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Submission on 2006 Proposed Amendments to Occupational Health and Safety Regulation (Part 6)

We are writing in response to the proposed amendments to Part 6 of the WorkSafeBC (Workers' Compensation Board) Occupational Health and Safety (OHS) Regulations, dated October 12, 2006 pertaining to safety-engineered devices. Fraser Health is dedicated to providing a safe and healthy environment for all our healthcare workers. We have over 23,000 employees at over 80 locations, covering 20 municipalities and two electoral areas. We appreciate the opportunity to comment on the proposed regulation changes.

According to the WorkSafeBC Statistics stated in the July 31, 2006 Proposed Amendment Explanatory Notes, "All time loss disease claims accepted by WorkSafeBC over a 10-year period (1995-2004) that resulted in a person contracting a disease from an infected person involved hollow-bore needles used to draw blood, which are intravascular hollow-bore needles". From this statement, the movement requiring the use of safety devices on hollow-bore needles is evidence-based. However there is currently no scientific evidence to support expanding the scope of the regulation to include all medical sharps.

During the implementation of safety-engineered needles within our health authority, we have documented a number of "lessons learned" from our experience. We are please to share these experiences and provide insight to WorkSafeBC to form and clarify the proposed amendments to the biohazard regulations.

We understand the decision to expand the proposed scope of the regulation to include all medical sharps is well-intended. However, we have the following comments regarding particular sections of the proposed amendments and the associated timeline.

Definitions

Section 6.33 defines a medical sharp as "*a needle device, scalpel, lancet, broken glass, broken capillary tube or any other medical device that can reasonable be expected to penetrate the skin or any other part of the body*".

We recommend the definition be limited to medical devices that are specifically engineered to penetrate the skin or any other part of the body. "Accidental" sharps such as broken glass should not be considered as medical sharps because these items are not used in any medical treatment and are not engineered to penetrate the body.

Timeline

Section 6.36 (1.2) states 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”*.

The timeline stated is unreasonable to implement the use of safety-engineered medical sharps to replace their non-safety counterparts. An adequate amount of time is needed follow the process that any medical device/equipment undergoes when introduced into our health authority, such as determining which medical devices should be replaced; researching the alternatives available on the market; providing opportunity for companies to respond to the “call for tender”; trialing and evaluating the products from selected vendors; implementing the selected devices; and finally educating and training end users on the proper and safe use of the device.

Based on our past experience of implementing safety engineered needles, we do not feel that October 1, 2008 is an adequate amount of time to implement known safety engineered medical sharps.

Clinical Appropriateness

Section 6.36 (1.3) (a) and (b) state conditions that preclude the use of safety engineered needles. Conditions stated are that:

- (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.*

The term “clinically appropriate” has not been defined in the regulations and has thus been left to the interpretation of the reader. A definition should be included in the regulation to support the use of the term. The determination of a safety-engineered device’s clinical appropriateness is complex and involves consideration of many factors. During Fraser Health’s implementation of safety-engineered needles, several factors contributed to the “clinical appropriateness” of the safety devices. Factors include (1) suitability of the device with the acuity of the task; (2) compatibility of the device with other equipment and processes; (3) alignment of the device with established best practices and established standards of care; as well as (4) support of safe work practices through the use/activation of the safety device. The term “clinically appropriate” is subjective and the proposed regulations should address the criteria for a device to be “clinically appropriate”.

We also recommend that an additional exemption (c) be added to preclude the use of safety engineered needles if the safety engineered sharps or medically acceptable sharp has not been available in the market long enough to be adequately trialed and deemed clinically appropriate. As the regulations requiring the use of safety engineered sharps come into effect, more safety engineered devices will be developed. An adequate amount of time must be provided to prove the appropriateness of the safety device.

Highest Level of Protection

Of major concern is section 6.36 (1.4) which states that *"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"*.

We recommend that section 6.36 (1.4) be significantly altered to exclude the term "highest level of protection". The regulation should be altered to concentrate on the elimination of risk, not the method in which it is achieved. While the intention to provide a proven level of safety is noble, the wording of the subsection is too vague and can be falsely linked with the complexity of the safety device. The wording suggests a sophisticated device and process must be used. However a simple conventional device that is compatible with established safe work procedures that would minimize or eliminate the risk could also be considered to have the highest level of protection. When comparing two devices, one device cannot be scientifically proven superior in protection if both reduce the identified risks equally.

Two critical conditions must be taken into account when deciding the level of protection of a device: (1) the user's knowledge and (2) the reliability of the device. The first condition must assume that the user knows how to activate the safety mechanism properly. Increased complexity allows the potential for errors and complacency to activate the safety mechanism. The second condition is the reliability of the safety device. We can theorize that increasing complexity of a safety mechanism decreases its reliability. A case in point is the retractable needle devices. There is no scientific evidence proving that retractable devices provide a higher level of protection than devices that guard the needle. In fact, retractable devices that fail to deploy are just as hazardous as non-safety devices. The complexity of the needle guard mechanism should not be synonymous with the level of protection.

Product Evaluation

Section 6.36 (1.5) states that *“For the 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 or other reliable sources and, if that information is not available, based on other objective product evaluation criteria.”*

The accompanying subsection (1.5) should be altered to remove the term “highest level of protection”. Further, we recommend clarification of the term “reliable sources”. The selection of medical devices should include evidence-based practice evaluation, and not solely be based on the information that is provided by the manufacturers or biased independent testing agencies. The selection of a medical device should follow a process of specification evaluation and end-user trials.

We recommend that subsection (1.5) be revised to include end-user evaluations as a valuable and important source of product evaluation.

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From: Chua, Prescillia [Prescillia.Chua@fraserhealth.ca]
Sent: Friday, December 01, 2006 1:25 PM
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Cc: FrancesK@heabc.bc.ca
Attachments: Fraser Health response to 2006 Proposed Amendments to OHS Regulation - Part 6 (6.33 - 6.41).pdf

Please find attached a written submission response to the proposed 2006 changes to the Occupational Health and Safety Regulation - Part 6 (6.33 to 6.41).

Submitted on behalf of Fraser Health.

<<Fraser Health response to 2006 Proposed Amendments to OHS Regulation - Part 6 (6.33 - 6.41).pdf>>

Respectfully submitted,

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