





Health & Safety Risk Assessment Guidance

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|  | <h1>Health & Safety Risk Assessment Guidance</h1> | | |  |
| Ref: CF:024:04 | RE: Guidance on completing a Cytotoxic Drug Risk Assessment | | | |
| Issue date: | November 2015 | Revised date: | October 2022 | |
| Author(s): | National Health & Safety Function | | | |
| Legislation: | <p>Under the Safety Health and Welfare at Work (Carcinogens) Regulations, 2001, as amended 2015 and 2019 it is the duty of the employer to identify the hazards and assess the risks associated with the risk of exposure to carcinogens (Cat. 1A and 1B) and/or mutagens (Cat.1A and 1B) in the workplace.</p> <p>For the purpose of this risk assessment, all cytotoxic drugs (to include Cat. 2 carcinogens, Cat. 2 mutagens and/or reprotoxins (including teratogens)) (Cat R1A/B and R2) will be considered as subject to the Safety, Health and Welfare at Work (Carcinogens) Regulations, 2001.</p> <p>All risk assessments must be in writing and include the necessary control measures to eliminate or minimise the risks documented and implemented. When conducting risk assessments where Cytotoxic Drugs are involved consideration must be paid to the risk of exposure and the means of avoiding and mitigating any such risk so far as is technically possible.</p> <p><i>It is the responsibility of local management to implement any remedial actions identified.</i></p> | | | |
| Note 1: | Detailed guidance to support the carrying out / review of risk assessments is available in the HSE Guideline on the Safe Handling of Cytotoxic Drugs 2021 | | | |

| Key Amendments | |
|-----------------------|---------------------------------------|
| Section | Amendment |
| Pg 1 Note 2: | Removed reference to 2 meter distance |



Cytotoxic Drug Risk Assessment Form - Part 1 of 2

| | |
|---|-------------------------------------|
| Division: | Source of Risk: |
| HG/CHO/NAS Function: | Primary Impact Category: |
| Hospital Site/Service: | Risk Type: |
| Dept/Service Site: | Name of Risk Owner (BLOCKS): |
| Date of Assessment: | Signature of Risk Owner: |
| Unique ID No: | Risk Co-ordinator: |
| | *Risk Assessor (s): |
| Description of Work Activity: <i>Describe the work activity being undertaken:</i> | |
| A separate risk assessment must be completed for powders (prior to reconstitution); capsules/tablets; and liquids. Tick as appropriate <i>Powders <input type="checkbox"/> Capsules / tablets <input type="checkbox"/> Liquids <input type="checkbox"/></i> | |
| Identify the Cytotoxic Drugs covered by this risk assessment: (Please cross reference to database or attach drug list) | |



National Health and Safety Function, Workplace Health and Wellbeing Unit, National HR Division

Categories of employees likely to be exposed (Tick as appropriate)

Pharmacy personnel Nursing Staff Medical Staff Support Service Maintenance Housekeeping Other

If other, please state discipline(s) _____

Hazard and risk associated with cytotoxic drug(s): - For the purpose of this risk assessment cytotoxic drugs are 'grouped' collectively as CMRs (i.e. carcinogenic, mutagenic or reprotoxins) with the associated Hazard Statements (H) below:

| | |
|-------------------|--|
| Carc 1A, 1B | H350 - May cause cancer |
| Carc 2 | H351 - Suspected of causing cancer |
| Muta 1A/B | H340 - May cause genetic defects |
| Muta 2 | H341 - Suspected of causing genetic defects |
| Repro. Tox. 1A/1B | H360 - May damage fertility or the unborn child |
| Repro. Tox. 2 | H361 - Suspected of damaging fertility or the unborn child |

Exposure Route (Tick as appropriate)

Inhalation Dermal absorption Percutaneous Ingestion Mucosal

Tick the range of substances used and quantities stored for this activity (the range is based on an individual unit)

Small up to 1000 ml or g
Medium 1-1000 L or Kg
Large >1000 L or Kg



| Cytotoxic Drug Risk Assessment Form – Part 2 of 2 | | | | | |
|---|---|--|--|--|--------|
| **HAZARD & RISK DESCRIPTION | EXISTING CONTROL MEASURES | ADDITIONAL CONTROL REQUIRED | ACTION OWNER (i.e. the Person responsible for the action) | DUE DATE | |
| <p><i>Describe the risk associated with the activity being undertaken and the frequency and duration of potential exposure during the task. (refer to Step 2 of GD:002 HSE Guideline on the Safe Handling of Cytotoxic Drugs 2021).</i></p> | <p><i>Detail the control measures in place – include all measures to eliminate or reduce the risks to include</i></p> <ul style="list-style-type: none"> <i>• Engineering controls</i> <i>• Administrative controls to include SOPs</i> <i>• Training</i> <i>• PPE</i> <i>• Health surveillance</i> <i>• Spill/Incident management</i> <p><i>For further guidance refer to Step 4 of GD:002: HSE Guideline on the Safe Handling of Cytotoxic Drugs 2021</i></p> | <p><i>Detail the measures necessary to eliminate or further reduce the level of risk.</i></p> <p><i>Consider the hierarchy of controls: Elimination / substitution/ engineering / administrative/ PPE.</i></p> <p><i>Consider the interim and long term measures</i></p> | <p><i>Enter the name of the responsible person for implementation of each control measure</i></p> | <p><i>Enter the date by which implementation of the additional controls to mitigate the risk are due</i></p> | |
| INITIAL RISK | | | RISK STATUS | | |
| Likelihood | Impact | Initial Risk Rating | Open | Monitor | Closed |
| <p><i>Rating of risk is carried out taking account of existing control measures. Please refer to HSE Risk Assessment Tool for assignment of likelihood and impact scores and the rating of risk</i></p> | | | <p><i>Each of the risk should be assigned a risk status. Open, i.e. additional controls have been identified as necessary Monitor, i.e. existing controls are deemed adequate to manage the risk but these need to be periodically reviewed Closed, i.e. that the risk no longer exists e.g. where an unsuitable premises is replaced by a suitable one</i></p> | | |

*Risk Assessor to be recorded for OSH risks only.

**Where the risk being assessed relates to an OSH risks please ensure that the HAZARD and associated risk are recorded on the form. All other risk assessments require a risk description only