SOUTHERN NEVADA HEALTH DISTRICT REGULATIONS GOVERNING THE SANITATION AND SAFETY OF TATTOO ESTABLISHMENTS

WHEREAS, the Southern Nevada Health District (SNHD) has been established by the County of Clark and the cities of Las Vegas, North Las Vegas, Henderson, Mesquite, and Boulder City as the public Health Authority for those entities, and pursuant to Nevada Revised Statutes (NRS) 439; has jurisdiction over all public health matters in the health district; and

WHEREAS, the Southern Nevada District Board of Health (Board) is the governing body of the SNHD, and is authorized to adopt regulations to regulate sanitation and sanitary practices in the interest of public health, and to protect and promote the public health and safety in the geographical area subject to the jurisdiction of the health district; and

WHEREAS, the Board finds that the sanitary and safe practice of tattooing and sanitation and safety of tattoo establishments does affect the public health, and finds that it is necessary to adopt Regulations Governing the Sanitation and Safety of Tattoo Establishments to prevent and control the spread of communicable disease, and to promote and regulate the safety and sanitary condition of those establishments in which tattooing is performed; and

WHEREAS, the Board believes that the following Regulations are designed to protect and promote the public health and safety, it does therefore publish, promulgate and order compliance within Clark County, Nevada with the substantive and procedural requirements hereinafter set forth.

INTENT AND SCOPE

Intent

The purpose of these Regulations is to protect and promote the public health, safety and environment through preventive measures and timely correction of public health and environmental issues relating to tattoo establishments.

Scope

These Regulations establish definitions; set standards for the location, design, construction, operation, and maintenance of the tattoo establishment; outline requirements for the responsible person, event coordinator, tattoo operators, visiting artists, and patrons of the establishment; detail approved tattoo procedures, prohibited acts, and sterilization standards for equipment used in the establishment; outline record keeping and reporting requirements; provide for the issuance, modification, suspension, and revocation of Health Permits and Health Cards; give requirements for Body Art Special Events; and provide for enforcement.

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Section 1 DEFINITIONS

Summary of abbreviations of terms used in these Regulations

EPA	United States Environmental Protection Agency
°F	Degrees Fahrenheit
FDA	United States Food and Drug Administration
ISDS	Individual Sewage Disposal System
NAC	Nevada Administrative Code
NRS	Nevada Revised Statutes
ppm	Parts per million
SNHD	Southern Nevada Health District
SNWA	Southern Nevada Water Authority

As used in these Regulations, unless the context otherwise requires, the following words and terms defined have the meanings ascribed to them in this document.

- **1.1 "Administrative Hearing Officer"** defined. An **Administrative Hearing Officer** is the Administrator or any person designated by him to conduct a hearing relating to a citation or notice issued by the Health Authority pursuant to these Regulations.
- **1.2** "Adulterated cosmetic" defined. An adulterated cosmetic is any cosmetic that:

Bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual;

Consists in whole or in part of any filthy, putrid, or decomposed substance;

Has been produced, prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or rendered injurious to health:

Has a container that is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health;

Is not a hair dye and it is or it bears or contains a color additive which is unsafe within the meaning of the federal act. (NRS 585.500)

[See Appendix A for the full text of Nevada Revised Statutes (NRS), Food, Drugs, and Cosmetics: Adulteration; Labels; Brands and Appendix B for Nevada Administrative Code (NAC) 585, Drugs and Cosmetics]

1.3 "Adulterated device" defined. Adulterated device means any device that

Consists in whole or in part of any filthy or decomposed substance;

Has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been rendered injurious to health;

Has a strength that differs from or quality that falls below what it purports or is represented to possess.

Deviations of the standard strength or quality set forth in the compendium do not, alone, make a device adulterated as long as those deviations are clearly stated on its label. (NRS 585.370-390)

1.4 "Adulterated drug" defined. An Adulterated drug is any drug that

Consists in whole or in part of any filthy or decomposed substance;

Has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been rendered injurious to health;

Is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or Is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch certified under the authority of the Federal Act.

Is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. The determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in the compendium or, in the absence of or inadequacy of those tests or methods of assay, those prescribed pursuant to the Federal Act. A drug which is defined in an official compendium shall not be deemed to be adulterated under this section because it differs from the standard of strength, quality, or purity set forth in the compendium if that difference is plainly stated on its label.

Has a strength that differs from or a purity or quality that falls below that which it purports or is represented to possess *even if* the drug is not listed in the official compendium.

Is a drug and any substance has been mixed or packed with it so as to reduce its quality or strength; or substituted wholly or in part for it. (NRS 585.370-390)

- **1.5** "Advertisement" defined. Advertisement includes all representations disseminated in any manner or by any means, other than labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics. (NRS 585.030)
- 1.6 "Agency of jurisdiction" defined. The agency of jurisdiction is the local building department, safety authority, fire marshal, business licensing, police or other federal, state or local health agency, federal regulatory agencies, departments of agriculture, other than the Health Authority, having jurisdiction concerning construction, operation, maintenance, and public safety of a tattoo establishment.
- **1.7 "Apprentice"** defined. An **apprentice** is a person who is engaged in learning the occupation of a tattoo operator in a tattoo establishment and who is registered with the Health Authority to practice tattoo application as a tattoo operator's apprentice.
- **1.8** "Approved" defined. Approved means acceptable to the Health Authority based on conformance with adopted Regulations, good public health practices and recognized industry standards.
- **1.9** "Approved cosmetic" defined. An approved cosmetic is a cosmetic which is specifically approved by the Health Authority for its intended use within a tattoo establishment.
- **1.10 "Approved device"** defined. An **approved device** is a medical or other device which is specifically approved by the Health Authority for its intended use within a tattoo establishment by a person authorized to operate the device such as a licensed medical technician.
- **1.11** "Approved drug" defined. An approved drug is a drug which is specifically approved by the Health Authority for its intended use by a person authorized to administer the drug within a tattoo establishment, such as a licensed medical technician.
- **1.12** "Biocide" defined. A biocide is a chemical agent capable of killing microorganisms.
- **1.13 "Body art"** defined. **"Body art"** includes body piercing, permanent makeup, tattoo, and tattoo camouflage.
- **1.14 "Branding"** defined. **Branding** is a form of extreme body modification and scarification using a super-heated metal object, chemical, or electricity to burn an image into the human body.

- **1.15** "Camouflage" defined. Camouflage is a method of disguising or concealing permanently blotchy or irregularly pigmented skin, acne scarring or other permanent skin irregularities by the use of blending pigments into the skin.
- 1.16 "Cease and Desist Order" defined. A Cease and Desist Order is a written Order issued by the Health Authority which directs the responsible person to immediately stop doing or allowing a specific action to occur at a tattoo establishment. A Cease and Desist Order does not include a direction to completely cease operating a tattoo establishment. Under certain circumstances, a Cease and Desist Order can include a timeframe to achieve compliance with the Order so long as there is not an imminent threat to public health or safety.
- 1.17 "Chemical skin peeling" defined. Chemical skin peeling is a method for removing the superficial layer of the skin. One or more peeling chemicals are applied to the skin resulting in destruction of the superficial part of the skin. This allows a new layer of skin lining to develop.
- **1.18** "Clean" defined. Clean means free of visible dirt, dust, sludge, foam, slime (including algae and fungi), bodily excretions or secretions, rust, scale, mineral deposits, accumulation of impurities, and/or other foreign material.
- **1.19 "Communicable disease" defined**. A **communicable disease** is a disease which is caused by a specific infectious agent or its toxic products, and which can be transmitted, either directly or indirectly, from a reservoir of infectious agents to a susceptible host organism.
- **1.20 "Convenient"** defined. **Convenient** means located on the same floor and the same wing, where applicable. The maximum convenient distance is 200 feet unless further distance has been approved in writing by the Health Authority.
- **1.21 "Cosmetic"** defined. A **cosmetic** is an article intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, including wigs, hairpieces and postiches; and articles intended for use as a component of any such articles. "Cosmetic" shall not include soap. (NRS 585.060)
- **1.22** "Cross-contamination" defined. Cross-contamination is the transfer of pathogenic microorganisms to previously sanitized or sterilized surfaces, equipment, or products.
- 1.23 "Cutting" defined. Cutting is a method of extreme body modification and scarification which creates scars on the skin by using a sharp object, such as a scalpel or knife, to cut into the skin. Cutting is differentiated from a method called "skin peeling" in that no tissue is removed to create the scar during the cutting method.

- **1.24** "Dermal punching" defined. Dermal punching is a method of creating piercings in the body, which removes a segment of tissue, as opposed to traditional piercing, which makes a half moon shaped slice in the tissue. It is generally used when large gauge jewelry insertion is desired at the time of the procedure.
- 1.25 "Device" defined. Device means instruments, apparatus and contrivances, including their components, parts and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or to affect the structure or any function of the body of man or other animals.
- **1.26** "Disinfect" defined. Disinfect means to carry out a process which kills most or significantly reduces pathogenic microorganisms.
- **1.27** "Disinfectant" defined. A disinfectant is an EPA-registered antimicrobial agent, such as a chemical, or heat that destroys, neutralizes, or inhibits the growth of pathogenic microorganisms. All chemical disinfectants must provide a strength equivalent to at least 100 ppm of free available chlorine at a pH of 7.0 to 7.6 in their normal use concentration.
- **1.28** "Disinfection" defined. Disinfection is a process that reduces the number of pathogenic microorganisms, but not necessarily bacterial spores, from inanimate objects or skin, to a level which is not harmful to health.
- 1.29 "Disposable article" defined. A disposable article is an item such as a disposable razor, razor blade, paper product, drape, stencil, transfer or mimeograph paper, wooden spatula, tube, container, needle, sharp, paper towel, or any other similar item which is intended or designated to be discarded after single use or after use on a single patron during one session of tattoo application.

1.30 "Drug" defined. A Drug is:

An article recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them;

An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;

An article, other than food, intended to affect the structure or any function of the body of man or other animals; and

An article intended for use as a component of any article specified in the above paragraphs.

- 1.31 "Environmental Protection Agency (EPA)-Registered" defined. Environmental Protection Agency (EPA)-Registered means any chemical or substance, including sanitizers, sterilizers, biocides, pesticides or other substances, which is registered with the United States EPA under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) prior to their distribution and use by industry and consumers.
- **1.32 "Environmental surface"** defined. An **environmental surface** is the surface of any furniture, equipment, fixtures, walls, floors, ceilings, lavatories, toilets, tables, countertops, cabinets, or similar surface which is part of a tattoo establishment.
- **1.33 "Equipment"** defined. **Equipment** is any tattoo machine, tattoo gun, sterilizer, or similar item used in preparing for tattoo application, tattoo application itself, and cleanup and sterilization following tattoo application. This definition excludes disposable or single-use articles which are discarded after use.
- 1.34 "Extreme body modification" defined. Extreme body modification is any method, other than tattoo, permanent makeup, or body piercing methods used to alter the appearance, sensation, or function of the human body for decorative or cultural purposes. Some examples include, but are not limited to, scarification (branding, cutting, skin peeling), implantation, suspension piercing, dermal punching, single point piercing, voluntary amputation, tongue and penis splitting, and neck rings. Techniques of extreme body modification are considered medical or surgical procedures and are prohibited acts in Health Permitted tattoo, body piercing, or permanent makeup establishments.
- **1.35 "Foot-candle"** defined. **Foot-candle** is a unit of measure of the intensity of light falling upon a surface, equal to one lumen per square foot and originally defined with reference to a standardized candle burning at one foot from a given surface.
- **1.36 "Gross incompetence"** defined. **Gross incompetence** means a serious lack of ability or knowledge to perform one's duty in a sanitary manner or failure to comply with these Regulations. It shall also mean any conduct which endangers public health or safety.
- **1.37** "Health Authority" defined. Health Authority means the officers and agents of the Board and the SNHD.
- **1.38** "Hot water" defined. Hot water is water that attains and maintains a temperature between 90 and 120 degrees Fahrenheit (°F). Each use of hot water in a tattoo establishment may require a more specific temperature range.
- **1.39** "**Implantation**" defined. **Implantation** is a form of extreme body modification where items such as shaped metal are placed under the skin to produce the outline and texture of the desired image on the surface of the skin or a protrusion from the surface of the body.

- **1.40** "Jewelry" defined. Jewelry is any personal ornament inserted into a pierced area, which must be made of surgical implant-grade stainless steel, solid 14 karat (k) or 18k white or yellow gold, niobium, titanium, platinum, or approved plastics and which is free of nicks, scratches, or irregular surfaces.
- **1.41** "Laboratory" defined. A laboratory is a place equipped for experimental study in a science or for testing and analysis.
- **1.42** "Linens" defined. Linens include sheets, covers, blankets, pillow cases, drapes, towels, or any other similar item used to cover a table, mat, or a patron during a tattoo procedure.
- 1.43 "Medical professional" defined. A medical professional is a licensed, certified, or registered provider of health care such as a physician, physician assistant, osteopathic physician, advanced practitioner of nursing, registered nurse, podiatric physician, or a licensed hospital as the employer of any such person.
- **1.44** "Microdermabrasion" defined. Microdermabrasion is a facial exfoliation procedure in which the skin is "sandblasted" with ultra-fine crystals of aluminum-oxide or other ingredients to remove the top layer of skin.
- **1.45** "Misbranded cosmetic" defined. A misbranded cosmetic is a cosmetic that

Has in any way false or misleading labeling;

Does not bear a label that has, at a minimum, the name and place of business of the manufacturer, packer, and distributor; and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count;

Has a container that is made, formed, or filled to be misleading. (NRS 585.510)

1.46 "Misbranded device" defined. A misbranded device is a device that

Has in any way false or misleading labeling (NRS 585.410);

Does not bear a label that has, at a minimum, the name and place of business of the manufacturer, packer, and distributor; and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count (NRS 585.420);

If for use by humans, contains any quantity of narcotic or hypnotic substances or any chemical derivative thereof, unless its label bears the name and quantity or proportion of such substance or derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming" (NRS 585.430);

Does not have a label that bears adequate directions for use and adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods, duration, administration, or application in such manner and form as are necessary for the protection of users (NRS 585.440);

Is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof (NRS 585.470).

1.47 "Misbranded drug" defined. A misbranded drug is a drug that

Has in any way false or misleading labeling;

Does not bear a label that has, at a minimum, the name and place of business of the manufacturer, packer, and distributor; and an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. Labels affixed by a pharmacist are not required to include the name and place of business of the manufacturer, packer, or distributor;

If a prescription drug in its final dosage form intended for use by a human being, does not bear a label with the name and place of business of the manufacturer, and, if different, the name and place of business packer or distributor;

If for use by man, contains any quantity of narcotic or hypnotic substances or any chemical derivative thereof, unless its label bears the name and quantity or proportion of such substance or derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming;"

Is not designated solely by a name recognized in an official compendium unless its label bears the common or usual name of the drug, if there is one, and in the case of a drug fabricated from two or more ingredients, the common or usual name of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromide, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atrophine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances contained therein.

Does not have a label that bears adequate directions for use and adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods, duration, administration, or application in such manner and form as are necessary for the protection of users;

Is a drug and its container is so made, formed, or filled as to be misleading.

Is an imitation of another drug or is offered for sale under the name of another drug;

Is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof;

Is a drug sold at retail for use by man and contains any quantity of amidopyrine, barbituric acid, cinchophen, dinitrophenol, or sulfanilamide, unless it is sold on a written prescription signed by a member of the medical, dental, or veterinary profession who is licensed by law to administer such drug, and its label bears the name and place of business of the seller, the serial number and date of such prescription, and the name of such member of the medical, dental, or veterinary profession.

- **1.48** "Nuisance" defined. A nuisance is anything, which is injurious to health, or offensive to the senses, so as to interfere with the comfort or endanger the health or safety of the public as defined by NRS 202.450.
- **1.49** "Pathogenic" defined. "Pathogenic" means the ability to produce disease.
- **1.50 "Patron"** defined. A **patron** is any person other than an employee, responsible person, tattoo operator, or visiting artist, either paying or non-paying, that uses the services of a tattoo establishment and/or with whom a tattoo operator or visiting artist has an agreement to provide tattooing services. Anyone, including an employee of the tattoo establishment who is undergoing a tattoo procedure, is considered a patron.
- **1.51 "Permanent makeup"** defined. **Permanent makeup** is synonymous with cosmetic tattooing and includes the application of permanent eyeliner, eyebrows, lip liner, full lip color, repigmentation or camouflage using tattooing techniques of placing pigments under the skin.
- **1.52** "Permanent makeup establishment" defined. A Permanent makeup establishment is a place of business or other premises, whether or not operated for profit, where permanent makeup is applied, done, offered, sold or given whether advertising as a "parlor," "salon," "permanent makeup," "cosmetic tattooing," "body art" or other description.
- **1.53 "Potable water**" defined. **Potable water** is water that is safe for human consumption.
- **1.54 "Public area"** defined. A **public area** is any area open to public view, whether indoors or outdoors to which the public has approved access, excluding individual body art work stations and restrooms, at a tattoo establishment.

- **1.55** "Repigmentation" defined. Repigmentation is recoloration of the skin which has lost natural color as a result of burns, dermabrasion, chemical peels, removal of birthmarks, vitiligo or skin conditions which result in permanent loss of melanin from the skin; scars as a result of surgical procedures or trauma; and recreation of an areola or nipple following mastectomy.
- **1.56 "Responsible person"** defined. The **responsible person** is the individual designated by the tattoo establishment as being responsible for compliance with these Regulations.
- **1.57 "Restroom"** defined. A **restroom** is a public room that contains one or more toilets and one or more lavatories.
- **1.58** "Sanitized" defined. Sanitized means the treatment of equipment, utensils, and surfaces using a process which has been approved by the Health Authority as being effective in destroying pathogenic microorganisms.
- **1.59 "Scarification"** defined. **Scarification** is a form of extreme body modification that uses methods or techniques to produce scars on the human body for decorative purposes. Examples of scarification methods include branding, cutting, and skin peeling.
- 1.60 "Sewage" defined. Sewage is the water-carried human or animal waste from residences, buildings, industrial establishments, feedlots or other places, together with such ground water infiltration and surface water as may be present. The term includes the mixture of sewage with wastes or industrial wastes and gray water.
- **1.61 "Skin peeling"** defined. **Skin peeling** is a technique of extreme body modification and scarification which consists of cutting on the human body the outline of a design and removing the center, thereby creating a scar where the skin was removed.
- **1.62 "Spore test"** defined. A **spore test** is a bacterial endospore test designed to assess whether sterilization has actually occurred. Also known as biological spore test or biological spore monitor.
- 1.63 "Solid waste" defined. Solid waste is all putrescible and nonputrescible refuse in solid or semisolid form, including, but not limited to, garbage, rubbish, junk vehicles, ashes or incinerator residue, street refuse, dead animals, demolition waste, construction waste, and solid or semisolid commercial and industrial waste. The term does not include hazardous waste managed pursuant to NRS 459.400 to 459.600, inclusive.

- 1.64 "Standard Precautions" defined. Standard Precautions, formerly referred to as "Universal Precautions," are standard procedures used by employees to prevent transmission of disease from contact with blood or other body fluids which includes the following elements: hand washing after patron contact; using gloves when touching blood, bodily fluids, secretions, excretions, and contaminated items; using mask, eye protection, and protective clothing during procedures likely to generate exposure; handling contaminated equipment and linens in a manner that prevents the transfer of microorganisms to people or equipment; proper disposal of needles and other sharp instruments and bloodand body fluid-contaminated products, practicing care when handling sharps, and using a mouthpiece barrier device or other ventilation device as an alternative to mouth-to-mouth resuscitation. (See Appendix C, Standard Precautions).
- **1.65** "Sterilization" defined. Sterilization means destruction of all forms of microbial life including bacterial and fungal spores.
- **1.66 "Suspension piercing"** defined. **Suspension piercing** is the act of hanging the human body from or partially from hooks pierced through the flesh in various places around the body.
- **1.67** "**Tattoo**" defined. A **tattoo** is an indelible mark, figure or decorative design, fixed upon the body of a live human being by insertion of dyes or pigments into or under the skin.
- 1.68 "Tattoo camouflage" defined. Tattoo camouflage means using tattooing methods to cover up, mask, or alter an existing tattoo so that it is either rendered less noticeable or takes on a different design, thereby obliterating the original design. Flesh-colored ink is often tattooed over the design to render it less visible. Tattoo camouflage is not tattoo removal. Using tattoo methods to insert saline is considered tattoo camouflage. Tattoo camouflage is an approved act. Tattoo removal is a prohibited act.
- **1.69** "Tattoo establishment" defined. A tattoo establishment is a place of business or other premises, whether or not operated for profit, where tattoos are done, offered, sold or given whether advertising as a "tattoo parlor", "tattoo salon", "body jewelry" or other description.
- 1.70 "Tattoo establishment Closure Order" defined. A tattoo establishment Closure Order is a written notification to cease immediately all business operations of a tattoo establishment.

- 1.71 "Tattoo establishment Health Permit" defined. A tattoo establishment Health Permit is written approval by the SNHD to operate a tattoo establishment under the provisions of these Regulations. Approval is given in accordance with these Regulations and is separate from any other licensing requirements of other agencies of jurisdiction that may exist within communities or political subdivisions comprising the SNHD.
- 1.72 "Tattoo establishment Health Permit revocation" defined. A tattoo establishment Health Permit revocation occurs when the Health Authority permanently revokes approval to operate a tattoo establishment based on cause due to the presence of significant health and safety hazards.
- 1.73 "Tattoo establishment Health Permit suspension" defined. A tattoo establishment Health Permit suspension occurs when the Health Authority suspends, for an indefinite period of time, permission to operate a tattoo establishment based on cause due to the presence of significant health and safety hazards that are establishment wide or are of such severity to cause an imminent hazard to the health and safety of patrons and employees. Suspensions may lead to eventual tattoo establishment Health Permit Revocation.
- **1.74 "Tattoo operator**" defined. A **tattoo operator** is a person issued a Tattoo Operator Health Card under the provisions of these Regulations set forth in **Section 10** to practice tattooing.
- 1.75 "Tattoo Operator Health Card suspension" defined. Tattoo Operator Health Card suspension means that the individual tattoo operator to whom the Health Card was issued is not permitted to conduct any tattoo procedures while the Health Card is suspended. Suspended tattoo operators will be notified, in writing, when and under what conditions (if any) their Tattoo Operator Health Card will be reissued to them so that they may legally resume their profession.
- 1.76 "Tattoo removal" defined. Tattoo removal means using any method or substance to remove tattoo ink from the human body. Legitimate methods include laser treatments by a licensed medical professional. Illegitimate, unapproved methods include using chemicals such as caustics or medical devices in unapproved ways by individuals not licensed or qualified to administer such substances or procedures.
- **1.77 "Tattoo remover"** defined. **Tattoo remover** is any substance sold, applied, distributed, or otherwise made available to individuals for the purpose of removing tattoo ink from the human body.

1.78 "**Tattooing**" defined. **Tattooing** is any method of placing a pigment or dye into or under the skin by the use of needles or any other instruments designed to puncture the skin.

Cosmetic tattooing includes eyeliner, eyebrows, lip liner, full lip color, repigmentation or camouflage. It is also commonly known as "permanent makeup."

Figurative or decorative tattooing includes outlining or shading and the use of different sizes and configurations of needles to tattoo a design on a patron.

- "Unregulated (unapproved) invasive body modification" defined. "Unregulated (unapproved) invasive body modification" means the act of performing branding, cutting, dermal punching, implantation, scarification, suspension piercing, or any other extreme body modification not otherwise specifically approved in these Regulations, saline injection, or tattoo removal using tattoo methods that insert any substance other than tattoo ink or an approved saline solution into or under the skin; insertion of any substance other than tattoo ink into or under the skin; use of any drug or cosmetic other than topical over-the-counter anesthetic; and/or performing any recognized medical procedure not specifically approved in these Regulations by any person other than a licensed medical professional.
- 1.80 "Visiting artist" defined. A visiting artist is an individual tattoo operator who does not reside or routinely operate within the jurisdiction of the Health Authority, but who may occasionally perform tattoo procedures during a limited timeframe in a designated sponsoring tattoo establishment. Such individuals must be sponsored by a tattoo establishment which holds a current Health Permit in good standing issued by the Health Authority.

Section 2 SUBSTANTIAL HAZARDS TO PUBLIC HEALTH AND SAFETY

Substantial hazards to public health and safety include, but are not limited to:

- **2.1** Substantial damage to the tattoo establishment caused by earthquake, wind, fire, rain, or flood.
- 2.2 Loss of electrical power to critical systems, such as lighting, heating, cooling, or ventilation controls, or sterilization equipment for a period of two (2) or more hours.
- **2.3** A water outage to the entire tattoo establishment for a period of two (2) or more hours.
- **2.4** A water supply that is not approved by the Health Authority.
- 2.5 A defect or condition exists in the system supplying potable water that may result in the contamination of the water.
- 2.6 A cross-connection between the potable and non-potable water distribution systems, such as landscape irrigation, air conditioning, heating, and/or fire suppression.
- **2.7** A back siphonage.
- **2.8** Sewage that is not disposed of in an approved and sanitary manner.
- **2.9** Improperly installed toilet or hand washing facilities.
- **2.10** Infestation, harborage, or propagation of vermin.
- **2.11** The presence of toxic or noxious gases, vapors, fumes, mists, or particulates in concentrations immediately dangerous to life or health, or in concentrations sufficient to cause an environmental disease or a public nuisance.
- 2.12 The presence within the tattoo establishment of any pesticide not approved by the EPA, including any evidence of indiscriminate use of a pesticide, or herbicide which may be injurious to the health of humans.
- 2.13 The presence of any disease-causing organism in water exposed to the atmosphere at a level which has caused or is likely to cause an environmental disease in the tattoo establishment.

- **2.14** A tattoo operator or other employee infected with a communicable disease which represents an immediate hazard to fellow employees or patrons.
- **2.15** Responsible persons or tattoo operators not practicing strict standards of cleanliness, personal hygiene, and Standard Precautions.
- **2.16** Equipment that by condition, design, construction, or use poses an immediate risk of entrapment, fall, puncture, pinch, crush, tip, or other cause of injury.
- **2.17** Environmental surfaces, furnishings, mats, tattoo tables, pillows, cushions, linens, robes, garments, chairs, or other items within a tattoo establishment that are stained with blood or bodily fluids, soiled, or infested with vermin; or are in an otherwise unsanitary condition.
- 2.18 Any unmitigated biohazardous event that simultaneously involves more than one (1) individual, body art work station, or a public area exceeding 200 square feet.
- **2.19** Missing or inoperable smoke detection equipment.
- 2.20 Inability of heating and cooling equipment to maintain the room temperatures between 60°F and 90°F in all rooms and areas within the tattoo establishment used by patrons.
- 2.21 The presence of uncontrolled putrescible waste within the tattoo establishment, on the establishment grounds, or in waste accumulation and disposal areas in quantity and duration as to create a nuisance.
- **2.22** Improper disposal of biohazardous or potentially biohazardous wastes.
- **2.23** Any sharp instrument such as a needle or razor that is not appropriately placed in a sharps container <u>IMMEDIATELY</u> after use.
- **2.24** Reuse of any disposable or single-use equipment or pigments on another patron or on the same patron during a different tattooing session.
- 2.25 Lack of proper sterilization of needles, tubes or any part of the tattoo machine that comes in contact with the pigment or breaks the skin, when the items are not presterilized by the manufacturer prior to purchase.
- **2.26** A lack of adequate, currently tested, and fully functional sterilization equipment on the premises in strict compliance with **Section 4** of these Regulations.
- **2.27** All illegal clandestine drug laboratories and related activities.

2.28 If the substantial health hazard affects people or is unmitigated, then the Health Authority shall be notified by the tattoo establishment either during normal business hours at the Environmental Health Division phone number or after normal business hours through the 24-hour hotline. Such occurrences which have been corrected by the tattoo establishment must be reported to the Health Authority within normal hours the next business day.

Section 3 FACILITIES AND EQUIPMENT

3.1 Body art work stations

- **3.1.1** There shall be a minimum of one hundred (100) square feet of floor space provided for each tattoo operator in the establishment.
- **3.1.2** Each body art work station shall have a tattoo area that can be screened from the public to provide privacy and/or a private cubicle available.

3.2 Floors

- **3.2.1** All floors found in the tattoo area or restroom shall be made of a smooth, durable, nonabsorbent, nonporous material that is easily cleanable and can be maintained in a sanitary manner at all times.
- **3.2.2** Carpet is prohibited in the tattoo and restroom areas.
- 3.2.3 Every other floor and every floor covering not present in a tattoo area or restroom, such as lobby carpeting, must be kept clean and in good repair, sanitized or replaced so that it will not become a hazard to safety or health.
- 3.2.4 Every concrete, tile, ceramic and vinyl floor installed in the tattoo area or restroom must be coved at the junctures between the floor and the walls. All material used to cove the junctures must be fitted snugly to the floor and the walls so there are no openings large enough to permit the entrance of vermin.

3.3 Walls, ceilings, and closures

- **3.3.1** All environmental surfaces, including walls, ceilings less than eight feet in height, and closures found in the tattoo area or restroom shall be made of a smooth, durable, nonabsorbent and nonporous material that is easily cleanable and can be maintained in a sanitary manner at all times.
- **3.3.2** All walls, ceilings, doors, windows, skylights, other closures, fixtures, and decorative material must be kept clean and in good repair.
- **3.3.3** The materials used in constructing the walls and ceilings must be joined along the edges so there are no open spaces or cracks.
- **3.3.4** Studs, joists, rafters, and beams must not be left exposed in tattoo areas or restrooms. If left exposed in other areas, these structural members must be suitably finished and kept clean and in good repair.

3.4 Tattoo tables and chairs

Tables, chairs, cushions or any similar items used to provide tattoo services shall be constructed with smooth, durable, and easily cleanable material.

3.5 General furniture

All furniture that is not used in performing a tattoo procedure, such as chairs provided for lobby area seating must be cleanable, kept in good repair, and maintained in a clean and sanitary condition.

3.6 Lighting

- 3.6.1 An artificial light source that gives off at least twenty (20) foot candles ambient light measured at thirty (30) inches above floor level must be provided at all times.
- **3.6.2** At least fifty (50) foot candles of light shall be provided at the level where the tattoo is being performed.

3.7 Smoke alarms

Each distinct area of the tattoo establishment must be equipped with at least one working smoke alarm that is installed, maintained, and tested according to existing fire codes.

3.8 Heating and ventilation systems

- **3.8.1** Each system for heating, cooling, or ventilation must be properly maintained and operational at all times.
- **3.8.2** The establishment shall have mechanical heating and air conditioning equipment sufficient to maintain the facility at a temperature of 68°F to 82°F.
- **3.8.3** Ventilation equipment must be able to prevent moisture accumulation on environmental surfaces.

3.9 Hand sinks and restrooms

- **3.9.1** Hand sinks with hot and cold running water shall be located in each tattoo area/body art work station. Hand sinks must be supplied with liquid soap and disposable paper towels, both in dispensers.
- 3.9.2 Restrooms with hand sinks shall be provided. All restrooms must be supplied with liquid soap, disposable paper towels, and a supply of toilet paper. All supplies must be in dispensers.

3.9.3 Adequate covered solid waste containers shall be provided in each work station and restroom for disposal of debris and trash. These containers shall be easily cleanable, kept clean, and be emptied daily.

3.10 Water supply

- **3.10.1** The potable water supply for each tattoo establishment must be from a source approved by the State of Nevada Division of Environmental Protection, Bureau of Safe Drinking Water and must meet all NRS 445A requirements.
- **3.10.2** Each tattoo establishment must be supplied with or have available a hot and cold potable water supply that meets all sanitary purposes.

3.11 Plumbing

- **3.11.1** The potable water system must be installed and maintained in such a manner that there is no cross connection between it and any other system.
- **3.11.2** If a device used to prevent backflow or back siphonage is necessary, it must be installed on a potable water system in compliance with the standards for construction, installation, maintenance, inspection, and testing outlined in the most current Plumbing Code adopted by the agency of jurisdiction.
- **3.11.3** The written results of annual backflow prevention device testing must be made available at the tattoo establishment for Health Authority review.

3.12 Water damage evaluation

- 3.12.1 Whenever evidence of significant water/moisture intrusion from any source is found within or on the walls, ceilings, attic spaces, crawl spaces, floors, carpeted surfaces, ventilation ducts, insulation, or other materials or areas which may promote the growth of mold, the source of the water or moisture must be identified and stopped to prevent or reduce mold growth.
- **3.12.2** Whenever a need arises to conduct a large-scale mold remediation affecting more than 1,000 square feet within a tattoo establishment, the Health Authority must be notified in writing of actions taken.

3.13 Solid waste disposal

- 3.13.1 Each tattoo establishment must have solid waste containers of sufficient number and size to store all the solid waste in a manner that does not exceed the waste containers' capacities until the solid waste is removed. Tattoo establishments may use common solid waste dumpsters when the tattoo establishment is incorporated within a mall or other multi-business facility.
- 3.13.2 If the solid waste is not being removed in a manner that prevents a public health nuisance or danger, the Health Authority shall direct the responsible person at the tattoo establishment to increase their solid waste container capacity and/or increase the frequency of scheduled pickups until adequate removal of the solid waste is achieved.
- **3.13.3** The solid waste containers must be:
 - **3.13.3.1** Kept at locations approved by the Health Authority.
 - **3.13.3.2** Emptied at least twice weekly. The frequency of solid waste removal must be at an interval which prevents putrescible waste from becoming a nuisance even if such frequency is more often than twice weekly.
 - **3.13.3.3** Kept covered and closed with a tight fitting lid at all times except when being filled, emptied, or cleaned, unless the equipment is specifically designed to be operated as an open dumpster or trash compactor.
 - **3.13.3.4** Kept clean. Facilities for washing them must be provided and operated in a sanitary manner or appropriate contracts with a solid waste disposal company must be in place to clean and/or replace waste containers that become excessively dirty.

3.14 Sewage disposal

- **3.14.1** All sewage carried by water must be disposed of by means of public sewerage or by a system for disposal such as an ISDS, which is approved by the Health Authority.
- **3.14.2** If the tattoo establishment intends to discharge its sewage to an ISDS, the facility must submit plans for review and approval and obtain a permit for the ISDS from the Health Authority for that purpose.
- **3.14.3** Any sewage discharge, sewer pipe leaks, spills, or backflow onto the ground must be stopped and/or contained within four (4) hours or the facility may be subject to closure by the Health Authority.

3.14.4 All sewage spills must be remediated in a manner that eliminates potential disease transmission, offensive odors, sewage solids, and sewage litter.

3.15 Outdoor areas

All outdoor areas including, but not limited to, parking areas, walkways, landscaped areas, storage areas, and undeveloped grounds must have sufficient drainage to prevent water from collecting and stagnating in pools, and must be kept clean and free of any health hazards.

3.16 Sharp objects used in tattoo procedures

A sealable, rigid (puncture-proof) sharps container that is strong enough to protect the tattoo operator, patrons and others from accidental cuts or puncture wounds must be provided for disposal of sharp objects that come in contact with blood and/or body fluids. The sharps container must be properly labeled with the international biohazard symbol. (See examples of biohazard symbols in *Appendix D*.)

3.17 Service animals

- **3.17.1** Service animals are permitted in a tattoo establishment; however, no service animal may be allowed to create a nuisance.
- **3.17.2** Animal wastes must be cleaned up immediately.
- **3.17.3** No other animals of any kind shall be allowed except fish in aquariums.

Section 4 GENERAL SANITATION AND STERILIZATION

4.1 Public areas

The entire premises of the establishment must be kept clean, sanitary and in good physical condition at all times.

4.2 Cleaning and sanitizing

- **4.2.1** All tattooing areas, body art work stations, rooms, and articles used on a patron, other than those items requiring full sterilization, must be sanitized before use by a disinfectant or other method approved by the Health Authority.
- **4.2.2** The tattoo machine parts, excluding the electrical components and interior motor casing, used in administering the tattoo shall be cleaned thoroughly after each use by scrubbing with a soap solution containing a biocide and hot water.

4.3 Sterilization

- **4.3.1** Sterilizers must be kept clean, in good working order and must be operated in a clean area.
- 4.3.2 After cleaning, all instruments used in the tattoo procedure shall be packaged individually in paper peel-packs, heat-sealed plastic, or other autoclave packaging approved by the Health Authority, then sterilized by a steam, chemical, or dry heat sterilizer registered and listed with the FDA or equivalent foreign governmental agency that is used, cleaned, and maintained according to the manufacturer's instructions. Such packages must contain a temperature strip or sterilizer indicator listed with the FDA.
- 4.3.3 All packs must be marked with the date of sterilization. A colorimetric sterilizer indicator or internal temperature indicator must be used. Equipment packed in peel-packs or heat-sealed plastic and sterilized in house will be considered sterile for a maximum of six (6) months. Commercially available single use ethylene oxide or gamma radiation sterilized equipment may be used as long as all of the manufacturer's recommendations and expiration dates are followed.
- 4.3.4 All equipment used in the tattoo procedure must remain stored in sterile packages until just prior to performing a procedure. When equipment is assembled, the tattoo operator shall wear gloves and use great care to ensure that equipment is not contaminated.

- 4.3.5 Sterilizers are not required in tattoo establishments that exclusively use prepackaged, single-use, sterilized equipment and supplies. The owner or responsible person must submit a signed disclaimer to the Health Authority for review stating that only presterilized equipment will be used in tattoo procedures.
- **4.3.6** Single-use, prepackaged, sterilized equipment and supplies must obtained from reputable suppliers or manufacturers.
- **4.3.7** Single-use items shall not be reused for any reason.
- **4.3.8** If the tattoo establishment operator brings any reusable items or equipment into the tattoo establishment, the Health Authority shall be notified of this action immediately.
 - **4.3.8.1** A properly spore tested sterilizer will need to be provided immediately.
 - **4.3.8.2** The sterilizer shall not be used until approved by the Health Authority, following review of the spore test laboratory report described in **Section 4.4.3.4**. Until the Health Authority approves the sterilizer, the tattoo establishment must continue to use prepackaged, single-use, sterilized equipment and supplies.

4.4 Sterilizer testing

This Section shall not apply to tattoo establishments that exclusively use prepackaged, single-use, sterilized equipment and supplies.

- **4.4.1** Each responsible person shall demonstrate that the sterilizer(s) used at the tattoo establishment are capable of attaining proper heat and pressure and are operating correctly through testing, by the means specified below:
- **4.4.2** Thermal and/or chemical indicator strips consistent with the type of sterilization process used, to ensure sufficient temperature and proper functioning of equipment during the sterilization cycle, are required on all packaged instruments during each sterilization; and
- **4.4.3** A spore destruction test every 12 months or more often if recommended by the manufacturer. This spore destruction test must consist of the following criteria:
 - 4.4.3.1 A biological monitoring system (commercial preparation of spores consisting of a known quantity of *Geobacillus [Bacillus]* stearothermophilius spores produced without contamination and provided by an approved supplier) to ensure all microorganisms have been destroyed and sterilization has been achieved.

- **4.4.3.2** This test shall be verified through an independent approved laboratory which is capable of accurately analyzing the spore test.
- **4.4.3.3** Approved independent clinical laboratories will concurrently run quality control samples to ensure an accurate assessment of the spore sample. Therefore, an unsterilized sample from the same lot must be submitted with the processed sample to perform the quality control tests.
- 4.4.3.4 Records of the spore destruction test results shall be maintained at all times on site at the tattoo establishment. These records shall be made readily available for inspection during normal operating hours. Records shall contain at least the following information:
 - **4.4.3.4.1** Name, address, and phone number of the tattoo establishment submitting the spore sample for testing.
 - **4.4.3.4.2** Name, address, phone number, and certification number(s) for the approved independent clinical laboratory performing the spore test and quality control test.
 - **4.4.3.4.3** Name, address, and phone number of the manufacturer of the spore preparation used in the spore test.
 - **4.4.3.4.4** The brand name of the spore preparation and its lot number and expiration date.
 - **4.4.3.4.5** The date and time the spore test was conducted at the tattoo establishment. Include both start and stop times of the spore test.
 - **4.4.3.4.6** The date and start and stop times the spore sample and quality control sample were processed by the laboratory.
 - **4.4.3.4.7** The date the information from the spore test was reported back to the tattoo establishment.
 - **4.4.3.4.8** The results of the spore test and quality control test if requested by SNHD.
- **4.4.4** The Health Permit shall not be issued or renewed until documentation of the sterilizer's ability to destroy spores is reviewed on-site at the time of inspection by the Health Authority.
- **4.4.5** The following actions may result in suspension or revocation of the tattoo establishment's Health Permit:

- **4.4.5.1** Laboratory results that indicate the sterilizer failed the spore test.
- **4.4.5.2** Continuing to operate with the knowledge that the sterilizer failed the spore test.
- **4.4.5.3** Failure to comply with the requirements for spore testing specifically outlined in this section of these Regulations.

4.5 Dyes and pigments

All dyes and pigments used in tattoo procedures must be obtained from a reputable manufacturer. The pigments and dyes must be designated specifically for use in tattooing and must be used without adulteration or dilution (except when using sterile, distilled water) of the original formula. Repackaging quantities of dyes and pigments is prohibited.

4.6 Materials used in tattoo preparation and application

- **4.6.1** Materials such as mimeograph paper, markers, alcohol, lubricants, razors, etc. used in preparation for the application of a tattoo must be kept clean and in good condition.
- 4.6.2 All materials which are designed for multiple use (e.g., markers) shall only be applied directly to clean, unbroken skin. If such materials come into contact with blood or bodily fluids, they cannot be reused and must be immediately discarded.

Section 5 RESPONSIBLE PERSON AND EVENT COORDINATOR

5.1 Responsible person

- 5.1.1 The Health Permit holder for a tattoo establishment may designate a responsible person to act on his behalf within the establishment. The owner must notify the Health Authority in writing of any designation, providing the name and contact information for the responsible person.
- **5.1.2** The responsible person must ensure that all applicable permits, licenses, work cards, and Tattoo Operator Health Cards that are required to be visible to patrons and the public are properly displayed in the locations indicated by the Health Authority and other agencies of jurisdiction.
- **5.1.3** The responsible person is held accountable for compliance with all requirements issued by all relevant state, county, and local agencies of jurisdiction where the tattoo establishment conducts business.
- 5.1.4 Violation of any one or a combination of these requirements by the tattoo establishment, the responsible person, any employee, tattoo operator, or visiting artist may result in the suspension of the tattoo establishment's Health Permit and interruption of business operations while the matter is resolved with the affected agency of jurisdiction.
- 5.1.5 The responsible person may also act as an event coordinator during a Body Art Special Event (hereinafter referred to as "Special Event"), but must make separate application for each Special Event he wishes to coordinate.

5.2 Event coordinator

- **5.2.1** An event coordinator must be designated for each Special Event that is held within Southern Nevada.
- 5.2.2 The event coordinator must make application and pay applicable fees to the Health Authority thirty (30) days prior to the Special Event to avoid late fees and possible denial of the Health Permit.
- 5.2.3 It is the responsibility of the event coordinator to organize and ensure that any items needed during the Special Event are provided by the person or agency holding the event. These requirements are located in **Section 11-Body Art Special Events and Permits.**

- 5.2.4 The event coordinator must acknowledge in writing, as part of the application process, that failure to comply with all applicable Regulations may result in immediate revocation of the Special Event Health Permit and the issuance of a Cease and Desist Order to all of the tattoo operators at the event.
- 5.2.5 The event coordinator may be held responsible for the actions of visiting artists who do not comply with these Regulations. The event coordinator, the event sponsor, and the visiting artist all may be subject to enforcement actions.

Section 6 TATTOO OPERATORS AND VISITING ARTISTS

6.1 Tattoo operators

- 6.1.1 It shall be unlawful for any person to act as a tattoo operator within a tattoo establishment, or for any Health Permit holder or person to employ another person as a tattoo operator, unless such person has been issued a Tattoo Operator Health Card by the Health Authority in accordance with these Regulations under **Section 10-Health Card Requirements and Fees**.
- **6.1.2** The Health Permit holder of a tattoo establishment may also hire tattoo operators who have been approved to work as visiting artists by the Health Authority.
- **6.1.3** Tattoo operators must be free from all communicable disease while administering tattoos.
- **6.1.4** Tattoo operators must not smoke while administering tattoos.
- **6.1.5** Prior to and immediately following administering tattoos, tattoo operators must thoroughly wash their hands and nails in hot running water and liquid soap, rinse them in clear warm water and then dry their hands with a disposable paper towel.
- 6.1.6 Tattoo operators must also wash their hands if at any point in applying the tattoo there is an interruption which causes the tattooing process to cease. Upon returning to the patron, tattoo operators must again wash their hands before donning fresh gloves.
- **6.1.7** During tattoo procedures, tattoo operators shall wear exam gloves. These gloves shall be discarded after each procedure to prevent cross-contamination and when damaged, soiled, or when interruptions occur in the procedure.
- **6.1.8** Tattoo operators, while on duty, shall:
 - **6.1.8.1** Utilize or wear effective hair restraints if they have hair over the ears;
 - **6.1.8.2** Have clean fingernails;
 - **6.1.8.3** Wear clean outer garments; and
 - **6.1.8.4** Have good personal hygiene.

- **6.1.9** Tattoo operators must demonstrate a high level of competence. Gross incompetence may be cause for suspension or nonrenewal of a Tattoo Operator Health Card.
- 6.1.10 Tattoo operators are prohibited from providing tattoo services outside of a tattoo establishment operating with a current valid Health Permit unless they are participating in an approved Special Event with an unexpired Health Permit. Tattoo operators wishing to participate in a Special Event must complete a Body Art Special Event Person/Business name application and event coordinator application if necessary and pay all applicable fees.
- **6.1.11** Tattoo Operator Health Cards are not transferable from person to person.
- 6.1.12 Tattoo operators shall not apply tattoos while under the influence of an intoxicating substance. No alcoholic beverages are permitted in the body art work station. Evidence that the tattoo operator is applying tattoos while inebriated is sufficient cause for immediate suspension of that individual's Tattoo Operator Health Card.

6.2 Tattoo operator training and other requirements

- 6.2.1 Tattoo establishment Health Permit holders are required to comply with the State of Nevada Occupational Safety and Health Standards for General Industry (29 CFR Part 1910.1030) regarding occupational exposure to bloodborne pathogens.
- **6.2.2** Documentation of both hepatitis A and B immunizations of all tattoo operators working at the tattoo establishment must be maintained and available for review by the Health Authority. (See *Appendix E* for a sample documentation form for use by the tattoo establishment)
- **6.2.3** Health Permit holders or their designated responsible person are responsible for:
 - **6.2.3.1** Ensuring that tattoo operators working at their tattoo establishments initiate both the hepatitis A and B vaccination series within thirty (30) days of starting work unless:
 - 6.2.3.1.1 The tattoo operator has previously received the complete hepatitis A and/or B vaccination series and can provide documentation to the Health Authority that one or both of the series have been completed. If one has been completed, the tattoo operator must still complete the other series of vaccinations,
 - **6.2.3.1.2** Antibody testing has revealed that the tattoo operator is immune to either hepatitis A or B, or both. If antibody testing reveals that the

tattoo operator is immune to one form of hepatitis, but not the other, then either:

- **6.2.3.1.2.1** The vaccination series must be completed or
- 6.2.3.1.2.2 Documentation of completion of the vaccination series shall be provided once the series is completed, for the form of hepatitis for which the tattoo operator has no immunity.
- **6.2.3.1.3** The hepatitis A and/or B vaccines are contraindicated for medical or religious reasons; then the current SNHD policies regarding vaccine exemptions or deferrals shall be followed.
- 6.2.3.2 Ensuring that individuals working in the tattoo establishment have a current SNHD Tattoo Operator Health Card and comply with all applicable health, safety, sanitation and sterilization Regulations of the SNHD and other state agencies. Tattoo operators must have their Tattoo Operator Health Card on their person when working and the tattoo establishment must have a copy at the facility available for review by the Health Authority.
- **6.2.3.3** Notifying the Health Authority, verbally or in writing, when a tattoo operator starts or stops working at his tattoo establishment.
- 6.2.3.4 Ensuring that at least one (1) person trained in CPR and First Aid is available at the tattoo establishment during all hours of operation. Current certification documents must be provided to the Health Authority for each certified person.

6.3 Visiting artists

- 6.3.1 An individual who is not a tattoo operator within Southern Nevada; but who routinely works in the tattoo industry in an area outside the jurisdiction of the Health Authority, may apply to be a visiting artist in Southern Nevada. Visiting artists from other jurisdictions must be hosted by a tattoo establishment with a valid Health Permit for a period of time no greater than the limit set forth in this section.
- **6.3.2** Each visiting artist must make application to the Health Authority for each time interval in which he would like to participate. (Application forms for visiting artists may be found in **Appendix F**)
- **6.3.3** While performing tattoo procedures within the jurisdiction of the Health Authority, visiting artists shall comply with all applicable Regulations. Failure to do so may result in revocation of permission to participate.

- **6.3.4** Visiting artists shall not perform procedures in any location whatsoever except the tattoo establishment or Special Event for which they are registered.
- **6.3.5** Once the visitation period of time is over, the visiting artist no longer has permission to operate within the Health Authority's jurisdiction.

6.4 Failure to comply

Failure to comply with the provisions of this Section of these Regulations may result in Tattoo Operator Health Card suspension, revocation of permission for a visiting artist to operate, tattoo establishment or Special Event Health Permit suspension, and/or an administrative hearing.

Section 7 PATRONS

7.1 Patron age requirements and other age restrictions

- **7.1.1** No persons under the age of eighteen (18) shall be permitted to loiter in the tattoo area of the establishment, whether or not they are the children or wards of the Health Permit holder, responsible person, or any of the employees, operators, visiting artists, or patrons of the tattoo establishment.
- 7.1.2 Persons under the age of fourteen (14) shall not be permitted to enter the facility or have a tattoo applied in the tattoo establishment. Patrons between the ages of fourteen (14) and eighteen (18) are permitted in the tattoo area when receiving services in the presence of their legal parent or guardian or when they are legally emancipated by a court of competent jurisdiction and can provide documentation to that fact.
- **7.1.3** The tattoo establishment may set its own age restrictions regarding the presence of minors that are **more stringent** than those cited in these Regulations.
- 7.1.4 No person shall perform any tattoo procedure whatsoever upon a person under the age of fourteen (14) years, unless under the supervision of a medical professional. Tattoo procedures performed upon a person under the age of eighteen (18) years require the written consent and proper identification of a parent or guardian unless the person has been emancipated by a court of competent jurisdiction and can provide legal documentation stating this fact. Any tattoos performed on a minor must be done in the presence of a parent or guardian.
- **7.1.5** Nothing in this section is intended to require a tattoo operator to perform any tattoo on a person under eighteen (18) years of age, even with parental or guardian consent.
- **7.1.6** Age of <u>ALL</u> patrons must be verified by government-issued photographic identification and documented prior to the procedure being performed.
- 7.1.7 The government-issued photographic identification of <u>ALL</u> patrons twentyone (21) years of age or younger must be photocopied and kept with the patron's paperwork.

7.1.8 Government-issued photographic identification provided by the parent or guardian of a patron under the age of eighteen (18) must be photocopied and kept with the patron's paperwork. A certified copy of a birth certificate, guardianship papers, or other document where both the adult and minor's names are listed can be used to document the authenticity of the relationship.

7.2 Patron advisements

Before administering tattoos, the patron must be advised that the tattoo should be considered permanent; that it can only be removed with a surgical procedure; and that any effective removal may leave permanent scarring and disfigurement. A written cautionary notice to that effect, in a form approved by the Health Authority, must be furnished to the patron. The patron must sign a copy of the notice, indicating it was read and understood, which will then be placed in the patron's records kept at the tattoo establishment.

7.3 Patron assessments

- 7.3.1 Tattoos may not be administered to any person under the influence of drugs or alcohol. The tattoo operator and tattoo establishment are charged with the responsibility of making reasonable observations and inquiries to determine that the patron is in fact sober, and not under the influence of intoxicating substances. If the tattoo operator has reasonable suspicion that a person is under the influence he may decline to apply a tattoo at that time.
- **7.3.2** The patron must be asked before the tattoo procedure whether he has had a history of jaundice or hepatitis within twelve (12) months preceding that date.
- **7.3.3** The tattoo operator may decline to perform a procedure on any would-be patron whom the tattoo operator suspects to have a communicable disease.
- **7.3.4** The skin surface to be tattooed must be visibly free of rash, pimples, infection or scar tissue. The patron must be in apparent good health, and the skin to be tattooed generally must be in a healthy condition to all appearances.
- 7.3.5 The tattoo operator may decline to perform a procedure on any patron at any time for any reason if he deems it likely that the procedure is not appropriate for that person at that time or if he deems that the patron is currently likely to bring harm to the tattoo operator, himself, or others within the tattoo establishment (e.g., they are in an agitated or belligerent state).

7.4 No food, beverage, or smoking in tattoo area

The patron and/or the tattoo operator must not bring food or drink into a tattoo area, and must not smoke during the tattoo procedure. An enclosed beverage such as bottled water may be provided to prevent dehydration if the procedure is lengthy.

7.5 Record keeping

- **7.5.1** The tattoo establishment must keep a permanent record of all patrons receiving tattoos, stating:
 - **7.5.1.1** The patron's name, age, and address;
 - **7.5.1.2** The date of procedure,
 - **7.5.1.3** The tattoo operator's name,
 - **7.5.1.4** The place on the patron's body where the tattoo was applied, and
 - **7.5.1.5** A reasonably accurate description of the design of the tattoo that is sufficient to identify it as the tattoo applied by that particular tattoo establishment and tattoo operator.

7.5.2 Such records shall be:

- **7.5.2.1** Kept at the physical location of the tattoo establishment unless written permission is granted otherwise by the Health Authority.
- **7.5.2.2** Maintained in an orderly manner, filed by month and year, to facilitate retrieval of records.
- **7.5.2.3** Retained for a minimum of two (2) years.
- **7.5.2.4** Made available to the Health Authority upon request.

7.6 Failure to comply

Failure to comply with the provisions of this Section may result in Tattoo Operator Health Card suspension, tattoo establishment Health Permit suspension and/or an administrative hearing.

Section 8 TATTOO PROCEDURES

8.1 Preparing for tattoo procedure

- **8.1.1** The skin and the surrounding area where the tattoo is to be placed shall first be washed with soap and water or an approved surgical skin preparation.
- **8.1.2** If shaving is necessary, single-use disposable razors or safety razors with single-service blades shall be used. Blades shall be discarded in an appropriate sharps container after each use, and reusable holders shall be autoclaved after use.
- **8.1.3** Following shaving, the skin and the surrounding area must be gently washed with soap and water using a single-use paper product which shall be disposed of after use.
- 8.1.4 Substances applied to the client's skin to transfer designs from a stencil or paper shall be dispensed from containers in a manner to prevent contamination of the unused portion. Use of a spray bottle to apply liquid to the skin is acceptable. All creams and other semi-solid substances shall be removed from containers with a clean, sanitized spatula. Spatulas made of a washable, non-absorbent material and designed for multiple use may be sanitized and used again. Spatulas made of wood or otherwise designed for single-use shall be discarded after a single use. Single-use tubes or containers shall be discarded following the tattoo procedure.
- 8.1.5 Individual portions of dyes or pigments in clean single-use containers shall be used for each client. Any remaining unused dye or pigment and the single-use container(s) shall be discarded immediately following service.
- **8.1.6** Large batch containers of dyes or pigments that are used to dispense product into the single-use containers are permitted. No dye or pigment shall be reintroduced for any reason into these batch containers after it has been dispensed for single use, even if it is not actually used. It must still be discarded.

8.2 Single use items-rules and prohibitions

8.2.1 Single-use items shall not be reused for any reason. Tattoo needles are not reusable under any circumstances. After use, all needles, razors and other sharps shall be immediately disposed of in sharps containers, appropriately labeled with the international biohazard symbol.

- **8.2.2** A single tattooing session that is interrupted for a brief amount of time, such as is required to use the restroom, does not require disposal of all single-use items being used on a single patron. Using the same supplies to complete the tattooing session on a single patron does not constitute a case of reuse.
- **8.2.3** Keeping items used on a patron in storage for use later in the same day or on another day does constitute reuse, even though only one patron is involved.
- **8.2.4** Using supplies from one patron to another patron constitutes reuse.

8.3 Linens

- **8.3.1** Clean linens shall be used for each patron. A common towel is prohibited.
- **8.3.2** Clean linens, tissues or single-use paper products shall be stored in a clean, enclosed storage area until needed for immediate use.
- **8.3.3** Used linens shall be stored in a closed or covered container until laundered.
- **8.3.4** Soiled linens may be laundered in a washing machine with laundry detergent and chlorine bleach or by a regular commercial laundry service.

8.4 Biohazardous events and solid waste disposal

- 8.4.1 Contaminated waste which may release liquid blood or body fluids when compressed or may release dried blood or body fluids when handled must be contained in an appropriate red or orange bag and labeled with the international biohazard symbol. The bag and its waste must then be disposed of by a waste hauler authorized to dispose of biohazardous waste. Contaminated waste which does not release liquid or dried blood or body fluids when handled may be contained in a covered receptacle and disposed of through normal, approved disposal methods.
- **8.4.2** Tattoo operators shall maintain a sanitary environment during all procedures to prevent cross-contamination.
- **8.4.3** In the event of blood flow, all products used to check the flow of blood or to absorb blood shall be single use and disposed of immediately after use in appropriate covered containers, including containers marked to handle biomedical waste.

8.5 After care instructions

Both verbal and written instructions concerning proper care of the newly tattooed skin called "After-Care instructions" shall be provided to each patron following each procedure. "After Care Instructions" shall specify care following service, possible side effects and activity restrictions. The content of such instructions shall be approved by the Health Authority.

8.6 Infection reporting required

Any infection resulting from the tattoo procedure, which becomes known to the operator or the tattoo establishment, shall be immediately reported verbally to the Health Authority and followed up in writing within forty-eight (48) hours of the receipt of the initial information.

8.7 Prohibited acts

The following acts are **expressly prohibited** by the Health Authority:

- **8.7.1** Scarification (branding, cutting, skin peeling).
- **8.7.2** The implantation of jewelry or objects under the skin,
- **8.7.3** Dermal punching,
- **8.7.4** Single point piercing,
- **8.7.5** Suspension piercing,
- **8.7.6** Voluntary amputation,
- **8.7.7** Tongue or penis splitting,
- **8.7.8** Neck rings,
- **8.7.9** Foot binding,
- **8.7.10** Corseting,
- **8.7.11** Any other form of unregulated invasive or extreme body modification which may emerge in the future,
- **8.7.12** Tattoo or permanent makeup removal (unless under supervision by a licensed physician) by means of:
 - **8.7.12.1** Surgery,
 - **8.7.12.2** Treatment with a chemical or substance, or
 - **8.7.12.3** Medical device such as infrared coagulator or laser, or

- **8.7.13** The injection into the human body of:
 - **8.7.13.1** Botulinum toxin,

 - 8.7.13.2 Prescription numbing agents, or8.7.13.3 Any substance other than dyes or pigments approved for tattooing.

Section 9 HEALTH PERMITS

9.1 Tattoo establishment Health Permit required

All tattoo establishments must have a current and valid tattoo establishment Health Permit issued by the Health Authority in order to operate.

9.2 Tattoo establishment Health Permit exemptions and prohibitions

- **9.2.1** A physician, or a person working under the direct supervision of a physician, performing tattooing procedures in the physician's office or clinic, is exempt from these Regulations.
- **9.2.2** No Health Permits shall be issued to private residences, including apartments, condominiums, multi-family or single-family dwellings for tattooing activities.
- 9.2.3 Anyone applying tattoos to another person in any location in Southern Nevada, other than an approved, Health Permitted tattoo establishment or Special Event is in violation of these Regulations and will be ordered to cease and desist all activities. If the individual also holds a Tattoo Operator Health Card, the Tattoo Operator Health Card is subject to suspension and possible revocation if that tattoo operator engages in any prohibited activities.

9.3 Applications for and issuance of tattoo establishment Health Permits to operate

- **9.3.1** Prior to commencing the operation of any tattoo establishment, the responsible person or persons, business entity, or agent must make written application for a tattoo establishment Health Permit on forms provided by the Health Authority, pay all applicable fees, and receive written approval from the Health Authority to operate. Application forms may be found in **Appendix G** or online at www.southernnevadahealthdistrict.org.
- **9.3.2** When making application for a tattoo establishment Health Permit, the following information and items must be brought to the Health Authority for review and/or approval:
 - **9.3.2.1** The name, location address, and mailing address of the tattoo establishment:
 - **9.3.2.2** A statement indicating whether the applicant is a natural person, firm, or corporation, and;

- **9.3.2.3** The applicant's full name, mailing address, and signature or that of a representative designated by them, if the applicant is a firm or corporation;
- **9.3.2.4** The name of the responsible person/point of contact of the tattoo establishment and contact information such as addresses and phone numbers and signature, if different from the applicant or applicant's representative;
- **9.3.2.5** Proof of ownership or lease agreement for the property and buildings on which the tattoo establishment is or will be built or located:
- **9.3.2.6** A floor plan and specification of the tattoo establishment as it is proposed to be operated. If under new construction or major remodel, any construction plans, schedules, schematics, or drawings, may be provided by the applicant for consideration prior to formal plan review;
- **9.3.2.7** The proposed hours of operation;
- **9.3.2.8** The names of all employees and their exact duties:
- **9.3.2.9** A complete description of all tattoo services to be provided;
- 9.3.2.10 An exact inventory of all tattoo equipment to be utilized, including names of manufacturers. If the establishment intends to use items that require sterilization, a steam, chemical, or dry heat sterilizer registered and listed with the FDA or equivalent foreign governmental agency, spore tested within thirty (30) days of the Health Permit Application, must be at the establishment prior to the Health Permit being issued;
- **9.3.2.11** Names and addresses of all suppliers of tattoo equipment and supplies.

9.4 Tattoo establishment Health Permit issuance

- **9.4.1** If the Health Authority determines, after plan review, investigation, and inspection, that the proposed establishment can be operated in accordance with the provisions of these Regulations, a Health Permit may be issued to the applicant.
- **9.4.2** All Health Permits shall be renewed annually. Their issuance is conditional upon strict compliance with these Regulations.
- **9.4.3** Health Permits may be revoked or suspended for violation of these Regulations in accordance with the procedures set forth in **Section 14**.

9.4.4 Health Permits are not transferable from person to person or location to location.

9.5 Tattoo establishment Health Permit fee schedule

Pursuant to NRS 439.360(5), and under the authority of NRS 439.410(3), the District Board of Health adopts by reference, the current Health Permit Fee Schedule as it applies to tattoo establishments.

9.6 Tattoo establishment Health Permit posted

- **9.6.1** The current tattoo establishment Health Permit must be posted in plain view of the general public and shall not be altered or defaced in any manner.
- **9.6.2** The Health Permit holder must also post, in public view within the premises, next to the Health Permit, a disclosure statement approved by the Health Authority which advises of the risks and possible consequences of tattoo procedures. (See *Appendix H* for Public Notice).
- **9.6.3** Copies of these Regulations must also be prominently displayed in any Health Permitted tattoo establishment.

9.7 Failure to Comply with Health Permit requirements

Failure to comply with the provisions of this chapter may result in Tattoo Operator Health Card suspension, tattoo establishment Health Permit suspension and/or an administrative hearing.

Section 10 HEALTH CARD REQUIREMENTS AND FEES

10.1 Application for Tattoo Operator Health Card

Application for a Tattoo Operator Health Card shall be made to the Health Authority on forms approved by the Health Authority, which contain at least the following information:

- **10.1.1** Name;
- **10.1.2** Age;
- **10.1.3** Sex;
- 10.1.4 Social Security Number;
- **10.1.5** Residence address, and mailing address, if different;
- **10.1.6** Medical history of all communicable diseases;
- **10.1.7** Current state of health and physical disabilities;
- **10.1.8** Training and/or experience relating to tattoo or other body art procedures.

10.2 Application acceptance dates

Health Card applications will be accepted on predetermined calendar dates only. This calendar is located on the Health Authority's website at www.southernnevadahealthdistrict.org or can be picked up at the office where application is made.

10.3 Items required for application

The following items must be brought to the SNHD in order to make application for a Tattoo Operator Health Card:

- **10.3.1** Written proof from a previous employer that the applicant has a minimum of six (6) months' experience or training as a tattoo operator in a duly-licensed establishment in Nevada, or another state or country. Written proof must:
 - **10.3.1.1** Show current date,
 - **10.3.1.2** Be on company letterhead of former employer, if possible,
 - **10.3.1.3** List specific month and year dates of experience or training,
 - **10.3.1.4** Contain printed name of the person writing the letter of proof,
 - **10.3.1.5** Be signed by the person writing the letter of proof.
 - **10.3.1.6** Copies of these letters must be kept at the physical location of the tattoo establishment.

- 10.3.2 If the applicant currently does not have training or experience or if documentation of training or experience is unavailable, the applicant can enter into an apprenticeship with a Health Permitted tattoo establishment within Southern Nevada. At the time of application, the applicant must provide written proof from the tattoo establishment stating that the applicant will be apprenticing in the tattoo establishment writing the letter.
- **10.3.3** Upon completion of at least six (6) months training, the applicant must return to the SNHD with written proof of training and experience as described in **Section 10.3.1.**
- **10.3.4** Written verification of employment from the Health Permitted tattoo establishment where the applicant will be operating. This written proof must state clearly that the applicant will be working as a tattoo operator at the given tattoo establishment.
- **10.3.5** Fees for the written exam (non-refundable) as determined by the Health Authority Fee Schedule.

10.4 Written exam

During the application process, an appointment must be made to return to take the written exam administered by the SNHD regarding basic sanitation knowledge required for safe and sanitary tattoo application. A passing score on the examination is eighty (80) percent or better.

- **10.4.1** Written exams are held on predetermined calendar days only.
- **10.4.2** If an applicant does not pass the written exam with a score of eighty (80) percent or better, a new appointment to retake the exam must be made and the exam fee must be paid again.
- **10.4.3** If an applicant is a no-call or no-show for the exam, then they must pay the missed appointment fee as determined by the SNHD before they can reschedule for the next exam.

10.5 Exam study and organizational materials

During the application process, the applicant will be provided certain documents to assist in preparing for the exam and organizing the activities that must be completed to obtain the Tattoo Operator Health Card. Certain documents available are as follows:

10.5.1 A paper copy of this Regulation, for a fee. This Regulation in electronic form can also be located for no charge at www.southernnevadahealthdistrict.org.

- **10.5.2** A copy of the current SNHD Fee Schedule.
- **10.5.3** A hepatitis A and B vaccination information sheet.
- **10.5.4** A copy of the SNHD Identification Policy.
- **10.5.5** A SNHD Applicant Status worksheet. This worksheet provides guidance to complete the steps necessary to obtain a permanent Tattoo Operator Health Card.
- **10.5.6** A variety of study materials such as brochures and information sheets, when available.

10.6 Completion of application process

After the applicant successfully completes the requirements of **Sections 10.1 through 10.5**, then they must:

- **10.6.1** Complete the Health Card Application provided by the Health Card Section.
- **10.6.2** Submit to vaccines or any required medical tests.
- **10.6.3** Be screened for tuberculosis by skin test, chest x-ray or both. The applicant must return three days following the skin test or when otherwise directed to return by the Health Card Section nursing staff. Failure to return as directed will result in the need to readminister the test or vaccine. During the interim timeframe, an individual may not apply any tattoos.
- **10.6.4** Be photographed for their permanent Tattoo Operator Health Card.

10.7 Tattoo Operator Health Card issuance

Tattoo Operator Health Cards may be issued by the Health Authority, after satisfaction of the above requirements and the following additional requirements:

- **10.7.1** Verification by the applicant that he is free of communicable diseases that may be transmitted to a patron;
- **10.7.2** Presentation to the Health Authority of a government-issued photo identification showing that the applicant is a minimum of eighteen (18) years of age;

10.7.3 Presentation to the Health Authority of a certificate showing that the applicant has completed the required American Red Cross course in Preventing Disease Transmission (PDT) or documentation of equivalent training within the past two (2) years, as approved by the Health Authority. This documentation must also be provided, if not already available and current in the tattoo operator's file, upon renewal of the Health Card.

10.8 Hepatitis A and B vaccination or proof of immunity

Written certification that the operator has begun the hepatitis A and B vaccination series within thirty (30) days of being issued a Tattoo Operator Health Card must be provided to the Health Authority unless:

- 10.8.1 He has previously received the complete hepatitis A and/or B vaccination series and can provide documentation to the Health Authority that one or both of the series have been completed. If one has been completed, the operator must still complete the other series of vaccinations,
- **10.8.2** Antibody testing has revealed that the operator is immune to hepatitis either A or B, or both. If antibody testing reveals that the operator is immune to one form of hepatitis, but not the other, then either:
 - **10.8.2.1** The vaccination series must be completed or
 - **10.8.2.2** Documentation of completion of the vaccination series shall be provided once the series is completed, for the form of hepatitis for which the operator has no immunity.
- **10.8.3** The hepatitis A and/or B vaccines are contraindicated for medical or religious reasons, then the current SNHD policies regarding vaccine exemptions or deferrals shall be followed.
- **10.8.4** Failure to provide this documentation within the designated timeframe may result in immediate suspension of the operator's Health Card.

10.9 Tattoo Operator Health Card renewal

Tattoo Operator Health Cards must be renewed every two years. Tattoo operators must not perform tattoo procedures if their Tattoo Operator Health Cards are expired. Performing tattoo procedures with an expired Tattoo Operator Health Card is a violation of these Regulations and is subject to enforcement action, up to and including denial of a future Tattoo Operator Health Card.

10.10 Expired Tattoo Operator Health Cards

If the tattoo operator allows his Tattoo Operator Health Card to expire, then he will be required to repeat the application process (including retaking the basic sanitation examination and paying all applicable fees).

10.11 Current Tattoo Operator Health Card in tattoo operator's possession

A current original Tattoo Operator Health Card must be in the tattoo operator's possession, either on his person or readily available in his personal affects, at all times while engaged in the practice of tattooing.

- 10.11.1 Issuance of a tattoo operator's Tattoo Operator Health Card is conditional upon full compliance with these Regulations. Temporary Tattoo Operator Health Cards will be issued in certain situations:
 - 10.11.1.1 Thirty (30) day temporary Tattoo Operator Health Cards will be issued to applicants who have not completed the American Red Cross training in Preventing Disease Transmission (PDT) or equivalent training. Tattoo operators who do not provide documentation of completing this training within thirty (30) days must cease any operations until the required Preventing Disease Transmission (PDT) training has been completed.
 - 10.11.1.2 Temporary Tattoo Operator Health Cards will be issued for applicants who have not completed the six (6) month training requirement in Section 10.3.1. The hard copy of the tattoo operator's Tattoo Operator Health Card will be issued after documentation of the required six (6) month experience has been received.
 - 10.11.1.3 Tattoo operators issued a temporary Tattoo Operator Health Card must complete the required Preventing Disease Transmission (PDT) training (Section 10.7.3) and begin the hepatitis A and B vaccination series (Section 10.8) within thirty (30) days of being issued a temporary Tattoo Operator Health Card or cease any operations until these requirements are met.

10.12 Applicant or tattoo operator's responsibilities

It is the responsibility of each individual applicant or tattoo operator to comply with the requirements of this Regulation. Failure to complete any step in the process or to provide in a timely manner information that is needed to complete the Tattoo Operator Health Card application process may result in the denial of the Tattoo Operator Health Card and a requirement to repeat the entire process from the beginning.

10.13 Tattoo establishment Health Permit holder's joint responsibility

The tattoo establishment Health Permit holder and/or responsible person hold joint responsibility in ensuring that all conditions of obtaining a valid Tattoo Operator Health Card are met for each individual they hire or consent to take as an apprentice. Allowing individuals to function in the capacity of a tattoo operator within a Health Permitted establishment when they have not complied with these Regulations is grounds for enforcement action, up to and including suspension of the Health Permit for the tattoo establishment.

Section 11 BODY ART SPECIAL EVENT PERMITS

11.1 Special Event permit application

- **11.1.1** A Body Art Special Event Health Permit (formerly known as "Temporary Demonstration Health Permit" and referred to here as the "Event Permit") may be issued by the Health Authority for educational, sales, or convention purposes.
- **11.1.2** The Event Permit can be valid from one (1) to fifteen (15) days. The length of event determines the necessary fees based on the Health Authority's current Fee Schedule.
- **11.1.3** Under the Event Permit, it is permissible to charge the patron for tattoo services.
- 11.1.4 A person who wishes to obtain an Event Permit must submit a "Body Art Special Event Health Permit Person/Business Name Application" to the Health Authority, at least thirty (30) days prior to the event. Information required for the application is found in *Appendix I*.

11.2 Special Event coordinator

- 11.2.1 Each convention or other entity hosting a Special Event must designate a Special Event coordinator who is responsible for each booth's compliance with the applicable Regulations and operational procedures over the span of the Special Event.
- **11.2.2** The event coordinator must make application and pay all applicable fees designated by the Health Authority.
- **11.2.3** If there is only one vendor at the Special Event, then an event coordinator is not required.
- **11.2.4** The event coordinator must be available during the inspection of the booth(s) and throughout the duration of the Special Event.

11.3 Special Event operator fee

All individual tattoo operators or visiting artists must pay a Special Event operator fee as designated by the Health Authority at the time of application for the Special Event.

11.4 Special Event operational requirements

- **11.4.1** The Event Permit must be posted at each booth operating during the Special Event. Event Permits are non-transferable to different booths.
- **11.4.2** The application of tattoos during the Special Event must be conducted inside a permanent building.
- **11.4.3** Compliance is required with all of the requirements of these Regulations, including but not limited to the availability of:
 - 11.4.3.1 Conveniently located hand washing facilities shall be provided, as approved by the Health Authority, with liquid soap, paper towels and hot and cold water under adequate pressure and drained in accordance with local plumbing codes. Disinfecting single-use hand wipes, approved by the Health Authority, in addition to the hand washing requirements of this Section, must be available in each booth/cubicle.
 - **11.4.3.2** A booth of standard size, which is ten (10) feet by ten (10) feet or one hundred (100) square feet of floor space. Under no circumstances may the booth size exceed one hundred fifty (150) square feet.
 - **11.4.3.3** At least fifty (50) square feet of floor space for each tattoo operator. This is an exception for Special Events only.
 - **11.4.3.4** At least fifty (50) foot-candles of light at the level where the tattoo is being applied.
 - 11.4.3.5 Facilities to properly sterilize instruments. Evidence must be provided that a spore test was performed and passed on sterilization equipment thirty (30) days or less prior to the date of the event or only single-use, prepackaged, sterilized equipment obtained from reputable suppliers or manufacturers will be allowed.
 - **11.4.3.6** Equipment and supplies to properly clean and sanitize the area used for tattooing.
 - **11.4.3.7** Locations and equipment to dispose of correctly all sharps and biohazardous waste.
 - **11.4.3.8** Locations and equipment to dispose of all non-hazardous solid waste.
- **11.4.4** The facility where the Special Event will be conducted must be inspected by the Health Authority and an Event Permit must be issued prior to the performance of any tattoo procedures.

11.5 Special Event Client Consent Form and patron instructions

- **11.5.1** A sample Client Consent Form must be submitted with the application and must include locations to document the following information:
 - **11.5.1.1** Name of patron,
 - **11.5.1.2** Age of patron. If the patron is between the ages of fourteen (14) and eighteen (18), appropriate documentation of parental or custodial consent to the procedure, as required in permanent tattoo establishment locations.
 - 11.5.1.3 Address of patron,
 - 11.5.1.4 Date of tattoo application,
 - **11.5.1.5** Tattoo operator's or visiting artist's name,
 - **11.5.1.6** Location on the body where the tattoo was placed,
 - 11.5.1.7 A reasonably accurate description of the design of the tattoo that is sufficient to identify it as the tattoo applied by that particular tattoo operator,
 - **11.5.1.8** A statement advising the patron that the tattoo should be considered permanent; that it can only be removed with a surgical procedure; and that any effective removal may leave permanent scarring and disfigurement,
 - **11.5.1.9** Whether or not the patron has a history of jaundice or hepatitis within the twelve (12) months preceding that date.
- 11.5.2 Following the procedure, the patron must be given both verbal and written instructions concerning the proper care of the skin where the tattoo was applied. Instructions shall specify care following service, possible side effects, and/or activity restrictions.

11.6 Special Event Permit suspension

Event Permits issued under the provisions of these Regulations may be suspended by the Health Authority for failure of the permit holder, event coordinator, tattoo operators, or visiting artists to comply with the requirements of these Regulations.

Section 12 PLAN REVIEW SUBMISSION AND APPROVAL

12.1 Regulation of new construction and renovation of a tattoo establishment

The construction of new tattoo establishments and remodeling of existing establishments shall be in accordance with all applicable State of Nevada laws and Regulations, these Regulations, all other applicable Health Authority Regulations, and local building ordinances and codes. In the event that there are any conflicts between these requirements, the more stringent requirement must be met.

12.2 Plans for construction and remodeling

At least thirty days prior to beginning construction or remodeling of a tattoo establishment, the Health Permit holder or responsible person must complete the <u>Instructions for Submission of Plans for Review</u> and the <u>Plan Review Application Form</u>. Both forms are available on the SNHD web site. Read the Instructions for Submission of Plans for Review carefully and submit plans with all the following information to the Health Authority for review and approval:

- **12.2.1** A floor plan of the establishment including the dimension of the room(s) plus where the sinks are located,
- **12.2.2** Documentation of spore testing of sterilizer within the past thirty (30) days,
- **12.2.3** A copy of a lease/rental agreement and/or Bill of Sale for the property address,
- **12.2.4** A written infection control plan that includes:
 - **12.2.4.1** Aseptic procedures for the protection of patrons, and
 - **12.2.4.2** General establishment cleaning and disinfection procedures
- **12.2.5** Copies of all employee:
 - **12.2.5.1** Current Tattoo/Permanent Makeup Health Cards,
 - **12.2.5.2** Records of hepatitis A and B vaccination series,
 - **12.2.5.3** Current American Red Cross class or equivalent cards for Preventing Disease Transmission, CPR and/or first aid classes.
- **12.2.6** Proposed "Client Consent Sheet" that includes:
 - **12.2.6.1** Patron's name, date of birth, and address;
 - **12.2.6.2** If necessary, documentation of parental or custodial consent for patrons between the ages of fourteen (14) and eighteen (18);
 - **12.2.6.3** Operator's/Technician's name;
 - **12.2.6.4** Date the procedure was done, type and placement of the tattoo;

- **12.2.6.5** Questions asking the patron if he has a history of hepatitis, jaundice, or other communicable diseases in the past twelve (12) months;
- **12.2.6.6** A statement cautioning the patron that the procedure is permanent.
- **12.2.7** Proposed "After Care Instructions" that includes:
 - **12.2.7.1** The proper care of the fresh tattoo;
 - 12.2.7.2 Possible side effects of the procedure; and
 - **12.2.7.3** Any activity restrictions.
- **12.2.8** Procedure cubicle descriptions, with at least:
 - **12.2.8.1** One hundred (100) square feet per cubicle;
 - **12.2.8.2** Twenty (20) foot-candles of light at thirty (30) inches above the floor in all areas:
 - **12.2.8.3** Fifty (50) foot-candles of light at thirty (30) inches above the floor in the area where procedures are performed;
 - **12.2.8.4** Walls sealed, at a minimum, with hard enamel paint;
 - **12.2.8.5** Floors made of a smooth, durable, nonabsorbent and nonporous material that is easily cleanable and can be maintained in a sanitary manner at all times.
 - **12.2.8.6** Counters constructed of cleanable, non-porous material;
 - **12.2.8.7** A sink provided in each cubicle and serviced with hot and cold running water;
 - **12.2.8.8** Dispensers for antimicrobial hand soap and paper towels at each sink;
 - **12.2.8.9** A covered waste receptacle provided at each hand sink;
 - **12.2.8.10** An approved plastic sharps container marked with the international biohazard symbol provided to dispose of sharp objects;
 - **12.2.8.11** If a steam, chemical, or dry heat sterilizer is provided then the specification sheets must be brought to the plan review;
 - **12.2.8.12** An approved type of tattoo machine provided and specification sheets brought to the plan review;
 - **12.2.8.13** A cleanable storage area for the tattoo machinery;
 - **12.2.8.14** A cleanable storage area for sterilized equipment in packages, and other supplies such as surgical gloves, ink caps, razors, and gauze.
 - **12.2.8.15** Restrooms must be provided and equipped with:
 - **12.2.8.15.1** A toilet which is conveniently located;
 - **12.2.8.15.2** A hand sink that is conveniently located and provided with hot and cold running water, antimicrobial hand soap, paper towels, and a covered waste receptacle:
 - **12.2.8.15.3** Counters that are constructed of cleanable, non-porous material:
 - **12.2.8.15.4** Walls sealed, at a minimum, with hard enamel paint; and
 - **12.2.8.15.5** Floors constructed of non-porous tile.

12.3 Application fees

Application fees shall be in accordance with the Health Authority's fee schedule. Additional fees are required if construction or remodeling takes place before the plans are submitted and approved.

12.4 Change of ownership

Upon change of ownership, the would-be Health Permit holder or responsible person of any existing establishment must submit plans to the Health Authority for review to ensure they comply with existing Regulations and codes.

Section 13 INSPECTIONS

13.1 Agent of Health Authority identification

An agent of the Health Authority shall wear and show the responsible person his Health Authority-issued identification upon entering a tattoo establishment to make an inspection or other official visit pursuant to these Regulations. Such an inspection or official visit may be made as often as the Health Authority determines is necessary to ensure compliance with these Regulations.

13.2 Responsible person must provide immediate access to Health Authority

Upon providing the required identification to the responsible person, the Health Authority shall be provided immediate access to the tattoo establishment to perform an inspection or other official work. Any unreasonable denial of access by a responsible person or tattoo operator to body art work stations or other areas of the establishment for inspection after the Health Authority has properly identified himself may result in an immediate suspension of the tattoo establishment Health Permit. The tattoo establishment Closure Order may state that the tattoo establishment Health Permit is suspended and all procedures and business activities must be discontinued immediately. Any responsible person to whom such an order is issued shall comply with it immediately.

13.3 Unlawful to interfere with Health Authority

It is unlawful for any person to interfere with the Health Authority in the performance of his duties, pursuant to NRS 199.300.

13.4 Health Authority must provide written report

- **13.4.1** Upon completion of the visit to the tattoo establishment, the Health Authority representative shall prepare a report describing any findings. The report must set forth any deficiencies discovered during the inspection.
- **13.4.2** Deficiencies may be present that do not constitute a substantial threat to public health and safety. Corrective actions for these types of deficiencies shall be noted on the inspection report and be assigned a specified period of time within which the indicated corrections must be completed.
- **13.4.3** A copy of the completed report must be furnished to the Health Permit holder, responsible person or operator of the tattoo establishment upon completion of the inspection.
- **13.4.4** A copy of the completed report must also be retained by the Health Authority for the records of the tattoo establishment.

13.5 Failure to correct a deficiency

- **13.5.1** Failure of the responsible person to correct a deficiency within the period specified in the written report is a violation of these Regulations.
- **13.5.2** Violations that constitute a substantial threat to public health and safety and their remedies are addressed in **Section 2** of these Regulations.

13.6 Frequency of inspection

Tattoo establishments shall be inspected at least twice each year for permitting purposes.

Section 14 ENFORCEMENT

14.1 Cease and Desist Orders and tattoo establishment Closure Orders

If any violation or combination of violations noted on the inspection report constitutes a substantial threat to health and safety, then the following actions may be taken by the Health Authority:

- 14.1.1 If a substantial health hazard exists and is limited to a distinguishable area or function of the tattoo establishment, then a Cease and Desist Order shall be issued by the Health Authority for that area or function. The Cease and Desist Order shall describe the violation, its location within the tattoo establishment, the corrective action necessary to remedy the situation, and a time frame within which the corrective action must be completed. That area or function is considered closed to patron or staff use. Other areas may continue to function as normal as long as the area where activities have been directed to cease does not constitute a substantial health hazard to areas remaining in operation.
- **14.1.2** Areas or functions of a tattoo establishment ordered to cease and desist operation may not resume their functions until released by the Health Authority.
- 14.1.3 When a substantial part of a tattoo establishment and/or its functions and services are issued a Cease and Desist Order or are closed, then the facility may be issued a tattoo establishment Closure Order. This Order requires that all activities related to the entire establishment's operation must cease until the substantial health hazards noted on the Order are corrected and a satisfactory reinspection has occurred.
- 14.1.4 If a violation exists that is considered not critical to the operation of the tattoo establishment and does not present an imminent threat to public health and safety, then it shall be noted on the inspection report, given a corrective action to remedy the violation, and a timeframe in which to perform the corrective action. Correction of the violation shall occur within the dictated time frame and may be reinspected at that time or upon the next routine inspection.

14.2 Reinspection protocol for Cease and Desist Orders and tattoo establishment Closure Orders

14.2.1 A tattoo establishment which has any area ordered to cease and desist operation or has been entirely closed due to a substantial health hazard must pay a reinspection fee and closure fee prior to requesting a reopening inspection of the area(s) in question (see the current edition of the Southern

- Nevada Health District Fee Schedule).
- 14.2.2 Once the tattoo establishment pays the reinspection fee and closure fee and requests the reinspection, the Health Authority shall reinspect, or make mutually agreed upon arrangements with the responsible person to reinspect, within 72 hours of the receipt of the request.

14.3 Tattoo establishment Health Permit suspension

- 14.3.1 When conditions at the tattoo establishment result in the issuance of a tattoo establishment Closure Order or when the responsible person fails to remedy deficiencies previously addressed in an inspection report, Cease and Desist Order, or Closure Order, the Health Authority may suspend the tattoo establishment's Health Permit.
- **14.3.2** The Health Authority may also suspend a tattoo establishment Health Permit or business operation if the Health Authority has reasonable cause to suspected that:
 - **14.3.2.1** The tattoo establishment does not have a **valid** tattoo establishment Health Permit, license, or other authorization required by applicable agencies of jurisdiction.
 - **14.3.2.2** An unabated substantial health hazard is present, which may cause illness, injury, or death of patrons, operators, other employees, or others in or near the establishment;
 - **14.3.2.3** Knowingly allows illegal activity to occur at the tattoo establishment, which may cause potential illness, injury, or death of patrons or employees or others in or near the tattoo establishment;
 - **14.3.2.4** A communicable disease is being transmitted, or may be transmitted by a tattoo operator;
 - **14.3.2.5** Unapproved or malfunctioning equipment is being used which constitutes a substantial hazard to public health;
 - **14.3.2.6** Prohibited acts as defined by these Regulations are being performed at the tattoo establishment:
 - **14.3.2.7** The tattoo establishment is engaging in the sale, use, or promotion of substances or devices claiming to remove or alter tattoos or permanent makeup by methods other than camouflage;
 - **14.3.2.8** The tattoo establishment is engaged in the development, distribution, sale, advertisement, use, or has other involvement with a misbranded or adulterated cosmetic, drug, or device;

14.3.2.9 Rents, leases, or otherwise uses a room or area within the tattoo establishment which has been closed by the Health Authority.

14.4 Procedure for request of tattoo establishment Health Permit reinstatement

- **14.4.1** When a tattoo establishment Health Permit has been suspended, a responsible person representing the facility may make application for a reinspection, which may result in the reinstatement of the tattoo establishment Health Permit.
- **14.4.2** The applicant must provide to the Health Authority a written request for reinspection and reinstatement within ten (10) calendar days of the initial suspension of the Health Permit.
- **14.4.3** Following a timely review of the application, the Health Authority shall make a reinspection of the tattoo establishment.
- **14.4.4** The Health Authority shall determine if the conditions have been corrected, which caused the threat to public health and resulted in the suspension of the tattoo establishment Health Permit.
- **14.4.5** Unless the Health Authority is pursuing permanent revocation of the tattoo establishment Health Permit, if the conditions have been corrected and the applicant is complying with the requirements of these Regulations, the tattoo establishment Health Permit shall be reinstated.

14.5 Tattoo establishment Health Permit revocation

- 14.5.1 The Health Authority may permanently revoke a tattoo establishment's Health Permit under certain conditions. For serious or repeated violations of any of the requirements of this Regulation or for interference with the Health Authority in the performance of his duties, the tattoo establishment Health Permit or Tattoo Operator Health Card may be permanently revoked after an opportunity for a hearing has been provided by the Health Authority, as outlined in these Regulations.
- 14.5.2 Health Permit holders, responsible persons, or tattoo operators may be subject to fines and penalties as determined by the Administrative Hearing Officer upon each notice of violation upheld for each offense taken before administrative hearing. If a tattoo establishment Health Permit holder, responsible person, or tattoo operator violates any of the provisions of these Regulations after three (3) consecutive inspections, then their privileges to operate may be revoked. Before taking such action, the Health Authority shall notify the tattoo establishment Health Permit holder, responsible person, or tattoo operator, in writing, stating the reasons why the tattoo establishment Health Permit or Tattoo Operator Health Card is subject to

revocation and advising the affected parties of the requirements for filing a request for an administrative hearing. A tattoo establishment Health Permit or Tattoo Operator Health Card may be suspended for cause pending its revocation or an administrative hearing.

14.5.3 Upon receipt of the revocation Order (Notice of Revocation), the tattoo establishment must cease immediately all provision of any tattoo services or adjunct services. The tattoo establishment must close all facilities such as retail sales operated under the tattoo establishment Health Permit pending a hearing pursuant to an exercised right of appeal. Revocations are intended to result in permanent closure of the tattoo establishment. The tattoo establishment may seek relief through the appeal process outlined in these Regulations.

14.6 Appeal rights

Upon written petition submitted to the Health Authority within five (5) business days after receipt of a Notice of Suspension or Revocation of a tattoo establishment Health Permit, the recipient of the written Notice may exercise his right of appeal and must then be afforded a hearing as soon as possible, and in any event in not more than ten (10) business days from the receipt of the petition by the Health Authority. Hearings shall be conducted by a Health Authority Administrative Hearing Officer and in accordance with the following:

- **14.6.1** Any party may be represented by counsel.
- **14.6.2** Opportunity shall be afforded all parties to respond and present evidence and argument on all issues involved.
- **14.6.3** Each party may call and examine witnesses, introduce exhibits, crossexamine of opposing witnesses on any matter relevant to the issues whether or not the matter was covered in the direct examination, impeach any witness, regardless of which party first called him to testify, and rebut the evidence against the party itself.
- **14.6.4** Every witness shall declare, by oath or affirmation, that he will testify truthfully. Unless limited by a specific statute, the Administrative Hearing Officer may administer oaths or affirmations to witnesses appearing before him in the hearing.
- 14.6.5 Irrelevant, immaterial or unduly repetitious evidence must be excluded. Evidence may be admitted, except where precluded by statute, if it is of a type commonly relied upon by reasonable and prudent persons in the conduct of their affairs. Effect shall be given to the rules of privilege recognized by law. Objections to evidentiary offers may be made and shall be noted in the record. Subject to these requirements, when a hearing will be expedited and the interest of the parties will not be prejudiced

- substantially, any part of the evidence may be received in written form.
- **14.6.6** The Administrative Hearing Officer may issue subpoenas to compel attendance of any person at the hearing, and require the production of books, records and other documents material to a hearing.
- **14.6.7** The Administrative Hearing Officer may inquire of any witness following any segment of testimony.
- **14.6.8** Members of the public may testify in cases before the Administrative Hearing Officer.
- **14.6.9** All testimony shall be recorded verbatim, by human or electronic means. Any party requesting a transcript of any oral proceeding, or any part thereof, shall pay the cost thereof.
- **14.6.10** The decision of the Administrative Hearing Officer must be reduced to writing and shall be final ten (10) days after mailing to by certified mail, return receipt requested or personal service upon each party.
- **14.6.11** Any party aggrieved by a decision of the Administrative Hearing Officer may seek judicial review of the decision of the Administrative Hearing Officer, in accordance with the provisions of NRS 233B.130(2), and NRS 233B.131 through 233B.150, inclusive.

14.7 Health Authority additional legal remedy

- **14.7.1** Whenever the responsible person, operator, or owner fails to comply with the provisions of these Regulations in a timely manner, relief may also be sought through a court of competent jurisdiction.
- 14.7.2 Whenever responsible persons or tattoo operators are operating without legal authority to do so or in a prohibited manner, such as from their unpermitted, unlicensed private residences, the Health Authority, under its authority granted by NRS 439, may conduct an investigation into the matter. The terms, conditions, and policies of other applicable statutes and ordinances are intended to be applied in conjunction with the enforcement of all other ordinances of the state, county, and its municipalities designed for the protection of the public health, safety, morals, and welfare. The fact that such statutes or ordinances are not specifically referred to in these Regulations in no manner precludes their application to tattoo establishment permittees and tattoo operators.
- **14.7.3** Licensing authorities shall be notified by the Health Authority of the revocation of any tattoo establishment Health Permit.

Section 15 MISCELLANEOUS

15.1 Severability clause

Should any section, paragraph, sentence, phrase, or provision of these Regulations be held invalid for any reason, the remainder of these Regulations shall not be affected.

15.2 Effective date

- **15.2.1** These Regulations became effective upon approval by the Nevada State Board of Health.
- **15.2.2** These Regulations were adopted at a duly noticed public hearing and filed by the Clark County Clerk's Office on June 10, 2009.

Tattoo & Permanent Makeup Establishments Regulations

Effective June 2009

Appendix A:

Nevada Revised Statutes (NRS) Chapter 585, Food, Drugs and Cosmetics: Adulteration; Labels; Brands

Serving Boulder City, Clark County, Henderson, Las Vegas, Mesquite and North Las Vegas



NEVADA REVISED STATUTES CHAPTER 585-FOOD, DRUGS AND COSMETICS: ADULTERATION; LABELS; BRANDS

GENERAL PROVISIONS

NRS 585.010	Short title.
NRS 585.020	Definitions.
NRS 585.030	"Advertisement" defined.
NRS 585.040	"Commissioner" defined.
NRS 585.050	"Contaminated with filth" defined.
NRS 585.060	"Cosmetic" defined.
NRS 585.070	"Device" defined.
NRS 585.080	"Drug" defined.
NRS 585.090	"Federal Act" defined.
NRS 585.100	"Food" defined.
NRS 585.110	"Immediate container" defined.
NRS 585.120	"Label" defined.
NRS 585.130	"Labeling" defined.
NRS 585.140	"New drug" defined.
NRS 585.150	"Official compendium" defined.
NRS 585.170	Factors to be considered in determining whether label or advertisement is
	misleading.
NRS 585.180	Construction of representation that drug is antiseptic.
NRS 585.190	Scope of provisions regulating sales.
	ADMINISTRATION
NRS 585.200	Appointment of Commissioner of Food and Drugs.
NRS 585.210	Regulations.
NRS 585.220	Hearings.
NRS 585.230	Record of adulterated, mislabeled or misbranded foods, drugs, devices and
	cosmetics; biennial report of Commissioner; dissemination of information.
NRS 585.240	Inspection of factories and vehicles: Purposes; examination of samples.
NRS 585.245	Licensing of persons manufacturing, compounding, processing or packaging
	drugs, devices or cosmetics: Regulations; fees; inspection.
NRS 585.250	Tagging of articles believed to be dangerous to health: Contents of tag; unlawful
	sales.
NRS 585.260	Removal of tag or marking from detained or quarantined article; liability of
	person removing tag or other marking.
NRS 585.270	Petition for condemnation and destruction of adulterated or misbranded article.
NRS 585.280	Destruction of article found to be adulterated or misbranded.
NRS 585.290	Correction of defect by proper labeling or processing.
NDG #0# 400	FOOD
NRS 585.300	Adulterated food: Poisonous or insanitary ingredients.
NRS 585.310	Adulterated food: Absence, substitution or addition of constituents.
NRS 585.320	Adulterated food: Standards of purity, quality or strength.
NRS 585.330	Adulterated food: Confectionery containing nonnutritive substance.
NRS 585.350	Misbranded food.
NRS 585.355	Use of "honey" in product label or designation restricted: "honey" defined.

NRS 585.360 Food containing filthy, decomposed or putrid substance declared nuisance; condemnation or destruction by Commissioner.

DRUGS AND DEVICES

	DRUGS AND DEVICES	
NRS 585.370	Adulterated drugs and devices: Poisonous or insanitary ingredients.	
NRS 585.380	Adulterated drugs and devices: Strength, quality or purity differing from official compendium.	
NRS 585.390	Adulterated drugs and devices: Misrepresentation of strength, quality or purity if drug not in compendium.	
NRS 585.400	Adulterated drugs and devices: Mixture with or substitution of another substance.	
NRS 585.410	Misbranded drugs and devices: False or misleading label.	
NRS 585.420	Misbranded drugs and devices: Contents of label on package.	
NRS 585.430	Misbranded drugs and devices: Habit-forming substances.	
NRS 585.440	Misbranded drugs and devices: Designation of drug by name not in compendium.	
NRS 585.450	Misbranded drugs and devices: Directions for use and warnings on label.	
NRS 585.460	Misbranded drugs and devices: Misleading container; imitation; offer for sale under another name.	
NRS 585.470	Misbranded drugs and devices: Health-endangering when used as prescribed.	
NRS 585.480	Misbranded drugs and devices: Drug containing amidopyrine, barbituric acid, cinchophen, dinitrophenol or sulfanilamide sold without prescription.	
NRS 585.485	Restrictions on sale of dimethyl sulfoxide; penalty.	
NRS 585.490	Introduction or delivery for introduction of new drug into intrastate commerce before application is effective prohibited.	
NRS 585.495	Licensing of manufacture of amygdalin and procaine hydrochloride; duties and powers of Commissioner; injunctive relief.	
NRS 585.497	Assessment on gross receipts from sale of amygdalin and procaine hydrochloride.	
COSMETICS		
NRS 585.500	Adulterated cosmetics.	
NRS 585.510	Misbranded cosmetics.	

PROHIBITED ACTS AND PENALTIES

NRS 585.520	Prohibited acts.
NRS 585.530	When advertisement deemed false.
NRS 585.535	Unlawful to sell or offer to sell beverage container opened by detaching metal ring
	or tab; exceptions; penalty.
NRS 585.540	Duties of Attorney General and district attorneys; hearing by Commissioner
	before institution of criminal proceedings.
NRS 585.550	Penalties.

GENERAL PROVISIONS

NRS 585.010 Short title. This chapter may be cited as the Nevada Food, Drug and Cosmetic Act. [1:177:1939; 1931 NCL § 6206]

NRS 585.020 Definitions. For the purpose of this chapter, the words and terms defined in NRS 585.030 to 585.150, inclusive, have the meanings ascribed to them in those sections. [Part 2:177:1939; 1931 NCL § 6206.01]—(NRS A 1985, 530)

NRS 585.030 "Advertisement" defined. "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics. [Part 2:177:1939; 1931 NCL § 6206.01]

NRS 585.040 "Commissioner" defined. "Commissioner" means the Commissioner of Food and Drugs. [Part 2:177:1939; 1931 NCL § 6206.01]

NRS 585.050 "Contaminated with filth" defined. "Contaminated with filth" applies to any food, drug, device or cosmetic not securely protected from dust, dirt and, as far as may be necessary by all reasonable means, from all foreign or injurious contaminations. [Part 2:177:1939; 1931 NCL § 6206.01]

NRS 585.060 "Cosmetic" defined.

- 1. "Cosmetic" means:
 - (a) Articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance, including wigs, hairpieces and postiches; and
 - (b) Articles intended for use as a component of any such articles.
- 2. "Cosmetic" shall not include soap. [Part 2:177:1939; 1931 NCL § 6206.01]—(NRS A 1969, 877)

NRS 585.070 "Device" defined. Except when used in NRS 585.170, "device" means instruments, apparatus and contrivances, including their components, parts and accessories, intended:

- 1. For use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; or
- 2. To affect the structure or any function of the body of man or other animals. [Part 2:177:1939; 1931 NCL § 6206.01]

NRS 585.080 "Drug" defined.

- 1. "Drug" means:
 - (a) Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States or official National Formulary, or any supplement to any of them;
 - (b) Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals;
 - (c) Articles, other than food, intended to affect the structure or any function of the body of man or other animals; and
 - (d) Articles intended for use as a component of any article specified in paragraph (a), (b) or (c).
- 2. "Drug" does not include devices or their components, parts or accessories. [Part 2:177:1939; 1931 NCL § 6206.01]

NRS 585.090 "Federal Act" defined. "Federal Act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq., as that act exists on June 30, 1983. [Part 2:177:1939; 1931 NCL § 6206.01]—(NRS A 1983, 189)

NRS 585.100 "Food" defined. "Food" means:

- 1. Articles used for food or drink for man or other animals;
- 2. Chewing gum; and
- 3. Articles used for components of any such article. [Part 2:177:1939; 1931 NCL § 6206.01]

NRS 585.110 "Immediate container" defined. "Immediate container" does not include package liners. [Part 2:177:1939; 1931 NCL § 6206.01]

NRS 585.120 "Label" defined. "Label" means a display of written, printed or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this chapter that any word, statement or other information appear on the label shall not be considered to be complied with unless such word, statement or other information also appears on the outside container or wrapper, if there is any, of the retail package of such article, or is easily legible through the outside container or wrapper. [Part 2:177:1939; 1931 NCL § 6206.01]

NRS 585.130 "Labeling" defined. "Labeling" means all labels and other written, printed or graphic matter:

- 1. Upon an article or any of its containers or wrappers; or
- 2. Accompanying such article. [Part 2:177:1939; 1931 NCL § 6206.01]

NRS 585.140 "New drug" defined. "New drug" means any drug the composition of which is such that the drug:

- 1. Is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended or suggested in the labeling thereof; or
- 2. As a result of investigations to determine its safety and effectiveness for use under those conditions, has become so recognized, but which has not, other than in the investigations, been used to a material extent or for a material time under those conditions. [Part 2:177:1939; 1931 NCL § 6206.01]—(NRS A 1983, 189)

NRS 585.150 "Official compendium" defined. "Official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary or any supplement to any of them. [Part 2:177:1939; 1931 NCL § 6206.01]

NRS 585.170 Factors to be considered in determining whether label or advertisement is misleading. If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then, in determining whether the labeling or advertisement is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound or in any combination thereof, but also the extent to which the labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the

labeling or advertisement thereof or under such conditions of use as are customary or usual. [Part 2:177:1939; 1931 NCL § 6206.01]

NRS 585.180 Construction of representation that drug is antiseptic. The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body. [Part 2:177:1939; 1931 NCL § 6206.01]

NRS 585.190 Scope of provisions regulating sales.

- 1. The provisions of this chapter regarding the selling of foods, drugs, devices or cosmetics shall be considered to include:
 - (a) The manufacture, production, processing, packing, exposure, offer, possession and holding of any such article for sale;
 - (b) The sale, dispensing and giving of any such article; and
 - (c) The supplying or applying of any such articles in the conduct of any food, drug or cosmetic establishment.
- 2. The provisions of this chapter do not apply to the operation of any official establishment as defined in NRS 583.375. [Part 2:177:1939; 1931 NCL § 6206.01]—(NRS A 1969, 991)

ADMINISTRATION

NRS 585.200 Appointment of Commissioner of Food and Drugs. The Administrator of the Health Division of the Department of Human Resources shall designate and appoint, for the enforcement of this chapter, a Commissioner and such other agents as he may deem necessary. [14:177:1939; 1931 NCL § 6206.13]—(NRS A 1959, 616; 1963, 972; 1967, 1178; 1969, 616)

NRS 585.210 Regulations.

- 1. The authority to promulgate regulations for the efficient enforcement of this chapter is hereby vested in the Commissioner.
- 2. The Commissioner is hereby authorized to make the regulations promulgated under this chapter conform, insofar as practicable, with those promulgated under the Federal Act. [Part 15:177:1939; 1931 NCL § 6206.14]

NRS 585.220 Hearings. Hearings authorized or required by this chapter shall be conducted by the Commissioner or such officer, agent or employee as the Commissioner may designate for the purpose. [Part 15:177:1939; 1931 NCL § 6206.14]

NRS 585.230 Record of adulterated, mislabeled or misbranded foods, drugs, devices and cosmetics; biennial report of Commissioner; dissemination of information.

- 1. The Commissioner shall keep a record of adulterated, mislabeled or misbranded foods, drugs, devices and cosmetics, in which record shall be included a list of cases examined and violations found and a list of the articles found adulterated, mislabeled or misbranded and the names of the manufacturers, producers, jobbers and sellers.
- 2. The record, or any parts thereof, may, in the discretion of the Commissioner, be included in the biennial report which the Commissioner is authorized to make to the State Board of Health.
- 3. The Commissioner may also cause to be disseminated such information regarding foods, drugs, devices and cosmetics as he deems necessary in the interest of public health and the protection of the consumer against fraud. [17:177:1939; 1931 NCL § 6206.16]—(NRS A 1959, 617)

NRS 585.240 Inspection of factories and vehicles: Purposes; examination of samples.

- 1. The Commissioner or his duly authorized agent is entitled to free access at all reasonable hours to any factory, warehouse or establishment in which foods are manufactured, processed, packed or held for introduction into commerce, or may enter any vehicle being used to transport or hold such foods in commerce, for the purpose of:
 - (a) Inspecting such factory, warehouse, establishment or vehicle to determine whether any of the provisions of this chapter is being violated; and
 - (b) Securing samples or specimens of any food after paying or offering to pay for such sample.
- 2. The Commissioner shall make, or cause to be made, examinations of samples secured under the provisions of this section to determine whether any provision of this chapter is being violated. [16:177:1939; 1931 NCL § 6206.15]—(NRS A 1979, 1192)

NRS 585.245 Licensing of persons manufacturing, compounding, processing or packaging drugs, devices or cosmetics: Regulations; fees; inspection.

- 1. The Commissioner shall adopt regulations for the licensing of every person who manufactures, compounds, processes or packages drugs, devices or cosmetics in a factory, warehouse, laboratory or other location in this state. The regulations must set forth the requirements for issuance and renewal of a license. Only a person who complies with the requirements of this chapter is entitled to a license. A license is not transferable from person to person or from place to place. The regulations must prescribe the length of term for which a license is issued and must set forth grounds and procedures for the revocation, suspension or nonrenewal of a license.
- 2. A valid license is required for the manufacturing, compounding, processing or packaging of drugs, devices or cosmetics in any factory, warehouse, laboratory or other location in this state. Licensed pharmacies compounding or packaging prescriptions are exempt from this provision.
- 3. The Commissioner shall establish and collect fees for the purpose of paying the costs of inspecting, testing and other functions required under the provisions of this chapter with respect to any drug, device or cosmetic. Failure to pay any fee imposed pursuant to this subsection is a ground for revocation, suspension or nonrenewal of a license. All such fees collected by the Commissioner must be deposited with the State Treasurer for credit to the State General Fund.
- 4. As a condition for entertaining the application of any applicant for any license authorized under this chapter, and as a further condition for the issuance of any such license, the Commissioner or his authorized agent is entitled to free access at all reasonable hours to any factory, warehouse or other location in which drugs, devices or cosmetics are manufactured, compounded, processed or packaged or held for introduction into commerce, and may enter any vehicle being used to transport or hold such drugs, devices or cosmetics in commerce, for the purposes of:
 - (a) Inspecting the factory, warehouse, other location or vehicle to determine whether any of the provisions of this chapter is being violated; and
 - (b) Securing samples or specimens of any drug, device or cosmetic after paying or offering to pay therefor.
- 5. The Commissioner shall make, or cause to be made, examinations of samples and specimens secured under the provisions of this section to determine whether any of the provisions of this chapter is being violated. (Added to NRS by 1979, 1191)

NRS 585.250 Tagging of articles believed to be dangerous to health: Contents of tag; unlawful sales.

1. Whenever the Commissioner, any of his authorized agents, or any member or inspector of the State Board of Pharmacy finds, or has probable cause to believe, that any food, drug, device or cosmetic is

- adulterated, or so misbranded as to be dangerous or fraudulent, within the meaning of this chapter, he shall affix to such article a tag or other appropriate marking, giving notice that such article is, or is suspected of being, adulterated or misbranded and has been quarantined, and warning all persons not to remove or dispose of such article by sale or otherwise until permission for removal or disposal is given by such agent or the court.
- 2. It shall be unlawful for any person to remove or dispose of such quarantined article by sale or otherwise without such permission. [Part 4:177:1939; 1931 NCL § 6206.03]—(NRS A 1967, 1665)

NRS 585.260 Removal of tag or marking from detained or quarantined article; liability of person removing tag or other marking.

- 1. When the Commissioner, his authorized agent, or a member or inspector of the State Board of Pharmacy has found that an article so quarantined is not adulterated or misbranded, he shall remove the tag or other marking.
- 2. In any proceeding against the Commissioner, his authorized agent, or a member or inspector of the State Board of Pharmacy because of such quarantine, the Commissioner, his authorized agent, or member or inspector of the State Board of Pharmacy shall not be held liable if the court shall find that there was probable cause for such quarantine. [Part 4:177:1939; 1931 NCL § 6206.03]—(NRS A 1967, 1666)

NRS 585.270 Petition for condemnation and destruction of adulterated or misbranded article. When an article quarantined under NRS 585.250 has been found by the Commissioner, his authorized agent, or a member or inspector of the State Board of Pharmacy to be adulterated or misbranded, the Commissioner, his agent, or such member or inspector shall petition the judge of the district court in whose jurisdiction the article is quarantined for the condemnation and destruction of such article. [Part 4:177:1939; 1931 NCL § 6206.03]—(NRS A 1967, 1666)

NRS 585.280 Destruction of article found to be adulterated or misbranded. If the court finds that a quarantined article is adulterated or misbranded, such article shall, after entry of the decree, be destroyed under the supervision of the Commissioner, his authorized agent, or a member or inspector of the State Board of Pharmacy. [Part 4:177:1939; 1931 NCL § 6206.03]—(NRS A 1967, 1666)

NRS 585.290 Correction of defect by proper labeling or processing. When the adulteration or misbranding can be corrected by proper labeling or processing of the article to the satisfaction of the Commissioner, his authorized agent, or a member or inspector of the State Board of Pharmacy, the court, after entry of the decree, may by order direct that such article be delivered to the owner or defender thereof for such labeling or processing under the supervision of the Commissioner, his authorized agent, or a member or inspector of the State Board of Pharmacy. [Part 4:177:1939; 1931 NCL § 6206.03]—(NRS A 1967, 1666)

FOOD

NRS 585.300 Adulterated food: Poisonous or insanitary ingredients. A food shall be deemed to be adulterated if:

- 1. It bears or contains any poisonous or deleterious substance which may render it injurious to health unless the substance is not an added substance and the quantity of the substance does not ordinarily render it injurious to health;
- 2. It consists in whole or in part of a diseased, contaminated, filthy or decomposed substance, or if it is otherwise unfit for food;

- 3. It has been produced, prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or rendered diseased, unwholesome or injurious to health;
- 4. It is the product of an animal which was diseased, died otherwise than by slaughter or was fed upon the uncooked offal from a slaughterhouse;
- 5. Its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
- 6. It bears or contains any color additive which is unsafe within the meaning of the Federal Act. [Part 6:177:1939; 1931 NCL § 6206.05]—(NRS A 1983, 190)

NRS 585.310 Adulterated food: Absence, substitution or addition of constituents. A food shall be deemed to be adulterated:

- 1. If any valuable constituent has been in whole or in part omitted or abstracted therefrom;
- 2. If any substance has been substituted wholly or in part therefor;
- 3. If damage or inferiority has been concealed in any manner; or
- 4. If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is. [Part 6:177:1939; 1931 NCL § 6206.05]

NRS 585.320 Adulterated food: Standards of purity, quality or strength. A food shall be deemed to be adulterated if it falls below the standard of purity, quality or strength which it purports or is represented to possess. [Part 6:177:1939; 1931 NCL § 6206.05]

NRS 585.330 Adulterated food: Confectionery containing nonnutritive substance.

- 1. A food shall be deemed to be adulterated if it is confectionery and it bears or contains any nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 percent, harmless natural wax not in excess of four-tenths of 1 percent, harmless natural gum and pectin.
- 2. This section does not apply to any confectionery by reason of its containing less than 4 percent alcohol by weight, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances. [Part 6:177:1939; 1931 NCL § 6206.05]—(NRS A 1981, 908)

NRS 585.350 Misbranded food. A food shall be deemed to be misbranded:

- 1. If its labeling is false or misleading in any particular.
- 2. If it is offered for sale under the name of another food.
- 3. If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "Imitation," and immediately thereafter the name of the food imitated.
- 4. If its container is so made, formed or filled as to be misleading.
- 5. If it is not labeled as required by NRS 583.045.
- 6. If in package form, unless it bears a label containing:
 - (a) The name and place of business of the manufacturer, packer or distributor.
 - (b) An accurate statement of the quantity of the contents in terms of weight, measure or numerical count; but under this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulation prescribed by the Commissioner.
- 7. If it purports to be or is represented as a food for which a definition and standard of identity, quality and fill of container has been prescribed, unless it conforms to such standards of identity, quality and fill.
- 8. If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral and other dietary properties as the Commissioner determines to be,

- and by regulations prescribes as, necessary in order to inform purchasers fully as to its value for such uses.
- 9. If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact; but the provisions of this subsection with respect to artificial color shall not apply in the case of butter, cheese or ice cream. [7:177:1939; 1931 NCL § 6206.06]— (NRS A 1965, 433)

NRS 585.355 Use of "honey" in product label or designation restricted; "honey" defined. A person shall not prepare, package, deliver for shipment, ship, transport or sell:

- 1. Any food product which is labeled or designated by the term "honey" alone if such food product consists partly or entirely of ingredients other than honey.
- 2. Any food product, except a honeydew melon, designated by any combination of words which include the word "honey" in the label or brand name unless such food product contains honey as an ingredient and the other ingredients are disclosed.
- 3. As used in this section, "honey" means the natural product of honeybees, drawn from the nectar of flowers, transformed by the bees and stored in a honeycomb and later marketed in the honeycomb or taken from it and marketed in a liquid, candied or granulated condition. (Added to NRS by 1975, 813)

NRS 585.360 Food containing filthy, decomposed or putrid substance declared nuisance; condemnation or destruction by Commissioner. Whenever the Commissioner or any of his authorized agents shall find in any room, building or other structure, or vehicle of transportation, any meat, seafood, poultry, vegetable, fruit or other perishable articles which are unsound, or contain any filthy, decomposed or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the Commissioner or his authorized agents shall forthwith condemn or destroy the same, or in any other manner render the same unsalable as human food. [Part 4:177:1939; 1931 NCL § 6206.03]

DRUGS AND DEVICES

NRS 585.370 Adulterated drugs and devices: Poisonous or insanitary ingredients. A drug or device shall be deemed to be adulterated if:

- 1. It consists in whole or in part of any filthy or decomposed substance;
- 2. It has been produced, prepared, packed or held under insanitary conditions whereby it may have been rendered injurious to health;
- 3. It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or
- 4. It is a drug and it bears or contains, for coloring only, a color additive which is unsafe within the meaning of the Federal Act. [Part 8:177:1939; 1931 NCL § 6206.07]—(NRS A 1983, 190)

NRS 585.380 Adulterated drugs and devices: Strength, quality or purity differing from official compendium.

1. A drug shall be deemed to be adulterated if it is represented as a drug, the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in the compendium. The determination as to strength, quality or purity must be made in accordance with the tests or methods of assay set forth in the compendium or, in the absence of or inadequacy of those tests or methods of assay, those prescribed pursuant to the Federal Act.

2. A drug which is defined in an official compendium shall not be deemed to be adulterated under this section because it differs from the standard of strength, quality or purity set forth in the compendium if that difference is plainly stated on its label. [Part 8:177:1939; 1931 NCL § 6206.07]—(NRS A 1983, 190)

NRS 585.390 Adulterated drugs and devices: Misrepresentation of strength, quality or purity if drug not in compendium. A drug or device shall be deemed to be adulterated if it is not subject to the provisions of NRS 585.380 and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess. [Part 8:177:1939; 1931 NCL § 6206.07]

NRS 585.400 Adulterated drugs and devices: Mixture with or substitution of another substance.

A drug or device shall be deemed to be adulterated if it is a drug and any substance has been:

- 1. Mixed or packed therewith so as to reduce its quality or strength; or
- 2. Substituted wholly or in part therefor. [Part 8:177:1939; 1931 NCL § 6206.07]

NRS 585.410 Misbranded drugs and devices: False or misleading label. A drug or device shall be deemed to be misbranded if its labeling is false or misleading in any particular. [Part 9:177:1939; 1931 NCL § 6206.08]

NRS 585.420 Misbranded drugs and devices: Contents of label on package.

- 1. Except as provided in subsections 2 and 3, a drug or device shall be deemed to be misbranded if in package form unless it bears a label containing:
 - (a) The name and place of business of the manufacturer, packer or distributor; and
 - (b) An accurate statement of the quantity of the contents in terms of weight, measure or numerical count.
- 2. The label affixed to a container which contains a prescription drug intended for use by a human being shall include:
 - (a) The name and place of business of the manufacturer; and
 - (b) If different, the name and place of business of the packer or distributor,

→of the drug in its final dosage form.

- 3. A label affixed to a container by a pharmacist is not required to include the name and place of business of the manufacturer, packer or distributor.
- 4. Under paragraph (b) of subsection 1, reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Commissioner. [Part 9:177:1939; 1931 NCL § 6206.08]—(NRS A 1977, 632)

NRS 585.430 Misbranded drugs and devices: Habit-forming substances. A drug or device shall be deemed to be misbranded if it is for use by man and contains any quantity of narcotic or hypnotic substances or any chemical derivative thereof, unless its label bears the name and quantity or proportion of such substance or derivative and, in juxtaposition therewith, the statement "Warning—May be habit forming." [Part 9:177:1939; 1931 NCL § 6206.08]

NRS 585.440 Misbranded drugs and devices: Designation of drug by name not in compendium.

- 1. A drug or device shall be deemed to be misbranded if it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears:
 - (a) The common or usual name of the drug, if such there be; and
 - (b) In case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the kind and quantity or proportion of any alcohol, and also including,

whether active or not, the name and quantity or proportion of any bromide, ether, chloroform, acetanilid, acetophenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances contained therein.

2. To the extent that compliance with the requirements of paragraph (b) of subsection 1 is impracticable, exemptions shall be established by regulations promulgated by the Commissioner. [Part 9:177:1939; 1931 NCL § 6206.08]

NRS 585.450 Misbranded drugs and devices: Directions for use and warnings on label.

- 1. A drug or device shall be deemed to be misbranded unless its label bears:
 - (a) Adequate directions for use; and
 - (b) Such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration or administration or application, in such manner and form as are necessary for the protection of users.
- 2. Where any requirement of paragraph (a) of subsection 1, as applied to any drug or device, is not necessary for the protection of the public health, the Commissioner shall promulgate regulations exempting such drug or device from such requirements. [Part 9:177:1939; 1931 NCL § 6206.08]

NRS 585.460 Misbranded drugs and devices: Misleading container; imitation; offer for sale under another name. A drug or device shall be deemed to be misbranded:

- 1. If it is a drug and its container is so made, formed or filled as to be misleading;
- 2. If it is an imitation of another drug; or
- 3. If it is offered for sale under the name of another drug. [Part 9:177:1939; 1931 NCL § 6206.08]

NRS 585.470 Misbranded drugs and devices: Health-endangering when used as prescribed. A drug or device shall be deemed to be misbranded if it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended or suggested in the labeling thereof. [Part 9:177:1939; 1931 NCL § 6206.08]

NRS 585.480 Misbranded drugs and devices: Drug containing amidopyrine, barbituric acid, cinchophen, dinitrophenol or sulfanilamide sold without prescription. A drug or device shall be deemed to be misbranded if it is a drug sold at retail for use by man, and contains any quantity of amidopyrine, barbituric acid, cinchophen, dinitrophenol or sulfanilamide, unless it is sold on a written prescription signed by a member of the medical, dental or veterinary profession who is licensed by law to administer such drug, and its label bears the name and place of business of the seller, the serial number and date of such prescription, and the name of such member of the medical, dental or veterinary profession. [Part 9:177:1939; 1931 NCL § 6206.08]

NRS 585.485 Restrictions on sale of dimethyl sulfoxide; penalty.

- 1. Dimethyl sulfoxide may be sold, whether by wholesalers or retailers, in quantities of 1 gallon or more.
- 2. Dimethyl sulfoxide may be sold, prescribed or dispensed in quantities of less than 1 gallon only:
 - (a) Pursuant to prescription by a dentist, podiatric physician or veterinarian licensed to practice his profession in this state or by a licensed physician; or
 - (b) To a purchaser who gives his affidavit declaring that the dimethyl sulfoxide being purchased:
 - (1) Will not be used for medicinal treatment of any human being; or
 - (2) Will not be resold and will be used for industrial or commercial purposes in a laboratory or business which is licensed by the state or a local government.

- 3. A prescription for dimethyl sulfoxide may be filled only with a grade and quality of that substance which meets the requirements of the United States Food and Drug Administration.
- 4. Any person who gives a false affidavit for the purpose of obtaining dimethyl sulfoxide pursuant to paragraph (b) of subsection 2 is guilty of a misdemeanor. (Added to NRS by 1981, 1696; A 1993, 2237)

NRS 585.490 Introduction or delivery for introduction of new drug into intrastate commerce before application is effective prohibited. No person shall introduce or deliver for introduction into intrastate commerce any new drug which is subject to section 505 of the Federal Act (21 U.S.C. § 355), unless an application with respect to such drug has become effective thereunder. [10:177:1939; 1931 NCL § 6206.09]

NRS 585.495 Licensing of manufacture of amygdalin and procaine hydrochloride; duties and powers of Commissioner; injunctive relief.

- 1. State Board of Health shall license amygdalin (laetrile) and procaine hydrochloride with preservatives and stabilizers (Gerovital H3) for manufacture in this state. Such licensing is not a representation that either substance has any therapeutic effect.
- 2. The Commissioner shall:
 - (a) Adopt regulations which prescribe minimum standards for manufacturers in preparing, compounding, processing and packaging each substance.
 - (b) Make periodic tests and inspections of both the facilities for manufacture and samples of the substances to ascertain the purity, quality and identity of the substance and to determine that the substance meets the standards prescribed pursuant to paragraph (a).
 - (c) Before acting upon an application for a license, collect the fees necessary to pay the cost of investigating the applicant. A license shall not be issued until the applicant has paid all actual costs for the initial testing, inspection, investigation and hearings.
- 3. The Commissioner may, after notice and hearing, revoke, suspend or refuse to renew the license of any person who:
 - (a) Fails to maintain the standards required by paragraph (b) of subsection 2.
 - (b) Violates any regulation adopted by the Commissioner.
 - (c) Fails to pay any assessment prescribed in paragraph (c) of subsection 2 within a reasonable time.
- 4. The Attorney General shall, at the request of the Commissioner seek injunctive relief for any violation of the regulations adopted by the Commissioner. (Added to NRS by 1977, 1646; A 1979, 1193; 1983, 224)

NRS 585.497 Assessment on gross receipts from sale of amygdalin and procaine hydrochloride.

- 1. An assessment of 10 percent, payable quarterly to the Department of Taxation, is imposed upon the gross receipts of a manufacturer from the sale of each substance licensed for manufacture pursuant to NRS 585.495.
- 2. The Nevada Tax Commission shall prescribe by regulation appropriate forms for reporting such gross receipts, and shall when appropriate recompute the assessment and collect any deficiency in the manner provided for taxes required to be paid pursuant to title 32 of NRS. Each manufacturer shall report his sales and pay the assessment during the months of January, April, July and October for the respective preceding calendar quarters.
- 3. As used in this section:
 - (a) "Gross receipts" means the total amount of the sale of each substance, valued in money, whether received in money or otherwise, without deduction for any of the following:
 - (1) The cost of the substance sold.

- (2) The cost of the materials used, labor or service, any interest paid or any losses or other expense.
- (3) The cost of marketing the substance.
- (4) The cost of transporting the substance before its sale to the purchaser.
- (b) "Sale" includes any transfer of title or possession, exchange or barter, whether conditional or otherwise, of a substance for a consideration.
- (c) "Total amount of the sale" includes:
 - (1) Any services that are a part of the sale; and
 - (2) All receipts, cash, credits and property of any kind. (Added to NRS by 1983, 223)

COSMETICS

NRS 585.500 Adulterated cosmetics. A cosmetic shall be deemed to be adulterated:

- 1. If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement thereof, or under such conditions of use as are customary or usual; but this provision shall not apply to coal tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this subsection and subsection 5 the term "hair dye" shall not include eyelash or eyebrow dyes.
- 2. If it consists in whole or in part of any filthy, putrid or decomposed substance.
- 3. If it has been produced, prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.
- 4. If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.
- 5. If it is not a hair dye and it bears or contains a coal tar color other than one from a batch which has been certified by the United States Department of Agriculture. [11:177:1939; 1931 NCL § 6206.10]

NRS 585.510 Misbranded cosmetics. A cosmetic shall be deemed to be misbranded:

- 1. If its labeling is false or misleading in any particular.
- 2. If in package form unless it bears a label containing:
 - (a) The name and place of business of the manufacturer, packer or distributor; and
 - (b) An accurate statement of the quantity of the contents in terms of weight, measure or numerical count. Under this paragraph, reasonable variations shall be permitted, and exemptions as to small packages shall be established by regulations prescribed by the Commissioner.
- 3. If its container is so made, formed or filled as to be misleading. [12:177:1939; 1931 NCL § 6206.11]

PROHIBITED ACTS AND PENALTIES

NRS 585.520 Prohibited acts. The following acts and the causing thereof within the State of Nevada are hereby prohibited:

- 1. The manufacture, sale or delivery, holding or offering for sale of any food, drug, device or cosmetic that is adulterated or misbranded.
- 2. The adulteration or misbranding of any food, drug, device or cosmetic.
- 3. The sale, delivery for sale, holding for sale or offering for sale of any article in violation of NRS 585.490.
- 4. The dissemination of any false advertisement.

- 5. The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by NRS 585.240 or 585.245.
- 6. The giving of a guaranty or undertaking, which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by and containing the name and address of the person residing in the State of Nevada from whom he received in good faith the food, drug, device or cosmetic.
- 7. The removal or disposal of a detained or embargoed article in violation of NRS 585.250.
- 8. The alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of or the doing of any other act with respect to a food, drug, device or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded. [3:177:1939; 1931 NCL § 6206.02]—(NRS A 1979, 1193)

NRS 585.530 When advertisement deemed false. An advertisement of a food, drug, device or cosmetic shall be deemed to be false if it is false or misleading in any particular. [13:177:1939; 1931 NCL § 6206.12]

NRS 585.535 Unlawful to sell or offer to sell beverage container opened by detaching metal ring or tab; exceptions; penalty.

- 1. Except as otherwise provided in subsection 2, it is unlawful for a person to sell or offer for sale at retail a metal beverage container so designed and constructed that it is opened by detaching a metal ring or tab.
- 2. This section does not prohibit the sale of a beverage container which:
 - (a) Is sealed with laminated tape, foil or other soft material that is detachable; or
 - (b) Contains milk-based, soy-based or similar products which require heat and pressure in the canning process.
- 3. A person who violates the provisions of subsection 1 shall be punished by a fine of not more than \$500 for each violation. Each day of violation constitutes a separate offense. (Added to NRS by 1989, 277)

NRS 585.540 Duties of Attorney General and district attorneys; hearing by Commissioner before institution of criminal proceedings.

- 1. The Attorney General or any district attorney to whom the Commissioner or any of his authorized agents shall report any violation of this chapter shall cause appropriate proceedings to be instituted in the proper court without delay and to be prosecuted in the manner required by law.
- 2. Before any violation of this chapter is reported to the Attorney General or a district attorney for the institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views before the Commissioner or his designated agent, either orally or in writing, in person or by attorney, with regard to such contemplated proceeding. [5:177:1939; 1931 NCL § 6206.04]

NRS 585.550 Penalties.

- 1. A person who manufactures, compounds, processes or packages any drug in a factory, warehouse, laboratory or other location in this state without a license required by NRS 585.245 is guilty of a category D felony and shall be punished as provided in NRS 193.130.
- 2. A person who violates any other provision of this chapter is guilty of a gross misdemeanor. [18:177:1939; 1931 NCL § 6206.17]—(NRS A 1967, 619; 1979, 1194; 1995, 1306)

Tattoo & Permanent Makeup Establishments Regulations

Effective June 2009

Appendix B:

Nevada Administrative Code (NAC) Chapter 585, Drugs and Cosmetics

Serving Boulder City, Clark County, Henderson, Las Vegas, Mesquite and North Las Vegas



NEVADA ADMINISTRATIVE CODE CHAPTER 585-DRUGS AND COSMETICS

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MANUFACTURE OF DRUGS General Provisions

NAC 585.010 Scope. The criteria prescribed in NAC 585.010 to 585.640, inclusive, apply in determining whether the methods used in, or the facilities or controls used for, the manufacture, processing, packing or holding of a drug conform to, or are operated or administered in conformity with, current good manufacturing practice to ensure that the drug:

- 1. Meets the requirements of NRS 585.370 to 585.495, inclusive, as to safety; and
- 2. Has the identity, strength, quality and purity which it is purported or represented to possess. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 2.1, eff. 5-15-78]

NAC 585.020 Definitions. As used in NAC 585.010 to 585.640, inclusive, unless the context otherwise requires, the words and terms defined in NAC 585.030 to 585.180, inclusive, have the meanings ascribed to them in those sections. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.1, eff. 5-15-78]

NAC 585.030 "Active ingredient" defined.

- 1. "Active ingredient" means any component which is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or any function of the body of man or other animals.
- 2. The term includes components which may undergo chemical change in the manufacture of the drug and be present in the finished drug product in a modified form intended to furnish the specified activity or effect. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.2, eff. 5-15-78]

NAC 585.040 "Amygdalin," "laetrile" defined. "Amygdalin" or "laetrile" is defined by the formula contained in NAC 585.200. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.3, eff. 5-15-78]

NAC 585.050 "Batch" defined. "Batch" means a specific quantity of a drug which has uniform character and quality within specified limits and is produced according to a single manufacturing order during the same cycle of manufacture. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.4, eff. 5-15-78]

NAC 585.060 "Board" defined. "Board" means the State Board of Health. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.5, eff. 5-15-78]

NAC 585.070 "Commissioner" defined. "Commissioner" means the Commissioner of Food and Drugs. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.6, eff. 5-15-78]

NAC 585.080 "Component" defined. "Component" means any ingredient used in the manufacture of drugs in dosage form, whether or not the ingredient appears in the finished product. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.7, eff. 5-15-78]

NAC 585.090 "Drug" defined.

- 1. "Drug" has the meaning ascribed to it in NRS 585.080.
- 2. The term includes amygdalin (laetrile) or procaine hydrochloride with preservatives and stabilizers. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.8, eff. 5-15-78]—(NAC A 9-17-82)
- NAC 585.100 "Inactive ingredient" defined. "Inactive ingredient" means any component other than an active ingredient present in a drug. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.9, eff. 5-15-78]
- NAC 585.110 "In process" defined. "In process" means in the course of manufacture. Goods in process are distinguished from raw materials or finished products. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.10, eff. 5-15-78]
- NAC 585.120 "Licensee" defined. "Licensee" means a natural person, partnership, association, corporation or other form of business organization which is licensed pursuant to NRS 585.245 or 585.495 to manufacture, compound, process or package any drug. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.11, eff. 5-15-78]—(NAC A 9-17-82)
- NAC 585.130 "Lot" defined. "Lot" means a batch or any portion of a batch of a drug or, if the drug is produced in a continuous process, any amount of the drug produced in a unit of time or quantity in a manner that ensures its uniformity. A lot is identified by a distinctive number and has uniform character and quality within specified limits. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.12, eff. 5-15-78]
- **NAC 585.140 "Lot number" defined.** "Lot number" means any distinctive combination of letters or numbers, or both, from which the complete history of the manufacture, control, packaging and distribution of a batch or lot of drug can be determined. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.13, eff. 5-15-78]
- NAC 585.150 "Mixup" defined. "Mixup" means a miscalculation or misuse of any component in any step of the manufacture, control, packaging, labeling or distribution of a drug. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.14, eff. 5-15-78]
- NAC 585.160 "Procaine hydrochloride with preservatives and stabilizers" defined. "Procaine hydrochloride with preservatives and stabilizers" is defined by the formula contained in NAC 585.210. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.15, eff. 5-15-78]
- NAC 585.170 "Quality control unit" defined. "Quality control unit" means any organizational element having the authority and responsibility to approve or reject components, materials in process, packaging materials and final products. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.16, eff. 5-15-78]

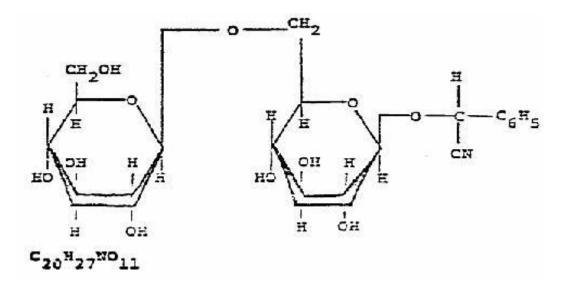
NAC 585.180 "Strength" defined. "Strength" means:

- 1. The concentration of each active ingredient of the drug; or
- 2. The potency of each active ingredient of the drug, which is the therapeutic activity of the ingredient as indicated by appropriate laboratory tests or by adequately developed and controlled clinical data (expressed, for example, in terms of units by reference to a standard). [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 1.17, eff. 5-15-78]

Licensing

NAC 585.200 Amygdalin: Ingredients.

1. The State Board of Health licenses amygdalin (laetrile) in the form of D-mandelonitrile-B-D-glucosido-6-B-D-glucoside:



2. No other active ingredient is permitted. [Bd. of Health, Licensing Reg. §§ 1.1 & 1.1.1, eff. 5-26-78]

NAC 585.210 Procaine hydrochloride: Ingredients.

1. The State Board of Health licenses procaine hydrochloride with preservatives and stabilizers in the form of procaine hydrochloride:

with preservatives and stabilizers.

2. Active ingredients other than procaine hydrochloride are not permitted. [Bd. of Health, Licensing Reg. §§ 1.2 & 1.2.1, eff. 5-26-78]

NAC 585.220 License required to manufacture, prepare or compound drug; qualifications for license.

- 1. No natural person, partnership, association, corporation or other business organization may manufacture, prepare or compound amygdalin (laetrile) or procaine hydrochloride with preservatives and stabilizers without a license from the State Board of Health.
- 2. The State Board of Health will not grant a license to manufacture amygdalin or procaine hydrochloride unless the applicant has satisfied the Commissioner that the applicant:
 - (a) Is a person of good character, honesty and integrity;
 - (b) Is a person whose background, reputation and associations will not result in adverse publicity for the State of Nevada and its drug manufacturing industry; and
 - (c) Has adequate business competence and experience for the role or position for which application is made.
- 3. The State Board of Health will not grant a license to manufacture amygdalin or procaine hydrochloride unless the applicant has satisfied the Commissioner that the proposed financing of the entire operation will be adequate for the nature of the operation and will be obtained from a suitable source. The Commissioner will determine the suitability of the source in accordance with the standards enumerated in subsection 2.
- 4. No natural person, partnership, association, corporation or other business organization may manufacture, prepare or compound any drug other than amygdalin or procaine hydrochloride without a license from the Commissioner.
- 5. The Commissioner will not issue a license to manufacture a drug other than amygdalin or procaine hydrochloride unless the applicant has satisfied the Commissioner that the applicant:
 - (a) Will construct or has constructed a plant in accordance with a set of plans approved by the Commissioner;
 - (b) Has the competence to manufacture the drug; and
 - (c) Has the business competence and adequate experience for performing in the role or position for which the application is made. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 7.1-7.2.2, eff. 5-15-78]—(NAC A 9-17-82)

NAC 585.225 License to manufacture drug other than amygdalin or procaine hydrochloride: Prerequisites to issuance.

- 1. An applicant for a license to manufacture a drug other than amygdalin or procaine hydrochloride must submit to the Commissioner for his examination and approval:
 - (a) The formula for the drug, including all its components; and
 - (b) The procedures to be used in processing the drug.
- 2. Before the Commissioner will issue such a license, he must be satisfied, based on information presented by the applicant, that the applicant has the ability to meet the requirements of this chapter. (Added to NAC by Comm'r of Food & Drugs, eff. 9-17-82)

NAC 585.230 Application for license to operate drug manufacturing plant.

- 1. An application for a license to operate a drug manufacturing plant must be completed and sent to the Commissioner.
- 2. The applicant must provide the Commissioner with complete information regarding ownership and must report promptly all significant changes in ownership. If the applicant is a publicly held corporation, only the information regarding the person holding a majority interest need be so provided.
- 3. A corporate applicant must provide the Commissioner with the name and address of each of its officers, directors and managers. An applicant who is not a corporation must provide the

- Commissioner with the name and address of each of his managerial employees. An applicant shall notify the Commissioner of any change in this information.
- 4. An applicant must state the proposed hours of operation of the plant. The applicant shall notify the Commissioner of any change in the hours of operation. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 7.3-7.3.4, eff. 5-15-78]

NAC 585.240 Application for license to manufacture amygdalin or procaine hydrochloride: Action by Commissioner and applicant.

- 1. The Commissioner will give a notice of hearing by letter to each applicant desiring to manufacture amygdalin (laetrile) or procaine hydrochloride with preservatives and stabilizers, stating the time and place for consideration of the application. The applicant must appear at the hearing. The Commissioner will notify the applicant in writing of the disposition of his application.
- 2. An applicant must submit the formula, including all components, for review and approval to ensure compliance with the formula contained in the license issued by the Board. An applicant must also submit the procedures to be used in processing the drug for review and approval to ensure that the formula contained in the license issued by the Board is not altered thereby.
- 3. An applicant shall cooperate fully in any background, financial or other investigation made to ensure the accuracy and truthfulness of the information supplied to the Commissioner. The investigation will be conducted before the issuance of any license.
- 4. An applicant is required to satisfy the Commissioner of its ability to meet the requirements of NAC 585.010 to 585.640, inclusive, before the issuance of any license. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 7.3.5-7.3.8, eff. 5-15-78]

NAC 585.245 Application for license to manufacture, prepare or compound amygdalin or procaine hydrochloride: Action by Board. (NRS 233B.050)

- 1. The Board will consider an application for a license required pursuant to NAC 585.220 to manufacture, prepare or compound amygdalin (laetrile) or procaine hydrochloride with preservatives and stabilizers, and the written recommendation of the Commissioner regarding the application, at a public hearing held:
 - (a) At the time and place of the next regularly scheduled meeting of the Board;
 - (b) At the next meeting of the Board that is scheduled in Reno or Las Vegas, whichever city is requested by the applicant; or
 - (c) As soon as the schedule of the Board permits.
- 2. The Board is not required to follow the written recommendation of the Commissioner regarding the application.
- 3. At the public hearing, the applicant and the Commissioner may address the Board and answer any questions of the Board regarding the application.
- 4. In addition to complying with the requirements set forth in NAC 585.220, the Board will not grant a license to manufacture, prepare or compound amygdalin (laetrile) or procaine hydrochloride with preservatives and stabilizers unless the applicant has satisfied the Commissioner that the applicant has complied with the requirements for the issuance of such a license that are adopted by the Commissioner.
- 5. At the conclusion of the presentations by the applicant and the Commissioner, the Board will render a decision granting or denying the application. The Board will notify the applicant in writing of its findings of fact, conclusions of law and decision regarding the application as soon as practicable after the date of the hearing. (Added to NAC by Bd. of Health, eff. 10-30-97)

NAC 585.250 Denial, suspension or revocation of license.

- 1. A failure or refusal of an applicant or a licensee to comply with any provision of NAC 585.010 to 585.640, inclusive, is a ground for denial, suspension or revocation of his license.
- 2. Notice of any denial, suspension or revocation of a license will contain the legal authority and reasons for the action and will be sent to the applicant or licensee by certified mail within 10 days after the action.
- 3. Within 30 calendar days after receipt of a notice of denial, suspension or revocation, the applicant or licensee may file a notice of appeal with the State Health Officer.
- 4. Within 30 calendar days after receiving a notice of appeal, the State Health Officer will hold a hearing on the appeal.
- 5. The State Health Officer will give the applicant or licensee notice of a hearing on appeal at least 15 working days before the date set for the hearing. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 7.4-7.4.4, eff. 5-15-78]

NAC 585.260 Fees.

- 1. An applicant for a license to manufacture amygdalin or procaine hydrochloride must pay an initial licensing fee of \$30,000 for the first year to the Commissioner before a license will be issued. To provide for receipt of licensing fees on the basis of fiscal years beginning July 1 and ending June 30, the Commissioner will prorate an initial licensing fee for the period from the date of issuance until the end of the current fiscal year.
- 2. A license to manufacture amygdalin or procaine hydrochloride is effective until June 30 of the fiscal year in which it is issued, but it is renewable on July 1 of each year. The fee for renewal is \$30,000. The Commissioner will prorate a fee for a renewal if it is for part of a fiscal year. An application for a renewal of a license must be received by the Commissioner 30 days before the expiration of the license.
- 3. An applicant for a license to manufacture a drug other than amygdalin or procaine hydrochloride must pay an initial licensing fee of \$2,000 for the first year to the Commissioner before a license will be issued. To provide for receipt of licensing fees on the basis of fiscal years beginning July 1 and ending June 30, the Commissioner will prorate an initial licensing fee for the period from the date of issuance until the end of the current fiscal year.
- 4. A license to manufacture a drug other than amygdalin or procaine hydrochloride is effective until June 30 of the fiscal year in which it is issued, but it is renewable on July 1 of each year. The fee for renewal is \$2,000. The Commissioner will prorate the fee for a renewal if it is for part of a fiscal year. An application for a renewal of a license must be received by the Commissioner 30 days before the expiration of the license.
- 5. An amount paid as a licensing fee, whether an initial fee or a fee for renewal, is not refundable. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 7.5-7.5.2, eff. 5-15-78; A 12-20-79]—(NAC A 9-17-82)

Personnel, Facilities, Equipment and Components

NAC 585.270 Qualifications of personnel.

- 1. The personnel who are responsible for directing the manufacture and control of a drug must be adequate in number and have sufficient education, training and experience, or a combination thereof, to ensure that the drug will have the safety, identity, strength, quality and purity that it is purported or represented to possess.
- 2. All personnel must have:
 - (a) Capabilities commensurate with their assigned functions;
 - (b) A thorough understanding of the manufacturing or control operations which they perform;
 - (c) The necessary training or experience; and
 - (d) Adequate information concerning the reasons for the application of the pertinent provisions of this chapter to their respective functions. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 2.3 & 2.3.1, eff. 5-15-78]—(NAC A 9-17-82)

NAC 585.280 Exclusion of certain employees from direct contact with drugs.

- 1. A licensee shall exclude from direct contact with drugs or their components any person shown at any time (either by medical examination or supervisory observation) to have an apparent illness or open lesion that may adversely affect the safety or quality of the drugs until the condition is corrected.
- 2. A licensee shall instruct all his employees to report to supervisory personnel any conditions that may have an adverse effect on drugs or their components. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 2.4 & 2.4.1, eff. 5-15-78]

NAC 585.290 Buildings used in manufacturing drugs.

- 1. A licensee shall maintain in a clean and orderly condition the buildings used in the manufacture of drugs. The buildings must be of suitable size, construction and location to facilitate adequate cleaning, maintenance and proper operations in the manufacturing, processing, packing, labeling and holding of a drug. Separate rooms may be required to prevent cross-contamination of products.
- 2. A licensee shall provide buildings with adequate space for:
 - (a) The orderly placement of equipment and materials to minimize the risk of mixups between different drugs, components of drugs, materials in process, packaging materials, or labeling and to minimize the possibility of contamination;
 - (b) The receipt, storage and withholding from use of components, pending their sampling, identification and testing before release for manufacturing or packaging;
 - (c) The holding of rejected components before disposition to preclude the possibility of their use in any manufacturing or packaging procedure for which they are unsuitable;
 - (d) The storage of components, containers, packaging materials and labeling;
 - (e) Any manufacturing and processing operations;
 - (f) Any packaging or labeling operations;
 - (g) The storage of finished products; and
 - (h) The control of production and laboratory operations. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 3.1-3.1.1.8, eff. 5-15-78]

NAC 585.300 Requirements for manufacturing facilities. A licensee shall provide:

- 1. Adequate lighting (at least 50 foot-candles), ventilation and screening and, if necessary for intended production or control purposes, facilities for adequate control of air pressure, microbiological contamination, dust, humidity and temperature in order to:
 - (a) Minimize contamination of products by extraneous adulterants, including cross-contamination of one product by dust or particles of ingredients arising from the manufacture, storage or handling of another product;
 - (b) Minimize dissemination of microorganisms from one area to another; and
 - (c) Maintain suitable conditions for storage of drug components, materials in process and finished drugs in conformance with information on stability derived pursuant to NAC 585.530.
- 2. Near working areas adequate locker facilities and hot and cold water washing facilities, including soap or detergent, air drier or single service towels and clean toilet facilities.
- 3. An adequate supply of potable water under continuous positive pressure in a plumbing system free of defects that could cause or contribute to contamination of any drug. Drains must be of adequate size and, where connected directly to a sewer, must be equipped with traps to prevent back siphonage.
- 4. Suitable housing and space for the care of all laboratory animals.
- 5. For the safe and sanitary disposal of sewage, trash and other refuse within and from the buildings and immediate premises. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 3.1.2-3.1.6, eff. 5-15-78]

NAC 585.310 Approval of plans for construction, remodeling of plants.

- 1. Before a licensee constructs or extensively remodels a plant for manufacturing drugs, or converts an existing structure for use as such a plant, he must submit the plans to the Commissioner for his approval. The plans must include:
 - (a) The layout and arrangement of the plant;
 - (b) The materials to be used in construction; and
 - (c) The location, size and type of fixed equipment and facilities.
- 2. Approval of plans by the Commissioner does not constitute final approval of the facility. The Commissioner will not issue a license until his inspection of the facility is made and he gives his final approval of the facility. [Comm'r of Food and Drugs, Amygdalin and Procaine Hydrochl. §§ 3.3 & 3.3.1, eff. 5-15-78]—(NAC A 9-17-82)

NAC 585.320 Use of equipment in production and control. The use of precision, automatic or electronic equipment in the production and control of a drug is permissible if procedures for inspection and checking are used to ensure proper performance. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 2.2, eff. 5-15-78]—(NAC A 9-17-82)

NAC 585.330 Maintenance, construction of equipment. A licensee shall maintain in a clean and orderly condition all equipment used for the manufacturing, processing, packaging, labeling, holding, testing or controlling of drugs. The equipment must be of suitable design, size, construction and location to facilitate cleaning, maintenance and operation for its intended purpose. The equipment must:

- 1. Be so constructed that all surfaces which come into contact with a drug or any of its components are not reactive, additive or absorptive in a way which alters the safety, identity, strength, quality or purity of the drug or any of its components.
- 2. Be so constructed that any substances required for operation of the equipment, such as lubricants or coolants, do not come into contact with any drug in a way which alters the safety, identity, strength, quality or purity of the drug or any of its components.

- 3. Be constructed and installed to facilitate adjustment, disassembly, cleaning and maintenance to ensure reliability of control procedures, uniformity of production and exclusion from the drugs of contaminants from previous and current operations that might affect the safety, identity, strength, quality or purity of the drug or any of its components.
- 4. Be of suitable type, size and accuracy for any testing, measuring, mixing, weighing or other processing or storage operation. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 3.2-3.2.4, eff. 5-15-78]

NAC 585.340 Identification of containers, lines and other equipment used during production.

Each container, line and other piece of equipment used during the production of a batch of a drug must be properly identified at all times to indicate accurately and completely its content and, when necessary, the stage of processing of the batch. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 4.1.2, eff. 5-15-78]

NAC 585.350 Containers.

- 1. A licensee shall use suitable specifications, test methods and cleaning procedures and, when necessary, sterilization procedures to ensure that containers, closures and other component parts of drug packages are suitable for their intended use.
- 2. A licensee shall clean containers for parenteral drugs or products or components of drugs with water which has been filtered in accordance with NAC 585.360.
- 3. Containers of products and their components must not be reactive, additive or absorptive, so as to alter the safety, identity, strength, quality or purity of the drug or its components beyond the official or established limitations.
- 4. Containers of products and their components must provide adequate protection against external factors that can cause deterioration or contamination of the drug. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.4-4.4.3, eff. 5-15-78]

NAC 585.360 Filters.

- 1. Filters used in manufacturing, processing or packaging the components of any drug for parenteral injection in humans must not release fibers into the drug. No filter containing asbestos or releasing any other fiber may be used in manufacturing, processing or packaging such a drug unless the drug or its component cannot be manufactured without the use of such a filter.
- 2. Filtration must be accomplished by a filter which does not release fiber, except as provided in subsections 3 and 4.
- 3. If use of a filter which releases fiber is required, an additional filter which does not release fiber and has a maximum pore size of 0.22 microns (0.45 microns if the manufacturing conditions so dictate) must subsequently be used to reduce the content of any asbestos-form particles in the drug or component.
- 4. Use of a filter containing asbestos followed by use of a filter which does not release fiber is permissible only if the licensee submits proof to the Commissioner that use of only the latter filter will or is likely to compromise the safety or effectiveness of the drug.
- 5. For the purposes of this section:
 - (a) A "filter which does not release fiber" is a filter, other than an asbestos filter, which, after any appropriate pretreatment, such as washing or flushing, will not continue to release fibers into the drug or component being filtered.
 - (b) A "fiber" is any particle whose length is at least three times greater than its width. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.1.10-4.1.13.1, eff. 5-15-78]

NAC 585.370 Cleaning and storing of equipment. To minimize contamination and prevent mixups, all equipment, utensils and containers must be thoroughly and appropriately cleaned and properly stored and have previous identification removed between batches or at suitable intervals during continuous production. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 4.1.3, eff. 5-15-78]

NAC 585.380 Components: Storage; handling.

- 1. A licensee shall, upon receipt, store and handle in a safe, sanitary and orderly condition all components and other materials used in the manufacturing, processing and packaging of drugs and all materials necessary for maintenance of buildings and equipment.
- 2. A licensee shall take adequate measures to prevent any cross-contamination of drugs and products of drugs.
- 3. A licensee shall withhold components from use until they have been identified, sampled and tested for conformance with specifications and are approved for release by the quality control unit. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.2-4.2.3, eff. 5-15-78]

NAC 585.390 Components: Examination; testing.

- 1. A licensee shall visually examine each container of components before it is used to detect any damage, contamination or indication of breakage of the seal.
- 2. A licensee shall take an adequate number of samples from a representative number of component containers from each lot and shall subject the samples to a sufficient number of tests to establish their specific identity.
- 3. A licensee shall appropriately examine representative samples of components liable to contamination with filth, insect infestation or other extraneous contaminants.
- 4. A licensee shall test representative samples of all components intended for use as active ingredients to determine whether the strength of the ingredients conforms to the appropriate specifications.
- 5. The licensee shall subject representative samples of components liable to microbiological contamination to microbiological tests before they are used. The components must not contain microorganisms that are objectionable in view of the intended use of the components. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.3-4.3.5.1, eff. 5-15-78]

NAC 585.400 Components: Identification; use.

- 1. A licensee shall, as often as necessary, appropriately identify and retest approved components to ensure that they conform to appropriate specifications of identity, strength, quality and purity at the time of use.
- 2. A licensee shall rotate approved components in such a manner that the oldest stock is used first.
- 3. A licensee shall identify and hold rejected components to preclude their use in procedures of manufacturing or processing for which they are unsuitable. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.3.6-4.3.6.3, eff. 5-15-78]

NAC 585.410 Components: Records. A licensee shall maintain appropriate records, including:

- 1. A record of the identity and quantity of the component, the name of the supplier, the supplier's lot number and the date of receipt.
- 2. A record of examinations and tests performed and rejected components and their disposition.
- 3. An individual inventory and record for each component used in each batch of a drug manufactured or processed. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.3.7-4.3.7.3, eff. 5-15-78]

NAC 585.420 Components: Retention of sample. A licensee shall retain an appropriately identified, reserve sample of each active ingredient, consisting of at least twice the quantity necessary for all required tests, except those for sterility and determination of the presence of pyrogens, for at least 2 years after distribution of the last drug lot incorporating the component has been completed, or 1 year after the expiration date of the last drug lot, whichever period is longer. The samples must be representative and adequately identified. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.3.8, 4.5.2.1 & 4.5.3, eff. 5-15-78]

Controls on Production

NAC 585.430 Laboratory controls.

- 1. The laboratory controls of a licensee must include the establishment of scientifically sound and appropriate specifications, standards and test procedures to ensure that components, drugs in process and finished products conform to appropriate standards of identity, strength, quality and purity.
- 2. The laboratory controls must also include the establishment of master records containing appropriate specifications for the acceptance of each lot of drug components, product containers and their components used in the production and packaging of drugs and a description of the sampling and testing procedures used.
- 3. The records must also provide for appropriate retesting of drug components, product containers and their components subject to deterioration. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.5-4.5.2 & 4.5.2.2, eff. 5-15-78]

NAC 585.440 Security.

- 1. Every licensee shall provide effective procedures to prevent theft, diversion or adulteration of processed drugs or their components. The procedures must be registered with and approved by the Commissioner.
- 2. Every person responsible for security must be registered with the Commissioner and is subject to investigation by the Commissioner to determine his suitability for the role. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 9.1 & 9.2, eff. 5-15-78]

NAC 585.450 Provisions for control of quality. The licensee shall provide for:

- 1. The establishment of master records, when needed, containing specifications and a description of sampling and testing procedures for in-process drug preparation. The samples must be adequately representative and properly identified.
- 2. The establishment of master records containing a description of sampling procedures and appropriate specifications for finished drugs. The samples must be adequately representative and properly identified.
- 3. Adequate provisions for checking the identity and strength of drugs for all active ingredients and for ensuring:
 - (a) Sterility of drugs purported to be sterile and freedom from objectionable microorganisms for those drugs which should be so because of their intended use;
 - (b) The absence of pyrogens for those drugs purported to be free of pyrogens;
 - (c) Not more than minimal contamination of ophthalmic ointments by foreign particles and harsh or abrasive substances; and
 - (d) The pattern of drug release in products designed for a sustained release is tested by laboratory methods to ensure conformance to specifications for the release.
- 4. Adequate provision for auditing the reliability, accuracy, precision and performance of laboratory test procedures and laboratory instruments used.

- 5. A properly identified reserve sample of the finished product. The sample must be stored in the same immediate container and closure system in which the drug is marketed. The sample must consist of at least twice the quantity necessary to perform all the required tests except those for sterility and determination of the absence of pyrogens. The sample must be stored under conditions consistent with the labeling of the product. The licensee shall retain the sample for at least 2 years after the distribution of the drug is completed or at least 1 year after the expiration date of the drug, whichever period is longer.
- 6. A provision for retaining complete records of all laboratory data relating to each batch or lot of drug. A licensee shall retain such records for at least 2 years after the distribution is completed or 1 year after the expiration date of the drug, whichever period is longer.
- 7. A provision that animals must be maintained and controlled in a manner that ensures their suitability for their intended use. The licensee shall maintain appropriate records identifying the animals and providing a history of their use. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.5.4-4.5.10.1, eff. 5-15-78]

NAC 585.460 Checks and tests of significant steps in process.

- 1. Except as provided in subsection 2, each significant step in the process, such as the selection, weighing or measuring of components, the addition of ingredients during the process, the weighing and measuring during various stages of the process and the determination of the finished yield, must be performed by a competent and responsible person and checked by a second competent and responsible person.
- 2. If the significant steps are controlled by precision, automatic, mechanical or electronic equipment, the proper performance of the equipment must be adequately checked by one or more competent and responsible persons.
- 3. A written record of the tests and checks at the significant steps in the process must be made by the person performing these tests and by the person charged with checking these steps. An identification of each step must be recorded immediately following its completion. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.1.1 & 4.1.1.1, eff. 5-15-78]

NAC 585.470 Tests and checks upon drugs.

- 1. To ensure the uniformity and integrity of his products, a licensee must provide adequate controls during production, such as checks upon the weights and disintegration times of tablets, the adequacy of mixing, the homogeneity of suspensions and the clarity of solutions.
- 2. Sampling of drugs in process must be done at appropriate intervals and with suitable equipment.
- 3. A licensee shall test representative samples of all drugs in dosage form before their distribution to determine whether they conform to the applicable specifications. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.1.6-4.1.7, eff. 5-15-78]

NAC 585.480 Precautions generally. The procedure for production and control must include all reasonable precautions to ensure that the drugs produced will have the safety, identity, strength, quality and purity which they are purported or represented to possess. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 4.1, eff. 5-15-78]

NAC 585.490 Precautions against contamination.

- 1. A licensee shall take appropriate precautions to minimize microbiological and other contamination in the production of drugs purporting to be sterile or which, because of their intended use, should be free from objectionable microorganisms.
- 2. A licensee shall establish appropriate procedures to minimize cross-contamination of drugs while they are being manufactured or stored. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.1.4 & 4.1.5, eff. 5-15-78]

NAC 585.500 Precautions respecting penicillin.

- 1. If penicillin is being manufactured on the same premises or with the same equipment as is being used to manufacture products subject to NAC 585.010 to 585.640, inclusive, and the products may reasonably be regarded as susceptible to contamination by penicillin, the licensee shall provide for testing the products to determine whether any of them have become contaminated by the penicillin.
- 2. A licensee shall not market such products if they are intended for use in man and they are contaminated with an amount of penicillin:
 - (a) Equivalent to 0.05 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for parenteral administration; or
 - (b) Equivalent to 0.5 unit or more of penicillin G per maximum single dose recommended in the labeling of a drug intended for oral use. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.5.11 & 4.5.11.1, eff. 5-15-78]

NAC 585.510 Review of records before release of batch. Each licensee shall establish procedures for the review and approval of all records regarding production and control, including those for packaging and labeling before the release or distribution of any batch. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. § 4.1.8, eff. 5-15-78]

NAC 585.520 Investigation of unexplained discrepancies in batches.

- 1. A licensee shall immediately order a thorough investigation of any unexplained discrepancy or failure of a batch to meet any of its specifications, whether or not the batch has already been distributed.
- 2. The investigation must be undertaken by a competent and responsible person and must extend to other batches of the same drug and other drugs that may have been associated with the specific failure.
- 3. The licensee shall make a written record of the investigation, which must include the conclusions and following action. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.1.8.1-4.1.8.1.2, eff. 5-15-78]

NAC 585.530 Stability of finished drugs. The stability of finished drugs must be ensured. The stability must be:

- 1. Determined by reliable, meaningful and specific methods of testing;
- 2. Determined on drugs in the same system of container and closure in which they are marketed;
- 3. Determined on any dry drug that is to be reconstituted at the time of dispensing (as directed on its labeling) as well as on the reconstituted drug.
- 4. Recorded and maintained in such a manner that the data on stability may be used to establish expiration dates for the drug. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.6-4.6.1.4, eff. 5-15-78]

NAC 585.540 Date of expiration of drugs.

- 1. To ensure that drugs liable to deterioration meet appropriate standards of identity, strength, quality and purity at the time of use, the label of all such drugs must show expiration dates which relate to stability tests performed on the drug.
- 2. Expiration dates appearing on the drug labeling must be justified by readily available data from stability studies described in NAC 585.530.
- 3. An expiration date must be related to the appropriate storage condition. The condition must be stated on the labeling wherever the expiration date appears.
- 4. When a drug is marketed in its dry state for use in preparing a liquid product, the label must bear information concerning the expiration date for the reconstituted product as well as the expiration date for the dry product. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.7-4.7.1.3, eff. 5-15-78]

NAC 585.550 Control of packaging, labeling operations.

- 1. A licensee shall control his packaging and labeling operations adequately to:
 - (a) Ensure that only drugs which meet the standards and specifications established in the master production and control records are distributed;
 - (b) Prevent mixups during filling, packaging and labeling operations;
 - (c) Ensure that correct labels and labeling are employed for drugs; and
 - (d) Identify each finished product with a lot number that permits determination of the history of the manufacture and control of the batch.
- 2. A code for the hour, day or shift is appropriate as a lot number for drugs manufactured or processed by equipment used in continuous production.
- 3. Packaging and labeling operations must be separated by a partition or sufficient distance from operations on other drugs in a manner adequate to avoid mixups and minimize the possibility of cross-contamination. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 5.1-5.1.1.1, eff. 5-15-78]

NAC 585.560 Labeling: Controls; disclosure.

- 1. A licensee shall include the following controls in his packaging and labeling operations:
 - (a) An inspection of the facilities before use to ensure that all drugs and materials which were previously used for packaging and labeling have been removed.
 - (b) The holding of labels and package labeling upon receipt, pending their review and proofing against an approved final copy by a competent and responsible person, to ensure that they are accurate regarding identity and content and are in conformity with the approved copy before they are released to inventory.
 - (c) The maintenance and storage of each type of label and package labeling, representing different products, strength, dosage forms or quantity of contents in a manner that will prevent mixups and provide proper identification.
 - (d) A suitable system for ensuring that only current labels and package labeling are retained and that stocks of obsolete labels and package labeling are destroyed.
 - (e) Restriction of access to labels and package labeling to authorized personnel.
 - (f) Avoidance of "gang" printing of cut labels, cartons or inserts where the labels, cartons or inserts are:
 - (1) For different products or different strengths of the same products; or
 - (2) Of the same size and have identical or similar format or color schemes.

- (g) If "gang" printing is employed, added control procedures must be provided for. In devising these added controls, the licensee shall consider the problems related to sheet layout, stacking, cutting and handling during and after printing.
- (h) Strict control of the package labeling issued for use with the drug. Such labeling must be carefully checked by a competent and responsible person for identity and conformity to the labeling specified in the production record for the batch. The record must identify the labeling and the quantities issued and used and must reasonably reconcile any discrepancy between quantities of the finished drug and the quantities of the issued labeling. All excess package labeling which bears lot numbers must be destroyed. If any significant, unexplained discrepancy occurs, the licensee shall carry out an investigation pursuant to NAC 585.520.
- (i) Adequate examination or laboratory testing of representative samples of finished products after packaging and labeling to safeguard against any errors in the finishing operations and to prevent distribution of any batch until all required tests have been made.
- 2. Each label on a container of amygdalin or procaine hydrochloride must state that the drug has not been approved as a drug by the United States Food and Drug Administration or by the State of Nevada. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 5.1.2-5.2, eff. 5-15-78]—(NAC A 9-17-82)

NAC 585.570 Returned drugs.

- 1. A licensee shall identify any returned drugs as such and hold them for disposition as follows:
 - (a) If the conditions under which the returned drugs have been held, stored or shipped (before or during their return) or if the condition of the drugs, their containers, cartons or labeling as a result of the storing or shipping cast doubt upon the safety, identity, strength, quality or purity of the drugs, they must be destroyed or subjected to adequate examination or testing to ensure that they meet all appropriate standards or specifications before being returned to stock for warehouse distribution or repacking; or
 - (b) If the drugs are neither destroyed nor returned to stock, they may be reprocessed if the final product will meet all its standards and specifications and is approved by the Commissioner.
- 2. A licensee shall maintain records of any returned drugs and shall indicate the quantity returned, the date and their actual disposition.
- 3. If the reason the drugs are returned implicates associated batches, the licensee shall make an appropriate investigation in accordance with <u>NAC 585.520</u>. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 4.1.9-4.1.9.4, eff. 5-15-78]

Records

NAC 585.580 Master record of drugs. To ensure uniformity from batch to batch, a master record for each drug and each batch of drug must be prepared, dated and signed or initialed by a competent and responsible person and must be independently checked, reconciled, dated and signed or initialed by a second competent and responsible person. The master record must include:

- 1. The name of the drug, a description of the dosage form and a specimen or copy of each label and all other labeling associated with the retail or bulk unit, including copies of the labeling signed or initialed and dated by the person responsible for its approval.
- 2. The name and weight or measure of each active ingredient per dosage unit or per unit of weight or measure of the finished drug and statement of the total weight or measure of any dosage unit.
- 3. A complete list of ingredients, designated by names or codes sufficiently specific to indicate any special characteristic of quality, and the following information:

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- (a) An accurate statement of the weight or measure of each ingredient, regardless of whether it appears in the finished product, except that reasonable variations are permitted in the amount of components necessary in the preparation in dosage form if provisions for such variations are included in the master record;
- (b) An appropriate statement concerning any calculated excess of an ingredient;
- (c) An appropriate statement of theoretical weight or measure at various stages of processing; and
- (d) A statement of the theoretical yield.
- 4. A description of the containers and closures and the packaging and finishing materials.
- 5. The manufacturing and control instructions, procedures, specifications, special notations and precautions to be followed. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 6.1-6.1.5, eff. 5-15-78]

NAC 585.590 Records of batches.

- 1. A licensee shall prepare a record containing complete information concerning the production and control of each batch of a drug which he produces. He shall retain the record for at least 2 years after the distribution of the batch is complete or at least 1 year after the expiration date of the batch, whichever period is longer. The record must identify the specific labeling and lot numbers used on the batch and must be readily available during the retention period.
- 2. The record must include:
 - (a) An accurate reproduction of the appropriate master formula. The reproduction must be checked, dated and signed or initialed by a competent and responsible person.
 - (b) An entry for each significant step in the manufacturing, processing, packaging, labeling, testing and controlling of the batch, including:
 - (1) The date:
 - (2) The major equipment and lines employed;
 - (3) The specific identification of each batch of components used;
 - (4) The weights and measures of components and products used in processing;
 - (5) In-process and laboratory control results; and
 - (6) The identification of the person who actively performs and who directly supervises or checks that step in the operation.
- 3. A batch number that identifies all the production and control documents relating to the history of the batch and all lot numbers associated with the batch.
- 4. A record of any investigation made pursuant to NAC 585.520. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 6.2-6.3.4, eff. 5-15-78]

NAC 585.600 Records of distribution.

- 1. The procedures for warehouse control and distribution of finished goods must include a system by which the distribution of each lot of a drug can be readily determined to facilitate recall of a drug if necessary.
- 2. Records within the system must contain the name and address of the consignee, the date and quantity shipped and the lot number of the drug.
- 3. A licensee shall retain the records of distribution for at least 2 years after distribution of the drug has been completed or 1 year after the expiration date of the drug, whichever period is longer.
- 4. To ensure the quality of the product, a licensee shall include in his warehouse control of finished goods a system whereby the oldest approved stock is distributed first whenever possible. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 6.4-6.4.2, eff. 5-15-78]

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NAC 585.610 Complaints.

- 1. A licensee shall maintain records of all written and oral complaints regarding each product and notify the Commissioner immediately upon the receipt of any complaint.
- 2. A licensee shall make an investigation of each complaint pursuant to NAC 585.520.
- 3. A licensee shall maintain the record of each investigation for at least 2 years after distribution of the drug has been completed or 1 year after the expiration date of the drug, whichever period is longer. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 6.5-6.5.1.2, eff. 5-15-78]

NAC 585.620 Confidentiality of records. All records acquired or compiled by the Commissioner relating to formulas, processing procedures, earnings, revenue and other internal financial matters of any applicant or licensee are confidential and will not be revealed in whole or in part except:

- 1. For the necessary administration of NAC 585.010 to 585.640, inclusive; or
- 2. Upon the order of a court of competent jurisdiction. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 10.1-10.1.2, eff. 5-15-78]

Enforcement

NAC 585.630 Inspections.

- 1. The Commissioner will make an initial inspection of a licensee's plant before the license is granted. At least annually he will make such additional inspections as he deems necessary for enforcement of chapter 585 of NRS and NAC 585.010 to 585.640, inclusive.
- 2. A licensee shall permit the Commissioner or his agent, after proper identification, to enter at any reasonable time any drug manufacturing, processing or packaging plant of the licensee within the State of Nevada to make an inspection to determine compliance with chapter 585 of NRS and NAC 585.010 to 585.640, inclusive. The licensee shall permit the Commissioner or his agent to examine the records of the establishment to obtain pertinent information.
- 3. After an inspection is made, the Commissioner will prepare a written report of the inspection and give a copy of the report to the licensee. Whenever the licensee is found not to be in compliance with NAC 585.010 to 585.640, inclusive, the Commissioner will take action pursuant to chapter 585 of NRS.
- 4. The Commissioner or his agent will pick up samples of finished drugs or their components from time to time and take the samples for testing at a laboratory approved by the Commissioner. Samples of finished drugs will be picked up and tested at least two times a year. [Comm'r of Food & Drugs, Amygdalin and Procaine Hydrochl. §§ 8.1-8.3, eff. 5-15-78]—(NAC A 9-17-82)

NAC 585.640 Amygdalin, procaine hydrochloride: Verification of substances; appeal.

- 1. The Commissioner of Food and Drugs shall analyze any substance or formulation purporting or represented to be amygdalin (laetrile) or procaine hydrochloride with preservatives and stabilizers to determine whether it is the substance licensed by the State Board of Health.
- 2. Any denial of a substance purporting or represented to be amygdalin (laetrile) or procaine hydrochloride with preservatives and stabilizers may be appealed to the State Board of Health. The appeal must follow the Board's regulations governing procedures for seeking variances. [Bd. of Health, Licensing Reg. §§ 2.1 & 2.2, eff. 5-26-78]

TAXATION OF AMYGDALIN AND PROCAINE HYDROCHLORIDE

NAC 585.650 Applicability. NAC 585.660 and 585.670 apply to the substances amygdalin (laetrile) and procaine hydrochloride with preservatives and stabilizers (Gerovital H3) which are licensed for manufacture pursuant to NRS 585.495. [Tax Comm'n, Amygdalin and Procaine Hydrochloride Reg. part No. 1, eff. 2-5-82]

NAC 585.660 Definitions. As used in this section and NAC 585.670:

- 1. "Gross receipts" means the total amount of the sale of each substance, valued in money, whether received in money or otherwise, without a deduction for any of the following:
 - (a) The cost of the substance sold.
 - (b) The cost of the materials used, labor or service, or interest paid, or for losses or any other expense.
 - (c) The cost of marketing the substance.
 - (d) The cost of transporting the substance before its sale to the purchaser.
- 2. "Sale" includes any transfer of title or possession, exchange or barter, whether conditional or otherwise, of a substance for a consideration.
- 3. "Total amount of the sale" includes:
 - (a) Any services that are part of a sale; and
 - (b) All receipts, cash, credits and property of any kind. [Tax Comm'n, Amygdalin and Procaine Hydrochloride Reg. part No. 1, eff. 2-5-82]

NAC 585.670 Reporting of gross receipts by manufacturers.

- 1. A manufacturer of these substances shall report his gross receipts based upon his designated sales price whether or not the revenue from the sales is actually received by him in the quarter covered by the report or in a subsequent quarter. The manufacturer's report must be made on a form prescribed by the Nevada Tax Commission.
- 2. No allowance for nonpayment of the sales price by any purchaser may be deducted from the manufacturer's gross receipts.
- 3. Any sales of the substances to the manufacturer's subsidiaries must be included in the manufacturer's gross receipts at the sales price computed and charged to the subsidiaries without deduction for expenses incurred for intercorporate accounting or transactions.
- 4. Each manufacturer shall maintain accurate and complete records of all sales of the substances for at least 4 years. [Tax Comm'n, Amygdalin and Procaine Hydrochloride Reg. part No. 1, eff. 2-5-82]

COSMETICS

NAC 585.700 Definitions. As used in NAC 585.700 to 585.840, inclusive, unless the context otherwise requires:

- 1. "Batch" means a specific quantity of a cosmetic which has a uniform character and quality within specified limits and is produced according to a single manufacturing order during a cycle of manufacture.
- 2. "Control number" means any distinctive combination of letters or numbers, or both, from which the complete history of the manufacturing, control, packaging and distribution of a lot can be determined.
- 3. "Licensee" means a person who is licensed by the Commissioner to manufacture, process or package cosmetics.
- 4. "Lot" means a batch or any portion of a batch of a cosmetic or, if the cosmetic is produced in a continuous process, any amount of the cosmetic produced in a unit of time or quantity in a manner that ensures its uniformity. [Comm'r of Food & Drugs, Cosmetics § 2, eff. 12-16-82]

NAC 585.705 Use, inspection of equipment. A licensee may use precision, automatic or electronic equipment to manufacture, process or package cosmetics if he adequately inspects and checks the equipment to ensure its proper performance. [Comm'r of Food & Drugs, Cosmetics § 3, eff. 12-16-82]

NAC 585.710 Qualifications of employees. A licensee shall ensure that:

- 1. Employees who are responsible for directing the manufacture and control of a cosmetic have sufficient education, training and experience, or a combination thereof, to ensure that the cosmetic will have the safety, identity, quality and purity that it purports or is represented to possess.
- 2. Employees must have capabilities which are commensurate with their assigned duties, a thorough understanding of the manufacturing or control operations they perform, the appropriate training or experience and adequate information concerning the reasons for statutes and regulations relating to the manufacture of cosmetics. [Comm'r of Food & Drugs, Cosmetics § 4, eff. 12-16-82]

NAC 585.715 Exclusion of persons with illness or open lesions. A licensee shall exclude from direct contact with any cosmetic any person shown at any time, either by medical examination or supervisory observation, to have an apparent illness or open lesion that may adversely affect the safety or quality of the cosmetic until the condition is corrected. [Comm'r of Food & Drugs, Cosmetics § 5, eff. 12-16-82]

NAC 585.720 Report on adverse effects. A licensee shall instruct all of his employees to report to their supervisor any conditions that may have an adverse effect on any cosmetic. [Comm'r of Food & Drugs, Cosmetics § 6, eff. 12-16-82]

NAC 585.725 Buildings used to manufacture cosmetics: Condition; size, construction, location; separate rooms.

- 1. A licensee shall maintain in a clean and orderly condition the buildings used to manufacture cosmetics. The buildings must be of suitable size, construction and location to facilitate adequate cleaning, maintenance and proper operations in the manufacturing, processing, packing, labeling and storage of a cosmetic.
- 2. The licensee shall provide any separate rooms which are necessary to prevent a cosmetic product from being contaminated by another. [Comm'r of Food & Drugs, Cosmetics § 7, eff. 12-16-82]

NAC 585.730 Buildings used to manufacture cosmetics: Space. A licensee shall use buildings to manufacture cosmetics which have adequate space for:

- 1. The orderly placement of equipment and materials to minimize the risk of contamination and confusion between different components, materials in process, packaging materials or labeling materials.
- 2. The storage of components, containers, packaging materials and labeling materials.
- 3. Any manufacturing and processing operation.
- 4. Any packaging or labeling operation.
- 5. The storage of finished products.
- 6. The control of production and laboratory operations. [Comm'r of Food & Drugs, Cosmetics § 8, eff. 12-16-82]

NAC 585.735 Buildings used to manufacture cosmetics: Lighting, facilities; water; sewage disposal. A licensee shall provide in a building used to manufacture cosmetics:

1. Adequate lighting of at least 50 foot-candles, and ventilation and screening, if necessary, to:

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- (a) Minimize the contamination of products by extraneous adulterants, including the cross-contamination of one product by dust or particles or ingredients arising from the manufacture, storage or handling of another product;
- (b) Minimize the dissemination of micro-organisms from one area to another; and
- (c) Maintain suitable conditions for the storage of components, materials in process and finished cosmetics.
- 2. Adequate lockers and facilities near working areas with soap and hot and cold water for washing hands.
- 3. An adequate supply of potable water under continuous positive pressure in a plumbing system which is free of defects that could cause or contribute to the contamination of any cosmetic. Drains must be of adequate size and, where connected directly to a sewer, must be equipped with traps to prevent back siphonage.
- 4. For the safe and sanitary disposal of sewage, trash and other refuse within and from the building and immediate premises. [Comm'r of Food & Drugs, Cosmetics § 9, eff. 12-16-82]

NAC 585.740 Equipment.

- 1. A licensee shall maintain in a clean and orderly condition all equipment used in the manufacturing, processing, packaging, labeling, holding, testing or controlling of cosmetics. The equipment must be of a suitable design, size, construction and location to facilitate cleaning, maintenance and operation for its intended purpose.
- 2. Any equipment must:
 - (a) Be constructed so that all surfaces which come into contact with a cosmetic are not reactive, additive or absorptive in a way which alters the safety, quality or purity of the cosmetic;
 - (b) Be constructed and installed to facilitate adjustment, disassembly, cleaning and maintenance and to ensure uniformity of production and the exclusion from the cosmetics of contaminants from previous and current operations that might affect the safety and quality of the cosmetics; and
 - (c) Be of a suitable type, size and accuracy for any testing, measuring, mixing, weighing or other processing or storage. [Comm'r of Food & Drugs, Cosmetics § 10, eff. 12-16-82]

NAC 585.745 Submission, approval of plan to construct, remodel plant.

- 1. If, after December 16, 1982, a plant for manufacturing cosmetics is constructed or extensively remodeled, or an existing structure is converted for such a use, an applicant must submit plans to the Commissioner for his approval before the work is begun.
- 2. The plans must include:
 - (a) The layout and arrangement of the plant;
 - (b) The materials to be used in construction; and
 - (c) The location, size and type of any fixed equipment and facilities.
- 3. The Commissioner's approval of a plan does not constitute his final approval of the facility. An actual inspection of the completed facility must be made before a final approval will be given to the applicant. Until such inspection is made and final approval of the facility is granted, the Commissioner will not issue a license. [Comm'r of Food & Drugs, Cosmetics § 11, eff. 12-16-82]

NAC 585.750 Procedures for production and control.

- 1. The procedures for the production and control of cosmetics which are adopted by a licensee must include all reasonable precautions, including those contained in this section, to ensure that the cosmetics which are produced will have the safety and quality which they purport or are represented to possess.
- 2. Each significant step in the manufacturing process, such as the selection, weighing or measuring of components, the addition of ingredients during the process and the determination of the finished yield, must be performed by a competent and responsible person. If these steps are controlled by precision,

SNHD Regulations Governing the Sanitation and Safety of Tattoo Establishments Appendix B: Nevada Administrative Code (NAC) Chapter 585, *Drugs and Cosmetics*

- automatic, mechanical or electronic equipment, the proper performance of the equipment must be adequately checked by at least one competent and responsible person.
- 3. Each container, line and piece of equipment used during the production of a batch must be properly identified at all times to show accurately and completely its contents and, when necessary, the stage of the processing of the batch.
- 4. To minimize contamination and prevent confusion, all equipment, utensils and containers must be thoroughly and appropriately cleaned and properly stored. The identification marking for the previous batch must be removed between batches or at suitable intervals during a continuous production.
- 5. A licensee shall establish appropriate procedures:
 - (a) To minimize the cross-contamination of cosmetics while they are being manufactured or stored.
 - (b) For the review and approval of all records concerning production control, including those for packaging and labeling, before the release or distribution of any batch. [Comm'r of Food & Drugs, Cosmetics § 12, eff. 12-16-82]

NAC 585.755 Components: Storage, handling; conformance with specifications.

- 1. A licensee shall store and handle in a safe, sanitary and orderly manner, all components and other materials used in the manufacturing, processing and packaging of cosmetics and all materials necessary for the maintenance of the buildings and equipment.
- 2. A licensee may not use any component until it has been identified and examined for conformance with the specifications of the product. [Comm'r of Food & Drugs, Cosmetics § 13, eff. 12-16-82]

NAC 585.760 Components: Examination; testing. A licensee shall:

- 1. Visually examine each container of components before the components are used to detect any damage or contamination.
- 2. Appropriately examine samples of components which are susceptible to contamination by filth, insects or other extraneous contaminants.
- 3. Subject the final product to microbiological tests. The product shall not contain microorganisms that are objectionable.
- 4. Handle and store approved components in such a manner as to guard against their contamination by other cosmetics or components. [Comm'r of Food & Drugs, Cosmetics § 14, eff. 12-16-82]

NAC 585.765 Containers. The containers which are used by the licensee for his products and their components must not be reactive, additive or absorptive so as to alter the safety or quality of the cosmetic. The containers must provide adequate protection against any element which can cause the deterioration or contamination of the cosmetic. [Comm'r of Food & Drugs, Cosmetics § 15, eff. 12-16-82]

NAC 585.770 Laboratory controls. A licensee shall include in his laboratory controls, provisions for:

- 1. The establishment of scientifically sound and appropriate specifications and testing procedures to ensure the quality of the finished cosmetic.
- 2. Verifying the reliability and accuracy of the laboratory testing procedures and instruments which are used
- 3. The retention of a properly identified sample of each finished cosmetic. The sample must be stored in a container which is identical to the container in which the cosmetic is marketed. The sample must contain at least twice the quantity necessary to perform all tests performed, except for net weight content, to ensure quality. The licensee shall retain the sample for at least 2 years.
- 4. The retention of complete records of all laboratory data relating to each lot for at least 1 year after the distribution of the lot is completed. [Comm'r of Food & Drugs, Cosmetics § 16, eff. 12-16-82]

NAC 585.775 Packaging and labeling.

- 1. A licensee shall control his packaging and labeling operations to:
 - (a) Ensure that only cosmetics which meet the standards and specifications established in the master record of production and control are distributed;
 - (b) Prevent confusion during filling, packaging and labeling operations;
 - (c) Ensure that correct labels and labeling materials are used; and
 - (d) Identify each finished product with a control number that permits the determination of the history of the manufacture and control of the batch.
- 2. The licensee may use a code for the day or for the shift as a number for cosmetics which are manufactured or processed by equipment which is used in continuous production.
- 3. The licensee may not use labels for containers and package labeling until they have been reviewed and proofed against an approved final copy by a competent and responsible person. The person shall ensure that they are accurate regarding identity and content and in conformity with the approved copy before they are released for distribution. The licensee shall establish a suitable system for ensuring that only current labels for containers and package labeling are retained and that obsolete labels and package labeling are destroyed. [Comm'r of Food & Drugs, Cosmetics § 17, eff. 12-16-82]

NAC 585.780 Master record of production and control.

- 1. To ensure the uniformity of batches, a licensee shall prepare a master record of production and control for each cosmetic and each batch.
- 2. The record must be dated and signed or initialed by a competent and responsible person and must include:
 - (a) The name and weight or measure of each ingredient.
 - (b) A complete list of ingredients, designated by names or codes which are sufficiently specific to show any special characteristic of quality, including statements concerning:
 - (1) Any calculated amount of excess of an ingredient;
 - (2) The theoretical weight or measure at the various stages of processing; and
 - (3) The theoretical yield.
 - (c) A description of the containers, closures and packaging of finished materials.
 - (d) The instructions regarding manufacturing and control, and the procedures, specifications, and special notations and precautions to be taken. [Comm'r of Food & Drugs, Cosmetics § 18, eff. 12-16-82]

NAC 585.785 Records of batches.

- 1. A licensee shall prepare a record which is readily available containing complete information concerning the production and control of each batch which he produces.
- 2. The licensee shall retain the record for at least 2 years after the distribution of the batch has been completed.
- 3. The record must:
 - (a) Identify the specific labeling and control numbers used on the batch; and
 - (b) Note the number that identified all of the documents concerning the production, control and history of the batch and all other control numbers associated with the batch. [Comm'r of Food & Drugs, Cosmetics § 19, eff. 12-16-82]

NAC 585.790 Records of distribution of lots.

- 1. A licensee shall include in the procedures for the control and distribution of finished goods, a record system by which the distribution of each lot can be readily determined to facilitate the recall of a cosmetic, if necessary. The records must contain the name and address of the consignee, the date of each shipment, the quantity shipped and the lot or control number of the cosmetic. The licensee shall retain these records for at least 2 years after the distribution of the cosmetic has been completed.
- 2. The licensee shall establish a system whereby his oldest approved stock is distributed before newer stock is distributed, whenever possible. [Comm'r of Food & Drugs, Cosmetics § 20, eff. 12-16-82]

NAC 585.795 Records of complaints. A licensee shall maintain records of all written and oral complaints he receives regarding each product and shall notify the Commissioner immediately upon the receipt of any such complaint. [Comm'r of Food & Drugs, Cosmetics § 21, eff. 12-16-82]

NAC 585.800 Qualifications of applicant for license. The Commissioner will not issue a license pursuant to NRS 585.245 unless the applicant has satisfied the Commissioner that the applicant is competent and has adequate business experience to conduct the activity for which the application for a license is made. [Comm'r of Food & Drugs, Cosmetics § 22, eff. 12-16-82]

NAC 585.805 Application for license.

- 1. Any person who desires to operate a plant for the manufacture of cosmetics must submit to the Commissioner an application for a license.
- 2. The applicant must provide the Commissioner with complete information regarding the ownership of the plant and report promptly all significant changes in its ownership.
- 3. A corporate applicant must provide the Commissioner with the name and address of each of its officers and managers. An applicant who is not a corporation must provide the Commissioner with the name and address of each of his managerial employees. Each applicant must notify the Commissioner of any change in this information.
- 4. The applicant must:
 - (a) State the proposed hours of operation of the plant and notify the Commissioner of any change in the hours of operation.
 - (b) Submit the formula of the cosmetic he intends to manufacture, including all components, to the Commissioner for review and approval.
 - (c) Satisfy the Commissioner of his ability to meet the requirements of NAC 585.700 to 585.740, inclusive, of this regulation before the Commissioner will issue any license. [Comm'r of Food & Drugs, Cosmetics § 23, eff. 12-16-82]

NAC 585.810 Denial, suspension, revocation of license.

- 1. The failure or refusal of an applicant or a licensee to comply with any applicable statutes or regulations is a ground for the denial, suspension or nonrenewal of a license.
- 2. The Commissioner will include in the notice of any denial, suspension, revocation or nonrenewal of a license the legal authority and reasons for the action. He will send the notice to the applicant or licensee by certified mail within 10 days after the action is taken. [Comm'r of Food & Drugs, Cosmetics § 24, eff. 12-16-82]

NAC 585.815 Fees; renewal of license.

1. An applicant must pay an initial licensing fee of \$300 to the Commissioner before a license will be issued. The Commissioner will prorate an initial licensing fee for the period from the date of the issuance of the license until the end of the fiscal year.

SNHD Regulations Governing the Sanitation and Safety of Tattoo Establishments Appendix B: Nevada Administrative Code (NAC) Chapter 585, *Drugs and Cosmetics*

- 2. A license is effective until June 30 of the fiscal year in which it is issued and must be renewed by July 1 of each year. The renewal fee is \$300. In certain cases, the Commissioner may prorate a renewal fee for part of a fiscal year. An application for the renewal of a license must be received by the Commissioner at least 30 days before the expiration of the license.
- 3. The fees collected pursuant to this section will not be refunded. [Comm'r of Food & Drugs, Cosmetics § 25, eff. 12-16-82]

NAC 585.820 Inspections.

- 1. The Commissioner will make an initial inspection of an applicant's plant before a license is granted and will make such an inspection at least annually. He will make such additional inspections as he deems necessary for the enforcement of chapter 585 of NRS and this regulation.
- 2. The Commissioner will give to the licensee a written report of the findings of any inspection the Commissioner makes at the licensee's factory, warehouse or plant. [Comm'r of Food & Drugs, Cosmetics § 26 + part § 27, eff. 12-16-82]

NAC 585.825 Examination of records. A licensee shall permit the Commissioner to examine the records of the establishment to obtain information which is pertinent to the licensee's operation. [Comm'r of Food & Drugs, Cosmetics part § 27, eff. 12-16-82]

NAC 585.830 Federal regulations adopted by reference. Parts 700 to 740, inclusive, of Title 21 of the Code of Federal Regulations, as those regulations existed on April 1, 1982, are hereby adopted by reference. A copy of the volume containing these parts may be obtained from the Superintendent of Documents, United States Government Printing Office, Washington, D.C. 20402, for the price of approximately \$6. [Comm'r of Food & Drugs, Cosmetics § 28, eff. 12-16-82]

NAC 585.835 Exemptions.

- 1. A licensee may petition the Commissioner for an exemption from a particular provision of NAC 585.700 to 585.840, inclusive.
- 2. The petition must contain:
 - (a) The section for which the licensee requests the exemption; and
 - (b) Facts sufficient to show the Commissioner that, because of the harmless nature of the cosmetic the licensee manufactures, the section should not apply.
- 3. A decision by the Commissioner is final and may not be appealed. [Comm'r of Food & Drugs, Cosmetics § 29, eff. 12-16-82]

NAC 585.840 Severability. If any provision of NAC 585.010 to 585.840, inclusive, or any application thereof to any person, thing or circumstance is held invalid, the Commissioner intends that the invalidity not affect the remaining provisions or applications to the extent that they can be given effect. [Comm'r of Food & Drugs, Cosmetics § 30, eff. 12-16-82]

Tattoo & Permanent Makeup Establishments Regulations

Effective June 2009

Appendix C:

Standard Precautions

Serving Boulder City, Clark County, Henderson, Las Vegas, Mesquite and North Las Vegas



STANDARD PRECAUTIONS

The STANDARD PRECAUTIONS, published by the Centers for Disease Control (CDC), are a set of guidelines which workers should employ consistently with all patrons, in order to prevent parenteral, mucous membrane, and nonintact skin exposure to pathogens. They have been adopted here in reference to tattoo establishments.

The following Standard Precautions have been summarized for their relevance.

Needlestick injuries

Take care to prevent injuries when using needles, scalpels, and other sharp instruments or devices: a) when handling sharp instruments after procedures; b) when cleaning used instruments; c) when disposing of used needles.

Do not recap used needles by hand; do not bend, break, or otherwise manipulate used needles by hand.

Place used needles and other sharp items in puncture-resistant containers for disposal. Locate these containers as close to the use area as is practical.

Gloves and other protective barriers

Use protective barriers to prevent exposure to blood, body fluids containing visible blood, and other fluids to which Standard Precautions apply. The types of protective barriers used should be appropriate for the procedures being performed and the type of exposure anticipated.

Hand washing

Immediately and thoroughly wash hands and other skin surfaces that are contaminated with blood, body fluids containing visible blood, or other body fluids to which Standard Precautions apply.

Health problems

Operators who have weeping dermatitis or draining lesions should refrain from all tattoo application and from handling tattoo equipment until the condition has cleared.

Pregnancy

Pregnant women are not known to be at greater risk of contracting HIV infection than non-pregnant women. However, they should be especially familiar with, and strictly adhere to, precautions to minimize this risk.

Excerpted from, "CDC. Update: Universal Precautions for prevention of transmission of human immunodeficiency virus, hepatitis B virus, and other bloodborne pathogens in health-care settings." Morbidity and Mortality Weekly Report, June 24, 1988; 37(24):377-78.

Tattoo & Permanent Makeup Establishments Regulations

Effective June 2009

Appendix D:

Biohazard Symbol Examples

Serving Boulder City, Clark County, Henderson, Las Vegas, Mesquite and North Las Vegas



Appendix D Examples of Biohazard Symbols, Bags, and Sharps Container























Tattoo & Permanent Makeup Establishments Regulations

Effective June 2009

Appendix E:

Hepatitis A and B Vaccination Record

Serving Boulder City, Clark County, Henderson, Las Vegas, Mesquite and North Las Vegas



Appendix E—HEPATITIS A and B IMMUNIZATION RECORD

	Name of Establishment					
Street	Address/City/State/Zip					
Permit Nu	umber of Establishment					
Name of T	attoo Operator or Body Piercing Technician					
Hire Date		Date of Birth		SS#		
	Hepatitis B Immuniza	tion Record:				
	Date-1 st shot	Shot g	iven by		Facility	
	Date-2 nd shot	Shot given by			Facility	
	Date-3 rd shot	Shot given by		Facility		
	AND Hepatitis A Immuniza					
	Date-1 st shot	Shot g	iven by		Facility	
	Date-2 nd shot	Shot gi	ven by		Facility	
OR TWINRIX VACCINATION IN LIEU OF TWO SEPARATE IMMUNIZATIONS AI						
	Hepatitis A and B (Twinrix) Immunization Record:					
	Date-1 st shot	Shot g	iven by		Facility	
			ven by			
	Date-3 rd shot	Shot a	iven by		Facility	

This hepatitis A & B documentation must be kept on file at the establishment and a copy given to the tattoo operator or body piercing technician.

Tattoo & Permanent Makeup Establishments Regulations

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Appendix F:

Visiting Tattoo Operator/Body Piercing Technician Application

Serving Boulder City, Clark County, Henderson, Las Vegas, Mesquite and North Las Vegas





VISITING

TATTOO OPERATOR/BODY PIERCING TECHNICIAN APPLICATION \$145 PER TATTOO OPERATOR OR BODY PIERCING TECHNICAN

Please Print: Applicant Name:	☐ TATTOO	☐ PERMANENT MAKEUP	■ BODY PIERCING				
Home Address:							
Phone Number:	Applicant Name:		Date:				
Name of Facility:	Home Address:	City/State/Zip:					
Date of first day of work: Date of last day of work: ATTACH THE FOLLOWING DOCUMENTATION: 1. A copy of minimum of six (6) months training and/or experience in the tattoo, permanent makeup, or body piercing field. 2. A copy of your State Drivers License or State-issued Identification Card. Upon approval, application is valid for up to ten (10) consecutive days from first day of work noted above. Exceeding ten (10) days of work within any 365 day timeframe (per calendar year) will require the tattoo operator or body piercing technician to obtain a Southern Nevada Health District (SNHD) Tattoo/Permanent Makeup Operator or Body Piercing Technician Health Card. Tattoo operator or body piercing technician may only work in a Health Permitted body art facility. A separate application must be submitted for each period of one (1) or more consecutive days. I UNDERSTAND THAT FAILURE TO COMPLY WITH ALL APPLICABLE REGULATIONS MAY RESULT IN IMMEDIATE REVOCATION OF THE APPLICATION. Applicant Signature For Official Use Only:	Phone Number:	Fax Nu	umber:				
ATTACH THE FOLLOWING DOCUMENTATION: 1. A copy of minimum of six (6) months training and/or experience in the tattoo, permanent makeup, or body piercing field. 2. A copy of your State Drivers License or State-issued Identification Card. Upon approval, application is valid for up to ten (10) consecutive days from first day of work noted above. Exceeding ten (10) days of work within any 365 day timeframe (per calendar year) will require the tattoo operator or body piercing technician to obtain a Southern Nevada Health District (SNHD) Tattoo/Permanent Makeup Operator or Body Piercing Technician Health Card. Tattoo operator or body piercing technician may only work in a Health Permitted body art facility. A separate application must be submitted for each period of one (1) or more consecutive days. I UNDERSTAND THAT FAILURE TO COMPLY WITH ALL APPLICABLE REGULATIONS MAY RESULT IN IMMEDIATE REVOCATION OF THE APPLICATION. Applicant Signature For Official Use Only:	Name of Facility:	SNHD Hea	alth Permit #:				
1. A copy of minimum of six (6) months training and/or experience in the tattoo, permanent makeup, or body piercing field. 2. A copy of your State Drivers License or State-issued Identification Card. Upon approval, application is valid for up to ten (10) consecutive days from first day of work noted above. Exceeding ten (10) days of work within any 365 day timeframe (per calendar year) will require the tattoo operator or body piercing technician to obtain a Southern Nevada Health District (SNHD) Tattoo/Permanent Makeup Operator or Body Piercing Technician Health Card. Tattoo operator or body piercing technician may only work in a Health Permitted body art facility. A separate application must be submitted for each period of one (1) or more consecutive days. I UNDERSTAND THAT FAILURE TO COMPLY WITH ALL APPLICABLE REGULATIONS MAY RESULT IN IMMEDIATE REVOCATION OF THE APPLICATION. Applicant Signature For Official Use Only:	Date of first day of wor	rk: Date of last	t day of work:				
For Official Use Only:	makeup, or body piercing field. 2. A copy of your State Drivers License or State-issued Identification Card. Upon approval, application is valid for up to ten (10) consecutive days from first day of work noted above. Exceeding ten (10) days of work within any 365 day timeframe (per calendar year) will require the tattoo operator or body piercing technician to obtain a Southern Nevada Health District (SNHD) Tattoo/Permanent Makeup Operator or Body Piercing Technician Health Card. Tattoo operator or body piercing technician may only work in a Health Permitted body art facility. A separate application must be submitted for each period of one (1) or more consecutive days. I UNDERSTAND THAT FAILURE TO COMPLY WITH ALL APPLICABLE REGULATIONS						
		Appl	icant Signature				
Date Rec'd: Approved By: Date Approved:	For Official Use Only:						
	Date Rec'd:	Approved By:	Date Approved:				