CALIFORNIA CONFERENCE OF DIRECTORS OF ENVIRONMENTAL HEALTH

CALIFORNIA SAFE BODY ART ACT GUIDELINES

Questions and Answers

Permits and Registration

Q) Would a person applying permanent cosmetics in a medical spa, doctor's office, surgery center or similar, be required to be a registered practitioner or have a body art facility permit?

A) H&SC Section 119304 addresses not restricting the activities physicians and surgeons. It is not the intent of the Safe Body Art Act to require sites (e.g. doctor's offices, surgery centers) where permanent cosmetics may be applied under a physician's or surgeon's care to obtain a Body Art Facility Permit. It is also not the intent of the Safe Body Art Act to require a practitioner to register if that practitioner only operates at sites that are under the control and direction of a physician or surgeon. If a practitioner intends to provide any service outside of those directed by a physician, then they will need to have a Practitioner Registration and the site will need a Body Art Facility Permit.

Q) What kind of experience is required to meet the 6 months of related experience for a practitioner registration in H&SC Section 119306 (b)(5)?

A) Since no guidelines or statute exists to define a body art training program, it is recommended that this provision is not used for registration of a practitioner.

Q) Are there any conditions were a practitioner would not have to get a practitioner registration?

A) Any individual who is going to perform body art on a person must be a registered practitioner, even if no money is exchanged or the body art occurs as part of a training course. The only exception is for a practitioner who only provides procedures at sites under the control and direction of a physician or surgeon.

Q) Does a Practitioner have to show that they can comply with H&SC Sections 119306-119311 to gain or maintain their registration?

A) Only H&SC Sections 119306 and 119307 are required for a practitioner to gain or maintain their registration. H&SC Sections 119308-119311 are meant as operational requirements that can be applied to the practitioner or the facility during the course of an inspection.

Q) Can a Registered Practitioner provide Body Art from a non-permitted location?

A) It is the intent of the Act to require that registered practitioners operate from permitted Body Art Facilities.

Training and Documentation - top

Q) Can we accept Bloodborne Pathogen Exposure Control Training (commonly referred to as BBP) certificates from another state or from outside the United States for temporary events?

A) That is at the discretion of the LEA. The person with the training certificate would have to provide proof that shows that the course meets all the requirements as noted in California Health and Safety Code (H&SC) Section 119307. If it can't be provided or cannot be read by staff (in a foreign language), then the individuals should be required to take a California specific BBP course from an LEA approved trainer.

Q) Is an Infection Prevention Control Plan the same as an Exposure Control and Prevention Plan?

A) The Infection Prevention and Control Plan, as listed in H&SC Section 119313, requires a body art facility to spell out processes and standard operating procedures that allow the facility to comply with the Safe Body Art Act such as cleaning and sterilizing, set-up and tear down of procedure areas and ways to keep instruments and procedure areas from being contaminated. An Exposure Control Plan, which is required by OSHA, requires, among other things, an operator to list all positions that may have exposure, how they will be trained to minimize exposure, who is responsible for the site and how to report and handle an incident of exposure to Blood or other potentially infectious materials.

Q) How can a Body Art Facility comply with the requirement to keep records/logs of pre-sterilized & pre-packed instruments set forth in H&SC Section 119315(f)?

A) The intent of the section is to provide a vehicle to trace back equipment if any complaints or problems implicate the pre-packaged, pre-sterilized instruments. A facility should always keep records of shipments of these types of goods and that should include lot numbers or other identifiers that single out a particular package or shipment. A facility can keep a separate, master log showing day, date and consumer that each piece was used on or it would also be acceptable to have an area on the clients consent form that allows the practitioner to list each pre-packaged, pre-sterilized instrument used during a procedure, which would include a box, lot number or other reference to identify the material source.

Q) How do I confirm that pre-sterilized instruments are acceptable if there is no label or indicator on the individual packaging?

A) If the pre-sterilized instruments are not individually labeled to show sterility or have any marking that would indicate when the sterility is no longer valid, it is the operator's responsibility to either keep the instruments in a box that has the details of the sterility and use by date or to provide some type of documentation that shows the items are sterile. If the box does not have that information or the documentation does not show that information, then the operator should change suppliers to one that provides that information.

Q) Who is required to take the Bloodborne Pathogen Exposure Control training?

A) Any person who will be performing body art on a person is required to take and maintain a Bloodborne Pathogen Exposure Control training certificate. This includes students working in a classroom setting, if they are working on a live person. This would also include an individuals working in the decontamination and sterilization room, as they may be exposed to instruments with human fluids or tissue on it.

Q) Does H&SC Section 119303 (c) contradict HIPAA laws by requiring the Body Art Facility to shred confidential medical information after two years?

A) A Body Art Facility is not technically a medical facility so it is not clear whether HIPAA applies, but the two year timeframe is too restrictive for a variety of reasons and it is recommended that this provisions is not applied as part of the inspection. This provision is on a list of items to be removed from the code in the next legislative session.

Cleaning and Sterilizing - top

Q) Does the Safe Body Art Act or applicable guidance address the proper use of ultrasonic cleaners, sterilizers or other equipment (e.g. covers over ultrasonic cleaners, equipment operating timeframes)?

A) Proper usage of sterilizers is addressed in H&SC Section 119315 (b) which states the sterilizer shall be loaded, operated, decontaminated and maintained according to manufacturer's directions. Although no such language exist to address mechanical cleaning systems, such as ultrasonic cleaners, it is the intent of the Safe Body Art Act that they are also operated and maintained according to the manufacturers guidelines.

Q) In H&SC section 119315 (b)(3), is the inclusion of the term Class V integrators too restrictive to allow for the new technologies that may become available in the future?

A) The Class 5 integrators requirement derives from ANSI/AAMI standards for autoclave testing. The Safe Body Art Act States the Class V Integrator is the minimum standard. Other testing methods can be proposed but they must at least meet the standards set for the Class V integrators.

Q) Is there language in the Safe Body Art Act that restricts or allows for different types of autoclaves?

A) H&SC Section 119315 (b)(1) requires all sterilization equipment used be manufactured for sterilization of medical equipment. H&SC Section 119309 (e) Requires all instruments that need to be sterilized, be sterilized by steam. This would specifically exclude chemical sterilizers. Statim machines, that use steam and a cartridge system but not peel packs, may be used to sterilize instruments or jewelry for immediate use as long as a Class V integrator or better is used with each sterilization run.

Operations - top

Q) Is it acceptable to use scalpels or other types of surgical tools in a body art procedure?

A) Per The California Medical Board any cutting of skin/tissue with scalpels or other medical devices should be referred to them as a complaint. The complaint form is available on their website and it should be mailed to the following address:
Medical Board of California
Central Complaint Unit
2005 Evergreen Street, Suite 1200
Sacramento, CA 95815
http://www.mbc.ca.gov/consumer/complaint_info.html

Q) What is the difference between sharps waste and non-sharps waste?

A) Sharps waste is any disposable instruments or disposable parts of an instrument that has acute rigid corners, edges, or protuberances capable of cutting or piercing.

Q) **Can Sharps waste be moved offsite for disposal at locations like a household Hazardous Waste Collection Site?**

A) H&SC Section 119314 (e)(3)(A) clearly states that sharps waste must be removed from a site by a disposal company or through an approved mail-back system.

Q) Does H&SC Section 119314 (f) exclude service animals from a Body Art Facility?

A) Service Animals were not addressed in the Safe Body Art Act, but it is not the intent of the act to circumvent ADA requirements so service animals should be allowed as defined by ADA. This oversight will be addressed in the next legislative session.

Q) How can I confirm what practitioner did a procedure or worked with a client?

A) There is no clear connection with a practitioner and a procedure in the Safe Body Art Act but it would be advisable to ask the Body Art Facility to put the practitioner name on the client consent form.

Q) What should I tell an operator to do if they have a client say that they have any of the conditions spelled out in H&SC Section 119303 (b)?

A) No clear path is provided in the Safe Body Art Act. The following guidance is based on consultation with Body Art Industry representatives who have worked on the Safe Body Art Act. A pregnant individual should postpone the procedure until after they are no longer pregnant. If a client gives a positive response to any of the conditions in Section 119303 (b) (2), (b) (3) or (b) (4), than that individual should be asked to provide a doctor's note outlining that they are fit or that it is safe to provide them with the procedure. These responses are in no way required by the practitioner but the intent of the consent questions was to enlighten the practitioner so they could make an informed decision before potentially providing a risky procedure, both for them and the client.

Q) Is there a grandfathering clause in the Safe Body Art Act?

A) There is no grandfathering language in the Act but it was not the intention to require that all facilities in business prior to July 1st 2012 to immediately retrofit to meet the Act's provision if they can show that they can operate in substantial conformance with the Act.

Temporary Events - top

Q) Is the 4 hour or 4 procedure trigger for temporary event hand wash station turn-over feasible?

A) Although Section 119317 (f) is very clear in it direction for when a hand wash sink set-up must be emptied and refilled, the time and procedure limits may not be realistic based on the type of operations at the event. It is more advisable to use a best practice stance on the hand washing stations used at temporary events and to focus on proper use and maintenance of the hand wash station then to try and hold practitioners to a strict hours or procedures schedule.

Q) Why are temporary events required to have eyewash stations available when a fixed facility does not?

A) This was an oversight in the creation of the Safe Body Art Act and it will be removed in the next legislative session. It was not the intent of the Act to require eyewash station at temporary events.