



PROPOSED RULE MAKING

CR-102 (June 2004)

(Implements RCW 34.05.320)

Do NOT use for expedited rule making

Agency: Department of Health

- Preproposal Statement of Inquiry was filed as WSR 09-21-042 ; or
- Expedited Rule Making--Proposed notice was filed as WSR _ ; or
- Proposal is exempt under RCW 34.05.310(4).

- Original Notice
- Supplemental Notice to WSR
- Continuance of WSR

Title of rule and other identifying information: (Describe Subject)

Chapter 246-145 WAC, Body Art, Body Piercing, Electrology and Tattooing Standards for Sterilization Procedures and Infection Control

Hearing location(s): Department of Health
Point Plaza East, Room 152/153
310 Israel Road NE
Olympia WA 98501

Date: 05/03/2010

Time: 1:30 p.m.

Submit written comments to:

Name: Patti Rathbun
Address: Department of Health
PO Box 47890
Olympia WA 98504-7890
Website: <http://www3.doh.wa.gov/policyreview/>
fax (360) 586-7424 by (date) 04/26/2010

Assistance for persons with disabilities: Contact

Tami Thompson by 04/26/2010

TTY (800) 833-6388 or () 711

Date of intended adoption: 05/06/2010

(Note: This is **NOT** the **effective** date)

Purpose of the proposal and its anticipated effects, including any changes in existing rules:

The purpose of the proposed rules is to establish sterilization and infection control requirements for body art and body piercing in addition to tattoo artists and electrologists. Sterilization and infection control requirements have been in place for tattooing and electrology since 2002. Sterilization and infection control requirements for body art, body piercing and tattooing will be enforced by the Department of Licensing through its licensing program.

Reasons supporting proposal:

SSB 5391 which passed in 2009 amended RCW 70.54.340 to require the Department of Health to establish sterilization and infection control requirements for body artists and body piercers in addition to electrologists and tattoo artists.

Statutory authority for adoption:

RCW 70.54.340

Statute being implemented:

RCW 70.54.340

Is rule necessary because of a:

- Federal Law? Yes No
 - Federal Court Decision? Yes No
 - State Court Decision? Yes No
- If yes, CITATION:

DATE 03/24/10

NAME (type or print)

Mary C. Selecky

SIGNATURE

TITLE

Secretary, Department of Health

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: March 24, 2010

TIME: 10:20 AM

WSR 10-07-158

Agency comments or recommendations, if any, as to statutory language, implementation, enforcement, and fiscal matters:

The requirements established by these rules will be enforced by the Department of Licensing through the licensing program.

Name of proponent: (person or organization) Department of Health

- Private
 Public
 Governmental

Name of agency personnel responsible for:

Name	Office Location	Phone
Drafting..... Patti Rathbun	101 Israel Road SE, Tumwater WA 98501	(360) 236-4067
Implementation.... Ben Rogers	405 Black Lake Blvd. SW, Olympia WA 98502	(360) 664-1380
Enforcement..... Ben Rogers	405 Black Lake Blvd., Olympia WA 98502	(360) 664-1380

Has a small business economic impact statement been prepared under chapter 19.85 RCW?

Yes. Attach copy of small business economic impact statement.

A copy of the statement may be obtained by contacting:

Name:

Address:

phone

fax

e-mail

No. Explain why no statement was prepared.

A small business economic impact statement was not prepared. The proposed rule would not impose more than minor costs on businesses in an industry.

Is a cost-benefit analysis required under RCW 34.05.328?

Yes A preliminary cost-benefit analysis may be obtained by contacting:

Name: Patti Rathbun

Address: P.O. Box 47890

Olympia WA 98504-7890

phone (360) 236-4067

fax (306) 586-7424

e-mail patti.rathbun@doh.wa.gov

No: Please explain: The agency did not complete a cost benefit analysis under RCW 34.05.328. RCW 34.05.328(5)(b)(iii) exempts rules that adopt or incorporate by reference without material change federal statutes or regulations, the rules of other Washington state agencies, or national consensus codes that generally establish industry standards;

Chapter 246-145 WAC

**BODY ART, BODY PIERCING, ELECTROLOGY AND TATTOOING STANDARDS FOR
STERILIZATION PROCEDURES AND INFECTION CONTROL**

AMENDATORY SECTION (Amending WSR 02-11-109, filed 5/20/02, effective 6/20/02)

WAC 246-145-001 Purpose and scope. These rules establish standard universal precautions for preventing the spread of diseases by using sterilization procedures and infection control in the ~~((commercial))~~ practices of electrology, body art, body piercing, and tattooing.

AMENDATORY SECTION (Amending WSR 02-11-109, filed 5/20/02, effective 6/20/02)

WAC 246-145-010 Definitions. For the purpose of these rules, the following words and phrases have the following meanings unless the context clearly indicates otherwise.

(1) "Antiseptic" means an agent that destroys disease causing microorganisms on human skin or mucosa.

(2) "Aseptic technique" means a procedure that prevents contamination of any object or person.

(3) "Bloodborne pathogens" means 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 (HBC) and human immunodeficiency virus (HIV).

(4) "Body art" means the practice of invasive cosmetic adornment including the use of branding and scarification. Body art also includes the intentional production of scars upon the body. Body art does not include any health-related procedures performed by licensed health care practitioners under their scope of practice.

(5) "Body piercing" means the process of penetrating the skin or mucous membrane to insert an object, including jewelry, for cosmetic purposes. Body piercing also includes any scar tissue resulting from or relating to the piercing. Body piercing does not include the use of stud and clasp piercing systems to pierce the

earlobe in accordance with the manufacturer's directions and applicable FDA requirements. Body piercing does not include any health-related procedures performed by licensed health care practitioners under their scope of practice, nor does anything in this act authorize a person registered to engage in the business of body piercing to implant or embed foreign objects into the human body or otherwise engage in the practice of medicine.

(6) "Branding" means inducing a pattern of scar tissue by use of a heated material (usually metal) to the skin creating a serious burn which eventually results in a scar.

(7) "Department" means the department of licensing.

(8) "Disinfectant" means a substance or solution, registered with the United States Environmental Protection Agency (EPA) that kills or inactivates viruses and pathogenic microorganisms, but not necessarily their spores.

(9) "Disinfect" or "disinfection" means the destruction of disease-causing microorganisms on inanimate objects or surfaces, thereby rendering these objects safe for use or handling.

(10) "Electrologist" means a person who practices the business of electrology for a fee.

~~((2))~~ (11) "Electrology" means the process of permanently removing hair by using solid needle or probe electrode epilation, including:

(a) Thermolysis, being of shortwave, high frequency type;

(b) Electrolysis, being a galvanic type; or

(c) A combination of both which is accomplished by a superimposed or sequential blend.

~~((3))~~ (12) "FDA" means United States Food and Drug Administration.

(13) "Gloves" means single-use disposable medical grade gloves that are FDA approved.

~~((4) "Sterilization" means a process that destroys all forms of microbial life, including highly resistant bacterial spores.~~

~~(5) "Tattoo artist" means a person who practices the business of tattooing for a fee.~~

~~((6))~~ (14) "Hand sanitizer" means an alcohol-based sanitizer with a concentration of 60% to 95% ethanol or isopropanol.

(15) "Jewelry" means any personal ornament inserted into a newly pierced area, which must be made of surgical implant-grade stainless steel, solid 14k or 18k white or yellow gold, niobium, titanium, or platinum, or a dense, low-porosity plastic, which is free of nicks, scratches, or irregular surfaces and has been properly sterilized prior to use.

(16) "Licensee" means a shop, business or individual licensed to practice body art, body piercing or tattooing.

(17) "Procedure(s)" means body art, body piercing, and tattooing procedures.

(18) "Sanitize" means a procedure that reduces the level of microbial contamination so that the item or surface is considered safe.

(19) "Scarification" means altering skin texture by cutting the skin and controlling the body's healing process in order to

produce wounds, which result in permanently raised wheals or bumps known as keloids.

(20) "Sharps" means any objects (sterile or contaminated) that may purposefully or accidentally cut or penetrate the skin or mucosa including, but not limited to, presterilized, single-use needles, scalpel blades, and razor blades.

(21) "Sharps container" means a puncture-resistant, leak-proof container that can be closed for handling, storage, transportation, and disposal and that is labeled with the international biohazard symbol.

(22) "Single-use" means products, instruments or items that are intended for one-time use and are disposed of after each use including, but not limited to, cotton swabs or balls, tissue or paper products, paper or plastic cups, gauze and sanitary coverings, razors, needles, scalpel blades, stencils, ink cups and protective gloves.

(23) "Sterilization" means a process that destroys all forms of microbial life, including highly resistant bacterial spores.

(24) "Sterilizer" means an apparatus that is registered and listed with the FDA for destroying all forms of microbial life, including highly resistant bacterial spores.

(25) "Tattooing" means ~~((the))~~ to pierce or puncture the human skin with a needle or other instrument for the purpose of implanting an indelible mark, ~~((figure, or decorative design introduced by insertion of nontoxic dyes))~~ or pigment~~((s))~~ into ~~((or under the subcutaneous portion of))~~ the skin ~~((upon the body of a live human being for cosmetic or figurative purposes))~~.

(26) "Universal precautions" is an approach to infection control as defined by the Center for Disease Control (CDC). According to the concept of universal precautions, all human blood and certain body fluids are treated as if known to be infectious for human immunodeficiency virus (HIV), Hepatitis B virus (HBV) and other bloodborne pathogens.

NEW SECTION

WAC 246-145-015 Restrictions. (1) Electrologists, and individuals licensed to perform body piercing, body art and tattooing, shall not perform procedures:

- (a) While under the influence of alcohol or drugs;
- (b) If they have weeping dermatitis or draining sores;
- (c) On a client who appears to be under the influence of alcohol or drugs; or
- (d) On a client who has evident skin lesions or skin infections in the area of the procedure, including sunburn.

(2) Animals are not permitted in body art, body piercing and tattooing procedure areas, except for guide and service animals accompanying persons with disabilities. Aquariums are allowed in

a waiting room and nonprocedural area. No animals are allowed in the sterilization area.

AMENDATORY SECTION (Amending WSR 02-11-109, filed 5/20/02, effective 6/20/02)

WAC 246-145-020 Standard universal precautions for preventing the spread of disease in electrology. (~~((1) Electrologists~~))

The following universal precautions must be used by electrologists in the care of all clients.

~~((a))~~ (1) Wash hands with soap and water immediately before and after each client contact;

~~((b))~~ (2) Wash hands and other skin surfaces immediately and thoroughly if contaminated with blood or other body fluids;

~~((c))~~ (3) Wash hands immediately before ~~((fresh, unused))~~ single-use disposable gloves are put on and after gloves are removed;

~~((d))~~ (4) Clean the client's skin by applying an antiseptic or antibacterial solution prior to and following treatment;

~~((e))~~ (5) Wear ~~((fresh, unused))~~ new gloves with each client to prevent skin and mucous membrane exposure contact with blood or other body fluids of each client;

~~((f))~~ (6) Wear gloves for touching blood and body fluids, mucous membranes, or nonintact skin of all clients, and for handling items or surfaces soiled with blood or body fluids;

~~((g))~~ (7) Change gloves after contact with each client;

~~((h))~~ (8) Immediately remove gloves that are torn or have small pinholes, wash hands and put on ~~((fresh, unused))~~ new gloves;

~~((i))~~ (9) Take precautions to prevent injuries caused by needles and other sharp instruments or devices during procedures; when cleaning used instruments; during disposal of used needles; and when handling sharp instruments after procedures;

~~((j))~~ (10) Prevent needlestick injuries by not recapping needles ~~((, not bending))~~ or breaking needles by hand and by not otherwise manipulating contaminated needles by hand;

~~((k))~~ (11) Dispose of used disposable needles and other sharp items in puncture-resistant containers;

~~((l))~~ (12) Inspect hands for small cuts, sores and abrasions; if present, use a Seal-skin product or bandage. If the electrologist has weeping dermatitis or draining sores, the electrologist should avoid contact with clients and equipment until the weeping dermatitis or draining sores are healed;

~~((m))~~ (13) Regularly clean and disinfect countertops; regularly clean walls when visibly soiled; regularly vacuum and clean carpets and floors; and

~~((n))~~ (14) Clean and disinfect other frequently touched surfaces including, but not limited to, equipment and lamps between each client.

~~((2) Tattoo artists -- The following universal precautions must be used by tattoo artists in the care of all clients.~~

~~(a) Wash hands with soap and water immediately before and after each client contact;~~

~~(b) Wash hands and other skin surfaces immediately and thoroughly if contaminated with blood or other body fluids;~~

~~(c) Wash hands immediately before fresh, unused gloves are put on and after gloves are removed;~~

~~(d) Clean the client's skin by applying an antiseptic or antibacterial solution prior to and following treatment;~~

~~(e) Wear fresh, unused gloves with each client to prevent skin and mucous membrane exposure contact with blood or other body fluids of each client;~~

~~(f) Wear gloves for touching blood and body fluids, mucous membranes, or nonintact skin of all clients, and for handling items or surfaces soiled with blood or body fluids;~~

~~(g) Change gloves after contact with each client;~~

~~(h) Immediately remove gloves that are torn or have small pinholes, wash hands and put on fresh, unused gloves;~~

~~(i) Take precautions to prevent injuries caused by needles and other sharp instruments or devices during procedures, when cleaning used instruments, during disposal of used needles, and when handling sharp instruments after procedures;~~

~~(j) Prevent needlestick injuries by not recapping needles, not bending or breaking needles by hand and by not otherwise manipulating by hand;~~

~~(k) Dispose of used disposable needles and other sharp items in puncture-resistant containers;~~

~~(l) Inspect hands for small cuts, sores, and abrasions; if present, use a Seal-skin product or bandage. If a tattoo artist has weeping dermatitis or draining sores, the tattoo artist should avoid contact with clients and equipment until the weeping dermatitis or draining sores are healed;~~

~~(m) Regularly clean and disinfect countertops; regularly clean walls when visibly soiled; and regularly vacuum and clean carpets and floors;~~

~~(n) Clean and disinfect other frequently touched surfaces such as, clip cords, pigment holders, pigment bottles, pens, equipment and lamps between each client; and~~

~~(o) Take other measures to prevent cross contamination as included in national standards per RCW 70.54.340.)~~

AMENDATORY SECTION (Amending WSR 02-11-109, filed 5/20/02, effective 6/20/02)

WAC 246-145-030 Sterile procedures in electrology. ~~((1) Electrologist --))~~ To ensure that clients are not exposed to disease through needles or other instruments, electrologists must:

~~((a))~~ (1) Use single-use, presterilized disposable needles on one client and then dispose of the needle immediately in a puncture-resistant container;

~~((b))~~ (2) Not use reusable needles;

~~((c))~~ (3) Use single-use sharp items on only one client and dispose of the items immediately in a puncture-resistant container;

~~((d))~~ (4) Only reuse cleaned and sterilized sharp items and instruments that are intended for multiple use;

~~((e))~~ (5) Thoroughly clean and sterilize reusable sharp items and instruments between clients;

~~((f))~~ (6) Accumulate reusable sharp items and instruments in a holding container by submersion in a solution of a protein-dissolving enzyme detergent and water;

~~((g))~~ (7) Sterilize reusable items in a steam autoclave or dry-heat sterilizer, which is used, cleaned and maintained according to the manufacturer's instructions;

~~((h))~~ (8) Resterilize a reusable sterile instrument before using it on a client, if it is contaminated by dropping, by touching an unsterile surface, by a torn package, by the package being punctured, damaged, wet or by some other means;

~~((i))~~ (9) Immediately dispose of a single-use item in a puncture-resistant container, if it is contaminated by dropping, by touching an unsterile surface, by a torn package, by the package being punctured, damaged, wet or by some other means;

~~((j))~~ (10) Immediately dispose of an instrument in a puncture-resistant container if the expiration date has passed; and

~~((k))~~ (11) Monitor sterilizers to determine that all conditions of sterilization are met. This includes:

~~((i))~~ (a) Assuring that sterilizers have a thermometer and timer to indicate whether adequate heat has been applied to packaged equipment;

~~((ii))~~ (b) Using or checking chemical indicators on each package to assure the items have been exposed to the sterilization process;

~~((iii))~~ (c) Sterilizers must be tested by biological spore tests according to the manufacturer's instructions. In the event of a positive biological spore test, the electrologist must take immediate action to ensure all conditions of sterilization are met; and

~~((iv))~~ (d) Documentation of monitoring must be maintained either in the form of a log reflecting dates and person(s) conducting the testing or copies of reports from an independent testing entity. The documentation must be maintained at least three years.

~~((2) Tattoo artists — To ensure that clients are not exposed to disease through needles or other instruments, tattoo artists must:~~

~~(a) Use single-use, presterilized disposable needles on one client and then dispose of the needle immediately in a puncture-resistant container;~~

~~(b) Not use reusable needles;~~

~~(c) Use single-use sharp items on only one client and dispose~~

~~of the items immediately in a puncture-resistant container;~~

~~(d) Only reuse cleaned and sterilized sharp items and instruments that are intended for multiple use;~~

~~(e) Thoroughly clean and sterilize reusable sharp items and instruments between clients;~~

~~(f) Accumulate reusable sharp items and instruments in a holding container by submersion in a solution of a protein-dissolving enzyme detergent and water;~~

~~(g) Sterilize reusable items in a steam autoclave or dry-heat sterilizer, which is used, cleaned and maintained according to the manufacturer's instructions;~~

~~(h) Resterilize a reusable sterile instrument before using it on a client, if it is contaminated by dropping, by touching an unsterile surface, by a torn package, by the package being punctured, damaged, wet or by some other means;~~

~~(i) Immediately dispose of a single-use item in a puncture-resistant container, if it is contaminated by dropping, by touching an unsterile surface, by a torn package, by the package being punctured, damaged, wet or by some other means;~~

~~(j) Immediately dispose of an instrument in a puncture-resistant container if the expiration date has passed; and~~

~~(k) Monitor sterilizers to determine that all conditions of sterilization are met. This includes:~~

~~(i) Assuring that sterilizers have a thermometer and timer to indicate whether adequate heat has been applied to packaged equipment;~~

~~(ii) Using or checking chemical indicators on each package to assure the items have been exposed to the sterilization process;~~

~~(iii) Sterilizers must be tested by biological spore tests according to the manufacturer's instructions. In the event of a positive biological spore test, the tattoo artist must take immediate action to ensure all conditions of sterilization are met; and~~

~~(iv) Documentation of monitoring must be maintained either in the form of a log reflecting dates and person(s) conducting the testing or copies of reports from an independent testing entity. The documentation must be maintained at least three years.)~~

AMENDATORY SECTION (Amending WSR 02-11-109, filed 5/20/02, effective 6/20/02)

WAC 246-145-040 Penalty for not complying with rules. Any electrologist (~~or tattoo artist~~) out of compliance with the rules in this chapter will be guilty of a misdemeanor.

NEW SECTION

WAC 246-145-050 Standard universal precautions for preventing the spread of disease in body art, body piercing, and tattooing.

The following universal precautions must be used by persons licensed to practice body art, body piercing, and tattooing:

(1) Use sterile instruments and aseptic techniques at all times during a procedure.

(2) Use only presterilized single-use disposable needles for body piercing and tattooing on one client and then dispose of the needles immediately in a sharps container.

(3) Wear a clean outer garment and prevent hair from coming into contact with the client. All necklaces, bracelets, or other personal items must be removed or covered by the outer garment or gloves to prevent the item coming in contact with the client.

(4) Wash hands and wrists thoroughly in warm running water with soap for at least twenty seconds, scrub around and under fingernails, rinse completely and dry with a clean single-use towel or hand dryer. Handwashing must be done immediately before and after performing a procedure.

(5) Inspect hands for small cuts, sores and abrasions. If present, use a Seal-skin product or bandage.

(6) Licensees with weeping dermatitis or draining sores must avoid contact with clients and equipment until the weeping dermatitis or draining sores are healed.

(7) Wear gloves during procedures and while assembling instruments. Licensees must wash hands immediately before single-use disposable gloves are put on and after gloves are removed.

(8) Wear gloves to prepare the client's skin (washing and shaving) and then discard the gloves after completing the preparation. A new pair of gloves must be put on before continuing the procedure.

(9) Remove gloves immediately, wash hands or use a hand sanitizer, and put on new gloves, when gloved hands break aseptic technique (e.g., touching eyes, nose or mouth, answering the phone, opening a door, or retrieving an item from the floor) during a procedure, or when gloves are torn or have small pinholes.

(10) If a licensee sustains a needle stick, they shall resume the procedure with clean and sterile equipment after rewashing hands and putting on new gloves.

(11) Change gloves after contact with each client.

(12) Clean and disinfect chairs, tables, work spaces, counters, and general use equipment in the procedure area between each client. Follow manufacturers' instructions for proper use of disinfecting (or detergent) products.

(13) Use appropriate barrier films to cover all items gloved hands would normally come into contact with during a procedure. These items include, but are not limited to, machine heads, clip cords, spray bottles, seat adjustment controls, power control dials or buttons and work lamps.

(14) Use single-use stencils. Petroleum jellies, soaps and other products used in the application of stencils must be

dispensed and applied using aseptic technique and in a manner to prevent contamination of the original container and its contents. The applicator must be single-use.

(15) Use only single-use pigment or ink containers for each client. Pigments and ink shall be dispensed from containers in a manner to prevent contamination to the unused portion. Individual containers of ink or pigment must be discarded after use.

(16) Use single-use razors during procedures and dispose of them in a sharps container.

(17) In the event of blood flow, use products that are single-use to control or check the blood flow or absorb the blood. Used products must be disposed of immediately in appropriate covered container. The use of styptic pens or alum solids to control blood flow is prohibited.

(18) Inks or pigments must not be banned or restricted by the FDA and must not be mixed with improper ingredients. Information indicating the source of all inks and pigments shall be available to the department upon request.

(19) Use single-use marking instruments or instruments sanitized by design, such as alcohol based ink pens, on intact skin that has been treated with an antiseptic solution. Any marking instrument that comes in contact with mucous membranes or broken skin shall be single-use.

(20) All jewelry, as defined in WAC 246-145-010, must be obtained in presterilized packaging from the manufacturer or be sterilized on-site prior to the procedure.

(21) Cleanse the client's skin before and after a procedure by washing the skin with a FDA registered antiseptic solution applied with a clean, single-use product. A sanitary covering must be placed over the procedure site when appropriate.

(22) Wearing new gloves open each package containing a sterile instrument in the presence of the client and handle each instrument in a manner to prevent contamination of the instrument.

(23) Prevent needlestick injuries by not recapping needles or breaking needles by hand and by not otherwise manipulating contaminated needles by hand.

(24) Disposal of sharps containers must comply with the local solid waste program through the licensee's local county health department.

NEW SECTION

WAC 246-145-060 Sterile procedures in body art, body piercing and tattooing. (1) To prevent clients from being exposed to diseases through needles or other instruments, licensees must:

(a) Use single-use, presterilized disposable needles on one client and then dispose of the needle immediately in a sharps container. Reusable needles must not be used.

(b) Use single-use sharps on only one client and dispose of the items immediately in a sharps container.

(c) Reuse only cleaned and sterilized instruments that are intended for multiple use between clients. A distinct, separate area must be used for cleaning instruments, wrapping/packaging the items and for handling and storing sterilized instruments. Prior to sterilizing and as soon as practical after use, instruments must be brushed or swabbed to remove foreign material or debris, rinsed, then either:

(i) Submersed and soaked in a protein dissolving detergent or enzyme cleaner; or

(ii) Immersed in detergent and water in an ultrasonic cleaning unit used according to the manufacturer's instructions; and

(iii) Rinsed and dried prior to packaging for sterilization. Ensure that the rinse step is adequate for removing cleaning residues to levels that will not interfere with the subsequent sterilization process.

(iv) Inspect instrument surface for breaks in integrity that would impair either cleaning or sterilization. Ensure that detergents or enzymatic cleaners are compatible with the metals and other materials used in the instruments.

(d) Seal cleaned instruments in bags/packing materials that are compatible with the sterilization process and are sufficiently strong to resist puncture and tears and are cleared by the FDA. Label sterilized instruments with a load number that indicates the sterilizer used, the cycle or load number, and the date of sterilization.

(e) Sterilize instruments using a monitored sterilizer. Follow the sterilization times, temperatures and other parameters recommended by the manufacturers of the instruments, sterilizer and packaging used.

(f) Arrange all items to be sterilized so all surfaces will be directly exposed to the sterilizing agent, which means loading procedures must allow for free circulation of steam (or another sterilant) around each item.

(g) Use mechanical, chemical and biologic monitors to ensure the effectiveness of the sterilization process.

(i) Monitor each load with mechanical (e.g., time, temperature, pressure) and chemical (internal and external) indicators. If the internal chemical indicator is visible, an external indicator is not needed.

(ii) At least monthly use biologic indicators to test effectiveness of sterilizer with an FDA cleared commercial preparation of spores intended specifically for the type and cycle parameters of the sterilizer.

(h) For each sterilization cycle, record the type of sterilizer and cycle used; the load identification number; the load contents; the exposure parameters (e.g., time and temperature); the operator's name or initials, and the results of the mechanical, chemical and biological monitoring. Records must be retained for three years and must be provided to the department upon request.

(i) Perform preventive maintenance of sterilizer as directed

by the manufacturer's instructions.

(j) Handle sterilized instruments using aseptic technique to prevent contamination. Store in secure, dry, clean cabinets or other secure covered containers to prevent contamination and packaging being compromised (e.g., wet, punctured, torn).

(2) If a licensee only uses sterile single-use, disposable instruments, sharps and products, and uses sterile supplies, a sterilizer is not required.