6.32.

VANCOUVER ISLAND health authority

VIHA Public Hearing Response (November 30, 06) to: WSBC Proposed Regulatory Amendments – Part 6: Substance Specific Requirements

The proposed scope of the proposed amendments to part 6: Substance Specific requirements (GIU#172, October 12th) include not only safety needles for venous/ arterial access but all needles and medical devices.

In the current form, the scope of the recommended changes by the WSBC Board of Directors (BOD) is using a "shot gun" approach relying on emotional arguments and current conversion trends to validate /support this regulatory change.
Scientific data does not support this approach or the proposed scope. In addition, this regulation in its current form is questionable in the ability to enforce and not realistic to neither attain BC wide nor achieve in the healthcare industry. Wording and definitions are not clearly, accurately or adequately defined to provide meaningful plain language to those who work in or supply healthcare. This will result in confusion, false understandings, and misinterpretation of the regulation.

Given the current scope of this proposed amendment, a cost benefit and competitive analysis must be completed by WSBC before putting any of the amendments into force. The current regulation exceeds and is more limiting and prescriptive than those of Manitoba or Saskatchewan. Using the basis that all the health authorities are considering or in process of converting to safety engineered needles does not constitute due diligence or evidence / result based (statistical data) decision making on the part of WSBC. Further to using the "everyone is doing it" argument, the proposed amendment changes do not reflect current workplace practices (evidence based best practices), clinically appropriate technology in use or being considered by the health authorities. It is also important to remember that while the Health Authorities are a major part in the healthcare industry, they are only a part.

Key Presentation Points:

1) Scope of the regulation is too broad and prescriptive.
    a. Focus should only be on high risk devices involving venous/ arterial access
    b. Scope expansion should be phased in over the next 3 years
    c. Selection of devices / decision to implement medical safety sharps must be based on risk assessment, clinical/ medical appropriateness
2) Definition clarification
    a. Medical sharp
    b. Highest level of safety
    c. Safety engineered needle definition
    d. Clinically appropriate (and medically acceptable)
3) Selection of Safety Devices

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WSBC Proposed Regulatory Amendments – Part 6: Substance Specific Requirements

1) Proposed Regulation Scope

Earlier this year, the regulatory focus was on those procedures and related devices that represented the greatest risk – venous / arterial access. The current draft does not focus on the clearly identified areas of greatest risk.

- The wording of the regulation was superior and supportive of the intended purpose. *(It was not perfect but it was certainly better that the current proposed amendment).*
- The health authorities also supported safety needles for arterial/ venous access devices.
- The current proposed regulation promotes technologically sophisticated devices as the control mechanism. Historical and statistical data does not support this approach.
- Statistical and historical data clearly identifies the greatest risk from a BBF exposure comes from arterial/ venous access tasks (starting e.g. an IV, phlebotomy).
    i. There is a greater risk if the needle has been in a vein or artery (e.g. IV/ phlebotomy) than in a muscle (IM) or subcutaneous tissue.
- The proposed time line was manageable for the greater part of healthcare industry given the venous/ arterial access device scope.
- Adequate time was / would be allowed for risk assessment, product investigations, trials, selection and implementation.
- While the effects of a BBF exposure can be traumatic, Sero-conversion as a result of a BBF is low. This is especially true of intramuscular and subcutaneous injections.
- The rational expressed by the WSBC BOD to validate expanding the regulation
    i. "all the Health authorities are moving in the direction of safety engineered needles anyways"
    ii. All BBF's follow the same process

are not valid reasons to increase the scope by including all needles and medical devices.

- Risk assessments are key to determining the root cause of exposures and risks. Implementation of controls must be based on controlling the root cause, not the assumption that an engineering control is the best or only solution.
- The Health Authorities are at different stages of the process and some will not be able to achieve the time frame for implementation.
- The current scope of the amendment put a number of areas in an imposable position to comply. For example;
    i. Scientific laboratories,
    ii. Dental offices
    iii. Minor or day surgery centers
    iv. Community treatment programs
    v. Provincial programs.
- Other heath service areas have not even started (or are in the infancy stages) of evaluating safety-engineered products.

- Implementation and conversion to safety products constitutes a significant financial and resource investment that some care facilities are not able to meet / sustain.

Proposed regulation scope and approach:
Expansion of the regulations should be put on hold or phased in over a longer period to ensure that the most clinically appropriate and medically acceptable devices are chosen. This would also allow for financial and resource allocation and promote sustainability in the conversion process.

- Jan 1, 2007 – Dec. 31, 2007 Venous and arterial access devices
- Jan 1, 2008 – Dec. 31, 2008 Other safety needles (IM and subcutaneous)
- Jan 1, 2007 – Dec. 31, 2007 Other medical sharps

2) Definition clarification

a. 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;

The inclusion of "broken glass" as a medical sharp requires clarification and context. While the indented reference may be for items such as "glass vaccuatainer vials" The simpler solution would be to have the term removed from the regulations.

- Broken glass represents a cut or puncture risk and must be handled and disposed of appropriately regardless of the situation.
- Broken glass is not used in medical treatment but may occur as a result of a container of device being broken. Safety glass can also present injury risks.
- Numerous medications are supplied in glass ampoules that must be "broken" in order to access the medication. While their inclusion in the definition may be appropriate, it may represent significant consequences to the healthcare industry, medication manufactures, end users and ultimately the patients.
- If the broken glass is contaminated with blood/ body fluids, then it requires special handling and disposal. For example a glass vial or specimen/ suction container.
- Glass from a broken window would need to be considered a medical sharp. As such it would be required to be put into an appropriate sharps container and be disposed of as a medical sharp. This would have a significant impact on all industries and result in global non-compliance / inability to comply.

The phrase "or any other part of the body" is misleading and may lead to confusion and inaccurate interpretation where items or devices are used in body cavities such as the mouth (e.g. toothbrush), ear canals (e.g. Q-tips), urethra (e.g. Foley catheters) etc.

b. Highest level of safety

The phrase "highest level of safety" is prescriptive, vague and misleading. It reflects the WSBC BOD acceptance of lobby group(s) misinformation that only technologically sophisticated devices are the safest and appropriate in all situations.

- This false belief is clearly evident in end user groups who also believe this to be true despite the lack of scientific or proven data to support this approach.
- In clinical trials end users using the technologically sophisticated devices (e.g. retractable needles) indicated that they were not appropriate.

In addition the phrase identifies the maximum standard and does not allow for clinical / procedural variables.

- Alternate terminology should be considered/ used to support a shift from those conventional devices that, based on a risk assessment, are deemed to increase the risk of exposure.
- Highest level of safety must be appropriately defined to shift the focus from technical sophistication of an engineered sharp or medical device to the process which involves determining the root cause and required interventions used to create the highest level of safety.
- Statistical data and research supports the use of engineering controls in conjunction with other controls to manage risk.
- It is misleading and negligent to make the assumption that any safety device will provide the highest level of safety in the absence of identifying the root cause of the risk.
- Reliance on the device sophistication negates the importance of safe work practices and evidence based clinical practices.
- In addition, the reliance on the device sophistication does not take into account clinical appropriateness, medical acceptability, usability, end user issues, client based interactions or the environment in which these devices are to be used
- A conventional device that is compatible with established safe work practices that reduce or eliminate identified risks could easily be considered the highest level of safety.
- If the device and the work practice no longer maintain that level of safety, then intervention is warranted based on the identification of the root cause – is it the device or the work practice?
- In most cases a simpler intuitive device that is more end user friendly and/or task friendly provides the highest level of safety.
- Devices for similar tasks that have different activation features may decrease the activation frequency due to confusion or frustration related to the various activation methods.

Recommended definition for highest level of safety:

The use and selection of technology or device that is most appropriate to the health care environment and culture it is intended to support. It might involve using the simplest and least cumbersome level of technology required to

effectively achieve the intended purpose while maintaining clinical acceptability and clinical appropriateness.

c. Safety engineered needle definition

"safety-engineered needle" **includes a** *self-sheathing needle device and a retractable needle system.*

Definition is too narrow and focuses only on needless or technically sophisticated devices.

- Failure to be representative of the wider range of devices with in the body of the regulation is misleading and confusing to the target group the regulation is intended for.
- Other safety needles also offer safer alternatives over conventional needles (e.g. integrated safety mechanism) and are more appropriate in a wider variety of applications.
- Consideration must also be given to the current safety engineered needles and future devices that may come into use.
- Despite the expanded explanation in the guidelines, numerous individuals are incorrectly drawing a correlation between technically sophisticated device (e.g. retractable needle system) and highest level of safety.

This definition must include:
"integrated needle guard mechanism" or similar wording to prevent continued confusion and incorrect conclusions about appropriate safety engineered needles.

d. Clinically appropriate (and medically acceptable)

The definition of "clinically appropriate" needs to be concise, simple and easily understood for those in the healthcare industry. In addition a definition of medically acceptable needs to be included to ensure completeness.

- The addition of this information and definition will quantify and qualify the chosen product.
- Promote selection through a process involving risk assessment and product trials and reviews.
- Significantly reduce the likelihood of an inappropriate device being selected or an appropriate device being rejected due to personal bias.
- Defining and determining Safety Engineered Needles (SEN's) and other Safety Engineered Devices (SED's) that are "clinically appropriate" is complex. It involves many aspects such as;
  - specific applications,
  - device acceptability,
  - acute versus emergent use
  - willingness to explore SED's,

- perception,
- comfort
- safe work practices.

- What may be deemed clinically appropriate for one medical procedure may not be for another task.
- There is a balance between subjective and objective clinical appropriateness of SED's. Some primary factors to consider for SED's include:
  - Evidence based clinical standards
  - Suitable for task and acuity
  - Does not impede or compromise established clinical standards
  - Is acceptable to the end user (sufficient comfort/ proficiency level)
  - Use of / activation of safety feature compliments or supports safe work practices

Recommended definition for "clinically appropriate"
Health care products that a healthcare provider uses for the purpose of providing health care in a manner that is:
(a) in accordance with evidence based clinical standards of practice;
*(b) not primarily for the convenience of the *patient or health care provider.*
*(*Note: term "patient" is synonymous with "client" and "resident" depending on the context of practice.)*

Recommended definition for "medically acceptable" device
Medically acceptable devices must:
(a) be approved/ certified for use in Canada through the appropriate regulatory body (Health Canada, CSA etc) and
(b) *facilitate meeting clinical standards and/ or be used in accordance with the device's intended purpose.*

3) <u>Selection of Safety Devices</u>
While employer must make the determination of the "highest level of safety", the regulation identifies the resources the employer is to use to make this determination. While manufacturers and independent testing agencies are worth looking at, they are not appropriate sources to base a final decision on.

- Information and claims by manufacturers, independent testing agencies or other "reliable sources" can be self-serving and may make false or inappropriate product claims.
- The healthcare industry must be allowed to conduct clinical trials/ reviews and not be forced to rely solely on information and claims that may not be accurate or misleading.
- Selection of medical equipment and devices must be based on clinical and medical appropriateness, not solely on manufactures or independent testing.
- Identification of the need to move towards a safety device should be based on a risk assessment.

- Clinical trials and evaluation by the employer and end users must be the determining factor to move towards a engineered sharps or medical device.
- Awareness that a particular engineered sharp or medical device may not be clinically appropriate or medically acceptable in all instances.
- While objective data is preferable, the reality is that there will be a degree of subjectivity in any engineered sharps or medical device trial and selection.
- While cost should never be the primary motivator to select a particular engineered sharp or medical device, impact on other equipment and processes must be seriously considered in the process.

Dean, Sue

From: Kamsteeg, Kenneth [Kenneth.Kamsteeg@viha.ca]
Sent: Tuesday, November 28, 2006 1:48 PM
To: Dean, Sue
Subject: RE: Public Hearing Registration
Attachments: Nov30WSBC public hearing Response GU172.pdf

Sue,

In light of the cancellation of the November 30 public hearing in Naniamo, please find attached a copy of my presentation/ submission.

I realize that this is a complex issue and a written submission does not provide the same depth, detail or interaction (e.g. question/ answer abilities). I would like to extend an offer to speak with Roberta and/ or the other panel members on this topic at a later, mutually convenient time if they feel it would be beneficial.

Ken Kamsteeg

-----Original Message-----
From: Regulation Review - External Queries (SM) [mailto:REGQUERY@worksafebc.com]
Sent: Tuesday, October 31, 2006 1:44 PM
To: Kamsteeg, Kenneth
Subject: Public Hearing Registration

Thank you for registering to make an oral presentation on behalf of the Vancouver Island Health Authority on the proposed amendments to the *Occupational Health and Safety Regulation* relating to:

- Part 6, Substance Specific Requirements (Safety-Engineered Needles)

Your presentation time is confirmed as follows:
Date: November 30, 2006
Time: 3:35 pm - 3:45 pm

Location: Coast Bastion Inn
11 Bastion Street,
Nanaimo, BC V9R 6E4

We confirm that written submissions and transcripts of oral presentations will be posted on WorkSafeBC's website, and that all submissions are releasable under the *Freedom of Information and Protection of Privacy Act.*

If you have any questions please contact the Public Hearing Information line at (604) 232-7744.

Thank you.

Sue Dean