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RECEIVED

FEB 16 2018

OCCUPATIONAL SAFETY AND HEALTH
STANDARDS BOARD

Sirs-in response to a reply by Director Berg, I believe I am eligible to petition Cal-OSHA to change or re-direct a Bloodborne Pathogens Regulation standard. I have developed, patented, produced, and received regulatory approval world wide, for revolutionary medical and dental sharps safety protocol and practice. It is not an idea, philosophy, or opinion, but a brand new system that will address and protect almost every human clinical needle. We have not "invented" non-integral sharps safety protocol, although have greatly improved it.

It was originally developed for dentistry, as our oral anatomy dictates the smallest possible instrument to safely administer injectable dental anesthesia. The 1.8 cc aspirating metal dental syringe has proved more than adequate in almost a century of service. However, there is absolutely no room for retrofitted safety devices hanging off of the end. In fact, any change to increase syringe size and/or include a safety attempt add-on, has met with utter failure. All dental sharps safety attempts are outside the oral cavity and employ an engineering control, a piece of paper, plastic or metal, to merely hold a manufacturer's cap in place, nothing more. It permits one handed recapping, but does not prevent needle perforations of the furnished manufacturer's shield, address the back end, as contaminated as the front, safely receive bent or angled needles, address interligamental syringes, nor prevent a needlestick incident on the way to the sharps container, if falls to floor, and once inside the container. It lacks safety when and if the needle cap falls off, as the dental anesthetic is a 10 cent device, lacking high definition quality.

This same device will protect any medical needle as well or better than a retrofitted needle safety attempt device, a definitive danger, according to the ASA, The ASA has petitioned for non-safety needles because of the perceived danger to both the clinician and patient, and Cal-OSHA has granted it to them as well as any other clinician simply claiming that the retrofitted sharps safety attempt add-ons will jeopardize the patient's safety or clinical success of a medical, dental, or nursing procedure involving the patient.

Please correct me if I am wrong, but now a system wherein the State has no control of sharps safety protocol, in appeasing a clinical group, becomes merely a transference of risk. Now the clinician and staff assume sharps safety risks, along with all downstream groups, and especially the institution, at the gravest risk, if and when a needle stick incident occurs. Our solution does not involve any clinical judgment, calling out a clinician for inordinate clinical decisions regardless of his/her reasoning, while

permitting any clinician to employ any non-safety standard sharp. We have perfected non-integral universal sharps safety ,our initial customer, Henry Schein Dental. We also have an enclosed OSHA private letter, permitting 2 handed needle recapping, utilizing our instrumentation and protocol. If the clinician chooses ours or any competitive non-integral sharps safety protocol at the end of any injection for any reason or for any device, this safety protocol will convert all non-integral needles into instant safety devices.

It will no longer be a judgment call, all HCWS and beyond will now be protected, the clinician can still use standard non-safety devices, and the State of California and the US will again retain complete control over sharps safety protocol. There are already a sufficient number of non-integral sharps producers to delete this untoward, dangerous exception, trading the health and welfare for one group (patients) at the expense of ALL others. As the inventor, one would

not expect anything other than my stating that we have the most superior non-integral sharps safety protocol to date. I realize that Cal-OSHA is not an advertiser for any improvement, but nevertheless, I am asking Cal-OSHA to demand sharps safety protocol for every possible sharp. Non-integral safety, ours or the competition, is decidedly superior to exactly nothing, now permissible for any HCW choosing to take that undecidedly risky for everyone route. If interested in seeing our protocol, sent u tube sites to Director Berg. This is not a question of right and wrong, but of being complete. I believe that we definitively close a circle. I am also trying to be as brand neutral as possible, but would send any other information, and/or production models, if interest. -Mike Schaffer AB U of Rochester, DMD U of Pittsburgh

which a needle device with engineered sharps injury protection is available.

3. Non-Needle Sharps. If sharps other than needle devices are used, these items shall include engineered sharps injury protection.

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

a. Market Availability. The engineering control is not required if it is not available in the marketplace.

b. Patient Safety. The engineering control is not required if a licensed healthcare professional directly involved in a patient's care determines, in the reasonable exercise of clinical judgement, that use of the engineering control will jeopardize the patient's safety or the success of a medical, dental or nursing procedure involving the patient. The determination shall be documented according to the procedure required by (c)(1)(B)7.

c. Safety Performance. The engineering control is not required if the employer can demonstrate by means of objective product evaluation criteria that the engineering control is not more effective in preventing exposure incidents than the alternative used by the employer.

d. Availability of Safety Performance Information. The engineering control is not required if the employer can demonstrate that reasonably specific and reliable information is not available on the safety performance of the engineering control for the employer's procedures, and that the employer is actively determining by means of objective product evaluation criteria whether use of the engineering control will reduce the risk of exposure incidents occurring in the employer's workplace.

(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 the procedure is performed using a mechanical device or a one-handed technique, and the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

3. Sharps that are contaminated with blood or OPIM shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

4. Disposable sharps shall not be reused.

5. Broken Glassware. Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

6. The contents of sharps containers shall not be accessed unless properly reprocessed or decontaminated.



Michael Schaffer <mschaffermeddesign@gmail.com>

Re: universal approved sharps safety

Berg, Eric@DIR <EBerg@dir.ca.gov>

Sun, Jan 7, 2018 at 7:20 PM

To: Michael Schaffer <mschaffermeddesign@gmail.com>

The California Occupational Safety and Health Standards Board (Board) is the only agency in the State authorized to adopt occupational safety and health standards or orders. You may petition the Occupational Safety and Health Standards Board to remove the exception you discuss in your email from title 8 section 5193 Bloodborne Pathogens (<https://www.dir.ca.gov/title8/5193.html>). Instructions for submitting a petition are at: <http://www.dir.ca.gov/oshsb/petitions.html>.

You can contact the Occupational Safety and Health Standards Board at oshsb@dir.ca.gov or

Occupational Safety & Health Standards Board
2520 Venture Oaks Way, Suite 350
Sacramento, California 95833
Telephone: (916) 274-5721

California Code of Regulations, Title 8, Section 5193 ...

www.dir.ca.gov

(a) Scope and Application. This section applies to all occupational exposure to blood or other potentially infectious materials as defined by subsection (b) of this ...

Petitions - California Department of Industrial Relations

www.dir.ca.gov

Occupational Safety & Health Standards Board; Petitions. Occupational Safety and Health Standards Board Information sheet regarding petitions to adopt, amend, or repeal

Y

From: Michael Schaffer <mschaffermeddesign@gmail.com>

Sent: Sunday, January 7, 2018 2:17 PM

To: Berg, Eric@DIR

Subject: universal approved sharps safety

Mr B-some time ago sent you an FDA approved private OSHA letter approved universal sharps safety device description. I understood the reply about not wanting to do private marketing on the public trough, but California has an exception that renders the entire reason for requiring sharps safety protocol, laughable. And as long as only private enterprise is responsible for these varied sharps safety attempts, you have written an exception that makes the entire body of laws subject to interpretation-and not the Government's. The patient safety clause is an exception that can and probably makes your legislative powers almost moot. A large bulky protuberance at the end of any invasive instrument is certainly reason enough for not using that device. Because we are non-integral, we do not transform any clinical manual operation, yet safely embody and enclose the sharp immediately after use. Our initial distributor, one Henry Schein, had and has absolutely no clinical skills nor knowledge. You have never seen this commercially available answer to any exception, safety or otherwise, and neither has anyone else. While California is taking care of business, they are not protecting any HCWs, and results of your actions have been numerous fines for state coffers, not safety solutions for state HCWs. Cal-OSHA is definitely politically correct-Mike Schaffer DMD

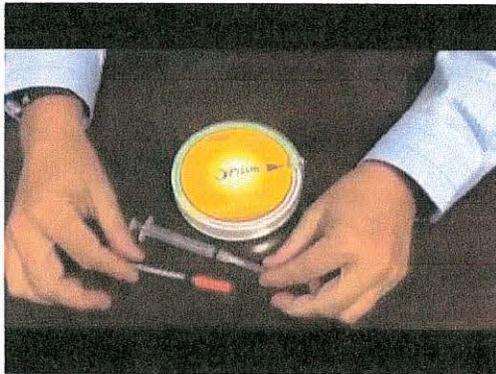
Drs.-here is safe, simple, rapid, fast, cheap, universal non-integral sharps protocol that will protect every needle, practitioner, and downstream personnel on the planet.

TWO HANDED recapping is legal, and OSHA, not me states so. They have sent us a private letter stating that our protocol and instrumentation is a legitimate solution to the "sccop" method, whatever that is.-Mike Schaffer AB U of Rochester, DMD U of Pittsburgh PS-, Henry Schein dental offers it as "Protexsure", as originally developed for dentistry and permanent metal anesthetic syringes. However, all hormone pens, being at least semi-permanent. require the same recapping and unthreading protocol unknown, with selective needles being protected at an obscene price range. Of course it will address all syringes in the same manner. our only need, distribution, as completely approved around the world. PS-perfect for veterinary market as well, if anybody ever shows it to them. New US patent this month 9839489.

Click on the links below, see attached brochure

https://www.youtube.com/results?search_query=prism+safety+capsule+system

<https://www.youtube.com/watch?v=s9QrQMj7HSw>



Prism Safety Capsule System

www.youtube.com

Safest way to protect health care workers from dangerous needle sticks



Michael Schaffer <mschaffermeddesign@gmail.com>

Answer From ASK OSHA

1 message

osha_ecorrespondence@dol.gov <osha_ecorrespondence@dol.gov>
Reply-To: osha_ecorrespondence@dol.gov
To: mschaffermeddesign@gmail.com

Tue, Feb 6, 2018 at 11:35 AM

*** PLEASE DO NOT SELECT "REPLY" ***

THIS EMAIL HAS BEEN ROUTED TO YOU THROUGH AN AUTOMATED FEDERAL OSHA SYSTEM.
PLEASE REFER TO THE INFORMATION BELOW.

Disclaimer

Responses to the Electronic Mail Forms are for informational purposes only, and do not constitute an official communication of the U.S. Department of Labor or OSHA. For an official response, please submit your inquiry in writing.

Topic & Question

Topic: Other

Cal-OSHA has this regulation on their books."engineering control not required if licensed healthcare professional directly involved in a patient's care determines,in the reasonable exercise of clinical judgement,that use of the engineering control will jeopardize the patient's safety or success of a medical,dental or nursing procedure involving the patient. I have never seen this OSHA law on any Federal website,and realize that the 24 state OSHA regulators can be more demanding than the Feds,if they wish to be, and can have additional rules. Can you tell me the federal OSHA stand on this California regulation>-Mike Schaffer DMD U of Pittsburgh

Submit Date: 27-JAN-18 02:06:52 PM

OSHA Response(s)

Thank you for your email to the U.S. Department of Labor's Occupational Safety and Health Administration.

OSHA generally requires the use of engineering controls when it is feasible to do so. In the event of a conflict with administering proper patient care OSHA would have to assess feasibility in order to contemplate any enforcement action.

The following link to OSHA's frequently asked questions page may also be useful:

http://www.osha.gov/OSHA_FAQs.html

If these references do not help you or if after reviewing this information you have questions about OSHA regulations and compliance with them, the most timely way to get an answer to your question is to contact OSHA during weekly business hours of 8:00 am to 4:30 pm eastern time by calling toll free 1-800-321-OSHA (6742) and press option 4.

To find contact information for your local OSHA area office, please use this weblink ? <http://www.osha.gov/html/RAmap.html>

Thank you for your interest in occupational safety and health.

This response is for informational purposes only and does not constitute an official communication from the U.S. Department of Labor, or the Occupational Safety and Health Administration.

Standard Interpretations - Table of Contents

Standard Number: 1910.1030(b); 1910.1030(c)(1); 1910.1030(d)(2)(i)

June 3, 2005

Mr. Craig Voellmicke
Product Manager
BD Medical
MC 208
1 Becton Drive
Franklin Lakes, NJ 07417

Dear Mr. Voellmicke:

Thank you for your December 14, 2004, letter to the Occupational Safety and Health Administration's (OSHA's) Directorate of Enforcement Programs (DEP). Your letter requested clarification on the selection and use of engineering controls, e.g., sharps with engineered sharps injury protection (SESIPs), under the bloodborne pathogens standard 29 CFR 1910.1030. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question not delineated within your original correspondence. Your questions are rephrased below, followed by OSHA's responses. We apologize for the delay in providing a response.

Question 1: Does OSHA's definition for "contaminated sharp" include non-needle sharps such as blades and scalpels? If a facility used conventional blades and scalpels, and if safety-engineered options were commercially available, would healthcare facilities be required to use them?

Reply 1: As you know, the bloodborne pathogens standard defines "contaminated sharps" as "any contaminated object that can penetrate the skin, including but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires," 1910.1030(b). Scalpels and blades are included in this definition.

In response to the second part of this question, if safety-engineered blades and scalpels were commercially available, a healthcare facility would be required to evaluate them for appropriateness and effectiveness. Since no one device is appropriate for use in all circumstances, the decision to select a safety device is always based upon evaluation and a determination that the device is appropriate and effective for the particular procedure, 1910.1030(c)(1)(iv). Since safety-engineered blades and scalpels are types of engineering controls within the meaning of 1910.1030(b), their use is required by the employer if they are engineering controls which will eliminate or minimize employee exposure, 1910.1030(d)(2)(i).

Question 2: The standard does not require engineering controls if their use would compromise worker or patient safety or if they are not commercially available. Does the standard excuse an employer from using engineering controls because of practitioner preference?

Reply 2: In many cases, a practitioner's "preference" is a result of a familiarity with a device and a reluctance to break routine. It is true that clinicians might initially consider the use of a newly selected safety device to be cumbersome or awkward and in most cases they may simply need additional practice or training until they feel comfortable using a new and different device. Thus, practitioner preference is generally not an excuse for failure to use engineering controls. In some surgical procedures, however, the "feel" of a device in the hands of the surgeon may be crucial to properly executing the surgical technique. The importance of the "feel" of a device could be a critical factor which may affect the outcome of the procedure and, ultimately, the safety of the patient. The intent of the OSHA standard was never to usurp the practitioner's authority in deciding the best method of achieving a positive health outcome for a patient during a procedure. The standard requires that employers use engineering and work practice controls to eliminate occupational exposure to the lowest feasible extent, 1910.1030(d)(2)(i). OSHA recognizes there might be unique circumstances where the safety of the patient or the integrity of a procedure might be best served with the use of a device that is not a safety device. In those situations, it is important that good work practice controls, such as eliminating hand-to-hand instrument passing in the operating room, be implemented to provide protection to employees who are at risk of getting injured by an unprotected device.

Question 3: Practitioners may feel that in some specific procedures in certain clinical scenarios a situation may arise where implementation of an engineering control, such as SESIPs, might result in a potential negative clinical outcome. How must this be documented and demonstrated in order to fulfill compliance with the standard?

Reply 3: Engineering and work practice controls that the employer determines to be appropriate must be documented in the employer's Exposure Control Plan (ECP), 1910.1030(c)(1)(ii)(B). If a safer medical device compromises patient safety, worker safety or the medical integrity, its use would not be required. Whether or not an engineering control is chosen for a specific procedure, an annual review of safer medical devices is required and that review must be documented in the ECP, 1910.1030(c)(1)(iv)(B).

Thank you for your interest in occupational safety and health. We hope this provides the clarification you were seeking. OSHA requirements are set by statute, standards and regulations. Our interpretation letters explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. This letter constitutes OSHA's interpretation of the requirements discussed. Note that our enforcement guidance may be affected by changes to OSHA rules. Also, from time to time we update our guidance in response to new information. To keep apprised of such developments, you can consult OSHA's website at <http://www.osha.gov>. If you have any further questions, please feel free to contact the Office of Health Enforcement at 202-693-2190.

Sincerely,

Richard E. Fairfax, Director

Ask the expert: Safety needle use exceptions

Posted By [John Palmer](#) On July 8, 2010 @ 8:38 am In [Ask the Expert—Bloodborne Pathogens, Needlesticks & Sharps Injuries, OSHA - Citations & Fines](#) | [8 Comments](#)

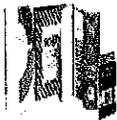
Q: What reasons are acceptable to OSHA for not using a safety needle?

A: "If a safer medical device compromises patient safety, worker safety, or the medical integrity of a procedure, its use would not be required," states a [June 3, 2005, letter of interpretation](#) [1].

But there is a caveat.

The OSHA interpretation continues, stating, "Whether or not an engineering control is chosen for a specific procedure, an annual review of safer medical devices is required, and that review must be documented in the exposure control plan."

Download the free Sharps Evaluation Results Form on to document both safety sharp device acceptance and non-safety device use.



Get into compliance with HCPro's Basic OSHA Compliance Manual Kits for [medical](#) [2] or [dental](#) [3] practices. Receive bimonthly electronic manual updates [through your newsletter subscription](#) [4] that keep your regulatory manual up to date and in compliance!

[2]

Article printed from OSHA Healthcare Advisor: <http://blogs.hcpro.com/osha>

URL to article: <http://blogs.hcpro.com/osha/2010/07/ask-the-expert-safety-needle-use-exceptions/>

URLs in this post:

[1] June 3, 2005, letter of interpretation: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=25123

[2] Image: <http://www.hcmarketplace.com/prod-6750-EOSHAB/Basic-OSHA-Compliance-Manual-Kit.html>

[3] dental: <http://www.hcmarketplace.com/prod-6752-EOSHAB/Basic-Dental-OSHA-Compliance-Manual-Kit.html>

[4] through your newsletter subscription: <http://www.hcmarketplace.com/prod-3265-EOSHAB.html>

U.S. Department of Labor

Occupational Safety and Health Administration
Washington, D.C. 20210



Reply to the attention of: DEP/OHE/GS/27422

OCT - 7 2016

Mr. Les Capella
Prism Medical & Design
9604 Exbury Court
Parkland, Florida 33076

Dear Mr. Capella:

Thank you for your letter to the Occupational Safety and Health Administration's (OSHA) Directorate of Enforcement Programs. You requested additional clarification of OSHA's Bloodborne Pathogens (BBP) standard, 29 CFR 1910.1030, as it pertains to recapping of needles after dental procedures. This letter constitutes OSHA's interpretation only of the requirements discussed and may not be applicable to any question not specifically delineated within your original correspondence. For clarification, your specific question is paraphrased below, followed by OSHA's response.

Background: In your letter, you referenced OSHA's Letter of Interpretation (LOI), dated February 8, 2016, to Michael H. Schaffer, DMD. You also stated that Prism Medical & Design is the business unit for Dr. Schaffer in regard to the *ProteXsure Safety Capsule System*®. With this system, at the end of the dental procedure the syringe is held in one hand while the needle tip is inserted into a small adhesive-filled tubular protective capsule that self-attaches to the needle tip, whether straight or bent, which is claimed to render the needle safe. The system is intended for use in administering multiple injections of anesthetic from a single dental syringe and then disposing of the used needles on these reuseable syringes.

Question: Is it acceptable to use our system as a one-handed technique, for safely recapping and removing a contaminated needle from reusable dental syringes?

Response: Again, as a preliminary matter, OSHA does not endorse or approve any manufacturers' specific products, devices, or processes. Compliance with OSHA standards is determined by OSHA after an on-site inspection based on the conditions observed or otherwise discovered during an inspection.

As you know, the BBP standard requires the use of engineering and work practice controls to eliminate or minimize employee exposure. [1910.1030(d)(2)(i)] Additionally, engineering controls include self-sheathing needles and other safer medical devices, such as sharps with engineered sharps injury protections (SESIPs) and needleless systems, which isolate or remove the bloodborne pathogens hazard from the workplace. [1910.1030(b)] As previously stated in our letter to Dr. Schaffer, regarding whether the use of the *ProteXsure Safety Capsule System* complies with the BBP standard, 1910.1030(d)(2)(vii)(A) and (B) provide:

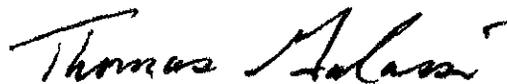
(A) Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

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

Based on the information provided by you and Dr. Schaffer, the *ProteXsure Safety Capsule System* would be comparable to a one-handed scoop method. OSHA is aware that currently there are very few commercially available SESIPs (i.e., devices that incorporate technologies in their design to eliminate exposures to needlesticks at the point of use) for this specific dental procedure. In those situations when those SESIPs are not feasible, the *ProteXsure Safety Capsule System*, which is similar to the one-handed scoop method, offers an option for reducing exposure to contaminated multi-use anesthetic needles in dentistry prior to the point of needle disposal. Employers must maintain a written justification, based on reliable evidence, for use of such methods and it must be included as part of the employer's BBP exposure control plan. [See 29 CFR 1910.1030(c)(1)(ii)] We continue to encourage advancement in SESIP technologies for this procedure.

Thank you for your interest in occupational safety and health. We hope this provides the clarification you were seeking and apologize for any confusion the earlier documents may have caused. As this letter demonstrates, OSHA's re-examination of an issue may result in the clarification or correction of previously stated enforcement guidance. OSHA requirements are set by statute, standards and regulations. Our interpretation letters explain these requirements and how they apply to particular circumstances, but they cannot create additional employer obligations. This letter constitutes OSHA's interpretation of the requirements discussed. Note that our enforcement guidance may be affected by changes to OSHA rules. Also, from time to time we update our guidance in response to new information. To keep apprised of such developments, you can consult OSHA's website at www.osha.gov. If you have any further questions, please feel free to contact the Office of Health Enforcement at (202) 692-2190.

Sincerely,



Thomas Galassi, Director
Directorate of Enforcement Programs