Appendix C

Exemptions Under Needle Safety Regulation

Regulation 474/07 provides for exceptions to the use of safety-engineered needles. One of them is contained in section 4 (2), which provides that:

> *"the worker may use a hollow-bore needle that is not a safety-engineered needle if he or she believes on reasonable grounds that in the particular circumstances, the use of a safety-engineered needle would pose a greater risk of harm than the use of the hollow-bore needle."*

Section 4(3) states that "risk of harm" includes the following:

1. *A risk of harm to the worker or to another worker.*
2. *If the work involves the use of a needle on a person, a risk of harm to him or her.*

Section 4 (4) of the Regulation also provides that "the employer shall develop, establish and provide training for workers to assist them in applying subsection (2)."

Section 5 of the Regulation also provides for exceptions where a declaration of emergency is in effect or situations that constitute or may constitute a serious risk to public health.

The exceptions in Regulation 474 are intended to describe situation-specific circumstances and are not meant to enable general exemptions based on institutional practices or preferences. Blanket exceptions would be contrary to both the letter and intent of Regulation 474 and could constitute a significant threat to worker safety.

Exceptions should be individual, procedure-specific and limited.

How to respond to employer requests for exemptions:

The following are examples of reasons employers have cited when requesting an exemption under the regulation, along with some proposed solutions. In most cases, a solution can be found; however, there may be some legitimate reasons for a specific exemption.

For situation-specific circumstances, a clinical needs assessment should be conducted to understand the opportunity to use an appropriate safety-engineered needle (SEN) for a specific procedure. This may be done in partnership with a vendor to understand device options.

- Situation: The pharmacy department supplies medications in pre-loaded syringes with a hollow-bore needle attached.

Solution: Pharmacy departments should supply only safety-engineered needles. A conventional syringe barrel may be used if no needle is attached and the medication delivery is being done via a needleless access system. A conventional syringe barrel may be used if no needle is attached when the syringe leaves the pharmacy and a safety-engineered needle is used at the time of medication delivery.

- Situation: A procedure requires the use of a hollow-bore needle of a specific length and gauge and no safety-engineered equivalent has been licensed as a medical device by Health Canada - i.e. there is no available safety-engineered needle within the meaning of the Regulation.

  Solution: Assuming there is no other safety-engineered needle that can be appropriately used for the work, the employer would likely be considered unable to obtain a safety-engineered needle appropriate for the work for the purposes of the exemption set out in subsection 3(2) of the Regulation. Therefore, the exemption would be acceptable.

- Situation: The SEN is not compatible with other equipment currently used.

  Solution: In most cases, a solution can be found, either by changing existing equipment or by sourcing a new SEN. If the incompatibility cannot be corrected, the exemption and the reasons for it should be discussed with the Joint Health and Safety Committee (JHSC) or Health and Safety Representative and trade union. It should be noted that the exemption is temporary until an appropriate SEN becomes available or the problematic equipment is replaced by compatible equipment.

- Situation: An infection control concern has been raised.

  Solution: A temporary exemption may be considered, only until the matter has been thoroughly investigated and a suitable safety-engineered needle has been selected.

- Situation: Not all workers have received training on a new device or technique.

  Solution: Any exemption is only temporary and applies only to *individuals* who have not successfully completed training with the new SEN or technique. Completion of training should be a priority and this exemption should not be extended to the entire organization.

- Situation: Use of a required device, needle, or sharp may require modification of a medical procedure.

  Solution: 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. Persons who make the determination of whether the use of the required device, needle, or sharp is clinically appropriate should:

  - Be qualified: this means being knowledgeable of the work, the hazards involved, and the means to control the hazards, by reason of education, training, experience
  - Have expertise in the procedure in question

- Have knowledge of the devices that are commercially available for the procedure

Documenting exemptions:

- Situations in which conventional hollow-bore needles are used instead of safety-engineered needles must be documented to justify departing from the regulatory requirements.

- Employers should document any exceptions to the regulatory requirements.

- Employers should ensure that any exception to a requirement in the regulation is limited to a risk of harm to patients or health care workers or the unavailability of appropriate safety-engineered needles.