exposure • frequency and duration of use • risk control measures already in place and their effectiveness
Review information relating to incidents or symptoms of exposure monitoring and health surveillance	**What to look for**: • incident records • problems associated with storage and transport of cytotoxic drugs • employee reports of any adverse effects • record of any spills • reported incidents and follow up • monitoring health surveillance records

Examine the existing control measures. The aim is to reduce the risk of exposure to as low as is technically possible.

Eliminate the risk In general it is not possible to eliminate cytotoxic drugs from the workplace. However, it may be possible to use a safer form of the cytotoxic drug.	**Consider the following examples:** • eliminate or discontinue a dangerous activity that exposes workers to risk • eliminate preparation of drugs outside a pharmaceutical isolator • purchase cytotoxic drugs in ready-to-use concentrations
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:** • 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 this must be referred to the Pharmacy Dept) • using drugs in vials, not ampoules • using drugs in plastic vials, or vials reinforced with plastic casings • using needleless systems • using tablets in a blister pack
Isolation Isolation involves separating people from the substance by distance or barriers to prevent or reduce exposure.	**Consider the following examples:** • conducting drug preparation work in a properly designed and secure clean room using a pharmaceutical isolator • 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
Engineering controls Engineering controls use technological means to isolate or remove hazards from the workplace.	**Consider the following examples:** • installing ventilation and air-filtering systems such as pharmaceutical isolators • using closed transfer systems in the pharmacy • using needleless injection sets for drug administration • incorporate secure storage facilities • introduction of a preventative maintenance programme

Administrative controls If a risk remains, administrative controls should be used to further reduce the risk. Administrative controls include work practices that help to reduce employee exposure to cytotoxic drugs and related waste. The effective use of administrative controls relies on the full cooperation of employees, and therefore, consultation is important during their development. Adequate supervision and training are paramount if work practices are to play an effective part in reducing employee exposure to cytotoxic drugs and related waste. Provide appropriate information on the cytotoxic drug and why and how exposures are kept as low as is technical possible.	**Consider the following examples:** • restricting the number of employees who work with cytotoxic drugs • cleaning work areas regularly • keeping containers of cytotoxic drugs secure and tightly lidded when not in use • Ensuring all containers of cytotoxic drugs are labeled 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 • developing and implementing standard operating procedures for all work activities • providing appropriate information, education and training to employees • 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 national policy • developing emergency procedures to deal with spills • testing of surfaces for cytotoxic drug residue • adequate supervision and follow up
Personal protective equipment (PPE) If a risk remains, the risk should be Controlled by providing PPE to employees at risk. PPE is something worn that provides a barrier between the person and the hazard. Effective protection will only be obtained if the PPE chosen is: • suitable for the task • suited to the wearer and environment • compatible with other PPE in use • in good condition • readily available • worn correctly • maintained in accordance with relevant standards	**This may include:** • impermeable coveralls and gowns • head covering • closed footwear • overshoes • gloves of appropriate material and thickness • safety glasses • respiratory protective equipment • Obtain information from the supplier of the cytotoxic drugs and suppliers of the PPE All PPE must meet the relevant technical standard.

Step 3 Assess and Rate the Risk

The next step is to assess how likely it is that harm may arise and whether existing control measures are adequate. For detailed guidance on risk rating, please refer to *HSE Risk Assessment Tool and Guidance, OQR012, October 2011.*

Step 4 Identify any Additional Control Measures that are required

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 identified and 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.

Where additional resources are required for the control of a hazard 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 escalation to the next level (HSE Risk and Incident Escalation Procedure *QCCD 001* 2010). In the interim the risk should continue to be managed and monitored.

Communicate and Consult

Communication and consultation 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.

Monitor and 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 regularly analysed to measure progress.

REVIEW CONTROL MEASURES	
Review the risk control measures to ensure they perform as originally intended and continue to provide adequate control	**This may include**: • auditing compliance with safe work practices • frequent inspections • testing of equipment • 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

Feidhmeanacht na Seirbhíse Sláinte Health Service Executive	**Health & Safety Risk Assessment Form**		
Ref: CF:003:01	**RE: Cytotoxic Drug Risk Assessment Form**		
Issue date:	November 2015	**Review date:**	November 2017
Author(s):	National Health & Safety Function		
Legislation	Under the **Safety Health and Welfare at Work (Carcinogens) Regulations, 2001,** it is the duty of the employer to identify the hazards and assess the risks associated with the risk of exposure /use of carcinogens in the workplace. All risk assessments must be in writing and the necessary control measures to eliminate or minimise the risks documented and implemented.		
Note:	*It is responsibility of local management to implement any remedial actions identified.* *To assist in carrying out the risk assessment guidance is provided on the cytotoxic drug risk assessment form "in italics".*		

Cytotoxic Drug Risk Assessment Form – Part 1 of 3

Administration Area: *Refer to OQR010*	**Primary Risk Category:** *Refer to OQR010*
Location: *Refer to OQR010*	**Secondary Risk Category:** *Refer to OQR010*
Section/Ward/Dept: *Refer to OQR010*	**Tertiary Risk Category:** *Refer to OQR010*
Date of Assessment: *Refer to OQR010*	**Name of Risk Owner (BLOCKS):**
Source of Risk : *Refer to OQR010*	**Signature of Risk Owner:**
Unique ID No: *Refer to OQR010*	

Description of Work Activity:	**Name(s) of cytotoxic(s) drug(s) in use in the work activity:**
Describe the work activity being undertaken	*Insert name of drug(s)*

Number of Employees Exposed:	**Categories of employees likely to be exposed: (Tick)**	**Duration and frequency of contact (Hr/day):**
Insert number of employees exposed	**Nursing Staff** ☐ **Medical Staff** ☐ **Care Staff** ☐ **Maintenance Staff** ☐ **Housekeeping** ☐ **Pharmacy** ☐ **Others (please specify)**	*E.g. 5 mins/4 times per day,* *10 mins/twice daily*

Safety Data Sheet(s) available: Yes ☐ **No** ☐	**Location of SDS(s) :** *Describe*	**Date of SDS(s):** *Insert date*

Amount used and quantity stored	**Hazard and risk associated with cytoxic drug(s):**	**Exposure Route(s) (Tick)**	**Dustiness or Volatility, High, Medium or Low**
Insert amount used and quantity stored	*Refer to section 2 of SDS. Insert hazard classification and hazard (H) statements or risk phrases.*	**Eyes** ☐ **Skin** ☐ **Ingestion** ☐ **Inhalation** ☐	*To determine volatility refer to section 9 of the SDS for boiling point if applicable.*

Cytotoxic Drug Risk Assessment Form – Part 2 of 3									
Hazard Symbols									
NEW SYMBOLS									
	Acute toxicity hazard	Serious long term health hazard	Health hazard	Corrosion Hazard	Environmental hazard	Flammability hazard	Oxidising Hazard	Explosion Hazard	Stored as gas under pressure
Tick appropriate pictogram. *Refer to section 2 of SDS*									
Insert appropriate **signal word** i.e. **danger** or **warning**. *Refer to section 2 of the SDS*									
OLD SYMBOLS									
	Acute toxicity	Toxic	Irritating (Xi) Harmful (Xn)	Corrosive	Highly Flammable /Extremely Flammable	Oxidising	Explosive	Dangerous to the environment	
Tick appropriate pictogram. *Refer to section 2 of the SDS*									

Unique ID Number: *Insert Number from Part 1*

Cytotoxic Drug Risk Assessment Form – Part 3 of 3					
HAZARD & RISK DESCRIPTION	**IMPACTS/ VUNERABILITIES**	**EXISTING CONTROL MEASURES**	**ADDITIONAL CONTROLS REQUIRED**	**PERSON RESPONSIBLE FOR ACTION**	**DUE DATE**
Describe the risks associated with the activity being undertaken. *For example - risk of ill health due to potential exposure to (name cytotoxic drug) of (specify category of staff) via (specify route of exposure, e.g. skin contact) while (describe work activity) on a (specify the frequency – e.g. daily) basis.*	*Refer to Impact Table as per the HSE Risk Assessment Tool (OQR010 and OQR012), and enter the impacts & vulnerabilities that the risk has on employees, service users and the Organisation.*	*Detail the control measures in place – include all measures to eliminate or reduce the risks* *For further guidance refer to Appendix III*	*Detail the measures necessary to eliminate or further reduce the level of risk.* *Consider the hierarchy of controls:* *Elimination/ substitution/ engineering/ administrative/ PPE.* *Consider the interim and long term measures.*	*Enter the name of the responsible person for implementation of each control measure.*	*Enter the date by which implementation of the additional controls to mitigate the risk are due.*

INITIAL RISK			**RESIDUAL RISK**			**STATUS**
Likelihood	**Impact**	**Initial Risk Rating**	**Likelihood**	**Impact**	**Residual Risk Rating**	*Open, closed or monitor?*
Insert score (1-5)	*Insert score (1-5)*	*Multiply LxI (1 – 25)*	*Insert score (1-5)*	*Insert score (1-5)*	*Multiply LxI (1 – 25)*	

Appendix IV – Sample Drugs Register

Hospital Name:	**Date:**
Area :	
Person Compiling Register:	

Product Name	Location or Process where Product is used	Is Product a Hazardous Substance Y/N	SDS Y/N	Risk Assessment Y/N	Action / Comments

Appendix V - Bibliography

- Government of South Australia, 2012. Guideline for South Australian Health Services. Safe Handling Cytotoxic Drugs and Related Wastes
- Health Service Executive and Department of Health, 2010. Healthcare Risk Waste Management Segregation, Packaging and Storage Guidelines for Healthcare Risk Waste 4th Edition
- *HSE Safety Incident Management Policy, 2014*
- Health and Safety Executive (UK) 2003. Information Sheet MISC615. Safe Handling of cytotoxic drugs
- Health and Safety Executive (UK), 2013. The Control of Substances Hazardous to Health Regulations 2002 (as amended) Approved Code of Practice (ACOP) L5 (Sixth edition)
- HesaMag#08/autumn-winter 2013. Revision of the Carcinogens Directive: anything happening?
- New South Wales Government, 2008. Cytotoxic Drugs and Related Waste Risk Management
- National Cancer Control Programme 2014 Oncology Medication Safety Review Report
- HSE Risk and Incident Escalation Procedure, QCCD 001 2010
- HSE Risk Assessment Tool and Guidance, OQR012, October 2011
- Developing and Populating a Risk Register Best Practice Guidance, OQRO10, April 2009

Appendix VI

Membership of the Sub Group for the development of the HSE Guideline on the Safe Handling and Use of Cytotoxic Drugs

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