

2007/03/20-03

THE WORKERS' COMPENSATION BOARD OF BRITISH COLUMBIA**RESOLUTION OF THE BOARD OF DIRECTORS****RE: Amendments to the *Occupational Health and Safety Regulation*
(B.C. Reg. 296/97, as amended), pertaining to
safety-engineered needles****WHEREAS:**

Pursuant to section 225(1) of the *Workers Compensation Act*, R.S.B.C. 1996, c. 492 and amendments thereto ("*Act*"), the Workers' Compensation Board ("*WCB*") may make regulations it considers necessary or advisable in relation to occupational health and safety and occupational environment;

AND WHEREAS:

Sections 6.33 and 6.36 of Part 6 of the *Occupational Health and Safety Regulation* ("*OHSR*") contain substance specific requirements for biohazardous materials;

AND WHEREAS:

Following public hearings held in May 2006, the Board of Directors ("*BOD*") in July 2006 approved amendments to Part 6, sections 6.33 and 6.36 of the *OHSR* requiring hollow bore needles used intravascularly or intravenously to be safety-engineered;

AND WHEREAS:

The BOD approved an additional public hearing as part of the 2006 regulatory process, to consider expanding the scope of sections 6.33 and 6.36 to include all hollow bore needles and other medical sharps as new technologies become available, and to include a provision that the safety-engineered devices used provide the highest level of protection available;

AND WHEREAS:

The WCB has given notice of the proposed amendments to sections 6.33 and 6.36 of Part 6 of the *OHSR* and has held public hearings on the proposed amendments in accordance with section 226(1) of the *Act*;

AND WHEREAS:

The BOD, after due consideration of all presentations to the WCB, considers it necessary and advisable in accordance with the WCB's mandate under the *Act* in relation to occupational health and safety and occupational environment, to amend sections 6.33 and 6.36 of Part 6 of the *OHSR*;

AND WHEREAS:

Pursuant to the Provincial Government's *Regulatory Reform Policy*, the BOD has evaluated the proposed regulatory amendments according to the established regulatory criteria;

THE BOARD OF DIRECTORS RESOLVES THAT:

1. The amendments to sections 6.33 and 6.36 of the *OHSR*, as set out in Appendix A, are approved.
2. The Regulatory Criteria Checklist in Appendix B is approved.
3. The above amendments will be deposited with the Registrar of Regulations in such form as may be required by the Registrar.
4. The above amendments will come into force 90 days after deposit with the Registrar of Regulations.

DATED at Richmond, British Columbia, March 20, 2007.

By the Workers' Compensation Board

**DOUGLAS J. ENNS, CHAIR
BOARD OF DIRECTORS**

APPENDIX A

THE BOARD OF DIRECTORS RESOLVES THAT:

1 Section 6.33 of the Occupational Health and Safety Regulation, B. C. Reg. 296/97 is amended

(a) by repealing the definition of “biohazardous material” and substituting the following:

“biohazardous material” 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 is known or reasonably believed to cause disease in humans; , **and**

(b) by adding the following definitions:

“medical sharp” means a needle device, scalpel, lancet or any other medical device that can reasonably be expected to make parenteral contact;

“parenteral contact” means piercing of 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; .

2 Section 6.36 (1.1), as enacted by B.C. Reg. 241/2006, is repealed and the following substituted:

(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.

3 Section 6.36 is amended by adding the following subsections:

(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.

(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

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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.

4 The above amendments come into force 90 days after their deposit under the Regulations Act.

Dated at Richmond, British Columbia, March 20, 2007.

By the Workers' Compensation Board

***DOUGLAS J. ENNS, CHAIR
BOARD OF DIRECTORS***

APPENDIX B

Regulatory Criteria Checklist

Title of Legislation/Regulation* Occupational Health and Safety Regulation ("OHSR")

***If Regulation, Title of Authorizing Legislation:** Workers Compensation Act

Purpose of Proposal (One-Line Summary): Amendments pertaining to requirements for safety-engineered needles.

If the answer is "No" for any of the criteria, please attach explanation.

Regulatory Criteria	Criteria Met
1. Reverse Onus: Need for Regulation is Justified	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
2. Regulatory Design is Results-Based	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
3. Transparent Development of Regulatory Requirements	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
4. Cost-Benefit Analysis	Formal Cost-Benefit Analysis Completed <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Not Required If <i>Not Required</i> , Impacts have been Analyzed <input type="checkbox"/> Yes <input type="checkbox"/> No
5. Competitive Analysis Completed	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
6. Regulatory Requirements Avoid or Eliminate Duplication with Other Jurisdictions	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
7. Timeliness of Regulatory Response	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
8. Plain Language	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
9. Sunset Review and Expiry Provisions	Sunset Review provision <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Sunset Expiry provision <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No
10. Replacement Principle Applied	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
11. Business Process Map Analysis Completed	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No

Number of Regulatory Requirements to be added:	5
Number of Regulatory Requirements to be eliminated:	0
NET CHANGE:	5

 Responsible Minister or Head of Regulatory Authority
Douglas J. Enns, Chair
Board of Directors
Workers' Compensation Board

 March 20, 2007
 Date

Contact:
Anne Burch, Director
Policy and Research Division
Workers' Compensation Board

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REGULATORY CRITERIA CHECKLIST

A. BACKGROUND

On March 11, 2002 the provincial government introduced a new Regulatory Reform Policy ("Policy"). The Policy was intended to "support the government's commitment to reducing the regulatory burden in British Columbia by one-third over three years." The Policy applied to all proposed legislation and regulations. On February 8, 2006 Cabinet re-confirmed government's commitment to regulatory reform and the target of a zero net increase in regulatory requirements for three years (through December 31, 2008).

The Policy requires the Chair of the Board of Directors ("BOD") to ensure that proposed regulations are evaluated according to regulatory criteria set out in the Policy, and to sign and make public the "Regulatory Criteria Checklist" ("Checklist") when regulations are enacted. The criteria are designed to ensure that all new regulations are results-based and contribute to a more competitive regulatory environment.

The Policy provides for exemptions from the Checklist if the head of the regulatory agency certifies that, in his or her opinion, the regulation satisfies one or more of the following conditions:

- Is non-regulatory in nature;
- Changes fees in respect of a financial year by an annual rate that has been approved by the Treasury Board;
- Relates only to the procedures or practices of a court or tribunal;
- Is required under a national uniform legislation or regulatory scheme, or by federal legislation that has already been assessed against criteria similar to that provided in the Checklist;
- Is fundamentally declaratory or machinery in nature, such as housekeeping changes that clarify or correct a provision without changing procedural requirements;
- Provides for the commencement of an Act or regulation or the commencement of a provision of an Act or regulation;
- Is consolidated and reviewed under the reversion powers in Part 2 of the *Regulations Act*;

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- Is transitional in nature;
- The special circumstances of the case, as identified by the responsible minister or head of the regulatory authority, make it impracticable to comply with the Regulatory Criteria.

The regulatory amendments relating to safety-engineered needle requirements do not meet the criteria for an exemption from the Checklist.

B. REGULATORY AMENDMENTS

Sections 6.33 and 6.36 of Part 6 of the Occupational Health and Safety Regulation (“OHSR”) contain substance specific requirements for biohazardous materials and related definitions.

Section 6.33 is amended by adding definitions for “medical sharp”, “parenteral contact” and “safety-engineered medical sharp”.

Section 6.36 is amended to require that all hollow bore needles and other medical sharps be safety-engineered by certain dates and under certain conditions.

C. EXPLANATORY NOTES

1. Reverse Onus: Need for Regulation is Justified

The regulatory amendments are necessary to maintain reasonable standards for the protection of worker health and safety.

2. Regulatory Design is Results-Based

One of the objectives of the Workers’ Compensation Board’s (“WCB”) ongoing regulation review is to strike a balance between establishing standards or practices for controlling risk and providing flexibility to enable workplaces to determine appropriate measures for achieving compliance. In the case of requirements for biohazardous material, the amendments are results-based in nature.

3. Transparent Development of Regulatory Requirements

Section 226 of the *Workers Compensation Act* (“Act”) requires that before making a regulation under Part 3, the WCB must give notice of the proposed regulation in the BC Gazette and at least three newspapers and must hold at least one public hearing on the proposed regulation.

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Public hearings were held between October 20, 2006 (date of formal notice) and January 31, 2007 (due date for written submissions) on the proposed regulatory amendments to Part 6 of the *Occupational Health and Safety Regulation*. Oral public hearings were conducted in Prince George (November 20, 2006); Vancouver (November 23, 2006); Kelowna (January 25, 2007); and Nanaimo (January 29, 2007), as part of the 2006 public hearing process.

A total of 59 submissions were either presented or received during the public hearings and comments were provided on the proposed regulatory amendments relating to safety-engineered needles.

4. Cost-Benefit Analysis Completed

A formal cost-benefit analysis was not completed.

BC will be the fourth province to require safety-engineered devices for all hollow bore needles, and the first to require safety devices for all medical sharps. All USA states have been required to use safety-engineered hollow bore devices since 2000.

The six health authorities have already transitioned to or are in the process of transitioning to the use of safety-engineered needles and some other medical devices.

WorkSafeBC does not introduce regulatory amendments based solely on whether they are cost-effective. It is a consideration, however, worker safety is the prime concern.

The California OSHA study released in 1998, which was a comprehensive cost analysis of the use of safety needles estimated a net savings of \$106 million/year. These projections were said to be conservative since the study didn't account for costs associated with follow-up treatment, lost worker productivity, worker's compensation, liability, etc.

The United States General Accounting Office ("GAO") published a report in 2000 and estimated that the use of safety-engineered needles may have financial benefits that exceed the cost of implementation. The extent to which needles with safety features are cost-effective depends on their incremental costs, the extent to which they reduce the risk of a needlestick injury, and the costs of post-exposure treatment. These factors and their potential costs and benefits cannot be measured precisely. Using a set of assumptions, the GAO estimated that the use of safety-engineered needles is cost-effective when the costs of post-exposure treatment is moderate or high, and the added costs per needle are low.

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The scope of this analysis is limited to the selected financial costs that hospitals might incur that are associated with using needles with safety features, but it omits the effects of several relevant factors. For example, we did not factor in

- (1) decreases in subsequent medical treatment costs for health care workers who become infected,
- (2) reductions in health care workers' risks to life and health,
- (3) reductions in time lost from work, and
- (4) the emotional distress suffered by injured and infected workers.

The report states that while it is not easy to quantify the additional benefits of using needles with safety features, they are real and likely to be substantial. If the GAO had been able to incorporate these additional factors, the estimated net benefits of needles with safety features would have been greater than those reported.

5. Competitive Analysis Completed

It is not clear why a competitive analysis would be required as the health care system in BC is publicly funded. The other provinces are not competing with BC for patients. However, an interjurisdictional analysis has been completed.

Manitoba, Saskatchewan and Nova Scotia have enacted legislation that mandates safety-engineered needles for all hollow bore needles (intravascular, intramuscular and subcutaneous). The requirements are effective on January 1, 2006, July 1, 2006, and January 1, 2007, respectively.

In the USA, the Federal Needlestick Safety and Prevention Act was signed into law on November 6, 2000. This Act mandated that the Occupational Safety and Health Agency's ("OSHA") 1991 Bloodborne Pathogens Standard be revised to strengthen the requirements related to the use of safety-engineered sharp devices. In part, the revised Bloodborne Pathogens Standard requires health care employers to document in their exposure control plan that they have evaluated and implemented safety-engineered sharp devices and needleless systems in order to reduce workers' occupational exposure to bloodborne diseases. It also requires that exposure control plans be reviewed and updated at least annually to reflect changes in sharps technology.

The 23 states and 2 territories that operate their own federally approved occupational safety and health plans were required to adopt a comparable amended standard within six months of the publication date of the Federal OSHA standard.

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California was the first state to revise its OSHA standard in 1999 to require the use of safety-engineered medical sharps.

6. Avoid or Eliminate Duplication with Other Jurisdictions

The amendments do not duplicate requirements imposed by other regulatory jurisdictions.

7. Timeliness of Regulatory Response

Changes to regulations must be deposited with the Registrar of Regulations and, pursuant to section 227 of the *Act*, may only come into force at least 90 days after their deposit under the *Regulations Act*. To ensure timely implementation, the amendments will come into force 90 days after deposit.

The amended regulation will be available on WCB's website and a communications strategy has been developed to ensure workplace parties are made aware of the changes. Guidelines have been drafted to provide additional clarity on the new requirements and assist with compliance.

8. Plain Language

The amendments are drafted in plain language.

9. Sunset Review and Expiry Provisions

Sunset review and expiry provisions are not required. Section 228 of the *Act* requires the WCB to undertake a process of ongoing review of and consultation on its regulations to ensure that they are consistent with current workplace practices, technological advances and other changes affecting occupational health and safety and occupational environment.

10. Replacement Principle Applied

The amendments result in a net addition of five regulatory requirements.