

PART 6: SUBSTANCE SPECIFIC REQUIREMENTS

BIOHAZARDOUS MATERIALS

Definitions	6.33	In sections 6.33 to 6.41:
<i>"biohazardous material"</i>		means a pathogenic organism, including a bloodborne pathogen, as determined by the World Health Organization, Health Canada, or other agency acceptable to the Board , which due to its is known or reasonably believed ability to cause disease in humans, would be classified as Risk Group II, III or IV as defined by the Medical Research Council of Canada, or any material contaminated with such an organism;
<i>"medical sharp"</i>		means a needle device, scalpel, lancet or any other medical device that can reasonably be expected to make parenteral contact;
<i>"occupational exposure"</i>		means reasonably anticipated, harmful contact with blood or other potentially biohazardous material that may result from the performance of a worker's duties;
<i>"parenteral contact"</i>		means piercing of mucous membranes or the skin;
<i>"safety-engineered medical sharp"</i>		means a medical sharp with a built-in safety feature or mechanism that eliminates or minimizes the risk of accidental parenteral contact while or after the sharp is used;
<i>"safety-engineered needle"</i>		includes a self-sheathing needle device and a retractable needle system.
Controls	6.36	<p>(1) Engineering controls and work practice controls must be established to eliminate or minimize the potential for occupational exposure to a bloodborne pathogen or other biohazardous material.</p> <p>(1.1) On and after January 1, 2008, when a hollow bore needle is used in a workplace to access a vein or artery for the purpose of collecting blood or caring for or treating a person, the employer must ensure that On and after January 1, 2008, a needleless device or safety-engineered hollow bore needle must be used for the following procedures performed to care for or treat a person:</p> <ul style="list-style-type: none">(a) if it is clinically appropriate, a safety-engineered needle that provides the highest level of protection from a needlestick injury is used, or a needleless device is used in place of a hollow bore needle, and withdrawal of body fluids;(b) safe work procedures and practices relating to the use of those safety-engineered needles or needleless devices are implemented. accessing a vein or artery;(c) administration of medications or fluids;(d) any other procedure involving the potential for an exposure to accidental parenteral contact for which a needleless system or safety-engineered hollow bore needle system is available. <p>(1.2) On and after October 1, 2008, any medical sharp used to care for or treat a person must be a safety-engineered medical sharp.</p> <p>(1.3) Subsections (1.1) and (1.2) do not apply if</p> <ul style="list-style-type: none">(a) use of the required device, needle or sharp is not clinically appropriate in the particular circumstances, or

(b) the required device, needle or sharp is not available in commercial markets.

(1.4) If more than one type of safety-engineered hollow bore needle or safety-engineered medical sharp is available in commercial markets, the needle or sharp that provides the highest level of protection from accidental parenteral contact must be used.

(1.5) For purposes of subsection (1.4), an employer must make a determination of the highest level of protection available based on information provided by manufacturers, independent testing agencies, objective product evaluation, or other reliable sources.

(1.6) Safe work procedures and practices relating to the use of safety-engineered hollow bore needles and safety-engineered medical sharps must be developed and implemented before use of these devices.

- (2) Personal protective equipment must be worn to shield workers from biohazardous material.
- (3) Housekeeping practices must be designed to keep the workplace clean and free from spills of biohazardous material.
- (4) Work procedures must ensure that laundry contaminated with biohazardous material is isolated and bagged, and handled as little as possible.
- (5) Repealed. [B.C. Reg. 312/2003.]
- (6) For bloodborne pathogens, the employer must implement a system of universal precautions for all tasks and procedures identified as having a potential for occupational exposure under section 6.35.

Explanatory note

In July, 2006 the Board of Directors (“BOD”) approved a requirement that when a hollow bore needle is used in a workplace to access a vein or artery for the purpose of collecting blood or caring for or treating a person, the employer must ensure that if it is clinically appropriate, a safety-engineered needle that provides the highest level of protection from a needlestick injury be used, or a needleless device is used in place of a hollow bore needle.

While the information available indicates that hollow bore needles for vascular access pose the greatest risk to workers’ health, any stick or cut can require the same treatment as a stick from a hollow bore needle for vascular access. The physical and emotional trauma to workers can be severe.

In response, the BOD directed that an additional public hearing be held in the fall of 2006, as part of the 2006 regulatory process, to consider expanding the scope of the requirements for safety-engineered devices in sections 6.33 and 6.36 of the *Occupational Health and Safety Regulation* (“OHSR”) to include all hollow bore needles (intravascular, intramuscular, and subcutaneous), and other medical sharps. In all cases, when clinically appropriate, the BOD has directed that the safety-engineered device with the highest level of protection be used.

Section 6.33, Definitions:

“Biohazardous material” is defined as a pathogenic organism, including a bloodborne pathogen, as determined by the World Health Organization, Health Canada, or other agency acceptable to

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the Board, which is known or reasonably believed to cause disease in humans. This change reflects that the Medical Research Council of Canada is no longer in existence.

“Medical sharp” is defined to clarify which medical sharps must be safety-engineered. The medical sharp must be a medical device that can reasonably be expected to make parenteral contact.

“Parenteral contact” is defined for clarity and means piercing of mucous membranes or the skin.

“Safety-engineered medical sharp” is defined to mean a medical sharp with a built-in safety feature or mechanism that eliminates or minimizes the risk of accidental parenteral contact while or after the sharp is used.

Section 6.36, Controls

Section 6.36 (1.1) which refers to needleless devices and hollow bore needles for vascular access only, is proposed to be amended to expand the scope to include all hollow bore needles. Health authorities are already transitioning to the use of safety-engineered hollow bore needles for vascular access by January 1, 2008, and the transitioning to all hollow bore needles will also be required by this date. Section (1.1) (a) is proposed to be deleted and the requirement for the highest level of protection moved to new section 6.36 (1.4) which now applies to hollow bore needles and safety-engineered sharps. The other requirement that the needleless device or safety-engineered hollow bore needle for vascular access be clinically appropriate is proposed to be moved to section 6.36 (1.3) (a) where it now applies to all safety-engineered hollow bore needles and medical sharps.

Section 6.36 (1.1) (b) is proposed to be deleted as it is moved to new section 6.36 (1.6) which now applies to all safety-engineered hollow bore needles and safety-engineered medical sharps.

Proposed new section 6.36 (1.1) (a) – (d) specifies the uses of needleless devices and safety-engineered hollow bore needles.

Proposed section 6.36 (1.2) requires that on and after October 1, 2008 any medical sharp used to care for or treat a person must be a safety-engineered medical sharp. It is anticipated that this date will provide sufficient time for the proper and safe implementation of safety-engineered medical sharps.

Proposed section 6.36 (1.3) provides exemptions to the use of safety-engineered hollow bore needles and medical sharps, and needleless devices. The requirements do not apply if the device is not clinically appropriate in the particular circumstance, or if it is not available in the commercial market.

Proposed section 6.36 (1.4) requires that if there are no exemptions, the safety-engineered needle or medical sharp that provides the highest level of protection from accidental parenteral contact must be used.

Proposed section 6.36 (1.5) requires the employer to make a determination of the highest level of protection referred to in new section 6.36 (1.4) based on information provided by manufacturers, independent testing agencies, objective product evaluation criteria, or other reliable sources. The wording of this subsection has been modified slightly from that taken to public hearing to make it clear that objective product evaluation is a primary source of information. Objective product evaluation may include post implementation surveys, data analyses and end-user clinical trials.

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Proposed section 6.36 (1.6) requires that safe work procedures and practices relating to the use of safety-engineered hollow bore needles and safety-engineered medical sharps must be developed and implemented before use of these devices.

Section 130 of the *Workers Compensation Act* outlines the duties and functions of the joint health and safety committees. Employers are required to consult with these committees. Section 5.54 (3) of the *OHSR* specifically mandates the involvement of the joint committee or worker representative in the review of the exposure control plan which is to occur at least annually.

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G6.36(1.3)-2 *Not clinically appropriate*

Proposed March 2007

Regulatory excerpt

Proposed changes to section 6.36 of the *OHS Regulation* (“*Regulation*”) include the addition of 6.36(1.1) to (1.3):

6.36 Controls

- (1) Engineering controls and work practice controls must be established to eliminate or minimize the potential for occupational exposure to a bloodborne pathogen or other biohazardous material.
- (1.1) On and after January 1, 2008, a needleless device or safety-engineered hollow bore needle must be used for the following procedures performed to care for or treat a person:
 - (a) withdrawal of body fluids
 - (b) accessing a vein or artery
 - (c) administration of medications or fluids
 - (d) any other procedure involving the potential for an exposure to accidental parenteral contact for which a needleless system or safety-engineered hollow bore needle system is available.
- (1.2) On and after October 1, 2008, any medical sharp used to care for or treat a person must be a safety engineered medical sharp.
- (1.3) Subsections (1.1) and (1.2) do not apply if
 - (a) use of the required device, needle or sharp is not clinically appropriate in the particular circumstances, or
 - (b) the required device, needle or sharp is not available in commercial markets.

Proposed section 6.36(1.6) of the *Regulation* states

Safe work procedures and practices relating to the use of safety-engineered hollow bore needles and safety-engineered medical sharps must be developed and implemented before use of these devices.

Proposed section 6.33 defines “medical sharp” and “safety-engineered medical sharp” as follows:

“medical sharp” means a needle device, scalpel, lancet, broken glass, broken capillary tube or any other medical device that can reasonably be expected to penetrate the skin or any other part of the body.

“safety-engineered medical sharp” means a medical sharp with a built-in safety feature or mechanism that eliminates or minimizes the risk of accidental parenteral contact while or after the sharp is used.

Purpose of guideline

This guideline

- Discusses the term “not clinically appropriate” under proposed section 6.36(1.3)

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- Highlights requirements for engineering controls even where sections 6.36(1.1) and 6.36(1.2) do not apply

Not clinically appropriate

Persons who make the determination of whether the use of the required device, needle or sharp is clinically inappropriate should

- Be qualified. Under section 1.1 of the *Regulation*, “qualified” means being knowledgeable of the work, the hazards involved and the means to control the hazards, by reason of education, training, experience or a combination thereof
- Have expertise in the procedure in question
- Have knowledge of the devices that are commercially available for the procedure

Additionally, the reasons for why the use of the required device, needle or sharp in a particular medical procedure is not clinically appropriate should be well documented for each procedure or type of procedure where that determination is made.

Use of the required device, needle or sharp may require modification of a medical procedure. This circumstance alone does not necessarily mean that the use of the required device, needle or sharp will compromise patient care or safety or worker safety. Therefore, it may be clinically appropriate to use the required device, needle or sharp even though the use requires modification of a medical procedure.

Safe work practice controls

Section 6.36(1) requires that work practice controls be established to eliminate or minimize the potential for occupational exposure to a bloodborne pathogen or other biohazardous material. Therefore, even if the required device, needle or sharp is not commercially available or not clinically appropriate to use, engineering controls (for example, puncture-resistant containers for sharps) and work practice controls must still be in place.

Where the required device, needle or sharp is used, section 6.36(1.6) requires that safe work procedures and practices relating to the use of the device, needle or sharp be developed and implemented before use.

For further information on other engineering controls and work practice controls that may be appropriate for use under section 6.36(1), see [OHS Guideline G6.36\(1\) Engineering and work practice controls](#).

G6.36 (1.4) and (1.5) Highest level of protection

Proposed March 2007

Regulatory excerpt

Proposed sections 6.36(1.4) and 6.36(1.5) of the *OHS Regulation* (“*Regulation*”) state:

- (1.4) If more than one type of safety-engineered hollow bore needle or safety-engineered medical sharp is available in commercial markets, the needle or sharp that provides the highest level of protection from accidental parenteral contact must be used.

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- (1.5) For purposes of subsection (1.4), an employer must make a determination of the highest level of protection available based upon information provided by manufacturers, independent testing agencies, objective product evaluation, or other reliable sources.
- (1.6) Safe work procedures and practices relating to the use of safety-engineered hollow bore needles and safety-engineered medical sharps must be developed and implemented before use of these devices.

Proposed section 6.33 includes the following definitions of “medical sharp,” “parenteral contact”, and “safety-engineered medical sharp”:

“medical sharp” means a needle device, scalpel, lancet, broken glass, broken capillary tube or any other medical device that can reasonably be expected to penetrate the skin or any other part of the body.

...

“parenteral contact” means piercing mucous membranes or the skin

“safety-engineered medical sharp” means a medical sharp with a built-in safety feature or mechanism that eliminates or minimizes the risk of accidental parenteral contact while or after the sharp is used.

Purpose of guideline

This guideline discusses requirements and considerations for selecting safety-engineered medical sharps (SEMS), including safety-engineered hollow bore needles, that provide workers the highest level of protection. The guideline also highlights some of the obligations of suppliers of these devices.

Considerations for “highest level of protection”

Many SEMS provide comparable levels of protection. However, where evidence suggests that one type provides a higher level than another in a particular circumstance, the employer is required to select the SEMS affording the highest of protection.

In ensuring that the SEMS that provide the highest level of protection are used consideration should be given to:

- Where there is evidence that other devices would reduce exposures in that workplace and for that task more effectively
- The different types of engineering controls that are commercially available for the relevant devices were considered and reviewed
- Information provided by manufacturers, independent testing agencies, “objective product evaluation” (see below), or other reliable sources, as specified section 6.36(1.5)
- Conducting a periodic review to ensure that the devices selected are appropriate based on the most current scientific knowledge of protection from sharps injuries. For example, a review may identify technological developments that may eliminate or reduce exposure to biohazardous materials, as well as any new information on the efficacy of the selected devices

Note regarding Regulation requirements for reviewing exposure control plans.

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- Section 6.34 requires the employer to develop and implement an exposure control plan (ECP) meeting the requirements of section 5.54 if a worker has or may have occupational exposure to the bloodborne pathogen, or to other biohazardous material as specified by WorkSafeBC.
- Section 5.54(3) requires the employer to review the ECP at least annually and update the ECP as necessary in consultation with the joint committee or the workers health and safety representative as applicable.
- Section 5.54(2)(b) requires that the exposure control plan incorporates the element of risk control, which includes the selection of devices under section 6.36(1.5) where applicable.

Objective product evaluation

Section 6.36(1.5) allows an employer to make a determination of the highest level of protection available based on an objective product evaluation. An objective product evaluation should enable the employer to assess the extent to which the SEMS eliminate or minimize the risk of parenteral contact while or after the device is used. An objective product evaluation should assess the factors that are relevant to determining the effectiveness of SEMS and be applicable to the groups of devices and procedures under consideration. Anecdotal evidence alone is not sufficient to determine that a device provides the highest level of protection.

The following are examples of criteria for employers to consider when using an objective product evaluation to determine which SEMS provide the highest level of protection:

- The device includes built in protection of the needle or other sharp
- The user can easily tell whether the safety feature is activated
- The device performs reliably
- The device is easy to use and self-evident
- The safety feature is in effect before disposal and remains in effect after disposal

Consideration of both “highest level of protection” and “clinically appropriate”

Section 6.36(1.3) recognizes that the use of SEMS affording the highest level of protection to a worker may not be clinically appropriate for certain clinical situations.

Consider the following example where an employer is initially considering three SEMS for use in a procedure:

	What level of protection from accidental parenteral contact does the SEMS provide the worker?	Is the SEMS clinically appropriate for procedure in question?
SEMS #1	High	No
SEMS #2	Medium	Yes
SEMS #3	Low	Yes

In this case, although SEMS #1 may provide the highest level of protection to the worker, it has been determined that it is not clinically appropriate to use it in the procedure in question. Therefore, for the purposes of section 6.36(1.4), SEMS #2 must be used because it provides the highest level of protection among those SEMS that are commercially available and clinically appropriate to use in the procedure in question.

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Suppliers' OHS obligations and highest level of protection

Section 120 of the *Workers Compensation Act* ("Act") places obligations on suppliers. For example, section 120 requires that every supplier must

- Ensure that any tool, equipment, machine or device, or any biological, chemical or physical agent, supplied by the supplier is safe when used in accordance with the directions provided by the supplier and complies with Part 3 of the *Act* and the *Regulation*
- Provide directions respecting the safe use of any tool, equipment, machine or device, or any biological, chemical or physical agent, that is obtained from the supplier to be used at a workplace by workers

For example, if a supplier fails to provide directions respecting the safe use of SEMS, then the supplier is in contravention of section 120. In this case, even if the SEMS could potentially provide the highest level of protection, the workers may not receive the highest level of protection because they are without adequate directions from the supplier.

Health Canada is the federal regulator that administers the [Medical Devices Regulations](#), issued under [The Food and Drugs Act](#). The [Medical Devices Regulations](#) apply to the sale and advertising for sale of a medical device and the importation of a medical device for sale or use on individuals. Under the [Medical Devices Regulations](#), manufacturers have obligations regarding the safety and effectiveness of the devices. Manufacturers' compliance with this regulation alone does not guarantee that the use of the device provides the highest level of protection in general or in particular circumstances.