

Safety Engineered Device Waiver Application Process

Background

It is a goal of Alberta Health Services to minimize the transmission of blood borne diseases to and from workers in the course of their employment. An effective vehicle through which to achieve this goal is the implementation of safety engineered devices across all zones.

Enacted July 1, 2010, Alberta law requires that safety devices be preferentially employed to protect healthcare workers from sharps injuries. Wherever possible, health care workers must use a commercially available safety engineered device in place of a conventional device. A commercially available device is one that is accessible through the marketplace and has been approved as a medical device by Health Canada.

In extraordinary occasions where:

1. An appropriate safety engineered device is not commercially available or,
2. The use of a safety engineered device is not clinically appropriate,

The user may apply for a waiver to continue use of a conventional device. In order to deem a device not appropriate for clinical use the waiver must be completed by an individual who has the clinical expertise and experience to make that assessment.

Definitions

Conventional Device – A sharps device that does not offer sharps injury protection

Medical Device – health or medical instruments used in the mitigation, treatment, diagnosis, prevention of a disease or abnormal physical condition

Safety Engineered Device (SED) – A device that has a built in sharps injury protection mechanism such as an attached sheath covering the needle or scalpel after use or needles that retract after use. Other types of safety devices include blunt needles or needle-less systems (Saskatchewan Labour, 2006). SEDs protect the user from exposure to blood borne pathogens or chemical hazards (i.e. cytotoxic medications).

Waiver Procedure:

Please note: Any existing waivers from previous SED implementations will no longer be valid after June 30, 2010.

In order to address legislative documentation requirements, the following procedure must be completed.

1. Complete the “Waiver Request for Use of Conventional Devices” form. The form should be completed electronically and returned to the Quality Assurance Officer. Alternatively the completed form can be printed and faxed.

References

Alberta Occupational Health & Safety Regulation and Code – Part 35
Saskatchewan Labour. Needle Safe Devices and Improved Exposure Control Plans
Vanderbilt Infection Prevention and Control
Revised: January 17, 2011
Originator: WHS

2. A completed hazard assessment must accompany the waiver. If the applicant requires support in completing the hazard assessment, they may contact their zone Workplace Health and Safety (WHS) for information. Each complete submission will be logged and tracked for quality assurance.
3. The application will be reviewed by a provincial panel comprised of:
 - WHS
 - Contracting, Procurement and Supply Management
 - Occupational Medicine Consultant to WHS
 - Other stakeholders at the discretion of the panel

A decision will be communicated to the originator. The originator is accountable for communicating the results of the decision to the affected departments/areas.

4. Incomplete submissions i.e. missing or incomplete waiver or hazard assessment forms will be returned to the originator and further consideration from the provincial panel will be suspended pending resubmission of a completed package.
5. Waivers will be approved for a maximum of one year from review and waiver renewals must be submitted within 30 days of the waiver expiration. The originator will be responsible for ensuring the timeline is met. The Renewal form is in Appendix Three.
6. The originator must keep a copy of the waiver in an accessible location in the event an Occupational Health and Safety Inspector requests the documentation.
7. Waivers may be suspended or revoked by WHS if it is discovered that the conventional device is being used for a non approved application.
8. For questions regarding the waiver process, please call:

**Quality Assurance Officer
Michelle Regier
Workplace Health and Safety
(403) 309-2883**

[mailto: SED.Waiver@albertahealthservices.ca](mailto:SED.Waiver@albertahealthservices.ca)

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