

PART 6: SUBSTANCE SPECIFIC REQUIREMENTS

- | | | |
|--------------------|-------------|---|
| Information | 6.44 | <p>If a cytotoxic drug is received, used, prepared, administered, stored or disposed of at a workplace, the employer must maintain and make readily available to workers information on its</p> <ul style="list-style-type: none">(a) acute and chronic toxicity, including any potential reproductive hazard,(b) acute exposure treatment, and(c) safe handling. |
| Procedures | 6.48 | <ul style="list-style-type: none">(1) When a cytotoxic drug is received, used, prepared, administered, stored or disposed of, written safe work procedures must be developed and implemented for applicable aspects of receiving, storage, preparation, administration and waste handling.(2) The work procedures required by subsection (1) must be readily available for reference by workers and where practicable, summaries of relevant procedures must be posted in the appropriate work areas. |

Explanatory Note

It is proposed that the act of receiving cytotoxic drugs be added to existing sections 6.44 and 6.48 in recognition that this activity, like the others listed, puts workers at risk of exposure to cytotoxic drugs. Workers involved in receiving cytotoxic drugs require both information on cytotoxic drugs as detailed in 6.44 as well as written safe work procedures for safe handling as outlined in section 6.48.

Further, it is proposed that the reference to “used” in sections 6.44 and 6.48 be repealed and replaced by the terms “prepared” and “administered”. This is consistent with other sections regarding cytotoxic drugs and better describes those aspects of handling cytotoxic drugs currently captured by the term “used”.

In addition, it is proposed that the term “storage” be added in section 6.48(1). The existing section identifies storage as an activity requiring written safe work procedures but does not reference it later in the section. This exclusion was unintentional.

PART 6: SUBSTANCE SPECIFIC REQUIREMENTS

BSCs-Drug preparation and administration	6.53	<p>(1) All mixing, preparation and priming of administration sets with a cytotoxic drug must be performed in one centralized area in a specially designated Class II Type B biological safety cabinet that</p> <ul style="list-style-type: none">(a) is exhausted to the outside atmosphere in a manner that prevents recirculation into any work area,(b) has exhaust and ventilation systems that remain in operation for a sufficient period of time to ensure that no contaminants escape from the biological safety cabinet into the workplace, and(c) is equipped with a continuous monitoring device to permit confirmation of adequate airflow and cabinet performance. <p>(2) The administration of cytotoxic drugs must be done by following safe work procedures.</p>
Disconnects	6.54	Syringes and intravenous sets used for cytotoxic drugs must have appropriate fittings, such as Luer locking fittings , which prevent accidental disconnection, such as Luer locks.

Explanatory Note

Although historically cytotoxic drugs were used exclusively in chemotherapy treatment, in recent years these drugs have proven to be an effective treatment in low doses, for other problems such as arthritis and psoriasis. These treatments are often delivered, typically using a syringe, to a patient in their own home or another setting away from the location where the administration set would have been prepared. Before a cytotoxic drug is administered by syringe, it needs to be primed. This activity, carried out in someone's home, is in contravention with a strict interpretation of the current regulations which indicate all mixing, preparation and priming of cytotoxic drug administration sets must be performed in a Class II Type B biological safety cabinet.

It is proposed that existing section 6.53 be amended to clarify that the mixing, preparation and what can be considered initial priming of cytotoxic drugs in a biological safety cabinet is separate from the administration of the drugs and the priming carried out in association with that activity. This clarification is achieved by renumbering the current requirement in 6.53 as 6.53(1) and adding new subsection, 6.53(2), specifically requiring that the administration of cytotoxic drugs be done following safe work procedures. Safe work procedures are intended to minimize or eliminate the risk of exposure to the cytotoxic drugs during its administration. An associated guideline will provide examples of safe work procedures for activities associated with administering a cytotoxic drug including procedures around priming.

In addition, it is proposed that section 6.54 be amended to clarify that the requirement for syringes and intravenous sets to have fittings that prevent disconnection is intended to prevent accidental disconnection.

PART 6: SUBSTANCE SPECIFIC REQUIREMENTS

- | | | |
|--------------------------------------|-------------|---|
| Personal protective equipment | 6.55 | <ol style="list-style-type: none">(1) Adequate personal protective equipment must be provided and worn whenever there is a risk of contact with a cytotoxic drug.(2) For the purposes of subsection (1) personal protective equipment includes<ol style="list-style-type: none">(a) gloves made of surgical latex or other material which provides equal or better protection medical gloves that are manufactured and designed for use when handling cytotoxic drugs,(b) a moisture resistant, long-sleeved gown with cuffs,(c) if there is a risk of contact with aerosols, an approved respirator, and(d) if there is a risk of eye contact, eye and face protection.(3) Used gowns and gloves must not be worn outside the preparation, administration or storage area and must be handled as hazardous waste or contaminated linen.(4) All other non-disposable personal protective equipment must be cleaned immediately after use. |
| Waste disposal | 6.57 | <ol style="list-style-type: none">(1) Adequate, leak-proof waste disposal containers, including sharps and solids containers, and distinctive plastic waste bags must be available in every area where cytotoxic drugs are prepared, administered or stored, and all cytotoxic drug-related waste must be placed into these containers or bags.(2) Any excreta from a patient being treated with cytotoxic drugs that is handled by a worker must be treated as cytotoxic drug-related waste. |
| Spills | 6.58 | <ol style="list-style-type: none">(1) Written emergency procedures to address spills of a cytotoxic drug must be developed and implemented which address requirements for small spill cleanup, both inside and outside the biological safety cabinet or fume hood, large spill cleanup, and personal decontamination.(2) Spill kits, clearly labelled, must be kept in or near cytotoxic drug preparation, administration and storage areas and a sign detailing spill procedures must be posted in all such areas. |

Explanatory Note

It is proposed that existing section 6.55 be amended to include a requirement for medical gloves specifically designed for use with cytotoxic drugs. These types of gloves will deliver greater protection than what is provided through the use of gloves made of surgical latex or other material providing protection equivalent to surgical latex.

Hazardous metabolites can be present in excreta of patients treated with cytotoxic drugs. It is proposed that to further worker safety, existing section 6.57 should be renumbered as 6.57(1) and new subsection 6.57(2) be added requiring that any excreta from a patient being treated with cytotoxic drugs that is handled by a worker, must be treated as cytotoxic drug-related waste and disposed of in accordance with 6.57(1).

**PROPOSED AMENDMENTS FOR PART 6: SUBSTANCE SPECIFIC REQUIREMENTS
IN THE OCCUPATIONAL HEALTH AND SAFETY REGULATION**

Section 6.58(1) requires, among other things, that written emergency procedures be developed and implemented to address a cytotoxic drug spill inside and outside a biological safety cabinet or fume hood. Although cytotoxic drugs can only be mixed and prepared inside a biological safety cabinet, this section appears to suggest that the mixing and preparation of a cytotoxic drug could be done in a fume hood. It is proposed that the reference to a fume hood be deleted to clarify that cytotoxic drugs can only be mixed and prepared in a biological safety cabinet.

DRAFT