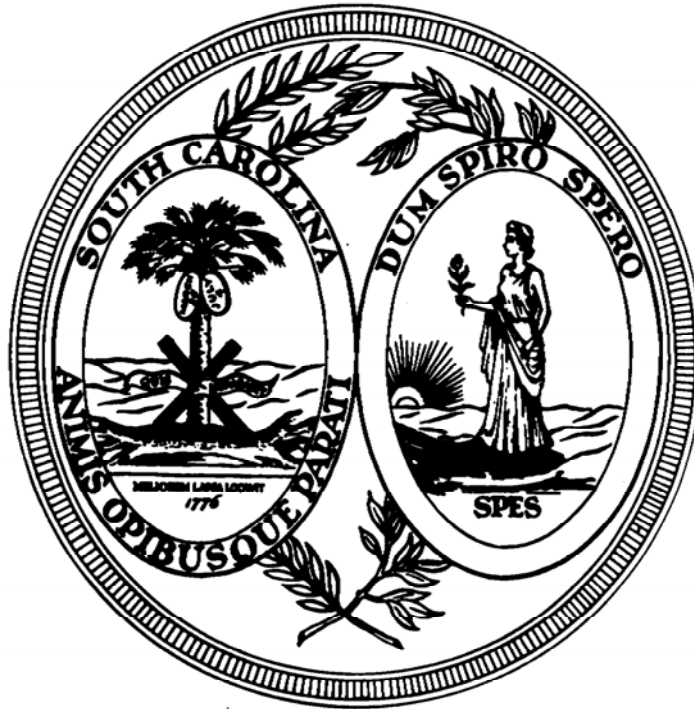




Regulation Number 61-109 Standards for Permitting Body Piercing Facilities



Promulgated by the Board of Health and Environmental Control

Administered by the Division of Health Licensing

Including Changes

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This is a courtesy copy of Regulation R61-109

The official document is on record in the *State Register* and the S.C. Code Ann. (2002). This regulation is provided by DHEC for the convenience of the public. Every effort has been made to ensure its accuracy; however, it is not the official text. DHEC reserves the right to withdraw or correct this text if deviations from the official text as published in the *State Register* are found.



DIVISION OF HEALTH LICENSING REGULATIONS

Provider-Wide Exceptions

In the interest of establishing reasonable standards that can be met by providers and yet do not compromise the health and well-being of the patients, residents, and participants cared for in South Carolina licensed facilities, it has been determined that alternative standards will be considered as acceptable. A Provider-Wide Exception (PWE) is the tool that is used to achieve a working relationship between the facility and their regulators.

Provider-Wide Exceptions for the facilities and activities that are licensed by the Division of Health Licensing can be downloaded from our Internet Website:

<http://www.scdhec.gov/health/licen/pwe.htm>

This website may also contain Position Statements that give guidance or interpretations of the regulation.

Provider-Wide Exceptions and Position Statements may also be obtained by contacting our office at (803) 545-4370. There is a ten-dollar (\$10.00) processing and handling fee assessed when copies are obtained through our office. Copies obtained over the Internet through our Website are free of charge. Payment must be by credit card, personal check or money order (no cash can be accepted).

Note: Some Provider-Wide Exceptions pre-date the publishing dates of specific Regulations established by the *State Register* and may no longer be in effect. In these instances, if there is a conflict between a PWE that pre-dates the publishing date of the regulation, the standard in the regulation shall supercede the PWE.

REGULATION 61-109

STANDARDS FOR PERMITTING BODY PIERCING FACILITIES

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REGULATION 61-109

STANDARDS FOR PERMITTING BODY PIERCING FACILITIES Statutory Authority - § 44-32-10, *et seq.*, S.C. Code of Laws, 1976, as amended

SECTION 100 - DEFINITIONS AND PERMIT REQUIREMENTS

101. Definitions.

For the purpose of this regulation, the following definitions shall apply:

A. Administrator. The individual designated by the facility permit holder to have the authority and responsibility to manage the facility.

B. Adult. A person 18 years of age or older, or a person under the age of 18 who has been emancipated in accordance with state law.

C. Aftercare. Services provided to clients, when necessary, after their release from a facility.

D. Authorized Healthcare Provider. An individual authorized by law and currently licensed in South Carolina (S.C.) to provide specific medical treatments, care, or services to technicians and/or clients. Examples of individuals who may be authorized by law to provide the aforementioned treatment/care/services may include, but are not limited to, advanced practice registered nurses, physician's assistants.

E. Body Piercing. The creation of an opening in the body of a human being so as to create a permanent hole for the purpose of inserting jewelry or other decoration. This includes, but is not limited to, piercing of an ear, lip, tongue, nose, or eyebrow, but does not include piercing an ear lobe with a disposable, single-use stud or solid needle that is applied using a mechanical device to force the needle or stud through the ear lobe.

F. Client. A person who has a body piercing procedure performed on his or her body.

G. Consultation. A visit to a permitted facility by individuals authorized by the Department to provide information to facilities to enable/encourage facilities to better comply with the regulations.

H. Contaminated or Contamination. The presence of blood, infectious materials, or other types of impure materials that have corrupted a surface or item through contact.

I. Department. The Department of Health and Environmental Control.

J. Disinfection. The killing of microorganisms, but not necessarily their spores, on inanimate objects.

K. Ear Lobe. The lower portion of the ear which contains no cartilage.

L. Existing Facility. A facility which was in operation and/or one which began the construction or renovation of a building, for the purpose of operating the facility, prior to the promulgation of this regulation. The permitting standards governing new facilities apply if and when an existing facility is not continuously operated and permitted under this regulation.

M. Facility. Any room, space, location, area, structure, mobile unit or business, or any part of any of these places, identifiable by a mailing address, where body piercing is practiced or where the business of body piercing is performed.

N. Inspection. A visit by authorized individuals to a facility or to a proposed facility for the purpose of determining compliance with this regulation.

O. Investigation. A visit by authorized individuals to a permitted or unpermitted entity for the purpose of determining the validity of allegations received by the Department relating to this regulation.

P. Minor. Any person whose age does not meet the criteria indicated in Section 101.B above.

Q. New Facility. All buildings or portions of buildings, new and existing building(s), that are:

1. Being permitted for the first time;
2. Providing a different modality or service when the permit holder has changed the type of permit;
3. Being permitted after the previous permit holder's permit has been revoked, suspended, or after the previous permit holder has voluntarily surrendered his or her permit.

R. Picture Identification.

1. A valid S.C. driver's license; or
2. An official photographic identification card issued by the S.C. Department of Revenue, a federal or state law enforcement agency, or an agency of the U.S. Departments of Defense or State, *e.g.*, military ID, passport.

S. Probation. An action taken by the Department in which a facility is notified that it must comply with the provisions of this regulation within a specified period of time or enforcement actions may be imposed.

T. Release. The point at which the client's active involvement with a facility is terminated and the facility no longer maintains active responsibility for the client.

U. Repeat Violation. The recurrence of a violation cited under the same section of the regulation within a 36-month period. The time-period determinant of repeat violation status is not interrupted by ownership changes.

V. Sanitize or Sanitization. A procedure that reduces the level of microbial contamination so that the item or surface is considered safe.

W. Sterilization. The destruction of all forms of micro-biotic life, including spores.

X. Suspend Permit. An action by the Department requiring a facility to cease operations for a period of time until such time as the Department rescinds that restriction.

Y. Technician. A person who practices body piercing in S.C. and is in compliance with this regulation.

102. References

The following publications are referenced in these regulations:

A. Departmental: Regulation 61-105, Infectious Waste Management Regulations.

B. Non-Departmental:

1. Standard Building Code;
2. American Association of Blood Banks;
3. Bloodborne Pathogens Standards, Occupational Safety and Health Act of 1970 (OSHA);
4. Civil Rights Act of 1964;
5. American Society for Testing of Materials Specifications;
6. Applicable guidelines from the Centers for Disease Control and Prevention

103. Permit Requirements (II)

A. Permit. (I)

1. No person, private or public organization, political subdivision, or governmental agency shall establish, operate, maintain, or represent his/her/itself (advertise or market) as a body piercing facility in S.C. without first obtaining a permit from the Department. Facilities that perform body piercing prior to the effective date of permitting are in violation of Section 44-32-10, *et seq.*, of the S.C. Code of Laws, 1976, as amended.

2. When it has been determined by the Department that body piercing is being performed at a location, and the owner has not been issued a permit from the Department to perform such procedures, the owner shall cease operation immediately.

3. Current or previous violations of the S.C. Code of Laws and/or Department regulations may jeopardize the issuance of a permit for the facility or the permitting of any other facility or addition to an existing facility which is owned or operated by the permit holder. The facility shall provide only the procedures or services it is permitted to provide pursuant to the definition in Section 101 of this regulation.

B. Compliance. An initial permit shall not be issued to a proposed facility that has not been previously and continuously permitted under Department regulations until the permit holder has demonstrated to the Department that the proposed facility is in substantial compliance with this regulation. In the event a permit holder who already has a facility or activity licensed or permitted by the Department makes application for another facility, the currently licensed or permitted facility or activity shall be in substantial compliance with the applicable standards prior to the Department issuing a permit to the proposed facility. A copy of this regulation shall be maintained at the facility. Facilities shall comply with applicable local, state, and federal laws, codes, and regulations, to include applicable federal OSHA requirements or guidelines.

C. Issuance and Terms of Permit.

1. A permit is issued by the Department and shall be posted in a conspicuous place in a public area within the facility.

2. The issuance of a permit does not guarantee safety conditions, or the adequacy of sanitation or sterilization procedures provided.

3. A permit is not assignable nor transferable and is subject to revocation at any time by the Department for the permit holder's failure to comply with the laws and regulations of this State.

4. A permit shall be effective for a specified facility, at a specific location(s), for a specified period following the date of issue as determined by the Department. A permit shall remain in effect until the facility is otherwise notified by the Department.

5. Mobile units shall have a permanent mailing address; permits will indicate that address, and that the facility is mobile. Schedules of mobile units' locations shall be submitted quarterly to the Department's Division of Health Licensing (DHL).

D. Existing facilities shall be required to comply with all standards within this regulation.

EXCEPTION: The square footage required in the procedure room (see Section 1401.A) shall not require modification.

E. Application.

1. Prior to applying to the Department for a permit, a proposed facility shall:

a. Obtain a copy of this regulation from the Department, sign an acknowledgment upon receipt, and return the receipt to the Department;

b. Ensure that all technicians comply with all applicable federal OSHA requirements or guidelines, and obtain certificates attesting to the successful completion of courses in:

(1) Bloodborne pathogens;

(2) Body piercing infection control as approved by the Department;

(3) American Red Cross First Aid;

(4) Adult cardiopulmonary resuscitation (CPR).

2. When applying for a permit issued by the Department, the facility shall:

a. Submit to the Department a completed application on a form prescribed and furnished by the Department prior to initial permitting and periodically thereafter at intervals determined by the Department. Applicants for a permit shall file application with the Department, that includes an oath assuring that the contents of the application are accurate and true, and in compliance with this regulation.

b. Provide a copy of the business license, as applicable, to the Department;

c. Submit a permitting fee.

F. Permitting Fees. Fees shall be made payable by check or money order to the Department and shall be used exclusively in support of activities pursuant to this regulation.

1. The initial and annual permit fee shall be \$300.00; an additional amount may be charged if necessary to cover the cost of inspection.

2. If a permit renewal is denied, a portion of the fee shall be refunded based upon

the remaining months of the permitting year, or \$75.00, whichever is the lesser.

G. Permit Renewal. For a permit to be renewed, applicants shall file an application with the Department, pay a permit fee, and shall not be under consideration for, or undergoing enforcement actions by the Department. If the permit renewal is delayed due to enforcement actions, the renewal permit will be issued only when the matter has been resolved satisfactorily by the Department, or when the adjudicatory process is completed, whichever is applicable.

H. Change of Permit.

1. A facility shall request issuance of an amended permit by application to the Department prior to any of the following circumstances:

- a. Change of ownership;
- b. Change of facility location from one geographic site to another (not applicable to mobile facilities).

2. Changes in a facility name or address initiated by the post office (no location change) shall be accomplished by application or letter from the permit holder.

I. Upon completion of all the requirements of permitting, the facility shall receive a permit issued by the Department. The permit shall be posted in a conspicuous place in the facility.

J. Each facility shall conspicuously display a clearly legible notice to clients informing them of any disqualification that body piercing may confer upon a prospective blood donor according to the current and subsequent amendments to standards of the American Association of Blood Banks. This notice also shall appear in any informed consent or release form which a technician uses, and shall be signed by the prospective client, and contain, at a minimum, aftercare suggestions for the specific piercing site.

K. Technicians shall perform body piercing only in permitted facilities.

104. Exceptions to the Standards

The Department has the authority to make exceptions to these standards when it is determined that the health, safety, and well-being of the clients will not be compromised and provided the standard is not specifically required by statute.

SECTION 200 - ENFORCING REGULATIONS

201. General

The Department shall utilize inspections, investigations, consultations, and other pertinent documentation regarding a proposed or permitted facility in order to enforce this regulation.

202. Inspections/Investigations

A. An inspection shall be conducted prior to initial permitting of a facility and subsequent inspections conducted as deemed appropriate by the Department.

B. All facilities are subject to inspection or investigation at any time without prior notice by individuals authorized by the Department.

C. Individuals authorized by the Department shall be granted access to all properties and areas, objects, and records, and have the authority to require the facility or technician to make photocopies of those documents required in the course of inspections or investigations. Photocopies shall be used for purposes of enforcement of regulations and confidentiality shall be maintained except to verify individuals in enforcement action proceedings. (II)

D. When there is noncompliance with the standards of this regulation, the facility shall submit an acceptable written plan of correction to the Department that shall be signed by the administrator and returned by the date specified on the report of inspection or investigation. The written plan of correction shall describe: (II)

1. The actions taken to correct each cited deficiency;
2. The actions taken to prevent recurrences (actual and similar);
3. The actual or expected completion dates of those actions.

E. Reports of inspections or investigations conducted by the Department, including the facility response, shall be made available upon request with the redaction of the names of those individuals in the report as provided by Sections 44-7-310 and 315 of the S.C. Code of Laws, 1976, as amended.

F. The Department may conduct the following inspections or investigations of the locations where body piercing is being or will be performed:

1. An initial inspection as a condition of permitting;
2. An investigation following any complaint filed with the Department;

G. Inspections may be conducted by the Department at any time without previous notification to the facility.

203. Probation

A. The Department may place a facility on probation when it has been determined by the Department that the facility has failed to maintain a business address or telephone number at which the facility may be reached during business hours, or violated any other standard of this regulation, as deemed appropriate.

B. The facility shall post the probationary letter from the Department in a conspicuous place in the facility until such time that the Department has determined that sufficient corrective action has been taken.

204. Consultations

Consultations shall be provided by the Department as requested by the facility or as deemed appropriate by the Department.

SECTION 300 - ENFORCEMENT ACTIONS

301. General (II)

A. When the Department determines that a facility is in violation of any statutory provision, rule, or regulation relating to the operation or maintenance of such facility, the Department, upon proper notice to the permit holder, may deny, refuse to renew, suspend, or revoke permits.

B. Facilities shall accept delivery of U.S. Postal Service certified or registered mail from the Department.

302. Violation Classifications

Violations of standards in regulation are classified as follows:

A. Class I violations are those that the Department determines to present an imminent danger to the health, safety, or well-being of persons in the facility or a substantial probability that death or serious physical harm could result therefrom. A physical condition or one or more practices, means, methods or operations in use in a facility may constitute such a violation. The condition or practice constituting a Class I violation shall be abated or eliminated immediately unless a fixed period of time, as stipulated by the Department, is required for correction. Each day such violation exists after expiration of the time established by the Department may be considered a subsequent violation.

B. Class II violations are those, other than Class I violations, that the Department determines to have a negative impact on the health, safety or well-being of persons in the facility. The citation of a Class II violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

C. Class III violations are those that are not classified as Class I or II in these regulations or those that are against the best practices as interpreted by the Department. The citation of a Class III violation shall specify the time within which the violation is required to be corrected. Each day such violation exists after expiration of this time may be considered a subsequent violation.

D. The notations, "(I)" or "(II)," placed within sections of this regulation, indicate those standards are considered Class I or II violations if they are not met, respectively. Standards not so annotated are considered Class III violations.

E. In arriving at a decision to take enforcement actions, the Department will consider the following factors: the number and classification of violations; specific conditions and their impact or potential impact on health, safety or well-being of the clients; efforts by the facility to correct cited violations; behavior of the permit holder that would reflect negatively on the permit holder's character, such as illegal or illicit activities; overall conditions of the facility; history of compliance; any other pertinent conditions that may be applicable to current statutes and regulations.

F. Any decision by the Department to grant, deny, revoke, suspend, or refuse to renew a permit may be appealed by a party with standing in a manner pursuant to the Administrative Procedures Act, Section 1-23-310, *et seq.*, of the S.C. Code of Laws, 1976, as amended.

SECTION 400 - POLICIES AND PROCEDURES

401. General (II)

A. Policies and procedures addressing each section of this regulation regarding client procedures or services, rights, infection control, and the operation of the facility shall be developed and implemented by the facility, and revised as appropriate in order to accurately reflect actual facility operation. Facilities shall establish a time-period for review of all policies and procedures. These policies and procedures shall be accessible at all times. A hard copy of the client care policies and procedures shall be available or be readily accessible electronically at each facility.

B. The policies and procedures shall describe the means by which the facility shall assure that the standards described in this regulation, which the permit holder has agreed to meet as confirmed by his or her application, are met.

SECTION 500 - STAFF

501. General (II)

A. Appropriate technicians in numbers and training shall be available at the facility to provide appropriate, safe body piercing procedures to clients and meet the demands of effective emergency on-site action that might arise. Training requirements and qualifications for the tasks each performs shall be in compliance with all local, state, and federal laws, and current professional organizational standards.

B. Technicians shall not be under the influence of any substance that would impair his or her ability to perform body piercing.

C. Administrator.

1. The permit holder shall ensure that there is an administrator responsible for the day-to-day operation of the facility to ensure compliance with these regulations.

2. An individual shall be designated, in writing, to act in the absence of the administrator.

3. The administrator and the facility technician may be the same individual.

D. Technicians shall be provided the necessary training to perform the duties for which they are responsible in an effective manner.

E. All new technicians shall be oriented to acquaint them with the organization and environment of the facility, their specific duties and responsibilities, and clients' needs.

F. There shall be accurate information maintained regarding all technicians of the facility, to include at least current address, phone number, health, work, and training background, as well as current health and education information. All technicians shall be assigned certain duties and responsibilities that shall be in writing and in accordance with the individual's capability.

502. Inservice Training (II)

A. In all facilities, the following training, utilizing resources as approved by the Department, shall be provided to all technicians prior to client contact and at least annually:

1. Courses in adult CPR, and in bloodborne pathogens and body piercing infection control, as approved by the Department;

2. American Red Cross First Aid certification (required for each technician every three years).

B. Prior to independently performing body piercing procedures, a new technician shall spend in training a minimum of 400 hours under the direct supervision of an experienced technician who shall sign and maintain a statement attesting to the completion of such training.

503. Health Status (I)

No person infected with or a carrier of a serious communicable disease, *e.g.*, tuberculosis, which may be transmitted to clients in the facility, or having boils, open or infected skin lesions shall have client contact.

SECTION 600 - REPORTING

601. Incidents/Accidents (II)

A. A record of each accident and incident involving clients or technicians occurring in the facility shall be retained. Incidents or accidents resulting in serious medical conditions, *e.g.*, lacerations, hematomas, actual or suspected abuse of clients by technicians, *etc.*, in which the client is hospitalized, shall be reported via telephone to the next-of-kin or responsible person at the earliest practicable hour, but not to exceed 24 hours of the occurrence, and in writing to the Department's Division of Health Licensing (DHL) within 10 days of the occurrence.

B. Reports shall contain at a minimum: facility name, technician name, client age and sex, date of incident or accident, location, witness names, identified cause of incident or accident, extent and type of injury and how treated, *e.g.*, hospitalization, and the date of the report.

602. Fire/Disasters (II)

A. The facility permit holder shall notify DHL immediately via telephone or fax regarding any fire in the facility, and followed by a complete written report, to include fire department reports, if any, to be submitted within a time-period determined by the facility, but not to exceed 72 hours from the occurrence of the fire.

B. Any natural disaster or fire that jeopardizes the safety of any persons in the facility shall be reported to DHL via telephone or fax immediately, with a complete written report which includes the fire report from the local fire department, if appropriate, submitted within a time-period as determined by the facility, but not to exceed 72 hours.

603. Administrator Change

The facility permit holder shall notify DHL in writing within 10 days of any change in administrator. The notice shall include at a minimum the name of the newly-appointed individual and effective date of the appointment.

604. Facility Closure

Prior to the permanent or temporary closure of a facility, the facility permit holder shall notify DHL in writing of the intent to close and the effective closure date. On the date of permanent closure, the permit shall be returned to DHL. For temporary facility closures, the facility permit holder shall notify DHL in writing in advance of re-opening.

SECTION 700 - CLIENT RECORDS

701. Content (II)

A. The facility shall initiate and maintain a client record for every individual who has undergone body piercing. All entries shall be written legibly in ink or typed, signed and dated, and shall identify the author.

B. Specific entries shall include at a minimum:

1. Identification of the client;
2. Consent for piercing and explanation of client rights, as evidenced by the technician and client signatures;
3. Body piercing procedure performed;
4. Procedures followed if an unexpected event occurs, and emergency procedures taken if there is an adverse reaction.

C. A means of verification of client's identity, e.g, copy of the identification picture, shall be included in the record.

D. There shall be a release/aftercare note, completed at the time of release, which shall include at minimum:

1. Date and time of release, including condition at release;
2. The recommendations for aftercare, with a copy provided to the client.

702. Record Maintenance

A. The facility shall provide accommodations, space, supplies, and equipment adequate for the protection and storage of client records.

B. The facility shall determine the medium in which information is stored.

SECTION 800 - CLIENT PROCEDURES/SERVICES PROVIDED

801. General (I)

A. The facility shall perform body piercing only for those persons for which the facility can provide the appropriate accommodations and services.

B. Body piercing shall be rendered effectively and safely.

C. Body piercing shall not be performed upon a person impaired by drugs or alcohol to the extent that he or she is incapable of consenting to body piercing and incapable of understanding body piercing procedures and aftercare suggestions.

D. Body piercing shall not be performed on skin surfaces having sunburn, rash, keloids, pimples, boils, infections, open lesions, or manifest any evidence of unhealthy conditions.

E. Prior to performing a procedure on a client, the technician shall obtain information from the client regarding any existing condition(s), e.g., allergic to latex or nickel, that could affect the healing process. If a client indicates the presence of such a condition, the facility

shall obtain documentation from a physician or other authorized healthcare provider that the procedure is not contraindicated, prior to the body piercing procedure.

F. Clients shall be given the opportunity to participate in aftercare programs if offered by the facility. (II)

802. Procedures on Minors (II)

A. A body piercing technician shall not perform or offer to perform body piercing upon a person under the age of 18 years, unless the body piercing is performed in the presence of, or as directed by a notarized statement, in writing, by the person's parent or court-appointed guardian, or if the client is emancipated in accordance with state law.

B. The facility shall verify by means of a picture identification that a recipient is at least 18 years of age.

C. Body piercing shall not be performed upon a person under the age of 16 unless written approval is obtained from a physician in addition to complying with Section 802.A, above.

SECTION 900 - CLIENT RIGHTS

901. Informed Consent (II)

A. The facility shall inform the client, parent, or court-appointed guardian if the client is a minor, of the potential for any risks, and/or adverse effects or consequences regarding the body piercing procedure(s) to be performed. In all instances of body piercing, the client must voluntarily choose, in writing, to receive the procedure.

B. The facility shall inform clients of the metal content of jewelry utilized in each procedure and its safety for human implant. Such content shall comply with the American Society for Testing Materials Specifications.

902. Grievances/Complaints (II)

Clients shall be informed of the grievance or complaint procedure, including the address and phone number of DHL.

903. Procedures and Charges

Body piercing procedures performed by the facility and the charges for such procedures shall be delineated in writing, and the client or parent/guardian, if client is a minor, shall be made aware of such charges and procedures as verified by his or her signature, prior to the procedure.

SECTION 1000 - MAINTENANCE

1001. General

A. The facility, including its component parts and equipment, shall be properly maintained to perform the functions for which it is designed. (II)

B. The physical plant shall be maintained free of fire hazards or impediments to fire prevention. (I)

SECTION 1100 - INFECTION CONTROL AND ENVIRONMENT

1101. Staff Practices (I)

Staff practices shall promote conditions that prevent the spread of infectious, contagious, or communicable diseases and provide for the proper disposal of toxic and hazardous substances. These preventive measures or practices shall be in compliance, as applicable, with OSHA Bloodborne Pathogens Standards, the Department's R.61-105, applicable guidelines of the Centers for Disease Control and Prevention, other applicable federal, state, and local laws and regulations, and other professionally recognized organizations.

1102. Hepatitis B Vaccination (I)

A. All technicians shall have the hepatitis B vaccination series, or be offered the series and decline, in writing. Those who decline shall be tested for hepatitis B surface antigen (HBsAg) on an annual basis.

B. Each technician who elects to have the series shall have completed, within 30 days of employment, the initial vaccination.

1103. Infection Control (I)

A. A technician shall utilize the following infection control measures:

1. Before and after each body piercing procedure, wash his or her hands thoroughly for a minimum of 15 seconds with water and a liquid germicidal solution approved by the Department, and dried with a "C-fold" disposable paper towel from a wall-mounted dispenser;

2. When necessary to perform a procedure on certain individuals who must undergo shaving of hair, utilize either disinfected scissors or a single-use disposable razor;

3. Scrub the skin of the client in the area to be pierced in a sterile surgical manner with a liquid germicidal solution approved by the Department and used in accordance with the manufacturer's direction.

4. Utilize single-use sterile disposable gloves when setting up equipment and immediately replace upon notice of a tear, any contamination, or other defect;

5. Prior to any direct contact with the client, sterilely place all sterile instruments and

body piercing items or jewelry on a sterile disposable towel or drape to be used as a single sterile field throughout the procedure;

6. Re-gloving with single-use sterile disposable surgical gloves shall occur prior to initiation of the procedure, which is to be performed using strict sterile surgical techniques. Any non-sterile contact or contamination of the instruments, jewelry, or field shall immediately result in cessation of the procedure and nonuse of all equipment until re-sterilized.

7. Dispose of used, single-use needles and other disposable sharp supplies in safety puncture-proof containers as approved by the Department; these used containers shall be disposed of in a manner prescribed by the Department.

B. The use of gauze, alum, styptic pencils, or medical supplies deemed necessary to control bleeding is prohibited unless a separate disposable single-use sterile item is used.

C. Food, drink, and the use of tobacco products in the procedure and disinfection/sterilization rooms are prohibited.

D. Live animals shall not be permitted in the procedure and disinfection/sterilization rooms.

EXCEPTION: This standard does not apply to patrol dogs accompanying security or police officers, guide dogs, or other service animals accompanying handicapped individuals.

1104. Sterilization of Equipment (I)

A. All used surgical equipment intended for reuse shall be properly scrubbed clean of visible materials and soaked for a minimum of 20 minutes in a liquid germicidal solution approved by the Department, which shall be used in accordance with the manufacturer's direction. The equipment shall then be immediately placed in a mechanical ultrasonic cleanser for at least 25 minutes prior to being re-sterilized by autoclave. The ultrasonic cleanser shall be clearly labeled as "biohazardous" and shall be located as far apart as possible from the autoclave within the disinfection/sterilization room.

B. Facilities shall properly package and sterilize by autoclave those needles, instruments, other surgical equipment, and body piercing items or jewelry that are not single-use/disposable, include a sterile indicator, and label with the date of sterilization.

C. Single-use items shall not be used on more than one client for any reason unless properly sterilized. After use, all single-use needles, razors, and other sharps shall be immediately disposed of in approved sharps containers.

D. Each facility shall keep a written log for two years of autoclave use, to include, but not be limited to, date and time of use and sterilization spore test strip results conducted at least monthly. (II)

1105. Housekeeping (II)

The interior and exterior of the facility shall be neat, clean, and free of safety impediments, vermin, and offensive odors.

A. Interior housekeeping shall at a minimum include:

1. Cleaning each specific area of the facility;
2. Cleaning and disinfection, as needed, of equipment and supplies used and/or maintained in each area, appropriate to the area and purpose or use of the equipment or supplies;
3. Safe storage of harmful chemicals (as indicated on the product label), cleaning materials, and supplies, e.g., mops, brooms, in cabinets or well-lighted closets or rooms. Such storage shall not occur in areas where sterilization equipment/supplies are stored or where sterilization or body piercing procedures are performed.

B. All garbage and waste shall be collected, stored, and disposed of in a manner designed to prevent the transmission of disease.

1. Refuse shall be stored in containers which shall be emptied at sufficient frequencies and manner so as not to create a rodent, insect, or other vermin problem. The containers shall be sanitized prior to their return to work areas.

2. Dumpsters utilized by the facility shall be enclosed/covered.

C. Exterior housekeeping shall at a minimum include the general cleaning of all exterior areas, e.g., porches and ramps, and removal of safety impediments such as water, snow, and ice.

1106. Infectious Waste (I)

Accumulated waste, including all contaminated sharps, dressings, pathological, and/or similar infectious waste, shall be disposed of in a manner compliant with the Department's R.61-105 and OSHA Bloodborne Pathogens Standards.

SECTION 1200 - EMERGENCY PROCEDURES

1201. Emergency Call Numbers (I)

Emergency call data shall be posted in a conspicuous place and shall include, in addition to "911," the telephone numbers of fire and police departments and ambulance service.

1202. Medical Emergencies (I)

Medical emergencies shall be managed in a manner as to insure the health, safety and well-being of clients.

SECTION 1300 - FIRE PREVENTION

1301. Arrangements for Fire Department Response (I)

Facilities located outside of a service area or range of a public fire department shall arrange, by written agreement, for the nearest fire department to respond in case of fire. A copy of the agreement shall be kept on file in the facility and a copy shall be forwarded to DHL. If the agreement is changed, a copy shall be forwarded to DHL.

1302. Inspections (I)

Each facility shall be inspected by the local fire inspector or marshal prior to permitting and once each year thereafter.

1303. Evacuation Plan (I)

A plan for the evacuation of clients, technicians, and visitors, in case of fire or other emergency, shall be posted in conspicuous public areas throughout the facility.

1304. Fire Response Training (I)

Each technician shall receive training within one week of hiring, and at a frequency determined by the facility, but at least annually thereafter, addressing at a minimum, the following:

- A. Fire plan, to include evacuation routes and procedures, and the training of staff members;
- B. Reporting a fire;
- C. Use of the fire alarm system, if applicable;
- D. Location and use of fire-fighting equipment;
- E. Methods of fire containment;
- F. Specific responsibilities and duties of each individual.

SECTION 1400 - FACILITY ACCOMMODATIONS

1401. General (II)

A. A facility shall include a room for the purpose of disinfecting and sterilization of equipment that shall be physically separate from the room used for body piercing procedures to avoid cross-contamination of equipment. These areas shall be separated from each other and from waiting customers by a door. The procedure room shall be sized

to accommodate necessary equipment or supplies, personnel, and procedure table, but not less than 64 square feet of floor space, exclusive of fixed cabinets or shelves.

1. Wall and floor surfaces of the procedure and disinfection/sterilization rooms shall be nonporous and easily cleanable;

2. A separate, properly identified sink (with hot and cold running water) used for disinfection practices only shall be located in the disinfection/sterilization room.

B. Procedure tables shall be constructed of a nonporous, sanitizable material.

C. A standard first aid kit or equivalent first aid supplies shall be readily accessible in the facility, and shall contain as a minimum:

1. 4" X 4" gauze pads;

2. Benzalkonium swabs;

3. 2" X 2" gauze pads;

4. Gauze roller bandage.

D. Lighting in the procedure and disinfection/sterilization rooms shall be not less than 100 foot-candles.

E. There shall be an appropriate number of restrooms in the facility, to accommodate clients, technicians, and visitors; the restrooms shall be accessible during all operating hours of the facility. The restroom(s) shall be equipped with a toilet, toilet paper installed in a holder, a lavatory supplied with hot and cold running water, liquid or granulated soap, single-use disposable paper towels or electric air dryer, and a waste receptacle. Equipment and supplies used in the course of body piercing procedures or disinfection and sterilization procedures shall not be stored or utilized in the restroom.

F. Emergency electric services shall be provided for procedure room illumination in addition to other requirements of the Standard Building Code.

G. Each procedure room shall have a high-efficiency particulate air (HEPA) filter.

SECTION 1500 - MOBILE UNITS

1501. General (II)

All mobile units shall meet the current and existing standards of the state, federal, and local departments of transportation for the permitting and safe operation of the vehicle. In addition, all interior aspects of the vehicle shall meet the same standards as described in this regulation for nonmobile facilities.

SECTION 1600 - SEVERABILITY

1601. General

In the event that any portion of these regulations is construed by a court of competent jurisdiction to be invalid, or otherwise unenforceable, such determination shall in no manner affect the remaining portions of these regulations, and they shall remain in effect, as if such invalid portions were not originally a part of these regulations.

SECTION 1700 - GENERAL

1701. General

Conditions that have not been addressed in these regulations shall be managed in accordance with the best practices as interpreted by the Department.

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