OCCUPATIONAL SAFETY AND HEALTH
STANDARDS BOARD

PETITION FILE NO. 569

Submitted by: M.H. Schaffer, DMD

BOARD STAFF EVALUATION

Elisa M. Koski

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INTRODUCTION

Petition 569 was submitted by Michael H. Schaffer, DMD, to modify the exception in General Industry Safety Orders Section 5193 bloodborne pathogens regulation regarding medical procedures.

REQUESTED ACTION

Petitioner requests that the Board modify the bloodborne pathogens regulation exception under Title 8 Section 5193(d)(3)(B)2. for medical procedures to require that needles which do not have an integral sharp protector be capped using a capping device prior to placing the syringe in the sharps disposal container.

PETITIONERS ASSERTIONS

The Petitioner asserts that there are hazards associated with un-capped needles even if they are in a sharps container and that needles should be required to be re-capped even if they do not have an integral safety device.

The Petitioner is referring to the following exception:

> 5193(d)(3)(B) Prohibited Practices.
>
> 1. Shearing or breaking of contaminated needles and other contaminated sharps is prohibited.
>
> 2. Contaminated sharps shall not be bent, recapped, or removed from devices.
>
> **EXCEPTION**: Contaminated sharps may be bent, recapped or removed from devices if:
>
> a. The employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure; and
>
> b. The procedure is performed using a mechanical device or a one-handed technique.

The Petitioner enclosed several documents to support the petition. Among the enclosures were articles regarding the hazard of needle-sticks in the healthcare field, both medical and dental.

The Petitioner stated that technology exists which makes the exception in 5193(d)(3)(B)2. unnecessary for most medical procedures. However, if there is a procedure that requires the use of a needle that does not have an integral safety device, then the needle should be capped after the procedure and before it is deposited into a sharps disposal container.

The Petitioner stated that it is common practice in dentistry to use re-usable syringe bodies for anesthetic cartridges. Multiple injections are sometimes given to a patient with the same needle. Once the procedure is completed, the needle is removed from the syringe body and discarded, while the syringe body, itself, may be sterilized and re-used. The Petitioner asserts that because the human mouth cavity is relatively small, it is difficult or impossible to use a sharp with a safety device attached. Furthermore, the Petitioner states that dentists use a permanent 1.8 cc anesthetic syringe, almost exclusively, and that the needle must be re-capped with the manufacturer's cap acting as a wrench to unthread the needle.

STAFF EVALUATION

Board Staff spoke to the Petitioner by telephone and communicated by email to clarify what was being requested. The Petitioner's position is that the exception in the bloodborne pathogen regulation that permits the use of a non-safety needle should be amended to say that if a non-safety needle is being used, then a non-integral safety device should be required to cap the needle after the procedure.

The Petitioner is a retired dentist and is familiar with the common dental syringe consisting of a stainless steel, reusable syringe body that accepts anesthetic cartridges and a 1.8 cc removable needle used for injections within a patient's mouth for the administration of anesthetic. The Petitioner asserts that due to the small space within a patient's mouth, an integral safety device is not feasible. The Petitioner invented a mechanical device that will cap a needle using a one-handed technique.

The dental syringe is used by dentists to inject anesthetic into the patient's mouth. The patient may require more than one injection. The syringe may be placed on a tray between injections. Once the syringe is no longer needed, the needle is capped with the manufacturer's cap, unscrewed from the syringe body and disposed of. The anesthetic cartridge is removed and the syringe body may then be sterilized.

In order to comply with the bloodborne pathogens regulation, the needle must be re-capped using a mechanical device or one-handed technique that leaves the other hand out of the zone of danger of an accidental needle stick. The back end of the needle that punctured the anesthetic cartridge is also sharp and is a hazard to health care workers.

The Petitioner invented and patented a device that places a small cap on the end of the needle while keeping the other hand out of the zone of danger. The injection end of the needle is then rendered safe and the manufacturer's cap can be placed over the Petitioner's cap and used to unscrew the needle from the syringe. The back end of the needle can then be capped using the Petitioner's device. The needle being capped on both the front and back end, protects people from inadvertent needle sticks as well as protecting the needle from puncturing the sharps disposal container.

The Petitioner sought and received a Letter of Interpretation from Federal OSHA that indicated that the Petitioner's device was permitted under their regulation.

It is the Board Staff's position that using a non-integral, one-handed technique to cap a needle is permitted by the regulation. The device the Petitioner invented places a small cap on the tip of the needle, rendering it safe to permit the use of the manufacturer's cap to unscrew the needle from the syringe body and dispose of it in a sharps disposal container.

Although Petitioner stated that an integral safety device for a dental syringe is not feasible, Board Staff was able to find devices in the marketplace that have an integral safety device that protects both the application end of the needle and the back end of the needle, still fit comfortably in the patient's mouth, and appear to be feasible.

Board Staff conferred with the Division's Research and Standards Unit and with the Division's Medical Unit. The medical unit pointed out that although it is rare in the medical field to not use an engineered sharp, there are situations where is it preferred. They mentioned nuclear medicine procedures and pediatric eye surgery as two examples.

The exception was included in the regulation to allow a healthcare professional to choose the type of instrument based on his or her experience, comfort level and the safety of the provider as well as the patient's.

Although there have been many devices brought to market since the regulation became effective, it is the Board Staff's opinion there are still procedures for which the use of an engineered protective sharp are not used (as allowed by the exception). Adding a requirement that the needle must be capped prior to disposal into a sharps container seems unnecessary and potentially creates a hazardous situation by adding a delay to cap a needle rather than immediately disposing of it in a sharps container. Board staff was unable to find examples of employees being injured from needles penetrating a sharps disposal container. The injuries found were caused by over-filled sharps containers or the result of someone reaching into a sharps container.

Relevant Standards

Federal Standards

The Federal OSHA regulation for bloodborne pathogens is Code of Federal Regulations (CFR) 1910.1030. It was adopted in 1991. In the year 2000, Federal OSHA was mandated by the

Needlestick Safety and Prevention Act to modify the regulation. The Act directed OSHA to revise the Bloodborne Pathogens standard to include new examples in the definition of engineering controls along with two new definitions; to require that Exposure Control Plans reflect how employers implement new developments in control technology; to require employers to solicit input from employees responsible for direct patient care in the identification, evaluation, and selection of engineering and work practice controls; and to require certain employers to establish and maintain a log of percutaneous injuries from contaminated sharps. The entire regulation may be viewed here:

https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051

Federal OSHA has exceptions similar to California, see underlined wording (underlined for emphasis):

1910.1030(d)(2)(vii)

Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

1910.1030(d)(2)(vii)(A)

Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

1910.1030(d)(2)(vii)(B)

Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

California Standards

The California OSHA regulation for bloodborne pathogens is California Code of Regulations, Title 8 Section 5193 and was adopted in 1992 in response to Federal OSHA regulation CFR 1910.1030.

California enacted emergency revisions to the regulation in 1999 as a result of Assembly Bill (AB) 1208. AB 1208 was introduced on February 28, 1997 by Assembly Member Migden and was filed with the Secretary of State on September 30, 1997. The bill required that the Occupational Safety and Health Standards Board adopt an emergency regulation no later than January 15, 1999 and required that the final regulation be operative no later than August 1, 1999. (The emergency regulations became permanent in July 1999).

The bill added Section 144.7 to the Labor Code to revise the definition of engineering controls for sharps prevention technology, including needleless systems and needles with engineered

sharps injury protection. It required a few elements, germane to this petition was paragraph (b)(2): A requirement that sharps prevention technology specified in paragraph (1) be included as engineering or work practice controls, except in cases where the employer or other appropriate party can demonstrate circumstances in which the technology does not promote employee or patient safety or interferes with a medical procedure (emphasis added).

Those circumstances shall be specified in the standard, and shall include, but not be limited to, circumstances where the technology is medically contraindicated or not more effective than alternative measures used by the employer to prevent exposure incidents.

The exception in Section 5193(d)(3)(B)2. regulation states:

Exception. Contaminated sharps may be bent, recapped or removed from devices if

a. The employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure; and

b. The procedure is performed using a mechanical device or a one-handed technique.

Consensus Standards

Board staff is unaware of consensus standards related to engineered sharps protection.

Position of Division

The Division's evaluation dated July 3, 2018, stated that the use of non-integral devices are already required by Section 5193(d)(2)(A), where they would improve employee safety and engineered sharps injury protection cannot be used. The Division opined that to mandate a prescriptive type of engineering protection for every situation as proposed by the Petitioner may create greater risks to employees. Though the Division does suggest amending Section 5193(d)(3)(A) 4. to add a note to the exception.

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4. Exceptions. The following exceptions apply to the engineering controls required by subsections (d)(3)(A)1.-3.:

"Note: These exceptions do not apply to subsection (d)(2)(A), which contains general requirements to use engineering and work practice controls, including engineering controls other than needleless systems and engineered sharps injury protection."

Analysis

The Board approaches with particular caution, any proposed occupational safety and health standard which may affect the feasibility of established methods chosen by health care professionals to deliver optimum patient care. A clear showing must be made that any proposed method of assuring occupational safety and health be wholly compatible with well-established professional methods assuring optimum health care outcomes. With respect to the present petition, that showing has not been made, even with the benefit of supplemental research and analysis undertaken by Board staff, and Division industrial hygienists and safety engineers, in an effort to give it thorough consideration.

It is worth noting that the regulatory exception to which the Petitioner takes issue, does not preclude health care professionals from utilizing the proposed technology, to the extent it may supplement existing safety order requirements. In this respect, the existing exemption allows for the sort of safety technology advocated by Petitioner.

STAFF RECOMMENDATION

Consistent with the foregoing discussion and analysis, Board staff recommends Petition File No. 569 be DENIED.