

Michigan Department of Health
and Human Services
Requirements for Body Art
Facilities

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Michigan Department of Health and Human Services
Requirements for Body Art Facilities
2010 PA 375; MCL 333.13101 *et seq.*

UPDATES HIGHLIGHTED 06/29/2018

1. Section One: Purpose/Scope

- 1.1. These requirements were created to protect the health of all people seeking body art within the state of Michigan by requiring that an individual shall not tattoo, brand or perform body piercing on another individual unless it occurs in a licensed body art facility.
- 1.2. These requirements are designed to ensure that body art services are provided in a safe and sanitary manner and physical environment by individuals with documented education/training on safe and sanitary body art administration.
- 1.3. These requirements contain provisions for local health department inspection of body art facilities applying for and/or holding a body art facility's license.
- 1.4. These requirements also provide the authority to enforce these requirements and outline procedures for enforcement for any body art facility deemed to be in violation of requirements outlined in this document.

2. Section Two: Authority

- 2.1. These requirements were created pursuant to authority conferred upon the Michigan Department of Health and Human Services by the Public Health Code (PHC), 1978 PA 368, MCL 333.1101 *et seq.* and most recently with the enactment of the Body Art Facilities Act, (Act) 2010 PA 375; MCL 333.13101 *et seq.*

3. Section Three: Definitions

- 3.1. The following words and phrases included in these requirements are defined as indicated below:
 - 3.1.1. "Aftercare Instructions" means verbal and written instructions given to the client, specific to the body art procedure(s) rendered, about caring for the body art and surrounding area. These instructions shall include information about when to seek medical treatment, if necessary, as well as notice that the individual may be able to donate blood within the standard deferral period if the individual presents a copy of his/her body art facility's client record to the blood donor facility, based on local blood donor facility policy.
 - 3.1.2. "Alcoholic Liquor" means beer, wine, spirits or any beverage made with beer, wine, or spirits.
 - 3.1.3. "Antiseptic" means an agent that destroys pathogenic microorganisms on human skin or mucosa.

- 3.1.4. “Antibacterial” Anything that destroys bacteria or suppresses their growth or their ability to reproduce. Heat, chemicals such as chlorine, and antibiotic drugs all have antibacterial properties.
- 3.1.5. “Antimicrobial” An antimicrobial is a substance that kills or inhibits the growth of microorganisms such as bacteria, fungi, or protozoan’s. Antimicrobial drugs either kill microbes (microbicidal) or prevent the growth of microbes (microbistatic). “Antimicrobial” is a general term that refers to a group of drugs that includes antibiotics, antifungal, antiprotozoals, and antiviral.
- 3.1.6. “Applicant” means the person who submits an application for a body art facility license under this part and includes the owner or operator, an agent of the owner or operator, or any other person operating under the apparent authority of the owner or operator of a body art facility that is required to be licensed under PA 375.
- 3.1.7. “Aseptic Technique” is a set of specific practices and procedures performed under carefully controlled conditions with the goal of minimizing contamination by pathogens.
- 3.1.8. “Blood borne Pathogens” means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include but are not limited to hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV).
- 3.1.9. “Body Art” means: 1) tattooing, 2) branding and/or 3) body piercing. This definition does not include practices that are considered medical procedures by the state medical board; medical procedures with medical instruments shall not be performed in a body facility.
- 3.1.10. “Body Art Facility” means the location at which an individual performs one or more of the following for 1) tattooing, 2) branding, and/or 3) body piercing.
- 3.1.11. “Body Art Technician” means an individual who performs: 1) tattooing, 2) branding, and/or 3) body piercing.
- 3.1.12. “Body Jewelry” means adornment placed into a body piercing. Jewelry materials include metals (i.e. stainless steel), non-metals (i.e. FDA approved acrylic) or organic materials (i.e. hardwoods, bamboo, ivory, horn or antler.) (See *Appendix B*)
- 3.1.13. “Body Piercing” means the perforation of human tissue other than the ear for non-medical purposes.
- 3.1.14. “Branding” means a permanent mark made on human tissue by burning with a hot iron or other instrument.
- 3.1.15. “Cleaning” means the removal of visible soil, organic material or inorganic material from objects or surfaces and is usually accomplished by manual or mechanical means through water with detergents or enzymatic products.

- 3.1.16. “Client” means a person undergoing: 1) tattooing, 2) branding, and/or 3) body piercing.
- 3.1.17. “Contaminated” means the presence or the reasonably anticipated presence of blood or other potentially infectious material (OPIM) on an item or surface
- 3.1.18. “Contaminated Sharps” means any contaminated object that can penetrate the skin including, but not limited to tattoo needles, body piercing needles, and disposable razors.
- 3.1.19. “Controlled Substance” means any behavior altering or judgment altering drug, whether legal or illegal, whose possession and use are restricted by law, including narcotics, stimulants and hallucinogens.
- 3.1.20. “Critical Violations” are those items that are a priority to correct and are likely to cause an imminent health danger to the public and/or practitioner.
- 3.1.21. “Department” means the Michigan Department of Health and Human Services.
- 3.1.22. “Disinfectant” means an Environmental Protection Agency (EPA) registered tuberculocidal chemical or physical agent that kills vegetative forms of microorganisms, but not necessarily all microbial forms such as bacterial spores.
- 3.1.23. “Disinfection/Disinfected” means the process that kills pathogenic and other microorganisms on inanimate objects by physical or chemical means. Disinfection kills most recognized pathogenic microorganisms but not necessarily all microbial forms, such as bacterial spores. Disinfection processes do not ensure the margin of safety standards associated with sterilization processes.
- 3.1.24. “Dry Heat Sterilizer” means an apparatus used to sterilize supplies and equipment used in body art procedures through exposure to dry heat
- 3.1.25. “Equipment” means all machinery, including fixtures, containers, tools, devices, storage areas, sinks and other apparatus used in connection with performing body art procedures.
- 3.1.26. “Exposure” means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or OPIM that may result from the performance of an individual’s assigned duties in the body art facility. “Exposure” does not include incidental exposures which may take place on the job, which are neither reasonably nor routinely expected, and which the individual is not required to incur in the normal course of employment.
- 3.1.27. “Hand washing” means physically removing or reducing most microorganisms from the intact skin of the hands by using warm running water and liquid soap using friction on all surfaces of the hands and wrists for at least 15 seconds and drying hands with a clean, disposable paper towel and turning off the faucet with a clean disposable paper towel.

- 3.1.28. “Imminent Danger” means a condition which could reasonably be expected to cause death, disease or serious physical harm, immediately, or before the imminence of the danger can be eliminated through enforcement procedures otherwise provided.
- 3.1.29. “Informed Consent for a Minor” is the written, informed consent of the minor’s parent or legal guardian and proof of that individual’s authority to give the informed consent. The minor’s parent or legal guardian shall execute the written, informed consent in the presence of the licensee or and employee or agent of the licensee. The minor’s parent or legal guardian shall present to the licensee or employee or agent of the licensee the minor’s birth certificate or legal proof of guardianship to establish the individual’s authority to give the informed consent required under PA 375.
- 3.1.30. “Instruments” means needles, needles attached to the needle bars, body piercing needles, razors and other devices that may come in contact with a client’s body or that may have possible exposure to bodily fluids during the body art procedure.
- 3.1.31. “Licensee” means the person who is the holder of a license under this part or the person who is legally responsible for the operation of a body art facility and includes the owner or operator, and agent of the owner or operator, or any other person operating under the apparent authority of the owner or operator of a body art facility that is required to be licensed under PA 375.
- 3.1.32. “Local Governing Entity” means: 1) In the case of a single county health department, the county board of commissioners; 2) In the case of a district health department, the county boards of commissioners of the counties comprising the district; 3) In the case of a district health department, which includes a single city health department, the county boards of commissioners of the counties comprising the district and the mayor and city council of the city; 4) In the case of a single city health department, the mayor and city council of the city; 5) In the case of a local health department serving a county within which a single city health department has been created, the county board of commissioners elected from the districts served by the county health department.
- 3.1.33. “Medical Waste” means any of the following that are not generated from a household, a farm operation or other agricultural business, a home for the aged, or a home health care agency: 1) Cultures and stocks of infectious agents and associated biologicals, including laboratory waste, biological production wastes, discarded live and attenuated vaccines, culture, dishes and related devices; 2) Liquid human and animal waste, including blood and blood products and body fluids, but not including urine or materials stained with blood or body fluids; 3) Pathological waste; 4) sharps; 5) Contaminated wastes from animals that have been exposed to agents infectious to humans, these being primarily research animals. (See *Appendix E* on disposal.)

- 3.1.34. “Minor” means an individual less than 18 years of age who has not been emancipated.
- 3.1.35. “Non-critical Violations” are acceptable best practices cited for correction that may or may not create an imminent health danger.
- 3.1.36. “Other Potentially Infectious Material (OPIM)” means human body fluids including, but not limited to any body fluids visibly contaminated with blood, saliva in oral body art procedures, semen, vaginal secretions, and all body fluids where it is difficult or impossible to differentiate between body fluids.
- 3.1.37. “Pathological waste” means human organs, tissues, body parts other than teeth, products of conception, and fluids removed by trauma or during surgery or autopsy or other medical procedure and not fixed in formaldehyde.
- 3.1.38. “Personal Protective Equipment (PPE)” means specialized clothing or equipment that is worn by an individual working in a body art facility to protect him or her from a hazard. General work clothes, such as uniforms, pants, shirts, or blouses, which are not intended to function against a hazard, are not considered to be Personal Protective Equipment.
- 3.1.39. “Procedure Area” means the physical space that is used by one body art technician at a time to perform a body art procedure on one client at a time, and that contains all procedure surfaces, equipment, and instruments to perform the body art procedure.
- 3.1.40. “Procedure Surface” means any surface utilized during the body art procedure that has the potential to become contaminated and that may require cleaning and disinfecting.
- 3.1.41. “Scarification” means injury of the skin involving scratching, etching, or cutting of designs to produce a scar on a human being for ornamentation or decoration.
- 3.1.42. “Scarification implement” means any instrument which intentionally alters human skin for the purpose of scarification.
- 3.1.43. “Smoking” means the carrying, holding or inhalation by a person of a lighted cigar, cigarette, pipe, or other lighted smoking device.
- 3.1.44. “Steam Autoclave” means an apparatus used to sterilize supplies and equipment used in body art procedures by direct exposure to saturated steam under pressure as a sterilant.
- 3.1.45. “Sterilize/Sterilization” means the complete elimination or destruction of all forms of microbial life including bacterial spores.
- 3.1.46. “Surface Anchor” means jewelry is placed into the upper portion of the dermis with one point of entry, which also serves as the exit that exposes the jewelry stem to air. This procedure is performed utilizing a body piercing device (i.e. piercing needle).

- 3.1.47. “Surface Piercing” means any body piercings that takes place on the surface of the body under the epidermis but not to subcutaneous tissue. The surface piercing is done in areas which are not particularly concave or convex, where the piercing canal is under the surface of the skin with exit and entry points, which are perpendicular to the tissue. This procedure is performed utilizing a body piercing device (i.e. piercing needle).
- 3.1.48. “Tattoo” means: 1) An indelible mark made upon the body of another individual by the insertion of a pigment under the skin, and/or 2) an indelible design made upon the body of another individual by production of scars other than by branding. This includes cosmetic tattooing, permanent make-up and microblading/microstroking, eyebrow embroidery, feather touch and/or hair-like strokes.
- 3.1.49. “Temporary Body Art Convention” (also called expos, trade shows, swap meets, events): A gathering of varied body artists representing owners or operators of separate body art facilities. These body art facilities may be State of Michigan or out-of-state licensed facilities participating in an event lasting not more than 14 days with each owner operator obtaining their own individual State of Michigan temporary body art facility license.
- 3.1.50. “Temporary Body Art Facility” means a body art facility that operates at a fixed or temporary location in this state for a time period that does not exceed 14 consecutive days and includes out-of-state facilities operating within this state. An affiliated temporary body art facility is a temporary facility that is affiliated with a licensed State of Michigan Body Art Facility. A non-affiliated temporary body art facility is a temporary facility that is not affiliated with any licensed State of Michigan Body Art Facility.

4. Section Four: Body Art Facility Licensure

- 4.1. Beginning January 1, 2010, no person shall tattoo, brand or perform body piercing on another individual unless the tattooing, branding, or body piercing occurs at a body art facility possessing a valid Body Art Facility License issued by the Department
- 4.2. The owner or operator of a body art facility shall apply to the Department for a Body Art Facility License by using the Department’s on-line application process or by mailing an application form provided by the Department.
- 4.3. At the time of the application, the owner or operator shall pay to the Department one of the following non-refundable application fees:
- 4.3.1. For a new annual license, it is a \$500.00 fee. After July 1st the fee is \$250.00.
- 4.3.2. For a renewal license for an existing facility it is a \$500.00 fee. The renewal period each year is from October 1st to the December 1st deadline.
- 4.3.3. Applications for a renewal license must be received online or mailed before the deadline of December 1st. If mailed, the outside mailing

envelope containing the renewal application must be postmarked on or before December 1st to avoid the late fee.

- 4.3.4. If a licensee fails to submit an application for renewal on or before December 1st, in addition to the license fee of \$500.00, shall pay an additional \$250.00 late fee.
- 4.3.5. For a temporary license to operate a body art facility at a fixed location for not more than 14 consecutive days the license fee is \$150.00.
- 4.3.6. The department shall issue a duplicate license upon request of a licensee and the payment of a duplicate license fee of \$50.00.
- 4.4. Before issuing an annual license to an owner or operator, the Department must receive the results of a compliant inspection of that body art facility from the local health department for the jurisdiction in which the body art facility is located.
- 4.5. Before issuing a renewal license to an owner or operator, the Department shall verify that the local health department for the jurisdiction in which the body art facility is located has submitted results of a compliant inspection of the body art facility during the previous calendar year.
 - 4.5.1. The Department will issue a renewal license to the body art facility with the expectation that subsequent inspections would then at least occur at approximately one-year intervals. Each local health department retains the right to perform more inspections as deemed necessary.
 - 4.5.2. Upon receipt of inspection results that deem a facility not fit to operate, the Department or local health department that has jurisdiction shall send notice to the facility that their current license is null and void, pending a satisfactory inspection.
- 4.6. For annual and renewal licenses, the local health department shall convey the results of the inspection(s) to the Department as soon as possible after the inspection is completed.
- 4.7. For temporary body art facility licenses, the local health department shall convey the results of that inspection to the Department as soon as possible, but no longer than 30 days after the inspection is completed.
- 4.8. Mobile units will not be licensed as statewide transitory units.
- 4.9. The Department shall issue a license to the applicant for the operation of the body art facility upon receipt of the required license fee and a compliant inspection report from the local health department from the jurisdiction in which the body art facility is located.
- 4.10. A license is non-transferrable. It is issued under PA375 to a specific person for a body art facility at a specific permanent or temporary location.
- 4.11. Annual licenses and renewal licenses will be effective for the calendar year applied for and does not imply or guarantee a license of 365 days from initial approval.

- 4.12. Applications for licensure must be received not less than 30 days before tattooing, branding, or body piercing services are proposed to be provided.
- 4.13. Applications for temporary licenses must be received not less than 30 days before the first day on which tattooing, branding, or body piercing services are proposed to be provided at the temporary location and expires at 12 midnight on the final date described on the temporary license.

5. Section Five: Body Art Facility Requirements/General

- 5.1. The owner or operator of the body art facility must have a person(s) in charge and present during all hours of facility operation that is responsible for the operation of the body art facility.
- 5.2. The owner or operator of the body art facility must post the original license issued by the Department in a conspicuous place within the customer service area of the body art facility. An original license can be verified by revealing the State of Michigan seal upon photocopying.
- 5.3. The owner or operator of the body art facility must ensure that the facility is in compliance with the Department's *Requirements for Body Art Facilities*.
- 5.4. The owner or operator of the body art facility must post in a conspicuous place within the customer service area of the body art facility, the Department provided **Disclosure Statement and Notice for Filing Complaints**, which advises clients of the risks and possible consequences of body art procedures and provides information on how to lodge complaints about the body art facility related to compliance with the Department's *Requirements for Body Art Facilities*.
- 5.5. **CR** The owner or operator of the body art facility must prohibit smoking in the facility and must post signage indicating that the body art facility is a smoke-free facility.
- 5.6. **CR** The owner or operator of the body art facility must prohibit the tattooing, branding, or body piercing of a minor without the written informed consent and proper identification of the minor's parent or legal guardian.
- 5.7. **CR** The owner or operator of the body art facility shall not give or sell to a minor a tattooing, branding, or body piercing kit or other tattooing, branding or body piercing device.
- 5.8. **CR** The owner or operator of the body art facility must prohibit body art technicians from performing tattooing, branding, or body piercing while under the influence of alcoholic liquor or a controlled substance.
- 5.9. **CR** The owner or operator of the body art facility must prohibit the tattooing, branding or body piercing of an individual who is under the influence of alcoholic liquor or a controlled substance or who, in the opinion of the body art technician, is under the influence of alcoholic liquor or a controlled substance.
- 5.10. The owner or operator of the body art facility must maintain a file on the premises at the body art facility that includes the following information about the body art facility:

- 5.10.1. The full legal name of the body art facility.
- 5.10.2. The hours of operation of the body art facility.
- 5.10.3. The following for each owner and operator of the body art facility:
 - 5.10.4. Full legal name
 - 5.10.5. Home address.
 - 5.10.6. Home and work telephone numbers
 - 5.10.7. A complete description of all tattooing, branding, and/or body piercing performed at the body art facility.
 - 5.10.8. A complete record keeping of all instruments, body jewelry, sharps and inks used for tattooing, branding or body piercing at the body art facility. The inventory shall include the name of the item's manufacturers and serial or lot number. The facility may provide invoices or purchase orders to satisfy this requirement.
 - 5.10.9. A copy of the Department's *Requirements for Body Art Facilities*.
- 5.11. The owner or operator of the body art facility shall notify the Department of any changes in the facility's name, ownership, facility address, owner's mailing address, email address or telephone number to assure receiving licensure renewal notices. The owner or operator shall also notify the local health department responsible for body art facility inspection for the jurisdiction in which the body art facility is located.
- 5.12. The owner or operator of the body art facility must also maintain a file, on the premises of the body art facility, that includes the following for each body art technician employed by or who performs tattooing, branding or body piercing at the facility, as well as all other individuals whose job responsibilities put them at risk of exposure to blood and OPIM:
 - 5.12.1. Full legal name
 - 5.12.2. Exact duties/responsibilities at the body art facility
 - 5.12.3. Date of birth
 - 5.12.4. Gender
 - 5.12.5. Home address
 - 5.12.6. Home and work telephone numbers
 - 5.12.7. A listing of prior or current places of employment as a body art technician (if known.)
 - 5.12.8. A description of training and experience
 - 5.12.9. An identification photo
 - 5.12.10. Documentation of completion of training requirements delineated in the Department's *Requirements for Body Art Facilities*.

- 5.12.11. Documentation of hepatitis B vaccination status or documentation that the vaccination series was offered and declined in writing. All individuals who decline vaccination must sign a Vaccine Declination Form.
- 5.12.12. A copy of the signed statement ensuring confidentiality of client records, if the body art technician or other individuals working at the body art facility has access to those records.

6. Section Six: Body Art Facility Requirements/Michigan Occupational Safety and Health Administration (MIOSHA) Blood borne Infectious Diseases Standards

- 6.1. The owner or operator of a body art facility must ensure that the body art facility as a whole, and any individual working in the body art facility with potential exposure to blood and OPIM, is in compliance with the Occupational Safety and Health Act (OSHA) Blood borne Pathogens Standards under 29 CFR 1910:1030. This includes, but is not limited to individuals: 1) engaged in tattooing and/or cleaning, disinfecting, and sterilizing of tattooing instruments/equipment, 2) performing branding and/or cleaning, disinfecting, or sterilizing branding instruments/equipment, and/or 3) performing body piercing and/or cleaning, disinfecting, or sterilizing piercing instruments/ equipment, 4) front counter personnel working in general areas of the facility (customer waiting area, office), 5) studio owners that do not perform body art procedures, but work in the common area of the facility.
- 6.2. In Michigan, OSHA regulations are implemented under the jurisdiction of MIOSHA. As a result, the owner or operator of a body art facility must ensure compliance with MIOSHA Occupational Health Standards: Part 554 Blood borne Infectious Diseases Standards, as amended June 28, 2001. (R 325.70001-R325.70018 of Michigan Administrative code) A completed and current site specific MIOSHA Blood borne Infectious Diseases Exposure Control Plan for Employer with Limited Employee Exposure will satisfy this requirement.
- 6.3. **CR** The licensee shall maintain on-site documentation of annual blood borne pathogen training as well as the yearly updated exposure control plan for review.
- 6.4. Referrals concerning the employer/employee working relationships can be made to:

The Department of Licensing and Regulatory Affairs
Michigan Occupational Safety and Health Administration
P.O. Box 30644
Lansing, MI 48909-8144
Phone: 517-322-1831

7. Section Seven: Body Art Facility Requirements/Training

- 7.1. **CR** The owner or operator of a body art facility must ensure that any individual working in the body art facility with potential exposure to blood and OPIM meets the following training requirements. This includes, but is not limited to individuals: 1) engaged in tattooing and/or cleaning, disinfecting, and sterilizing of tattooing instruments/equipment, 2) performing branding and/or cleaning, disinfecting, or sterilizing branding instruments/equipment, 3) performing body piercing and/or cleaning, disinfecting, or sterilizing piercing instruments/ equipment,4) front counter

personnel working in general areas of the facility (customer waiting area, office), 5) studio owners that do not perform body art procedures, but work in the common area of the facility.

- 7.1.1. **CR** Individuals must complete an annual industry-specific training that provides: 1) information on blood borne pathogens; 2) blood borne pathogen prevention, and 3) MIOSHA Blood borne Infectious Diseases Standards.
- 7.1.2. **CR** Individuals must also complete an annual site-specific training that provides specific information on how MIOSHA Blood borne Infectious Diseases Standards will be implemented in the body art facility at which they work.
- 7.2. **CR** The industry-specific and site-specific trainings provided, in combination, must meet all MIOSHA Blood borne Infectious Diseases Standards training requirements.
- 7.3. **CR** Annual industry-specific and site-specific trainings must be provided to: 1) individuals working in the body art facility prior to annual licensure of the body art facility, 2) individuals who begin working at the body art facility before they start to carry out responsibilities with potential exposure to blood and OPIM, and 3) individuals currently working at the body art facility when they are assigned, and before they begin to carry out, responsibilities with potential exposure to blood and OPIM.
- 7.4. **CR** Industry-specific training and site-specific training must also be provided annually to all individuals working in the body art facility with potential exposure to blood and OPIM.

8. Section Eight: Body Art Facility Requirements/Vaccination

- 8.1. **CR** The owner or operator of the body art facility must make hepatitis B vaccination available to all individuals working in the body art facility with potential exposure to blood and OPIM unless the individual has previously received the complete hepatitis B vaccination series, antibody testing has revealed that the individual is immune, or vaccine is contraindicated for medical reasons. This would include but would not be limited to individuals: 1) engaging in tattooing and/or cleaning, disinfecting, or sterilizing tattoo instruments/equipment, 2) performing branding and/or cleaning, disinfecting or sterilizing branding instruments/equipment, and 3) performing piercing and/or cleaning, disinfecting or sterilizing piercing instruments/equipment.
- 8.2. **CR** Hepatitis B vaccination must be made available to: 1) individuals working in the body art facility prior to annual licensure of the body art facility, 2) individuals who begin working at the body art facility within ten days of being assigned to carry out responsibilities with potential exposure to blood and OPIM, and 3) individuals currently working at the body art facility within ten days of being assigned to carry out responsibilities with potential exposure to blood and OPIM.
- 8.3. **CR** Hepatitis B vaccination must be made available after training requirements are completed.

8.4. **CR** All individuals who decline vaccination must sign a Vaccination Declination Form.

9. **Section Nine: Requirements/Body Art Technicians and Other Individuals Who Assist with Body Art Procedures with the Potential Exposure to Blood and OPIM**

9.1. **CR** Body art technicians shall be a minimum of 18 years of age.

9.2. **CR** Body art technicians shall not perform tattooing, branding, or body piercing while under the influence of alcoholic liquor or a controlled substance.

9.3. **CR** Body art technicians shall not perform tattooing, branding or body piercing on non-intact skin or non-intact mucosal surfaces.

9.4. **CR** Body art technicians shall refuse body art services to any person who is under the influence of alcoholic liquor or a controlled substance, or who in their opinion is under the influence of alcoholic liquor or a controlled substance.

9.5. **CR** Body art technicians shall not perform tattooing, branding, or body piercing on a minor without documented parental or guardian identification and written, informed consent.

9.6. **CR** Body art technicians or any other individuals working in a body art facility shall not give or sell to a minor a tattooing, branding, or body piercing kit or other tattooing, branding or body piercing device.

9.7. **CR** Body art technicians, and any other individuals who assist with setting up for, performing, or cleaning up after body art procedures with the potential for exposure to blood and OPIM, shall maintain a high degree of cleanliness, conform to hygienic practices, including hand washing, and wear proper Personal Protective Equipment with clean clothes when performing body art procedures.

9.8. **CR** If the clothes of a body art technician, or any other individual who assists with setting up for, performing, or cleaning up after body art procedures with the potential exposure to blood or OPIM, become contaminated, contaminated clothing shall be removed as soon as possible in a way that prevents additional exposure to the contaminated areas of the clothing. Clean clothing shall be used prior to commencement of any further body art procedures.

9.9. **CR** Body art technicians, or any other individuals who assist with setting up for, performing, or cleaning up after body art procedures with the potential for exposure to blood and OPIM shall not be involved in body art procedures if they have open wounds, cuts, sores, burns or skin abnormalities on the hand, or on any other portion of the body that may result in uncontained drainage that could result in contamination of body art instruments, equipment, procedure surfaces or the client.

9.10. **CR** Body art technicians, or any other individuals who assist with setting up for, performing, or cleaning up after body art procedures with the potential for exposure to blood and OPIM, shall not eat, drink, apply cosmetics or lip balm, handle contact lenses or store food in work areas where tattooing, branding, or body piercing are performed or other areas where there is a likely exposure to blood and other OPIM.

- 9.11. **CR** When performing body art procedures, or assisting with setting up for, performing, or cleaning up after body art procedures, body art technicians and other individuals with the potential for exposure to blood and OPIM, shall perform appropriate hand washing. At a minimum, this includes:
- 9.11.1. **CR** Prior to donning gloves to set-up of equipment/instruments used for conducting body art procedures.
 - 9.11.2. **CR** Immediately prior to donning gloves to perform a body art procedure.
 - 9.11.3. **CR** Immediately after removing gloves at the conclusion of performing a body art procedure and after removing gloves at the conclusion of procedures performed in the sterilization area.
 - 9.11.4. **CR** When leaving the work area.
 - 9.11.5. **CR** As soon as possible after coming in contact with blood or OPIM or any potentially contaminated surface, including after cleaning and disinfecting after each client.
 - 9.11.6. **CR** Before and after eating, drinking, smoking, applying lip cosmetics or lip balm, handling contact lenses, or using the bathroom.
 - 9.11.7. **CR** When hands are visibly soiled.
- 9.12. **CR** Hand washing shall include thoroughly washing the hands in warm, running water with liquid soap using friction on all surfaces of the hands and wrists for at least 15 seconds, then rinsing hands and drying hands with a clean, disposable paper towel, and turning off the faucet with a new disposable paper towel.
- 9.13. **CR** Body art technicians shall perform tattooing, branding or body piercing in a manner that minimizes splashing, spraying or splattering of blood.
- 9.14. **CR** When involved in body art procedures, body art technicians and any other individuals involved in setting up for, performing, or cleaning up after body art procedures with the potential exposure to blood and OPIM, shall wear disposable medical-grade exam gloves to minimize the possibility of transmitting infections during body art procedures.
- 9.14.1. **CR** Under no circumstances shall a single pair of exam gloves be used for the entire body art procedure.
 - 9.14.2. **CR** A minimum of one pair of disposable, medical-grade exam gloves shall be used for each of the following stages of the body art procedure:
 - 9.14.2.1. Set-up of equipment/instruments used for conducting body art procedures and skin preparation of the body art procedure area.
 - 9.14.2.2. The body art procedure and post-procedure teardown.
 - 9.14.2.3. Cleaning and disinfection of the procedure area after each use/between clients.
- 9.15. **CR** If, when involved in body art procedures, the body art technician or any other individual involved in setting up for, performing, or cleaning up after body art

procedures, leaves the body art procedure area in the middle of a body art procedure, gloves must be removed before leaving the procedure area and a new pair of gloves put on when returning to the procedure area.

- 9.16. **CR** If, when involved in body art procedures, the body art technician's glove(s), or the glove(s) of any other individual involved in setting up for, performing, or cleaning up after body art procedures, is pierced or torn, or if the glove(s) become potentially contaminated by contact with non-clean/non-sterile surfaces, the glove(s) must be changed immediately. To ensure adequate protection for the practitioner, latex gloves shall not be used in conjunction with petroleum-based products.
- 9.17. **CR** Under no circumstances shall a single pair of gloves be used on more than one client.
- 9.18. **CR** The use of disposable exam gloves does not preclude or substitute for hand washing procedures.
- 9.19. **CR** Gloves and any other required PPE shall be applied and removed according to requirements that minimize contamination of the person using them.
 - 9.19.1. Disposable gloves and any required PPE shall be removed before leaving the area where tattooing, body piercing, and branding is performed.
 - 9.19.2. **CR** Disposable gloves and any other required disposable PPE shall be disposed of in an appropriate, covered waste receptacle.
 - 9.19.3. Any reusable PPE shall be placed in an appropriate provided receptacle for storage until they can be cleaned, disinfected and sterilized.
- 9.20. **CR** If while performing a body art procedure, an item or instrument used for body art is contaminated by coming in contact with a surface other than the procedure surface or the client, the item shall be discarded or removed from service and replaced immediately with a new disposable item or a new sterilized item or instrument before the procedure continues.
- 9.21. **CR** Body art technicians shall immediately dispose of all needles, including the needle bar, and other contaminated sharps directly into a conveniently placed and secured sharps disposal container. Body art technicians shall not bend, recap, break or shear contaminated sharps.

10. Section Ten: Information, Education, and Informed Consent

- 10.1. Before starting a body art procedure, each client receiving a tattoo, branding or body piercing shall receive a copy of the Department- provided Disclosure Statement and Notice for Filing Complaints, which advises clients of the risks and possible consequences of body art procedures and provides information on how to lodge complaints about the body art facility related to compliance with the Department's *Requirements for Body Art Facilities*.
- 10.2. Each client who receives a tattoo, branding or body piercing shall be provided with verbal aftercare instructions and a written aftercare information sheet approved by the Department that includes:

- 10.2.1. Instructions on the care of the tattoo site, brand site, or body piercing site.
 - 10.2.2. The signs and symptoms of infection.
 - 10.2.3. A recommendation that an individual seek medical attention if the tattoo site, brand site or body piercing site becomes infected or painful or if the person develops a fever shortly after being tattooed, branded or having body piercing performed.
 - 10.2.4. Notice that the person may be allowed to donate blood within the standard deferral period if the person presents a copy of his/her client record provided by the body art facility to the blood donor facility.
- 10.3. Before starting a body art procedure, each person seeking a tattoo, branding or body piercing shall be asked about the following conditions:
- 10.3.1. Diabetes or other conditions which may affect blood circulation and/or ability to fight infection
 - 10.3.2. History of hemophilia or excessive bleeding
 - 10.3.3. History of skin disease, skin lesions or skin sensitivities to soaps or disinfectants
 - 10.3.4. History of allergies or adverse reactions to latex, pigments, dyes, disinfectants, metals or other sensitivities related to body art procedures
 - 10.3.5. History of epilepsy, seizures, fainting or narcolepsy
 - 10.3.6. Treatment with anticoagulants or other medications that thin the blood and/or interfere with blood clotting.
 - 10.3.7. Current pregnancy and/or breast feeding
 - 10.3.8. Any other information that would aid the body art technician or any other individual involved in providing education on the client's suitability for receiving a body art procedure and the client's body healing process.
- 10.4. Any client reporting one or more of the above conditions shall advise clients to consult his/her physician before undergoing a body art procedure.
- 10.5. Client responses to the above questions shall be recorded on the consent form and the client shall sign and date the form indicating that the answers provided were true and correct, and, that, if the client reported one or more of the above conditions, the client will be provided advisement to consult a physician.

11. Section Eleven: Client Records

- 11.1. The body art facility shall maintain a record of each client who has been tattooed, branded or has had body piercing performed at the body art facility. The record shall include, at a minimum:
 - 11.1.1. The date of the procedure.
 - 11.1.2. The client's name, address, date of birth.

- 11.1.3. Information about how to contact the client in case of a communicable disease outbreak investigation, jewelry recall or other issues pertaining to the client's health. Contact information may include a phone number and/or an e-mail address.
 - 11.1.4. The client's signature on a Department-approved consent form that documents receipt of: 1) the Department-approved Disclosure Statement and Notice for Filing Complaints; 2) documentation of receipt of the Department-approved aftercare information sheet; and 3) documentation of completion of the client health questionnaire.
 - 11.1.5. A description of the design and location of the tattooing, branding, or body piercing.
 - 11.1.6. The name of the body art technician performing the tattooing, branding, or body piercing.
 - 11.1.7. Any known complication the client has during the procedure with any tattooing, branding or body piercing done at that body art facility.
 - 11.1.8. **CR** An individual shall not tattoo, brand, or perform body piercing on a minor unless the individual obtains the prior written informed consent of the minor's parent or legal guardian and proof of that individual's authority to give the informed consent required under PA 375. The minor's parent or legal guardian shall execute the written, informed consent required under PA 375 in the presence of the licensee or and employee or agent of the licensee. The minor's parent or legal guardian shall present to the licensee or employee or agent of the licensee the minor's birth certificate or legal proof of guardianship to establish the individual's authority to give the informed consent required under PA 375. The facility shall maintain with the client record a copy of the minor's photo identification, the parent or legal guardian's photo identification, and a copy of the minor's birth certificate or legal guardianship papers.
- 11.2. The owner or operator of the body art facility shall provide a copy of the record to the client at the time the individual is tattooed, branded or has body piercing performed.

12. Section Twelve: Record Retention

- 12.1. The owner, operator, or person in charge of the facility shall retain on the premises of the body art facility all client and employee records containing the information delineated in the *Requirements for Body Art Facilities* document and the person in charge shall have access to these records at all times.
- 12.2. All client and employee records, electronic or hard copy, shall be retained in a confidential manner in compliance with the following:
 - 12.2.1. All paper records shall be retained in a locked filing cabinet or a locked room. All electronic records must be password protected.

- 12.2.2. Access to **client** records must be limited to: 1) individuals working at the body art facility that must have access to the client records in order to carry out the responsibilities of their position at the body art facility; and 2) Department or local health department staff who need access to records to document body art facility compliance with requirements delineated in this document, to investigate a laboratory confirmed infection, or to conduct a communicable disease outbreak investigation.
- 12.2.3. Access to **employee** records shall be limited to: 1) individuals working at the body art facility that must have access to the employee records in order to carry out the responsibilities of their position at the body art facility and 2) Department or local health department staff who need access to records to document body art facility compliance with requirements delineated in this document or to conduct a communicable disease investigation.
- 12.2.4. All individuals working at the body art facility with access to **client** records shall sign a statement ensuring that they will protect client confidentiality. The signed statement shall be included in the employee record.
- 12.2.5. All individuals working at the body art facility with access to **employee** records shall sign a statement ensuring that they will protect employee confidentiality. The signed statement shall be included in the employee record.
- 12.3. All **client** records shall be retained for a minimum of three (3) years.
- 12.4. All **employee** records shall be retained for a minimum of three (3) years from the date employment ends.
 - 12.4.1. After the three-year minimum for record retention, all client and employee records may be destroyed. Destruction of records shall include shredding, incineration, electronic deletion or disposal in another manner that protects the confidentiality of all client and/or employee-related documents.
 - 12.4.2. Body art facilities that close and go out of business are required to properly dispose of records. Destruction of records shall include shredding, incineration, electronic deletion or disposal in another manner that protects the confidentiality of all client and/or employee-related documents.

13. Section Thirteen: Preparation and Care of the Body Art Area/Conducting the Body Art Procedure

- 13.1. **CR** Body art procedure areas shall be organized to prevent cross-contamination of clean, disinfected, or sterile instruments/equipment with contaminated equipment.
 - 13.1.1. A cleaned and disinfected field shall be established that contains all cleaned, disinfected, and sterilized instruments/equipment and supplies to be used in the body art procedure.

- 13.1.2. All supplies shall be organized before the procedure begins in a manner to minimize contamination of the field.
- 13.1.3. **CR** All sterilized supplies shall remain in the sterile package until opened in front of the client.
- 13.1.4. **CR** A separate disposable container or a container capable of being cleaned and disinfected shall be available and shall be used to hold and transport all post-procedure contaminated instruments/equipment from the procedure area to the cleaning, disinfecting, and sterilization area.
- 13.2. **CR** Before a body art procedure is performed, the immediate skin area and the areas of the skin surrounding where the body art is to be placed shall be washed with soap and water. The area shall then be prepared with an appropriate skin preparation allowing the preparation to dry on the skin before beginning the body art procedure. Washing pads shall be disposed of in a covered waste receptacle after a single use.
- 13.3. In the event of an oral body art procedure, the mouth shall be rinsed out with an oral antiseptic mouth rinse for at least 30 seconds.
- 13.4. **CR** If shaving is necessary, single-use disposable razors shall be used. Used razors shall be immediately disposed of in an approved, properly-labeled and secured sharps disposal container. Following shaving, the immediate skin area and the areas surrounding where the body art is to be placed shall be washed with soap and water. The area shall be prepared with an appropriate antiseptic skin preparation according to the manufacturer's instructions. Washing pads shall be disposed of in a covered, waste receptacle after a single use.
- 13.5. **CR** All tattoo pigments/inks, tattoo needles, and piercing needles and other instruments used for body art procedures shall be specifically manufactured for performing body art procedures and shall be used according to manufacturer's instructions
 - 13.5.1 **CR** Expired pigment shall not be used for body art procedures and must be discarded upon expiration.
 - 13.5.2 **CR** Pigments that have a secondary expiration date (i.e. time length once product is opened.) must be labeled with both the date opened and the new expiration date and must be discarded upon expiration.
- 13.6. **CR** All needles used for tattooing must be single-use, sterile needles. After use, needles, including the needle bar, shall be immediately disposed of in an approved, properly-labeled and secured sharps disposal container.
- 13.7. **CR** All products applied to the skin, including but not limited to body art stencils, markers, pencils and pens, shall be single-use and disposed of immediately after use.
- 13.8. **CR** Application of stencils shall be dispensed and applied on the area to be tattooed with clean paper toweling or an applicator in a manner to prevent contamination of the original container and its contents. The used paper toweling or applicator shall be disposed of in an appropriate covered waste receptacle after a single use.

- 13.9. **CR** Petroleum-based products **may not** be used in conjunction with latex gloves. If a petroleum-based product is used, non-latex based medical-grade exam gloves shall be used. (Reference Section 9.16 regarding use of petroleum-based products.)
- 13.10. **CR** Immediately before a tattoo is applied, the quantity of tattoo pigment/ink to be used shall be transferred from the tattoo pigment/ink bottle and placed in a single-use pigment cap. Upon completion of the tattoo, these single use pigment caps and their contents shall be discarded.
- 13.10.1. **CR** Before disposal, any tattoo pigment/ink remaining in liquid form shall be disposed of by placing absorbent materials into the cap to absorb the liquid and the caps disposed of in an appropriate covered waste receptacle after a single use.
- 13.10.2. Tattoo pigment/ink cannot, under any circumstances, be reused on another client or placed back in the original stock container.
- 13.11. **CR** Tattoo pigment/ink bottles must be stored in a clean, dry, closed cabinet or tightly covered container when not in use. If tattoo pigment/ink bottles are stored in the body art procedure area, they may not be accessed during the performance of a body art procedure without first removing and disposing of contaminated gloves and performing hand washing. New medical-grade exam gloves must be used to complete the body art procedure.
- 13.12. **CR** After performing a tattoo, excess pigment/ink shall be removed from the skin with a clean, single use paper towel. The completed tattoo shall be washed with an appropriate antiseptic solution. The tattooed area shall be allowed to dry. An ointment shall be applied either from a single-use packet or using an applicator in such a way that the original container is not contaminated. A non-stick dressing shall be applied to the site and secured with medical-grade adhesive tape or self-adhesive wrap. An acceptable dressing would be a non-stick dressing to prevent ink removal. Food-grade plastic wrap shall not be used as a dressing. (See Appendix C.)
- 13.13. **CR** For permanent make-up/cosmetic tattooing, the use of some rotary pens is permitted. Only rotary pens that have detachable, disposable, sterile combo couplers and detachable, disposable casings or casings that can be cleaned and sterilized can be used. The use of any rotary pen that uses a sponge at the opening of the chamber to stop the pigment or blood or OPIM from getting into the machine or is designed in a manner that does not allow it to be cleaned and sterilized shall not be permitted.
- 13.14. **CR** All needles used for piercing must be single-use, sterile needles. After use, needles shall be immediately disposed of in an approved, properly-labeled and secured sharps disposal container. Needles are not to be bent, broken or recapped before disposal into sharps disposal container. Expired needles are not to be re-autoclaved unless approved by manufacturer.
- 13.14.1. **CR Microblading** manual tattoo technique using a handle with a preassembled needle grouping tool, the entire implement must be disposed of immediately after use in an approved, properly-labeled and secure sharps disposal container.

13.15. **CR** All jewelry used for piercing must be sterilized before use. Jewelry for initial piercings must be made of implant grade materials which meet the minimum ISO or ASTM designation standards. (ASTM F-138 compliant or ISO 5832-1 compliant.) (See Appendix B.)

13.16. In the event of excessive bleeding at any time during a body art procedure, all products used to check the flow of blood or to absorb blood shall be sterile, unused, single-use items and must be disposed of immediately after use in appropriate, covered waste receptacles, unless the disposal product meets the definition of medical waste. No styptic pencils, alum blocks, or other solid styptics shall be used to stop excessive bleeding.

14. Section Fourteen: Cleaning, Disinfection and Sterilization Procedures (See Appendix F.)

14.1. **CR** All procedure surfaces shall be constructed of materials that are smooth, nonporous and easily cleaned and disinfected. This includes, but is not limited to, client chairs, tables, benches, and counters. For questionable surfaces such as leather procedure arm bars, barriers and/or barrier tape should be used during the procedure.

14.2. **CR** All procedure surfaces shall be cleaned and disinfected with an EPA-registered tuberculocidal disinfectant after each use/between clients regardless of whether contamination is visible. Many disinfectants need to stay on surfaces for a specific amount of time to fully disinfect the surface before being wiped down. Instructions included with the disinfectant shall be followed regarding the required chemical concentration and the amount of time needed to properly disinfect an area. (See Appendix D.)

14.3. **CR** Non-procedure surfaces and equipment shall not be touched during the body art procedure. If an object is likely to be touched during the procedure, it shall be covered with an appropriate barrier such as barrier film, a clip cord sleeve, dental bib or table paper.

14.3.1. Any barrier used to cover equipment must be discarded at the end of each procedure.

14.3.2. The underlying surface must be clean and disinfected after each use/between clients and before a new barrier covering is applied.

14.3.3. No cloth or fabric chairs shall be used in the procedure or sterilization area.

15. Section Fifteen: The cleaning, disinfecting and sterilizing of non-disposable items.

15.1.1. **CR** All non-disposable instruments used in body art procedures shall be thoroughly cleaned after each use. Cleaning is accomplished by manually scrubbing equipment with warm water and an appropriate detergent solution to remove blood and OPIM.

- 15.1.2. **CR** Once visible blood and OPIM is removed, all non-disposable instruments shall be placed in a disinfection tub filled with EPA-registered tuberculocidal disinfectant. Equipment shall be fully submerged to ensure contact with all surfaces for an amount of time specified in the manufacturer's instructions. All hinged equipment (e.g., piercing forceps) shall be in the open position.
- 15.1.3. **CR** When disinfection is completed, equipment shall be rinsed, patted dry and placed in an ultrasonic cleaner filled with an appropriate ultrasonic solution and the ultrasonic unit shall be run according to the manufacturer's suggestions. All hinged equipment (e.g., piercing forceps) shall be in the open position.
- 15.1.4. **CR** The ultrasonic unit shall be used, cleaned, and maintained in accordance with manufacturer's instructions and a copy of the manufacturer's recommended procedures for the operation of the ultrasonic unit shall be kept on file at the body art facility.
- 15.1.5. **CR** Upon removal from the ultrasonic unit, all non-disposable instruments used for body art shall be rinsed, air dried, and packed individually in peel-packs and subsequently sterilized in a steam autoclave or dry-heat sterilizer. All hinged equipment (e.g., piercing forceps) shall be packaged in an open position.
- 15.1.6. All peel-packs shall contain a chemical/temperature and/or humidity sensitive tapes, strips or pellets for monitoring each sterilization cycle. Reactions must be recorded in a log book for each sterilization cycle.
- 15.1.7. Peel-packs shall be labeled to include the date of sterilization.
- 15.1.8. The steam autoclave or dry-heat sterilizer shall be used, cleaned, and maintained in accordance with manufacturer's instructions and a copy of the manufacturer's recommended procedures for the operation of the steam sterilizer or dry heat sterilizer shall be kept on file at the body art facility.
- 15.1.9. **CR** After sterilization, the instruments used for body art procedures shall be stored in a dry, disinfected, closed cabinet or other tightly-covered container reserved for the storage of such instruments.
 - 15.1.9.1. The expiration date for sterilized instruments is one year from the date of sterilization unless the integrity of the package is compromised.
 - 15.1.9.2. Sterilized instruments may not be used if the package integrity has been breached, is wet or stained, or the expiration date has been exceeded without first repackaging and re-sterilizing.
 - 15.1.9.3. **CR** All instruments used in body art procedures shall remain stored in sterile packages until just prior to the performance of a body art procedure.

- 15.2. **CR** The owner or operator of a body art facility shall demonstrate that the sterilizer used is capable of attaining sterilization by monthly spore detection tests. These tests shall be verified through an independent laboratory. Test records shall be retained by the owner or operator for a period of at least three years and posted in a conspicuous place within the sterilization area.
- 15.3. **CR** If a spore test result is positive, the body art facility shall discontinue the use of that sterilizer until it has been serviced and a negative spore test has been recorded before putting that sterilizer back into service.
- 15.3.1. Until a negative spore test has been received, the body art facility shall: 1) use an alternative sterilizer: 2) use only instruments that have a sterilization date on or before the date before the last negative spore test was recorded: or 3) use only disposable and pre-sterilized instruments.
- 15.3.2. Instruments from sterilization runs after the last negative spore test must be repackaged and sterilized successfully before use.
- 15.3.3. The owner and/or operator of the body art facility shall also notify the local health department which inspects body art facilities in the jurisdiction in which the body art facility is located, of the positive spore test within 24 hours of the positive spore testing occurring.
- 15.4. Body art facilities that use only disposable instruments are not required to have a steam autoclave or a dry-heat sterilizer. A separate room for the sole purpose of cleaning, disinfecting and sterilizing contaminated tools and equipment is not needed.
- 15.5. **CR** Body art technicians and all other individuals working in the body art facility shall follow appropriate hand washing technique and wear gloves and other required PPE when involved in cleaning, disinfecting, and sterilization procedures.
- 15.6. **CR** The following procedures shall be followed when cleaning and disinfecting procedure surfaces/areas:
- 15.6.1. Gloves and other PPE shall be worn when cleaning and disinfecting body art procedure surfaces/areas, including the removal of any barrier materials. Gloves shall be either medical grade disposable gloves or heavy duty reusable gloves. Gloves shall be removed before leaving the procedure area.
- 15.6.2. Appropriate hand washing shall be performed immediately upon glove removal after cleaning and disinfecting body art procedure areas.
- 15.7. **CR** The following procedures shall be followed when cleaning and disinfecting non-disposable instruments: (1) Gloves and other required PPE shall be worn when cleaning and disinfecting non-disposable instruments. (2) Gloves shall be disposable medical grade exam gloves. (3) Gloves shall be removed after loading the ultrasonic cleaner. (4) Appropriate hand washing shall be performed immediately upon glove removal after loading the ultrasonic cleaner.
- 15.8. **CR** The following procedures shall be followed when sterilizing non-disposable instruments and handling sterilized instruments: (1) Gloves and/or other required

PPE shall be worn when preparing materials for sterilization and loading materials into the steam autoclave or dry heat sterilizer. (2) Gloves shall be disposable medical grade exam gloves. (3) Appropriate hand washing shall be performed immediately upon preparing the materials for sterilization and loading materials into the steam autoclave or dry heat sterilizer. (4) Appropriate hand washing shall be performed prior to donning gloves before unloading materials from the steam autoclave or dry heat sterilizer and placing them into storage (5) Appropriate hand washing shall be performed prior to donning gloves before retrieving sterilized materials from the storage area in preparing for setting up for a body art procedure. (6) A different pair of gloves shall be used for each of the above stages of cleaning, disinfecting, and sterilization.

- 15.9. **CR** All gloves and other required PPE shall be removed in a way that minimizes risk of contamination of the person using them.
- 15.10. **CR** If medical grade gloves and/or other disposable PPE are used, they shall be disposed of in an appropriate, covered waste receptacle.
- 15.11. **CR** If heavy duty reusable gloves and/or other reusable PPE are used, they shall be placed in a container for cleaning and disinfecting.
- 15.12. **CR** If heavy duty reusable gloves are used, each person using them shall have their own pair of gloves or reusable gloves should be disinfected with an environmental disinfectant, rinsed and allowed to dry between uses.

16. Section Sixteen: Medical Waste/Disposal

- 16.1. **CR** A three year “Certificate of Registration as a Medical Waste Producing Facility” shall be obtained for the body art facility from the Michigan Department of Environmental Quality (MDEQ) as required by the Medical Waste Regulatory Act (MWRA), “Part 138 of the Public Health Code, 1978 PA 368, as amended”, MCL 333.13801 *et seq.* Compliance with all other rules and regulations associated with the MWRA are required including the requirement to have a written medical waste management plan on file. Questions or enforcement is referred on to MDEQ to the Solid Waste Management Unit (SWMU), Solid Waste and Land Application Section at 517-241-2924.
- 16.2. **CR** Contaminated waste which may release liquid blood or OPIM when compressed or may release dried blood or other potentially infectious material (OPIM) when handled shall be placed in a biohazard bag or container which is properly labeled.
- 16.3. **CR** Sharps ready for disposal shall be placed in an approved sharps disposal container. Under the Administrative Rules (R 325.1541 (B) of the Medical Waste Regulatory Act, Part 138 of the Public Health Code, 1978 PA 368, as amended, sharps (including needles, syringes, scalpels and intravenous tubing with needles attached), shall be considered as medical waste and disposed of under subsection 13811(d) of the act whether or not they have become contaminated with and agent infectious to humans.

- 16.4. **CR** Contaminated waste which may release blood, body fluids, dried blood or dried body fluids, and sharps must be disposed of consistent with the MWRA.
- 16.5. **CR** Contaminated waste cannot be stored for more than 90 days before disposal.
- 16.6. Contaminated waste which does not release liquid blood or body fluids when compressed or does not release dried blood or body fluids when handled may be placed in a covered waste receptacle and disposed of through normal disposal methods.
- 16.7. **CR** “Pathological Waste” as defined under Section 13807(2) of Michigan’s Medical Waste Regulatory Act (MWRA), Part 138, 1978 PA 368, as amended, means “human organs, tissues, body parts other than teeth, products of conception, and fluids removed by trauma or during surgery or autopsy or other medical procedure and not fixed in formaldehyde.”
- 16.8. **CR** Skin or any other human tissue that is a pathological waste under Part 138 and removed during the process of “scarification” or any other related procedure in a body art facility, must be handled, packaged, treated and disposed of in accordance with Part 138 and the associated Administrative Rules promulgated pursuant to Part 138. This requirement has no provision for any exemption as to amount or volume of skin or other pathological waste removed.
- 16.9. **CR** In accordance with Part 138, Section 13811(c), pathological waste shall be disposed of by one or more of the following methods only:
 - 16.9.1. Incineration or cremation.
 - 16.9.2. Grinding and flushing into a sanitary sewer.
 - 16.9.3. Burial in a cemetery, if transported in leak-proof containers of sufficient integrity to prevent rupture.
 - 16.9.4. Grinding until rendered unrecognizable, stored in closed, puncture-resistant, properly labeled containers, and, if not in liquid form, disposed of in a sanitary landfill.
 - 16.9.5. Alternative methods of treatment that are currently approved are found on the MDEQ website www.michigan.gov/deqmedwaste. The document link is entitled, “Approved Alternative Treatment Technologies for Medical Waste”.
- 16.10. **CR** A Body Art Facility that produces and does not incinerate medical waste on site shall do all of the following to contain medical waste:
 - 16.10.1 Package, contain, and locate medical waste in a manner that protects and prevents the medical waste from release at the producing facility or at any time before ultimate disposal.
 - 16.10.2 Separate the categories of medical waste at the point of origin into appropriate containers that are labeled as required under subdivision 16.9.5.

- 16.10.3 Label the container required under subdivision 16.9 with a biohazard symbol or the words “medical waste” or “pathological waste” in letters not less than one inch high.
- 16.10.4 Not compact or mix medical waste with other waste materials before decontamination, incineration, and disposal.

17. Section Seventeen: Facility Requirements

- 17.1. All body art facilities shall be completely separated by walls extending from floor to ceiling, from any room used for human habitation, non-body art activities or any activity that may cause potential contamination of work procedure surfaces. Any doors between these rooms or areas must remain closed unless entering/exiting the facility, room or area.
- 17.2. The body art facility shall have self-closing doors and windows equipped with screens in good repair if the windows are intended to be used for ventilation.
- 17.3. Body art procedure areas shall be separated from the customer waiting area/retail area by a panel or wall at least four feet high.
- 17.4. There shall be a minimum of 45 square feet of floor space for each body art technician’s body art procedure area in the facility.
- 17.5. All walls and floors of a body art facility shall be smooth, free of open holes or cracks, washable and in good repair. Walls, floors and ceilings shall be maintained in a clean condition. Carpeting is allowed in the waiting area if waiting area is totally separate and not directly adjacent to procedure areas. Carpeting is not allowed in aisles between adjacent procedure areas.
- 17.6. All procedure surfaces in the body art procedure area, including client chairs, tables, benches, and counters shall be smooth, free of open holes or cracks, washable and in good repair. All procedure surfaces, including client chairs, tables, benches, and counters shall be of such construction as to be easily cleaned and disinfected after each use/between clients.
- 17.7. The facility shall be well-ventilated and provided with an artificial light source equivalent to at least 20-foot candles three feet off the floor, except that 100-foot candles shall be provided at the level where the body art procedures are being performed, and where instruments and sharps are handled/assembled. Spot lighting may be utilized to achieve this required degree of illumination for the purpose of conducting body art procedures. Fluorescent tube lighting over a procedure area shall be protected from accidental breakage during a procedure by an appropriate covering.
- 17.8. **CR** A separate, hand washing sink designated for staff use only with warm running water under pressure preferably equipped with wrist or foot-operated controls and supplied with liquid soap and disposable paper towels shall be readily accessible to the body art technicians. There shall be a covered waste receptacle by each sink for the disposal of paper towels. One hand sink shall serve no more than three body art technicians.

- 17.9. **CR** There shall be a minimum of one lavatory with a toilet and a separate sink in a body art facility.
- 17.10. **CR** A body art facility shall have a separate room or area for the sole purpose of cleaning, disinfecting and sterilizing contaminated tools and equipment. This area shall be separated from the remainder of the facility by a minimum of a wall or partition and shall be an area that does not allow client access. The cleaning, disinfecting, and sterilizing area shall be organized to prevent cross-contamination of clean, disinfected or sterile equipment with dirty equipment.
- 17.11. **CR** All sinks in the body art facility shall only be used for their designated purpose.
- 17.12. All chemical or cleaning supply containers shall be properly labeled.
- 17.13. **CR** At least one covered waste receptacle shall be provided in each body art procedure area and each toilet room. Waste receptacles in the body art procedure area(s) shall be emptied daily and solid waste shall be removed from the premises at least weekly. All waste receptacles shall be cleanable and kept clean, and capable of being disinfected.
- 17.14. **CR** Sharps disposal containers shall be made available at places as close as feasibly possible to any area where needles and sharps are used.
- 17.14.1. These containers must be hard, puncture-resistant, leak-proof containers specifically designed for the storage of contaminated sharps.
- 17.14.2. They must be labeled with the universal biohazard symbol or color-coded.
- 17.14.3. They must be maintained in an upright position and replaced to avoid over-filling.
- 17.14.4. When moving sharps containers, the containers must be closed. If leakage is possible, they must be placed in a second container that will contain all contents, prevent leakage, and be labeled with the universal biohazard symbol or be color-coded.
- 17.14.5. Sharps containers must be changed, at a minimum, 90 days after the date of first use.
- 17.15. **CR** No animals of any kind shall be allowed in the body art facility except service animals used by persons with disabilities (e.g., seeing-eye dogs). Fish aquariums shall be allowed in waiting rooms and non-procedural areas.
- 17.16. **CR** Effective measures shall be taken by the owner or operator of the body art facility to protect against entrance into the facility and against the breeding or presence on the premises of insects, vermin, and rodents. Insects, vermin, and rodents shall not be present in any parts of the facility.
- 17.17. For new body art facilities and for body art facilities undergoing renovation, an 8 ½ X 11 or larger scale drawing and floor plan of the proposed facility or the proposed renovation of the facility shall be submitted to the local health department responsible for body art facility inspection for the jurisdiction in which the body art facility will be/is located. This drawing shall show the accurate placement of each of the following items: walls, windows, doors, waiting area, procedure area(s),

bathroom(s), cleaning, disinfection, and sterilization area, equipment/instrument storage area(s) chairs, tables, and sinks. This scale drawing and floor plan shall be submitted at least 60 days before the proposed opening/planned renovation. **A pre-opening inspection of the premises will be required before body art services can be performed in this new facility/renovated area. Approval of the site plan shall be granted by the local health department prior to construction or renovation of the body art facility.**

17.18. *Requirements for Body Art Facilities* does not relieve the owner/operator of a licensed body art facility from the responsibility for securing a local permit or complying with applicable local codes, regulations or ordinances that are in addition to the *Requirements for Body Art Facilities*.

17.18.1. Water supply; plumbing.

17.18.1.1. The water system shall comply with the requirements of the local health authority.

17.18.1.2. **CR** Plumbing shall be designed, constructed, installed, and maintained to prevent cross-connection with the water system.

17.18.1.3. **CR** Sinks, lavatories, drinking fountains, and other water outlets shall be supplied with safe water, sufficient in quantity and pressure, to meet conditions of peak demand.

17.18.2. Sewage disposal.

17.18.2.1. Sewage and other water-carried wastes shall be disposed of through a municipal or private sewer system.

17.18.2.2. Private sewer/septic systems shall be designed and operated to safely dispose of all wastewater generated, shall be adequate in size for the projected use and meet the criteria of the local health department.

18. Section Eighteen: Body Art Facility Applications and Inspection.

18.1. Upon submission of an application with fee payment for a State of Michigan body art facility license, the applicant will receive a receipt of payment for the licensing fee from the on-line application process or their cancelled check notification if application is mailed. The local health department that is responsible for conducting inspections in the jurisdiction in which the body art facility is located shall be notified by the Department of this completed application by an automated application inspection request e-mail.

18.2. The local health department shall use the application inspection e-mail request sent by the Department to schedule a body art facility inspection.

18.3. A site plan submission by the applicant to the local health department and a Pre-Opening inspection by the local health department representative responsible for the jurisdiction in which the body art facility is located are needed for a new or a newly remodeled licensed body art facility.

- 18.4. A detailed site plan will be reviewed by the local health department to determine whether the body art facility is in compliance with the facility requirements found in Section 16 of the *Requirements for Body Art Facilities*.
- 18.5. A detailed site plan is also required before any remodeling changes are made to an existing State of Michigan licensed Body Art Facility.
- 18.6. After a satisfactory Pre-Opening inspection, the local health department may allow the body art facility to begin offering body art procedures to customers provided the body art facility has applied for State of Michigan licensure.
- 18.7. The inspection of a body art facility shall document whether or not the body art facility has met the requirements as detailed in the *Requirements for Body Art Facilities* and whether or not the facility should be licensed. This determination shall be noted on the inspection report form completed by the local health department and a copy of this signed and dated documentation shall be given to the owner or operator at the end of the inspection. A signed copy of a compliant MDHHS Inspection Report Form can be posted temporarily in lieu of an issued state license.
- 18.8. The Body Art Facility Inspection Report shall delineate inspection items that are critical and/or non-critical violations. If critical or non-critical violations are identified, they will be marked on the form and remedies for correction shall be noted in the comment section of the inspection form.
- 18.9. Violations noted on the inspection report may require a re-inspection by the local health department to assure corrective action has been taken. If a re-inspection is needed, the time frame for the follow up inspection shall be noted in the comment section of the inspection report form.
- 18.10. The local health department or its representative shall report back to the Department the status of new annual license inspection or an annual renewal license inspection as either compliant or non-compliant and whether or not licensure is recommended by use of the on-line reporting process.
- 18.11. The notification of a licensing inspection report shall be sent to the Department as soon as possible but no longer than 30 working days after the inspection was completed.
- 18.12. The Department shall send to the body art facility applicant a printed State of Michigan Body Art Facility license once the local health department has notified the Department of a compliant licensing inspection. This State of Michigan Body Art Facility license will be effective for the calendar year of the body art facility application and will be posted in the body art facility. The license will be issued to a specific person at a specific location and is nontransferable as per P.A. 375.
- 18.13. Those State of Michigan Body Art Facility licenses that were issued with a three-year expiration date per P.A. 169 are no longer considered valid as of 01/01/2013.
- 18.14. When submission for the renewal of a body art license application and licensing fee for a body art facility is received by the Department, the Department shall notify the local health department responsible for the jurisdiction in which the facility is

located. The Department shall notify license holders that their license is due for renewal by mail and email provided a facility email address is submitted.

18.14.1. This renewal application and license fee shall be submitted on or by December 1st. Failure to do so will result in a late fee as per P.A. 375.

18.14.2. The Department shall issue a renewal license to the body art facility provided the facility has had a satisfactory inspection done within the prior 12 months. This renewal license will be issued to a specific person at a specific location and is nontransferable as per P.A. 375.

18.14.3. The local health department shall submit a compliant inspection report for the licensed facility before Dec 1st of the next renewal cycle.

18.15. An applicant or licensee shall give the local health department access to the body art facility and all of its books and records during all hours of operation and during other reasonable hours to allow the local health department to determine if the body art facility is in compliance with PA 375. An inspection of a body art facility may be announced or unannounced.

18.16. An applicant or licensee shall not do any of the following:

18.16.1. Refuse to permit the local health department to enter or inspect a body art facility.

18.16.2. Refuse to produce the body art facility's books and records for inspection.

18.16.3. Any other activity that impedes the local health department's ability to carry out its duties prescribed in PA 375.

18.17. As part of an inspection under PA 375, the local health department may examine, take photographs, or make copies of the books and records of either a permanent or temporary body art facility.

19. Section Nineteen: Temporary Facility Permits/Requirements for Owners/Operators of Body Art Facilities

19.1. A temporary body art facility license is for the provision of tattooing, branding, or body piercing at a fixed location effective for not more than 14 consecutive days and expires at 12 midnight on the date prescribed on the temporary license application. This license also applies to out-of-state body art facilities seeking to offer services within the State of Michigan.

19.2. Temporary body art facility licenses are designated as affiliated or non-affiliated temporary body art licenses. (See definitions Section 3.1.49)

19.3. Applications for temporary body art facility licenses shall be received not less than 30 days before the first day on which tattooing, branding, or body art services will be provided at the temporary location.

19.4. At the time of the application, the owner or operator or other applicant shall pay to the Department the designated fee for a temporary body art facility license. An

inspection e-mail request will then be automatically sent to the local health department of jurisdiction.

- 19.4.1. In the case of an affiliated temporary body art facility, both the county where the permanent body art facility is located and the county of the temporary body art facility location will receive an e-mail inspection request.
- 19.5. The temporary body art facility, affiliated or non-affiliated, must be contained in a completely enclosed structure protected from wind, dust or outdoor elements.
 - 19.5.1. An owner or operator may have more than one technician working under the temporary license if there is a single set-up where individual procedures areas are adjacent or contiguous with one another.
 - 19.5.2. If there are multiple set up sites at the event that are not adjacent or contiguous with one another, the owner or operator must apply for a separate temporary license for each distinct artist space.
 - 19.5.3. If the event is one in which an individual body art facility owner or operator secures a distinct artist space in a temporary location (e.g. convention, expo, trade show, hall, event center) to perform body art procedures, then each owner or operator must obtain their own individual temporary body art facility license for each distinct artist space.
- 19.6. Affiliated temporary body art facility licenses are issued if the applicant is the owner or operator of a Michigan-licensed body art facility operating at a fixed or permanent location. The body art facility at that fixed or permanent location must have been inspected by the local health department responsible for body art facility inspection for the jurisdiction in which the body art facility is located, within the last 12 months. The results of that inspection must have documented compliance with the requirements delineated in the *Requirements for Body Art Facilities* document.
- 19.7. The affiliated temporary body art facility shall be in compliance with the requirements delineated in the *Requirements for Body Art Facilities*. However, the following adaptations are allowed for requirements related to hand washing, facility size, lighting, and sterilization of equipment.
 - 19.7.1. **CR** Hand washing facility requirements: Conveniently located hand-washing facilities with running water, supplied with liquid soap and disposable paper towels. Sink drainage must be in accordance with local plumbing codes.
 - 19.7.2. A minimum of 80 square feet of floor space.
 - 19.7.3. At least 100-foot candles of light at the level where the body art procedure is to be performed and where instruments and sharps are assembled. Spot lighting may be used to achieve this required degree of illumination for the purpose of conducting body art procedures.
 - 19.7.4. **CR** If reusable instruments are sterilized on site, there must be documentation that a spore test was performed on the steam sterilizer or

dry heat sterilizer 30 days or less before the first date that the temporary license will be in effect.

19.7.5. Acceptable alternatives to on-site sterilization include:

19.7.5.1. Only single-use, prepackaged, sterilized equipment shall be used.

19.7.5.2. **CR** Transport contaminated reusable instruments back to a licensed body art facility at a fixed or permanent location in a container that has a secure lid, is leak-proof on the sides and bottom is labeled and/or color-coded, and that it may contain liquid blood or OPIM.

19.7.5.3. Sharps containers may be transported to an accepting medical waste treatment facility per U.S. Department of Transportation Materials of Trade Exemptions guidelines. (See *Appendix E.*)

19.8. The site at which body art services will be provided under this temporary body art facility license must be inspected by the local health department responsible for body art facility inspection for the jurisdiction in which the temporary body art facility is located. Inspection of temporary body art will focus on the physical set-up and operation of the temporary facility.

19.8.1. Inspection of temporary body art facilities affiliated with a licensed permanent facility at a fixed location will not require the owner or operator to produce evidence of compliance with certain other requirements that have already been documented as part of the licensing or annual inspection of the permanent facility at a fixed location; these include employee vaccination status, employee training, and record-keeping.

19.8.2. Applicants applying for a temporary body art facility license that are not affiliated with a Michigan-licensed, permanent fixed facility, shall also undergo an inspection by the local health department who has jurisdiction for the location of the temporary license and are considered a non-affiliated temporary body art facility.

19.8.3. **CR** In addition to the inspection of the physical set-up and operation the non-affiliated temporary facility must provide evidence of compliance with all of the requirements delineated in the Requirements for Body Art Facilities. This includes but is not limited to documentation of employee vaccination status, employee training, client/employee record keeping, and spore testing.

19.9. If the local health department that has jurisdiction for the on-site inspection of an affiliated or non-affiliated temporary license documents compliance to the *Requirements for Body Art Procedures* document, the Department will grant a license to the applicant for the operation of a temporary body art facility. A body art facility inspection report form approved, dated and signed by the representative of

the local health department which has jurisdiction for the inspection shall be posted on site in lieu of a formalized Department license.

- 19.9.1. The temporary body art facility license, as well as the Department-provided Disclosure Statement and Notice for Filing Complaints shall be posted in a prominent and conspicuous place within the temporary body art facility where it may be readily seen by all clients.
- 19.9.2. Temporary facilities not found in compliance to the Requirements for Body Art Facilities shall be considered for remedial actions described in Chapter 20 of the Requirements for Body Art Facilities.

20. Section Twenty: Enforcement

- 20.1. An owner or operator of a body art facility shall not oppose or obstruct a local health department representative, health officer, or any other person charged with enforcement of a health law or in the performance of that person's legal duty to inspect a body art facility. Section 1291 of 2007 PA 375; MCL 333.1291.
- 20.2. The body art facility owner, operator or person in charge shall allow a local health department inspector or representative of a local health department to enter the body art facility, upon presentation of proper identification, at a reasonable time to conduct an inspection of the body art facility in order to ensure that the body art facility is in compliance with requirements of the Act.
- 20.3. Violations of the *Requirements for Body Art Facilities* shall be cited on the inspection report by the local health department for the jurisdiction in which the body art facility is located. The inspection report shall delineate **critical** and/or **non-critical violations**. **Non-critical** violations must be corrected by the next regular inspection or such period of time as may be specified. If the violations are considered as **critical** then those violations must be corrected immediately, or a follow up inspection will be scheduled.
- 20.4. Critical violations, if not corrected in the time specified, may lead to closure, suspension and/or revocation of the body art facility license as an imminent danger.
 - 20.4.1. If the local health department determines that the continued operation of a body art facility is an imminent danger, the local health department shall order the immediate cessation of the operation of that facility in the manner prescribed in PA 375. A body art facility ordered to cease operations shall immediately cease operations and shall not resume operations until the local health department has conducted an inspection, has determined the operation of the body art facility is no longer an imminent danger, and has issued an order allowing the body art facility to resume operations.
 - 20.4.2. At any time it determines appropriate, a local health department may place limitations on the license of a body art facility, which limitations include the imposition of restrictions or conditions or both, on the operations of that body art facility. A body art facility shall comply with all license limitations under the Act until the local health department has conducted

and inspection, has determined that the license limitations are no longer necessary, and has issued an order allowing the body art facility to resume operations without the license limitations.

- 20.4.3. The owner or operator may appeal an order to cease operation in writing to the local health department that recommended the cessation. The appeal letter will ask for a re-determination and request a follow up inspection by the local health department.
 - 20.4.4. If the local health department denies the appeal re-determination based on a follow up inspection, the owner or operator may ask in writing for an administrative hearing.
 - 20.4.5. Upon receipt of a letter from a body art facility requesting an administrative hearing regarding suspension of licensure, the local health department shall schedule a date and time for an administrative hearing and notify the Department.
 - 20.4.6. In addition to enforcement action authorized by law, a civil action in a court of competent jurisdiction may be brought for injunctive relief.
- 20.5. Complaints concerning an unlicensed or licensed body art facility submitted to the Department shall be referred to the local health department that has jurisdiction for the complaint as per P.A. 375.

21. Section Twenty One: Legal Penalties

- 21.1. A person, who violates PA375 or a rule promulgated under the Act, is guilty of a misdemeanor punishable by imprisonment for not more than 93 days or a fine of not more than \$2,500, or both for each violation.
- 21.2. A person who violates this part or a rule promulgated under PA 375 is liable in a civil action for actual damages or \$1,000, whichever is greater, plus reasonable court costs, attorney fees, and any other fines, fees, or claims for reimbursement as determined by the court or the Department.
- 21.3. **CR** A person shall not give or sell to a minor a tattooing, branding, or body-piercing kit or other body piercing devices. A person who violates PA 375 is responsible for a state civil fine of not more than \$500.00.

22. Section Twenty Two: Exemptions.

- 22.1. State of Michigan licensed physicians (M.D. or D.O.) or dentists who utilize body art procedures as part of patient treatment, as well as other licensed health care professionals working in the same office/health care facility as that physician or dentist, and are under the direct supervision of that physician, are exempt from PA 375. Documentation of direct supervision for exemption would contain at a minimum a letter from the physician on the physician's letterhead with the physician's license number to practice medicine and other cosmetic procedure certifications that may apply.

22.2. Facilities and individuals that only provide ear piercing services are exempt from PA 375.

23. Section Twenty Three: Supplemental References

- 23.1. A local governing entity of a local health department authorized to enforce PA 375 may adopt and enforce local codes, ordinances or regulations that are more stringent than the minimum applicable standards set forth in this Act, rules promulgated under this Act or any safety standards or other requirements issued by the department applicable to body art facilities. This Act shall not relieve the applicant or licensee from the responsibility for securing a local permit or complying with applicable local codes, regulations, or ordinances that are in addition to this Act.
- 23.2. A local governing entity of a local health department authorized to enforce PA 375 may fix and require the payment of fees by applicants and licensees for services required to be performed by the local health department.
- 23.3. Variances to requirements can be issued by the local health department if the local health department determines that the variance will not create or increase the potential for a health hazard or nuisance.
- 23.4. The applicant or licensee shall request the variance in writing. The writing shall include all of the following:
- 23.4.1. A statement of the proposed variance and a citation to the requirement for this the variance is requested.
 - 23.4.2. An analysis of the rationale for the variance.
 - 23.4.3. A written description of the alternative methods the applicant or licensee will utilize to ensure that the variance will not create or increase the potential for any health hazard or nuisance.
 - 23.4.4. A variance granted shall be in writing and shall be maintained in the records of the local health department for that body art facility.
- 23.5. Lasers are recognized by the U.S. Food and Drug Administration (FDA) as medical devices. Laser tattoo removal is regulated by the Michigan Department of Licensing and Regulatory Affairs (LARA) and not through the *MDHHS Requirements for Body Art Facilities*. Inquiries should be referred to the Medical Allegations number at 517-373-9196 or primary investigator at 517-373-7079. (See Appendix A.)

APPENDIX A

Use of Laser Equipment by Health Professionals

Position Statement of the Michigan Department of Health and Human Services

Lasers are recognized by the U.S. Food and Drug Administration (FDA) as medical devices. Their use constitutes a medical or dental practice, as further explained below.

Laser use falls within the definition of the practice of medicine in the Public Health Code because they are used for the “diagnosis, treatment, prevention, cure, or relieving of a human disease, ailment, defect, complaint, or other physical or mental condition by attendance, advice, device, diagnostic test, or other means.”

A thorough review of the laser literature, Public Health Code provisions and applicable FDA guidelines shows that dentists may also use FDA-approved lasers for patient care within the scope of their licensure.

The FDA has not approved the use of lasers for smoking cessation. While the FDA has granted investigational device exemptions for some lasers for use in smoking cessation, this is restricted to FDA-approved clinical trials.

A physician/dentist may delegate the use of laser equipment to a licensed or unlicensed individual if the delegated individual works under the physician/dentist’s supervision. In this context, supervision, as defined by the Public Health Code, requires at least all of the following:

- Acknowledgment by the physician/dentist that the delegated individual has the appropriate education, training or experience to properly use lasers.
- Continuous availability of direct communication in person, or by radio, telephone or other telecommunication, between the physician/dentist and the delegated individual.
- Regularly scheduled availability of the physician/dentist to consult, educate, and review the records and practice of the delegated individual in laser use.
- Development by the physician/dentist of written procedures and protocols to guide the delegated individual’s laser use.

Physician/dentists must adhere to these supervision requirements. As the delegated individual works under the authority of a license, the licensed physician/dentist is ultimately responsible for the outcome of the tasks and duties performed by the delegated individual. 12/5/05

APPENDIX B:

FROM THE ASSOCIATION OF PROFESSIONAL PIERCERS:

The revised Minimum Standard for Jewelry for Initial Piercings is as follows:

Steel that is ASTM F-138 compliant or ISO 5832-1 compliant

Steel that is ISO 10993-6, 10993-10, and/or 10993-11 compliant (EEC Nickel Directive compliant (Note: EEC compliance alone is not acceptable))

Titanium (Ti6Al4V ELI) that is ASTM F136 compliant or ISO 5832-3 compliant

Titanium that is ASTM F-67 compliant

Solid 14 karat or higher nickel-free white or yellow gold

Solid nickel-free platinum alloy

Niobium (Nb)

Fused quartz glass, lead-free borosilicate or lead-free soda-lime glass

Polymers (plastics) as follows:

Tygon® Medical Surgical Tubing S-50HL or S-54HL

Polytetrafluoroethylene (PTFE) that is ASTM F754-00 compliant

Any plastic material that is ISO 10993-6, 10993-10 and/or 10993-11 compliant and/or meets the United States Pharmacopeia (USP) Class VI material classification.

All threaded or press-fit jewelry must have internal tapping (no threads on posts).

- For body jewelry purposes, surfaces and ends must be smooth, free of nicks, scratches, burrs, polishing compounds and metals must have a consistent mirror finish.
- ASTM Standard F67, 2006, "Specification for Unalloyed Titanium, for Surgical Implant Applications," ASTM International, West Conshohocken, PA, 2003, DOI: 10.1520/C0033-03, www.astm.org/Standards/F67.htm
- ASTM Standard F136, 2001, "Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications," ASTM International, West Conshohocken, PA, 2003, DOI: 10.1520/C0033-03, www.astm.org/Standards/F136.htm
- ASTM Standard F138, 2008, "Specification for Wrought 18Chromium-14Nickel-2.5Molybdenum Stainless Steel Bar and Wire for Surgical Implants," ASTM International, West Conshohocken, PA, 2003, DOI: 10.1520/C0033-03, www.astm.org/Standards/F138.htm.

APPENDIX C:



S.C. Johnson & Son, Inc.
1525 Howe Street
Racine, WI 53403-2236
262.260.2000

February 4, 2008

Mr. David Vidra
CLPN, MA
Health Educators Inc.
1508 Rockway Ave
Lakewood, OH 44107-3421

Dear David,

Thank you for the opportunity to provide accurate usage information on Saran™ Brand Plastic Wraps. SC Johnson's Saran™ products are protective food wraps designed for refrigeration, freezing, and microwaving.

Please keep in mind that we design, formulate and test every product for specific household tasks. That is why we always recommend using our products according to their label directions and for their intended use.

Saran™ Brand Plastic Wraps are not approved for use as a medical device, blood barrier device, or a dressing. SC Johnson does not support, nor recommend our plastic wraps for this use.

If we can ever be of further assistance to you, feel free to contact us again.

Sincerely,

A handwritten signature in cursive script, appearing to read 'Judy'.

Judy K. Kehlstrom
Senior Consumer Representative
Consumer Relationship Center

Reference number: 013588369C

APPENDIX D:



COLGATE-PALMOLIVE COMPANY
A Delaware Corporation

300 Park Avenue
New York, NY 10022
Telephone 800-221-4607

U.S. Consumer Affairs Department

November 27, 2007

Mr David Vidra
1508 Rockway Ave
Lakewood, OH 44107-3421

Dear Mr Vidra:

Thank you for your recent inquiry about Murphy Oil Soap Liquid Cleaner. We appreciate your interest in our company and are pleased to have the opportunity to respond.

Our company tests all of its products extensively to be sure they provide consumer satisfaction when used for the purposes described on the label. Sometimes, consumers report that they have had good results using a product in other situations or ask if a product can be used in an alternate way. However, we can only recommend that our products be used as tested and described on the label.

We appreciate your taking the time to contact us. Please accept the enclosed with our compliments.

Sincerely,

Yvonne Bootbauer
Consumer Affairs Representative
Consumer Affairs

AFYFB1NA/WTI

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APPENDIX E:

Department of Transportation: § 173.6 Materials of trade exceptions.

When transported by motor vehicle in conformance with this section, a material of trade (see §171.8 of this subchapter) is not subject to any other requirements of this subchapter besides those set forth or referenced in this section.

- (a) Materials and amounts. A material of trade is limited to the following:
- (1) A Class 3, 8, 9, Division 4.1, 5.1, 5.2, 6.1, or ORM-D material contained in a packaging having a gross mass or capacity not over-
 - (2) A Division 2.1 or 2.2 material in a cylinder with a gross weight not over 100 kg (220 pounds), or a permanently mounted tank manufactured to the ASME Code of not more than 70 gallon water capacity for a non-liquefied Division 2.2 material with no subsidiary hazard.
 - (3) A Division 4.3 material in Packing Group II or III contained in a packaging having a gross capacity not exceeding 30 mL (1 ounce).
 - (4) A Division 6.2 material, other than a Category A infectious substance, contained in human or animal samples (including, but not limited to, secreta, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for research, diagnosis, investigational activities, or disease treatment or prevention, or is a biological product or regulated medical waste. The material must be contained in a combination packaging. For liquids, the inner packaging must be leak proof, and the outer packaging must contain sufficient absorbent material to absorb the entire contents of the inner packaging. For sharps, the inner packaging (sharps container) must be constructed of a rigid material resistant to punctures and securely closed to prevent leaks or punctures, and the outer packaging must be securely closed to prevent leaks or punctures. For solids, liquids, and sharps, the outer packaging must be a strong, tight packaging securely closed and secured against shifting, including relative motion between packages, within the vehicle on which it is being transported.
 - (i) For other than a regulated medical waste, the amount of Division 6.2 material in a combination packaging must conform to the following limitations:
 - (A) One or more inner packagings, each of which may not contain more than 0.5 kg (1.1 lbs) or 0.5 L (17 ounces), and an outer packaging containing not more than 4 kg (8.8 lbs) or 4 L (1 gallon); or
 - (B) A single inner packaging containing not more than 16 kg (35.2 lbs) or 16 L (4.2 gallons) in a single outer packaging.
 - (ii) For a regulated medical waste, a combination packaging must consist of one or more inner packagings, each of which may not contain more than 4 kg (8.8 lbs) or 4 L (1 gallon), and an outer packaging containing not more than 16 kg (35.2 lbs) or 16 L (4.2 gallons).
 - (5) This section does not apply to a hazardous material that is self-reactive (see §173.124), poisonous by inhalation (see §173.133), or a hazardous waste.
- (b) Packaging.
- (1) Packaging must be leak tight for liquids and gases, sift proof for solids, and be securely closed, secured against shifting, and protected against damage.

- (2) Each material must be packaged in the manufacturer's original packaging, **or a packaging of equal or greater strength and integrity.**
 - (3) Outer packagings are not required for receptacles (e.g., cans and bottles) that are secured against shifting in cages, carts, bins, boxes or compartments.
 - (4) For gasoline, a packaging must be made of metal or plastic and conform to the requirements of this subchapter or to the requirements of the Occupational Safety and Health Administration of the Department of Labor contained in 29 CFR 1910.106(d)(2) or 1926.152(a)(1).
 - (5) A cylinder or other pressure vessel containing a Division 2.1 or 2.2 material must conform to packaging, qualification, maintenance, and use requirements of this subchapter, except that outer packagings are not required. Manifolding of cylinders is authorized provided all valves are tightly closed.
- (c) Hazard communication.
- (1) A non-bulk packaging other than a cylinder (including a receptacle transported without an outer packaging) must be marked with a common name or proper shipping name to identify the material it contains, including the letters "RQ" if it contains a reportable quantity of a hazardous substance.
 - (2) A bulk packaging containing a diluted mixture of a Class 9 material must be marked on two opposing sides with the four-digit identification number of the material. The identification number must be displayed on placards, orange panels or, alternatively, a white square-on-point configuration having the same outside dimensions as a placard (at least 273 mm (10.8 inches) on a side), in the manner specified in §172.332 (b) and (c) of this subchapter.
 - (3) A DOT specification cylinder (except DOT specification 39) must be marked and labeled as prescribed in this subchapter. Each DOT-39 cylinder must display the markings specified in 178.65(i).
 - (4) The operator of a motor vehicle that contains a material of trade must be informed of the presence of the hazardous material (including whether the package contains a reportable quantity) and must be informed of the requirements of this section.
- (d) Aggregate gross weight. Except for a material of trade authorized by paragraph (a) (1) (iii) of this section, the aggregate gross weight of all materials of trade on a motor vehicle may not exceed 200 kg (440 pounds).
- (e) Other exceptions. A material of trade may be transported on a motor vehicle under the provisions of this section with other hazardous materials without affecting its eligibility for exceptions provided by this section.

Sgt. Susan M. Fries
Michigan State Police
Traffic Safety Division, Hazardous Materials & Investigations Unit
333 S. Grand Ave.
PO Box 30634
Lansing, MI. 48909-0634
517-241-0583

APPENDIX F:

Recommendation for Equipment Processing:

Proper order of operations for equipment processing protocol are as follows:

- a) Pre-cleaning with an enzymatic cleaner
- b) Cleaning (scrubbing)
- c) Disinfection
- d) Ultrasonic Cleaning
- e) Thoroughly drying
- f) Packaging w/ internal indicators
- g) Loading equipment into autoclave along with a pass/fail integrator.
- h) Running autoclave
- i) Removing sterile equipment from autoclave and placing it into temporary storage transport container
- j) Transporting sterile equipment to work area for storage

APPENDIX G:

Recommendation: The Society of Permanent Cosmetic Professionals Guidelines for Permanent Makeup Anesthetics

SPCP Guidelines
September 2007

Anesthetics sold by supplier members or vendors cannot be prepared by compounding pharmacies, but rather must be sold to the supplier member or vendor by FDA Manufacturers.

Explanation:

Whenever a pharmacy compounds a formula, even at over-the-counter levels, it is considered a prescription drug and cannot be dispensed without a prescription. Also, compounding pharmacies do not fall under FDA scrutiny. This lack of scrutiny has been linked to two deaths and resulted in FDA Public Advisories.

Please read the following advisories for more information.

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm054718.htm>

<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/PublicHealthAdvisories/ucm110625.htm>

Appendix H:

MDHHS Requirements for Body Art Facilities Workgroup Members. Body Art Work Group (Alphabetical Order) March 24, 2017

Jonathon Anderson
Serenity Tattoo
Fort Gratiot, MI 48058
Phone: 810-385-2222 or 810-357-5460
Email: jonathonanderson1983@gmail.com

Paul Barry, R.S.
Department Manager 2
Wayne County Environmental Health Section
5454 S. Venoy, Wayne, MI 48184
Phone: 734-727-7200
Fax: 734-727-7165
Email: pbarry@waynecounty.com

Jacqueline Beach, Owner
Tattoos by Jacqueline
1018 Ludington Street
Escanaba, MI 49829
Phone: 906-553-5199
Email: jackbeach@hotmail.com

Rebecca A. Burns, R.S.
Environmental Health Director
Branch-Hillsdale-St. Joseph Community Health Agency
1110 Hill Street
Three Rivers, MI 49093
Phone: 269-273-2161 ext. 228
Fax: 269-273-2452
Email: burnsr@bhsj.org

Ashley Castello
St. Clair County Health Department
3415 28th Street
Port Huron, MI 48060
Phone: (810) 987-5306
Email: acastello@hd.stclaircounty.org

DeAnne Derney
DeAnne's LA Permanent Makeup, LLC
48697 Hayes Road
Shelby Township, MI 48315
Phone: (586) 405-6306
Email: DeAnneAgar@comcast.net

Dawn D. Dotson RN, MPH, BSN
Ottawa County Department of Public Health
Maternal Infant Health Program Supervisor
Phone: (616) 393-5758
Mobile/Text: (616) 393-5620

Anthony Drautz, R.S., M.S.A.
Administrator - Environmental Health Services
Oakland County Health Division
North Oakland Health Center
1200 North Telegraph Road 34E
Pontiac, Michigan 48341-0432
Phone: 248- 858- 1320
Fax: 248- 858- 5428
Email: drautzto@oakgov.com

Seth Duimstra
Cloverland Tattoo Company
2108 Wildwood Avenue
Jackson, MI 49202
Phone: 517-962-2364
Email: cloverlandtattooco@gmail.com

Christopher Gonyou
DBA Aurora Piercing Boutique
110 N. Third Street
Marquette, MI 49855
Phone: 906-273-1769
Email: xchrisxpiercerx@live.com
[Facebook.com/christhepiercer](https://www.facebook.com/christhepiercer)

Andrea Gross
Pangea Piercing
211 E. Liberty St.
Ann Arbor, MI 48104
Phone: (734) 997-0608
Email: andrea@pangeapiercing.com
Web: www.pangeapiercing.com

Martha Hall
Environmental Health Director
Lenawee County Health Department
1040 S. Winter Street
Adrian, MI 49221
Phone: 517.264.5222

Cell: 517.673.4916
FAX: 517.264.0790
Email: mhall@hline.org

Dawn Dotson, RN
Ottawa County Health Department
12251 James Street, Suite 400
Holland, Michigan 49424
Phone: 616-393-5758
ddotson@miottawa.org

Zack June – Owner and Piercer
Kitten Flower Boutique
1501 Lake Drive S.E.
Grand Rapids, MI 49506-2753
Phone: (616) 323-3254
Email: kittenflowerboutique@gmail.com

Michael Kucab, REHS/RS, M.P.H.
Body Art Facility Licensing
HIV/STD/VH/TB/BE Epidemiology Section
Michigan Department of Health and Human Services
Capitol View Building
333 S. Grand Ave.
Lansing, MI 48933
Phone: 517-335-8165
Fax: 517-335-8121
Email: kucabm@michigan.gov

Kris Lachance, Owner
Splash of Color Tattoo and Piercing Studio
515 E. Grand River Avenue, Suite F
East Lansing, MI 48823
Phone: 517-333-0990
Fax: 517-336-5497
Cell: 517-281-7959
Email: Kris.Lachance@gmail.com

Cindy Merritt
Environmental Health Sanitarian II
Lenawee County Health Department
1040 S. Winter Street
Adrian, MI 49221
Phone: 517.264.5221
Fax: 517.264.0790
Email: cmerritt@hline.org

Tina Moore
Environmental Sanitarian
Genesee County Health Department
630 S. Saginaw Street
Flint, MI 48502-1540
Main: 810-257-3603
Direct: 810-257-3130
Fax: 810-257-3125
Email: tmoore@gchd.us

Angela Parsons, MA
Environmental Educator
Washtenaw County Department of Public Health
Environmental Health Division
705 N. Zeeb Rd., P.O. Box 8645
Ann Arbor, MI 48107-8645
Phone: (734) 222-3869 - Office
(734) 320-0094 - Cell
(734) 222-3920 - Fax
Email: parsonsa@ewashtenaw.org

Christopher Reich
Forever Ink Tattoos
666 ½ Leonard
Grand Rapids, MI 49504
Phone: (616) 451-9644
Email: foreverink.tattoos@yahoo.com

Tom Reichard
Environmental Health Director
District Health Department #10
521 Cobb St.
Cadillac, MI 49601
Phone: 231-876-3820
Fax: 231-775-5372
Email: treichard@dhd10.org

Debra Robins, Owner
Enhance by Debra
36880 Woodward Avenue, Suite 101B
Bloomfield Hills, MI 48304
Phone: 248-593-5555
Email: enhancebydebra@yahoo.com

Laura M. Riddell
Environmental Health Supervisor
Oakland County Health Division
1200 N. Telegraph Rd., Bldg. 34
Pontiac, MI 48341
Phone: 248-858-1322
Fax: 248-452-5193
Email: riddelll@oakgov.com

Steve Schmidt
Macomb County Health Department
43525 Elizabeth Road
Mt. Clemens, Michigan 48043
Phone: (586) 569-5236
Email: steve.schmidt@macombgov.org

Andrew L. Shannon
Environmental Quality Specialist
Medical Waste Regulatory Program
Solid Waste Section
Waste Management and Radiological Protection Section
Constitution Hall, Atrium North
525 West Allegan Street
P.O. Box 30241
Lansing, Michigan 48909-7741
Phone: 517-230-9800
Fax: 517-373-4051
Email: shannonal@michigan.gov

Sherry Scott
Departmental Manager/MVPP Manager
MIOSHA
Consultation Education and Training Division
Phone: 517.322.5817
Fax: 517.322.1374
Email: scottsl@michigan.gov
Website: www.michigan.gov/miosha

Terry Welker
Owner/Eternal Tattoos Inc.
2426 E. Grand River
Howell, MI 48843
Phone: (313) 505-2095
Email: eternaltattoos@aol.com

Patricia Yee, CPCP/Owner
Facial Art Permanent Cosmetics
42353 Garfield Road
Clinton Twp., MI 48038
Phone: (586) 596-4159
Email: Facialart1@gmail.com