Training Manual
For
The Tattoo Artist

Sponsored By: The American Tattooing Institute

COMPREHENSIVE TRAINING FOR THE PROFESSIONAL TATTOO ARTIST
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Who We Are

Staff at the American Tattooing Institute (ATI) developed this program as an important educational resource for the tattoo professional. Regulations vary from state to state as to the qualifications of a state compliant tattoo artist. Because of this, we strongly suggest you contact your local regulatory office for a written list of licensing requirements in your state. A list of Health departments and their summarized regulations can be found in chapter 6 of this manual.

We realize that it is often difficult for busy tattoo artists to attend educational seminars in person. With our program, you’ll find tattooing education more affordable and accessible. Our training program is available online nationwide 24 hour a day, 7 days a week.

Many tattooing facilities operate with a minimum number of personnel, not to mention limited budgets. The American Tattooing Institute provides a cost effective solution to training by allowing owners and staff to complete crucial education in their spare time.

We have carefully selected the educational material available through this program. We are confident that the material we offer will help you develop a tattooing facility that is professional as well as profitable.

ProEd Network

American Tattooing Institute is a division of ProEd Network. ProEd Network serves as an umbrella for continuing education, training programs, and educational services for other industries. Since 1997, staff at ATI has provided healthcare and service professionals with valuable, affordable and convenient education options.
Body Art Specialist’s Code of Ethics

- The body art specialist conducts himself or herself in a professional manner, responds to customer needs and supports colleagues and associates in providing quality customer service while following healthful standards.

- The body art specialist acts to advance the principal objective of the tattooing industry to provide services to clients with full respect for their overall well-being.

- The body art specialist practices healthful techniques founded upon theoretical knowledge and concepts, uses equipment and accessories consistent with the purpose for which they were designed and employs procedures and techniques appropriately while adhering to local, state, and federal guidelines.

- The body art specialist assesses situations; exercises care, discretion and judgment; assumes responsibility for professional decisions; and acts in the best interest of the client.

- The body art specialist uses equipment and accessories, employs techniques and procedures, and performs services in accordance with an accepted standard of practice while demonstrating high levels of expertise.

- The body art specialist continually strives to improve knowledge and skills by participating in continuing education and professional activities, sharing knowledge with colleagues and investigating new aspects of professional practice.
The Skin

Although the skin is less complicated than most other organs, it is still one of the most architecturally advanced of all. It covers the entire body and accounts for about 7% of our total body weight, making it the largest organ. It has been estimated that every square centimeter of skin contains 70 cm of blood vessels, 55 cm of nerves, 100 sweat glands, 15 oil glands, 230 sensory receptors, and about 500,000 cells that are constantly dying and being replaced.

The skin, which varies in thickness from 1.5 to 4 mm or more in different regions of the body, has two distinct layers. The outer layer is the epidermis, a thick membranous tissue. Located below the epidermis is the dermis, a fibrous connective tissue. And, just below the dermis lies a fatty layer called the hypodermis. Although the hypodermis is usually not thought of as part of the skin or integumentary system, it shares some of the skin’s functions and will be discussed in this chapter.

The skin performs many functions, most but not all of which are protective. It cushions and insulates the deeper body organs and protects the entire body from physical damage like bumps and cuts. The skin also offers helpful protection from harmful chemicals, thermal damage (heat and cold), and invading bacteria. The epidermis is waterproof, preventing unnecessary loss of water across the body surface. The skin’s rich abundance of blood flow and sweat glands regulate the loss of heat from the body, helping to control body temperature. The skin also acts as a mini-excretory system: Urea, salts, and water are lost as sweat. Skin also reduces ultraviolet (UV) rays from the sun, and its epidermal cells use these UV rays to synthesize vitamin D. Finally, the skin contains sensory organs called sensory receptors that are associated with nerve endings. By sensing touch, pressure, temperature, and pain, these receptors keep us aware of what is happening at the body surface. As this chapter describes the anatomy of the skin, we will explore its function in greater detail.
HYPODERMIS

Just below the skin is the fatty layer of the hypodermis (“below the skin” in Greek). This layer is also called the subcutaneous layer (“below the skin” in Latin). It consists of both areolar and adipose connective tissue, although the adipose tissue normally dominates. Besides storing fat, the hypodermis anchors the skin to the underlying structures (mostly to muscles) and allows the skin to slide relatively freely over those structures. Sliding skin protects us by ensuring most blows just glance off our bodies. The hypodermis is also and insulator: Since fat is a poor conductor of heat, it helps prevent heat loss from the body. The hypodermis thickens distinctly when one gains weight, but this thickening occurs in different body areas in the two sexes. In females, subcutaneous fat accumulates first in the thighs and breasts, whereas in males it first accumulates in the front abdominal area.

DERMIS

The dermis, the second major layer of the skin, is a strong, flexible connective tissue. The cells in the dermis are identical to those of any connective tissue in the body. The dermis binds the body together like a body stocking. Tattooing involves multiple punctures of the skin to instill pigment into the dermis.

The dermis is richly supplied with nerve fibers and blood vessels. The blood vessels of the dermis are so extensive that it can hold 5% of all blood in the body. When organs, such as exercising muscles, need more blood, the nervous system constricts the blood vessel located in the dermis. This shunts more blood into the general circulation, making it available to the muscles and other organs. On the other hand, the dermal blood vessels swell with warm blood on hot days, allowing heat to radiate from the body creating a cooling effect.

The collagen fibers of the dermis give skin its strength and resilience. Thus, many jabs and scrapes usually do not penetrate the tough dermis. Furthermore, elastic fibers in the dermis provides the skin with stretch and recoil properties.

The deeper part of the dermis is responsible for markings on our skin surface called flexure lines. These lines are easily observed as the deep skin creases on the palms. Flexure lines result from a continual folding of the skin, often over joints, where the dermis attaches tightly to underlying structures. Flexure lines are also visible on the wrists, soles of the feet, fingers, and toes.

EPIDERMIS

The epidermis contains four distinct types of cells: keratinocytes, melanocytes, Merkel cells, and Langerhans cells. Keratinocytes are by far the most abundant cells of these, so we will discuss them first. We will discuss the other types of cells later as we examine the various layers of the epidermis.
Keratinocytes

The chief role of the keratinocytes is to produce keratin, a tough fibrous protein that gives the epidermis its protective properties. Tightly connected to one another by a large number of desmosomes, the keratinocytes arise in the deepest part of the epidermis from cells that undergo almost continuous mitosis, or cell division. As these cells are pushed toward the skin surface by the production of new cells beneath them, they manufacture the keratin that eventually fills their cytoplasm. The cytoplasm makes up the bulk of the cell and is located between the outer layer of the cell and the nucleus.

By the time the keratinocyte reaches the skin surface, they are dead, flat sacs completely filled with keratin. Millions of these dead cells rub off every day, giving us an entirely new epidermis every 30 to 45 days—the average time from “birth” of a keratinocyte to its final wearing away. In the normal healthy epidermis, the production of new cells balances the loss at the surface of the skin. Where the skin experiences friction, both cell production and keratin formation are accelerated.

Layers of the Epidermis

In thick skin, which covers the palms of the hand and soles of the feet, the thickened epidermis consists of five layers, or strata. In thin skin, which covers the rest of the body, only four strata are present.

1. Stratum Basale (Basal Layer)

The stratum basale, the deepest layer of the epidermis, is firmly attached to the dermis along a wavy borderline. Also called the germinating layer, this stratum consists of a single row of cells representing the youngest keratinocytes. These cells divide rapidly. Occasional Merkel cells are seen among the keratinocytes. Each semi-circular Merkel cell is closely associated with a disc-like sensory nerve ending and may serve as a receptor for touch.

Between 10 percent and 25 percent of the cells in the stratum basale are melanocytes ("melanin cells"). These make the dark skin pigment melanin. The spider-shaped melanocytes have many branching processes that reach and touch all of the keratinocytes in the basal layer. Melanin is made in membrane-lined granules and then transferred through the cell processes to nearby keratinocytes. Consequently, the basale keratinocytes contain more melanin than do the melanocytes themselves. The melanin granules accumulate on the surface of each keratinocyte, forming a shield of pigment over the nucleus. In Caucasians, the melanin disappears a short distance above the basal layer, where it is digested by lysosomes in the keratinocytes. In black skinned individuals, no such digestion occurs, so melanin occupies keratinocytes throughout the epidermis. Although black skinned individuals have darker melanin and more pigment in each melanocyte, they do not have more melanocytes in their skin. In all but the darkest people, melanin builds up in response to ultraviolet rays, the response that we know as suntanning.
2. Stratum Spinosum (Spiny Layer)

The stratum spinosum is several cell layers thick. Mitosis, or cell production through division, occurs here, but less frequently than in the basal layer. Under microscopic imaging, the keratinocytes in this layer have many spine-like extensions.

Scattered among the keratinocytes of the stratum spinosum are Langerhans cells. These star-shaped cells are particulate ingesting microphages that help activate the immune system.

3. Stratum Granulosum (Granular Layer)

The thin stratum granulosum consists of three to five layers of flattened keratinocytes. These keratinocytes contribute to the formation of keratin in the upper layers of the epidermis. This keratin contains a waterproofing material that is secreted into the areas between the cells and is the major factor for slowing water loss from the epidermis. Furthermore, the external wall of the cells thicken, so that they become more resistant to destruction. You might say that the keratinocytes are “toughening up” to make the outer layers of the epidermis the strongest.

4. Stratum Lucida (Clear Layer)

The stratum lucid only occurs in thick skin, not thin skin. This layer consists of a few rows of flat dead keratinocytes. Electron microscopes show that its cells are identical to cells at the stratum corneum, the next layer.

5. Stratum Corneum (Horny Layer)

The most external part of the epidermis, the stratum corneum, is many cells thick. This layer is far thicker in thick skin than in thin skin. Its dead cells are flat sacs completely filled with keratin, because their nuclei and organelles were digested away by the lysosome enzymes upon cell death. Both the keratin and the thickened plasma membranes of the cells in the stratum corneum protect the skin against abrasion and penetration. It is amazing that a dead layer of cells can still perform such important functions.

The cells of the stratum corneum are referred to as horny cells. These cells are the dandruff shed from the scalp and the flakes that come off dry skin. The average person sheds about 40 pounds of these flakes in a lifetime. The common saying “Beauty is only skin deep” is especially interesting in the light of the fact that nearly everything we see when we look at someone is dead!

The Epidermis
Skin Color

Three pigments contribute to skin color: melanin, carotene, and hemoglobin. **Carotene** is a yellow to orange pigment derived from certain plant products, such as carrots. It tends to accumulate in the stratum corneum of the epidermis and in fat tissue of the hypodermis. Color derived from carotene is most obvious in the palms and soles, where the stratum corneum is thickest.

The pink tone of Caucasian skin reflects the red color of oxygenated **hemoglobin** in the capillaries of the dermis. Since Caucasian skin contains little melanin, the epidermis is nearly transparent in untanned individuals and allows blood’s color to show through more predominantly.

**Melanin**, the most prominent pigment and is made from an amino acid called tyrosine. Melanin ranges in color from yellow to reddish to brown to black. Its production depends on an enzyme in melanocytes called tyrosinase. Freckles and pigmented moles are localized accumulations of melanin.
Procedures for Studios and Artists

Tattooing facility owners and operators have a responsibility to operate their facility under the structure of well-developed, up to date and principled procedures. It is important to note that if your state has specific regulations regarding the operation of a tattoo business, these regulations should be included in your procedural policies. The following list of recommended procedures, taken from several state requirements, is considered to be a general and responsible list of operating procedures. You should consult your states Health Department to see if a required guideline exists for you.

Operation Procedures

(1) Sanitation

(a) Before working on each patron, the fingernails and hands of the tattoo artist shall be thoroughly washed and scrubbed with warm running water, antibacterial soap, and individual hand brush that is clean and in good repair, then air blown or dried by single use towel prior to beginning work on each person or when interrupted in the process.

(b) Disposable, latex examination gloves shall be worn during the tattooing process. Gloves shall be changed and properly disposed of each time there is an interruption in the application of the tattoo, the gloves become torn or punctured, or whenever their ability to function as a barrier is compromised.

(c) Each tattoo artist shall wear a clean outer garment, apron, smock, T-shirt, etc.
(d) Tattoo artists who are experiencing symptoms of diarrhea, vomiting, fever, rash, productive cough, jaundice or draining (or open) skin infections, boils, impetigo or scabies shall refrain from tattooing activities.

(e) Only sterilized or single use, disposable razors shall be used to shave the area to be tattooed.

(f) Before placing the design on the patron's skin, the tattoo artist shall treat the skin area with an antibacterial solution.

(g) If an acetate stencil is used by a tattoo artist for transferring the design to the skin, it shall be thoroughly cleaned and rinsed in a germicidal solution for at least twenty (20) minutes and then dried with sterile gauze or dried in the air on a sanitized surface after each use.

(h) If a paper stencil is used by a tattoo artist for transferring the design to the skin, it shall be single use and disposable.

(i) If the design is drawn directly onto the skin, it shall be applied with a single use article only.

(j) A registered tattoo artist or certified tattoo business may set up at fairs, festivals, expositions or any location other than a tattoo studio with the written approval of the local health department for a period not to exceed fourteen (14) days.

(k) Cabinets for the storage of instruments, dyes, pigments, single use articles, carbon, and stencils shall be provided for each tattoo artist and shall be maintained in a sanitary manner, which protects them from contamination.

(l) Bulk single use articles shall be commercially packaged and handled to protect them from contamination. Storage of single use articles shall not be in a toilet room or vestibule of toilet rooms nor under nonpotable water lines or exposed sewer lines.

(m) The surface of all work tables and chairs or benches shall be constructed of material which is smooth, light-colored, nonabsorbent, corrosive-resistant, and easily sanitized.

(n) Work tables and chairs or benches shall be sanitized with a germicidal solution after each tattoo application.

(o) Existing tattoo studios on the effective date of this administrative regulation shall be exempt from the required color of the work table.
(p) All materials applied to the human skin shall be from single use articles or transferred from bulk containers to single use containers and shall be disposed of after each use.

(q) No pets, except working dogs, guide dogs or security dogs from a certified trainer, shall be permitted in the studio.

(2) **Records**

(a) For each patron, proper records of tattoos administered shall be maintained by the holder of a studio certificate.

(b) Records of each patron shall be prepared prior to any procedure being performed and shall include the patron's name and signature, address and age, the date tattooed, the design of the tattoo, its location on the patron's body, and the name of the tattoo artist who performed the work.

(c) Records shall be entered in ink or indelible pencil shall be available at a reasonable time for examination by the local health department in the district or county where the tattoo is performed. The signature of the patron shall be on the record.

(d) Before tattoo administration, there shall be a discussion conducted with the patron on the risks involved in the tattoo requested, and its possible complications, which shall be entered in the record.

(e) Records required by this administrative regulation shall be kept on file for five (5) years by the holder of the studio certification for the studio in which the tattoo was performed.

(3) **Consent**

(a) Written consent for tattooing of minors shall be obtained from one (1) parent or guardian.

(b) Records of the written consents shall be kept on file for five (5) years by the holder of the studio certification for the tattoo studio in which the tattoo was performed.

(c) The person receiving the tattoo shall attest to the fact that they are not intoxicated or under the influence of drugs or alcohol.

(4) **Consumer Instructions**

(a) Printed instructions on the care of skin shall be given to each patron or customer after tattooing as a precaution to prevent infection.
(b) A copy of instructions shall be posted in a conspicuous place, clearly visible to the person being tattooed.

(5) Dyes or Pigments

(a) In preparing dyes or pigments to be used by a tattoo artist, only nontoxic sterile materials shall be used. Single-use or individual portions of dyes or pigments in clean, sterilized individual containers or single-use containers shall be used for each patron.

(b) After tattooing, the remaining unused dye or pigment in the single-use or individual containers shall be discarded along with the container.

(c) All dyes or pigments used in tattooing shall be from professional suppliers specifically providing dyes or pigments for the tattooing of human skin.

(6) Sterilization of Needles

(a) A set of individual, sterilized needles shall be used by a tattoo artist for each patron.

(b) To guard against a potential temptation to reuse single-service needles because of exhaustion of existing supplies, not less than twenty-four (24) sets per studio of sterilized needles and tubes shall be on hand for the entire day or night operation. Sterilized instruments shall be resterilized at intervals of no more than six (6) months from the date of the last sterilization.

(c) Used, nondisposable instruments shall be kept in a separate, puncture resistant container until brush scrubbed in hot water and soap, and then sterilized by autoclaving.

(d) If used instruments are ultrasoniced prior to being placed in the used instrument container, they shall be ultrasoniced, and then rinsed under running hot water prior to being placed in the used instrument container.

(e) The ultrasonic unit shall be sanitized with a germicidal solution daily.

(f) If used instruments are not ultrasoniced prior to being placed in the used instrument container, they shall be kept in a germicidal or soap solution until brush scrubbed in hot water and soap, and then sterilized by autoclaving.

(g) Nondisposable instruments including the needle tubes shall be sterilized and shall be handled as to prevent contamination. Instruments to be sterilized shall be sealed in bags specifically made for the purpose of autoclave sterilization, and include the date of sterilization. If nontransparent sterilization bags are utilized, the bag shall also list the contents.
(h) Autoclave sterilization bags, with a color code indicator which changes color upon proper steam sterilization shall be utilized during the autoclave sterilization process.

(i) Instruments shall be placed in the autoclave in such a manner as to allow live steam to circulate around them.

(j) No rusty, defective or faulty instruments shall be kept in the studio.

(7) Aftercare of Tattoo

(a) The completed tattoo shall be washed with a single-use towel saturated with an antibacterial solution.

(b) After drying, antibacterial solution shall be applied from a collapsible metal or plastic tube and the entire area covered with a single-use covering, which may, in turn, be covered with gauze and fastened to the site with adhesive tape.

Facilities and Equipment

(1) General physical environment.

(a) Tattoo studios shall have at least fifty (50) foot-candles of light measured at the height of the work table.

(b) Tattoo studios shall have adequate ventilation.

(c) Walls and ceilings shall be smooth and easily cleaned. Walls and ceilings shall be painted a light color.

(d) The floor of the tattoo work room shall be impervious material. The floor shall be swept and wet mopped daily. Floors, walls or ceilings shall not be swept or cleaned while tattooing is in operation.

(e) Convenient, clean, and sanitary toilet and hand washing facilities shall be made accessible to customers.

(f) The building and equipment shall be maintained in a state of good repair at all times. The studio premises shall be kept clean, neat, and free of litter and rubbish.

(2) Work room.

(a) Each tattoo studio shall have a separate work room not used for any other purpose.

(b) Work rooms shall not be used as a corridor for access to other rooms.
(c) Patrons or customers shall be tattooed only in the work room.

(d) Work rooms shall be equipped with hot and cold running water, and one (1) sink or basin per artist operating at the same time.

(e) Sinks and basins shall be for the exclusive use of the tattoo artists for washing their hands and preparing customers for tattooing.

(f) Sinks shall be equipped with foot, wrist, or single lever action controls, soap, a germicidal solution, single use towels, and individual hand brushes clean and in good repair for each tattoo artist.

(g) Plumbing shall be in compliance with the State or local Plumbing Code.

(h) No person shall consume any food or drink in the work room.

**Disposal of Waste**

The tattoo studio operators shall dispose of waste products in the following manner:

(1) Needles, scalpels, razors or other sharp instruments used for patient care procedures, shall be segregated from other wastes and placed in puncture resistant, closed containers immediately after use.

(2) Needles shall not be purposely bent or broken, or otherwise manipulated by hand.

(3) Containers of sharp wastes shall be sent to a facility where they are either incinerated or otherwise rendered nonhazardous.

(4) Disposable waste shall be placed in easily cleanable, closed containers provided with tight fitting lids, to prevent leakage or spillage.

(5) Waste containers shall be kept closed when not in use.

(6) Disposable waste shall be handled, stored, and disposed of to minimize direct exposure of personnel to waste materials.

(7) Disposable waste shall be sprayed with a ten (10) percent chlorine solution immediately following each tattoo application.
Due to its invasive nature, there is a potential for serious infection to occur during tattooing. The needles that are used to penetrate the skin at various sites on the body can become contaminated by blood or serum.

HIV (the virus which causes AIDS), Hepatitis B and Hepatitis C viruses are present in blood and spread by infected blood entering another person's bloodstream. This can happen during tattooing, when needles used for penetrating the skin are contaminated with infected blood or serum and are not replaced before use on another person.

The person at risk may be the next client being treated with the contaminated instrument or you, if you accidentally penetrate your skin with the contaminated instrument. This is called a 'needle-stick' injury. Contact with infected blood, serum or contaminated instruments on open cuts, sores or broken skin can also lead to infection.

Blood or serum does not have to be visible on an instrument or needle for infection to be transmitted. It is important to note: all instruments that penetrate the skin of a person, including needles and attachments such as nozzles, needle bars and tubes, must be sterile.
Cross-Contamination

Some of the ways which cross-contamination can occur in tattooing are as follows:

- If one or more operators share the same equipment or materials.
- If used and clean instruments come into contact with one another.
- If clean instruments are placed on unclean surfaces.
- If strict operator hygiene is not observed.
- If contaminated dressings, spatulas, disposable gloves are not disposed of immediately and appropriately after use.
- If structural facilities, furnishings and fittings of the premises are not adequately protected, or thoroughly cleaned between clients.
- If towels and other articles used on clients are not changed or thoroughly cleaned between clients.

Operators should be aware of the potential for unprotected surfaces and equipment to become contaminated with blood and serum during tattooing. Some examples of how this can occur are as follows:

- Adjusting overhead light fittings.
- Adjusting settings on power packs.
- Answering telephones.
- Touching ink bottles or ink trays.
- Touching curtains, drapes or bin lids.
- Adjusting furniture and equipment. Clients, operators and the community can be at risk if cross-contamination occurs.

OSHA 29 CFR 1910.1030

In March 1992, OSHA's Bloodborne Pathogen Standard, 29 CFR 1910.1030 took effect. This standard was designed to prevent deaths and bloodborne infections. While the standard was primarily aimed at hospitals, funeral homes, nursing homes, clinics, law enforcement agencies, emergency responders, and HIV/HBV research laboratories, anyone who can "reasonably expect to come in contact with blood or potentially infectious materials" as part of their job is covered by the standard. OSHA's summary of the standard is below.

Purpose

OSHA Standard 29 CFR 1910.1030 limits occupational exposure to blood and other potentially infectious materials since any exposure could result in transmission of bloodborne pathogens which could lead to disease or death.
Scope

Covers all employees who could be "reasonably anticipated" as the result of performing their job duties to face contact with blood and other potentially infectious materials. OSHA has not attempted to list all occupations where exposures could occur. "Good Samaritan" acts such as assisting a co-worker with a nosebleed would not be considered occupational exposure.

Infectious materials include semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid visibly contaminated with blood and all body fluids in situations where it is difficult or impossible to differentiate between body fluids. They also include any unfixed tissue or organ other than intact skin from a human (living or dead) and human immunodeficiency virus (HIV)-containing cell or tissue cultures, organ cultures and HIV or hepatitis B (HBV)-containing culture medium or other solutions as well as blood, organs or other tissues from experimental animals infected with HIV or HBV.

Exposure Control Plan

Requires employers to identify, in writing, tasks and procedures, as well as job classifications, where occupational exposure to blood occurs—without regard to personal protective clothing and equipment. It must also set forth the schedule for implementing other provisions of the standard and specify the procedure for evaluating circumstances surrounding exposure incidents. The plan must be accessible to employees and available to OSHA. Employers must review and update it at least annually--more often if necessary to accommodate workplace changes.

Methods of Compliance

Mandates universal precautions, (treating body fluids/materials as if infectious) emphasizing engineering and work practice controls. The standard stresses hand-washing and requires employers to provide facilities and ensure that employees use them following exposure to blood. It sets forth procedures to minimize needlesticks, minimize splashing and spraying of blood, ensure appropriate packaging of specimens and regulated wastes and decontaminate equipment or label it as contaminated before shipping to servicing facilities.

Employers must provide, at no cost, and require employees to use appropriate personal protective equipment such as gloves, gowns, masks, mouthpieces and resuscitation bags and must clean, repair and replace these when necessary.

The standard requires a written schedule for cleaning, identifying the method of decontamination to be used in addition to cleaning following contact with blood or other potentially infectious materials. It specifies methods for disposing of contaminated sharps and sets forth standards for containers for these items and other regulated waste. Further,
the standard includes provisions for handling contaminated laundry to minimize exposures.

Hepatitis B Vaccination

This Standard requires vaccinations to be made available to all employees who have occupational exposure to blood within 10 working days of assignment, at no cost, at a reasonable time and place, under the supervision of licensed physician/licensed healthcare professional and according to the latest recommendations of the U.S. Public Health Service (USPHS). Prescreening may not be required as a condition of receiving the vaccine. Employees must sign a declination form if they choose not to be vaccinated, but may later opt to receive the vaccine at no cost to the employee. Should booster doses later be recommended by the USPHS, employees must be offered them.

Post-Exposure Evaluation and Follow-Up

Specifies procedures to be made available to all employees who have had an exposure incident plus any laboratory tests must be conducted by an accredited laboratory at no cost to the employee. Follow-up must include a confidential medical evaluation documenting the circumstances of exposure, identifying and testing the source individual if feasible, testing the exposed employee's blood if he/she consents, post-exposure prophylaxis, counseling and evaluation of reported illnesses. Healthcare professionals must be provided specified information to facilitate the evaluation and their written opinion on the need for hepatitis B vaccination following the exposure. Information such as the employee's ability to receive the hepatitis B vaccine must be supplied to the employer. All diagnoses must remain confidential.

Hazard Communication

Requires warning labels including the orange or orange-red biohazard symbol affixed to containers of regulated waste, refrigerators and freezers and other containers that are used to store or transport blood or other potentially infectious materials. Red bags or containers may be used instead of labeling. When a facility uses universal precautions in its handling of all specimens, labeling is not required within the facility. Likewise, when all laundry is handled with universal precautions, the laundry need not be labeled. Blood which has been tested and found free of HIV or HBV and released for clinical use, and regulated waste which has been decontaminated, need not be labeled. Signs must be used to identify restricted areas in HIV and HBV research laboratories and production facilities.

Information and Training

This Standard mandates training within 90 days of the effective date, initially upon assignment and annually--employees who have received appropriate training within the past year need only receive additional training in items not previously covered. Training must include making accessible a copy of the regulatory text of the standard and
explanation of its contents, general discussion on bloodborne diseases and their transmission, exposure control plan, engineering and work practice controls, personal protective equipment, hepatitis B vaccine, response to emergencies involving blood, how to handle exposure incidents, the post-exposure evaluation and follow-up program, signs/labels/color-coding. There must be opportunity for questions and answers, and the trainer must be knowledgeable in the subject matter. Laboratory and production facility workers must receive additional specialized initial training.

**Recordkeeping**

Calls for medical records to be kept for each employee with occupational exposure for the duration of employment plus 30 years, must be confidential and must include name and social security number; hepatitis B vaccination status (including dates); results of any examinations, medical testing and follow-up procedures; a copy of the healthcare professional's written opinion; and a copy of information provided to the healthcare professional. Training records must be maintained for three years and must include dates, contents of the training program or a summary, trainer's name and qualifications, names and job titles of all persons attending the sessions. Medical records must be made available to the subject employee, anyone with written consent of the employee, OSHA and NIOSH--they are not available to the employer. Disposal of records must be in accord with OSHA's standard covering access to records.

**OSHA 29 CFR 1910.1030**

For a complete copy of the Occupational Safety and Health Administration's (OSHA's) Bloodborne Pathogen Standard, see chapter 4.
As mentioned in Chapter 3, OSHA Standards – 29 CFR-1910.1030 covers all employees who could be "reasonably anticipated" as the result of performing their job duties to face contact with blood and other potentially infectious materials. OSHA has not attempted to list all occupations where exposures could occur, however, it would be reasonably prudent to expect tattooing to fall under this standard.

**Scope and Application.** This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

**1910.1030(b)**

**Definitions.** For purposes of this section, the following shall apply:

**Assistant Secretary** means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

**Blood** means human blood, human blood components, and products made from human blood.

**Bloodborne Pathogens** means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

**Clinical Laboratory** means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

**Contaminated** means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.
Contaminated Laundry means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

Contaminated Sharps means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

Decontamination means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.

Director means the Director of the National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services, or designated representative.

Engineering Controls means controls (e.g., sharps disposal containers, self-sheathing needles, safer medical devices, such as sharps with engineered sharps injury protections and needleless systems) that isolate or remove the bloodborne pathogens hazard from the workplace.

Exposure Incident means a specific eye, mouth, other mucous membrane, non-intact skin, or parenteral contact with blood or other potentially infectious materials that results from the performance of an employee's duties.

Handwashing Facilities means a facility providing an adequate supply of running potable water, soap and single use towels or hot air drying machines.

Licensed Healthcare Professional is a person whose legally permitted scope of practice allows him or her to independently perform the activities required by paragraph (f) Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up.

HBV means hepatitis B virus.

HIV means human immunodeficiency virus.

Needleless systems means a device that does not use needles for:

(1) The collection of bodily fluids or withdrawal of body fluids after initial venous or arterial access is established; (2) The administration of medication or fluids; or (3) Any other procedure involving the potential for occupational exposure to bloodborne pathogens due to percutaneous injuries from contaminated sharps.

Occupational Exposure means reasonably anticipated skin, eye, mucous membrane, or parenteral contact with blood or other potentially infectious materials that may result from the performance of an employee's duties.
Other Potentially Infectious Materials means (1) The following human body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids; (2) Any unfixed tissue or organ (other than intact skin) from a human (living or dead); and (3) HIV-containing cell or tissue cultures, organ cultures, and HIV- or HBV-containing culture medium or other solutions; and blood, organs, or other tissues from experimental animals infected with HIV or HBV.

Parenteral means piercing mucous membranes or the skin barrier through such events as needlesticks, human bites, cuts, and abrasions.

Personal Protective Equipment is specialized clothing or equipment worn by an employee for protection against a hazard. General work clothes (e.g., uniforms, pants, shirts or blouses) not intended to function as protection against a hazard are not considered to be personal protective equipment.

Production Facility means a facility engaged in industrial-scale, large-volume or high concentration production of HIV or HBV.

Regulated Waste means liquid or semi-liquid blood or other potentially infectious materials; contaminated items that would release blood or other potentially infectious materials in a liquid or semi-liquid state if compressed; items that are caked with dried blood or other potentially infectious materials and are capable of releasing these materials during handling; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious materials.

Research Laboratory means a laboratory producing or using research-laboratory-scale amounts of HIV or HBV. Research laboratories may produce high concentrations of HIV or HBV but not in the volume found in production facilities.

Sharps with engineered sharps injury protections means a nonneedle sharp or a needle device used for withdrawing body fluids, accessing a vein or artery, or administering medications or other fluids, with a built-in safety feature or mechanism that effectively reduces the risk of an exposure incident.

Source Individual means any individual, living or dead, whose blood or other potentially infectious materials may be a source of occupational exposure to the employee. Examples include, but are not limited to, hospital and clinic patients; clients in institutions for the developmentally disabled; trauma victims; clients of drug and alcohol treatment facilities; residents of hospices and nursing homes; human remains; and individuals who donate or sell blood or blood components.

Sterilize means the use of a physical or chemical procedure to destroy all microbial life including highly resistant bacterial endospores.
**Universal Precautions** is an approach to infection control. According to the concept of Universal Precautions, all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV, and other bloodborne pathogens.

**Work Practice Controls** means controls that reduce the likelihood of exposure by altering the manner in which a task is performed (e.g., prohibiting recapping of needles by a two-handed technique).

1910.1030(c)

**Exposure Control --**

1910.1030(c)(1)

**Exposure Control Plan.**

1910.1030(c)(1)(i)

Each employer having an employee(s) with occupational exposure as defined by paragraph (b) of this section shall establish a written Exposure Control Plan designed to eliminate or minimize employee exposure.

1910.1030(c)(1)(ii)

The Exposure Control Plan shall contain at least the following elements:

1910.1030(c)(1)(ii)(A)

The exposure determination required by paragraph (c)(2),

1910.1030(c)(1)(ii)(B)

The schedule and method of implementation for paragraphs (d) Methods of Compliance, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, (g) Communication of Hazards to Employees, and (h) Recordkeeping, of this standard, and

1910.1030(c)(1)(ii)(C)

The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.
Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.1020(e).

1910.1030(c)(1)(iv)

The Exposure Control Plan shall be reviewed and updated at least annually and whenever necessary to reflect new or modified tasks and procedures which affect occupational exposure and to reflect new or revised employee positions with occupational exposure. The review and update of such plans shall also:

1910.1030(c)(1)(iv)(A)

Reflect changes in technology that eliminate or reduce exposure to bloodborne pathogens; and

1910.1030(c)(1)(iv)(B)

Document annually consideration and implementation of appropriate commercially available and effective safer medical devices designed to eliminate or minimize occupational exposure.

1910.1030(c)(1)(v)

An employer, who is required to establish an Exposure Control Plan shall solicit input from non-managerial employees responsible for direct patient care who are potentially exposed to injuries from contaminated sharps in the identification, evaluation, and selection of effective engineering and work practice controls and shall document the solicitation in the Exposure Control Plan.

1910.1030(c)(1)(vi)

The Exposure Control Plan shall be made available to the Assistant Secretary and the Director upon request for examination and copying.

1910.1030(c)(2)

Exposure Determination.

1910.1030(c)(2)(i)

Each employer who has an employee(s) with occupational exposure as defined by paragraph (b) of this section shall prepare an exposure determination. This exposure determination shall contain the following:

1910.1030(c)(2)(i)(A)
A list of all job classifications in which all employees in those job classifications have occupational exposure;

1910.1030(c)(2)(i)(B)

A list of job classifications in which some employees have occupational exposure, and

1910.1030(c)(2)(i)(C)

A list of all tasks and procedures or groups of closely related task and procedures in which occupational exposure occurs and that are performed by employees in job classifications listed in accordance with the provisions of paragraph (c)(2)(i)(B) of this standard.

1910.1030(c)(2)(ii)

This exposure determination shall be made without regard to the use of personal protective equipment.

1910.1030(d)

Methods of Compliance --

1910.1030(d)(1)

General. Universal precautions shall be observed to prevent contact with blood or other potentially infectious materials. Under circumstances in which differentiation between body fluid types is difficult or impossible, all body fluids shall be considered potentially infectious materials.

1910.1030(d)(2)

Engineering and Work Practice Controls.

1910.1030(d)(2)(i)

Engineering and work practice controls shall be used to eliminate or minimize employee exposure. Where occupational exposure remains after institution of these controls, personal protective equipment shall also be used.

1910.1030(d)(2)(ii)

Engineering controls shall be examined and maintained or replaced on a regular schedule to ensure their effectiveness.

1910.1030(d)(2)(iii)
Employers shall provide handwashing facilities which are readily accessible to employees.

1910.1030(d)(2)(iv)

When provision of handwashing facilities is not feasible, the employer shall provide either an appropriate antiseptic hand cleanser in conjunction with clean cloth/paper towels or antiseptic towelettes. When antiseptic hand cleansers or towelettes are used, hands shall be washed with soap and running water as soon as feasible.

1910.1030(d)(2)(v)

Employers shall ensure that employees wash their hands immediately or as soon as feasible after removal of gloves or other personal protective equipment.

1910.1030(d)(2)(vi)

Employers shall ensure that employees wash hands and any other skin with soap and water, or flush mucous membranes with water immediately or as soon as feasible following contact of such body areas with blood or other potentially infectious materials.

1910.1030(d)(2)(vii)

Contaminated needles and other contaminated sharps shall not be bent, recapped, or removed except as noted in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) below. Shearing or breaking of contaminated needles is prohibited.

1910.1030(d)(2)(vii)(A)

Contaminated needles and other contaminated sharps shall not be bent, recapped or removed unless the employer can demonstrate that no alternative is feasible or that such action is required by a specific medical or dental procedure.

1910.1030(d)(2)(vii)(B)

Such bending, recapping or needle removal must be accomplished through the use of a mechanical device or a one-handed technique.

1910.1030(d)(2)(viii)

Immediately or as soon as possible after use, contaminated reusable sharps shall be placed in appropriate containers until properly reprocessed. These containers shall be:

1910.1030(d)(2)(viii)(A)

Puncture resistant;
1910.1030(d)(2)(viii)(B)
Labeled or color-coded in accordance with this standard;

1910.1030(d)(2)(viii)(C)
Leakproof on the sides and bottom; and

1910.1030(d)(2)(viii)(D)
In accordance with the requirements set forth in paragraph (d)(4)(ii)(E) for reusable sharps.

1910.1030(d)(2)(ix)
Eating, drinking, smoking, applying cosmetics or lip balm, and handling contact lenses are prohibited in work areas where there is a reasonable likelihood of occupational exposure.

1910.1030(d)(2)(x)
Food and drink shall not be kept in refrigerators, freezers, shelves, cabinets or on countertops or benchtops where blood or other potentially infectious materials are present.

1910.1030(d)(2)(xi)
All procedures involving blood or other potentially infectious materials shall be performed in such a manner as to minimize splashing, spraying, spattering, and generation of droplets of these substances.

1910.1030(d)(2)(xii)
Mouth pipetting/suctioning of blood or other potentially infectious materials is prohibited.

1910.1030(d)(2)(xiii)
Specimens of blood or other potentially infectious materials shall be placed in a container which prevents leakage during collection, handling, processing, storage, transport, or shipping.

1910.1030(d)(2)(xiii)(A)
The container for storage, transport, or shipping shall be labeled or color-coded according to paragraph (g)(1)(i) and closed prior to being stored, transported, or shipped. When a
facility utilizes Universal Precautions in the handling of all specimens, the labeling/color-coding of specimens is not necessary provided containers are recognizable as containing specimens. This exemption only applies while such specimens/containers remain within the facility. Labeling or color-coding in accordance with paragraph (g)(1)(i) is required when such specimens/containers leave the facility.

1910.1030(d)(2)(xiii)(B)

If outside contamination of the primary container occurs, the primary container shall be placed within a second container which prevents leakage during handling, processing, storage, transport, or shipping and is labeled or color-coded according to the requirements of this standard.

1910.1030(d)(2)(xiii)(C)

If the specimen could puncture the primary container, the primary container shall be placed within a secondary container which is puncture-resistant in addition to the above characteristics.

1910.1030(d)(2)(xiv)

Equipment which may become contaminated with blood or other potentially infectious materials shall be examined prior to servicing or shipping and shall be decontaminated as necessary, unless the employer can demonstrate that decontamination of such equipment or portions of such equipment is not feasible.

1910.1030(d)(2)(xiv)(A)

A readily observable label in accordance with paragraph (g)(1)(i)(H) shall be attached to the equipment stating which portions remain contaminated.

1910.1030(d)(2)(xiv)(B)

The employer shall ensure that this information is conveyed to all affected employees, the servicing representative, and/or the manufacturer, as appropriate, prior to handling, servicing, or shipping so that appropriate precautions will be taken.

1910.1030(d)(3)

Personal Protective Equipment --

1910.1030(d)(3)(i)

Provision. When there is occupational exposure, the employer shall provide, at no cost to the employee, appropriate personal protective equipment such as, but not limited to, gloves, gowns, laboratory coats, face shields or masks and eye protection, and
mouthpieces, resuscitation bags, pocket masks, or other ventilation devices. Personal protective equipment will be considered "appropriate" only if it does not permit blood or other potentially infectious materials to pass through to or reach the employee's work clothes, street clothes, undergarments, skin, eyes, mouth, or other mucous membranes under normal conditions of use and for the duration of time which the protective equipment will be used.

1910.1030(d)(3)(ii)

Use. The employer shall ensure that the employee uses appropriate personal protective equipment unless the employer shows that the employee temporarily and briefly declined to use personal protective equipment when, under rare and extraordinary circumstances, it was the employee's professional judgment that in the specific instance its use would have prevented the delivery of health care or public safety services or would have posed an increased hazard to the safety of the worker or co-worker. When the employee makes this judgement, the circumstances shall be investigated and documented in order to determine whether changes can be instituted to prevent such occurrences in the future.

1910.1030(d)(3)(iii)

Accessibility. The employer shall ensure that appropriate personal protective equipment in the appropriate sizes is readily accessible at the worksite or is issued to employees. Hypoallergenic gloves, glove liners, powderless gloves, or other similar alternatives shall be readily accessible to those employees who are allergic to the gloves normally provided.

1910.1030(d)(3)(iv)

Cleaning, Laundering, and Disposal. The employer shall clean, launder, and dispose of personal protective equipment required by paragraphs (d) and (e) of this standard, at no cost to the employee.

1910.1030(d)(3)(v)

Repair and Replacement. The employer shall repair or replace personal protective equipment as needed to maintain its effectiveness, at no cost to the employee.

1910.1030(d)(3)(vi)

If a garment(s) is penetrated by blood or other potentially infectious materials, the garment(s) shall be removed immediately or as soon as feasible.

1910.1030(d)(3)(vii)

All personal protective equipment shall be removed prior to leaving the work area.
When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

**Gloves.** Gloves shall be worn when it can be reasonably anticipated that the employee may have hand contact with blood, other potentially infectious materials, mucous membranes, and non-intact skin; when performing vascular access procedures except as specified in paragraph (d)(3)(ix)(D); and when handling or touching contaminated items or surfaces.

**Disposable (single use) gloves** such as surgical or examination gloves, shall be replaced as soon as practical when contaminated or as soon as feasible if they are torn, punctured, or when their ability to function as a barrier is compromised.

Disposable (single use) gloves shall not be washed or decontaminated for re-use.

Utility gloves may be decontaminated for re-use if the integrity of the glove is not compromised. However, they must be discarded if they are cracked, peeling, torn, punctured, or exhibit other signs of deterioration or when their ability to function as a barrier is compromised.

If an employer in a volunteer blood donation center judges that routine gloving for all phlebotomies is not necessary then the employer shall:

1. Periodically reevaluate this policy;
2. Make gloves available to all employees who wish to use them for phlebotomy;
3. Not discourage the use of gloves for phlebotomy; and
1910.1030(d)(3)(ix)(D)(4)

Require that gloves be used for phlebotomy in the following circumstances:


When the employee has cuts, scratches, or other breaks in his or her skin;


When the employee judges that hand contamination with blood may occur, for example, when performing phlebotomy on an uncooperative source individual; and


When the employee is receiving training in phlebotomy.

1910.1030(d)(3)(x)

**Masks, Eye Protection, and Face Shields.** Masks in combination with eye protection devices, such as goggles or glasses with solid side shields, or chin-length face shields, shall be worn whenever splashes, spray, spatter, or droplets of blood or other potentially infectious materials may be generated and eye, nose, or mouth contamination can be reasonably anticipated.

1910.1030(d)(3)(xi)

**Gowns, Aprons, and Other Protective Body Clothing.** Appropriate protective clothing such as, but not limited to, gowns, aprons, lab coats, clinic jackets, or similar outer garments shall be worn in occupational exposure situations. The type and characteristics will depend upon the task and degree of exposure anticipated.

1910.1030(d)(3)(xii)

Surgical caps or hoods and/or shoe covers or boots shall be worn in instances when gross contamination can reasonably be anticipated (e.g., autopsies, orthopaedic surgery).

1910.1030(d)(4)

**Housekeeping --**

1910.1030(d)(4)(i)

**General.** Employers shall ensure that the worksite is maintained in a clean and sanitary condition. The employer shall determine and implement an appropriate written schedule for cleaning and method of decontamination based upon the location within the facility,
type of surface to be cleaned, type of soil present, and tasks or procedures being performed in the area.

1910.1030(d)(4)(ii)

All equipment and environmental and working surfaces shall be cleaned and decontaminated after contact with blood or other potentially infectious materials.

1910.1030(d)(4)(ii)(A)

Contaminated work surfaces shall be decontaminated with an appropriate disinfectant after completion of procedures; immediately or as soon as feasible when surfaces are overtly contaminated or after any spill of blood or other potentially infectious materials; and at the end of the work shift if the surface may have become contaminated since the last cleaning.

1910.1030(d)(4)(ii)(B)

Protective coverings, such as plastic wrap, aluminum foil, or imperviously-backed absorbent paper used to cover equipment and environmental surfaces, shall be removed and replaced as soon as feasible when they become overtly contaminated or at the end of the workshift if they may have become contaminated during the shift.

1910.1030(d)(4)(ii)(C)

All bins, pails, cans, and similar receptacles intended for reuse which have a reasonable likelihood for becoming contaminated with blood or other potentially infectious materials shall be inspected and decontaminated on a regularly scheduled basis and cleaned and decontaminated immediately or as soon as feasible upon visible contamination.

1910.1030(d)(4)(ii)(D)

Broken glassware which may be contaminated shall not be picked up directly with the hands. It shall be cleaned up using mechanical means, such as a brush and dust pan, tongs, or forceps.

1910.1030(d)(4)(ii)(E)

Reusable sharps that are contaminated with blood or other potentially infectious materials shall not be stored or processed in a manner that requires employees to reach by hand into the containers where these sharps have been placed.

1910.1030(d)(4)(iii)

Regulated Waste --
1910.1030(d)(4)(iii)(A)

Contaminated Sharps Discarding and Containment.

1910.1030(d)(4)(iii)(A)(1)

Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:


Closable;


Puncture resistant;

1910.1030(d)(4)(iii)(A)(1)(iii)

Leakproof on sides and bottom; and


Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard.

1910.1030(d)(4)(iii)(A)(2)

During use, containers for contaminated sharps shall be:


Easily accessible to personnel and located as close as is feasible to the immediate area where sharps are used or can be reasonably anticipated to be found (e.g., laundries);


Maintained upright throughout use; and


Replaced routinely and not be allowed to overfill.

1910.1030(d)(4)(iii)(A)(3)

When moving containers of contaminated sharps from the area of use, the containers shall be:

Closed immediately prior to removal or replacement to prevent spillage or protrusion of contents during handling, storage, transport, or shipping;


Placed in a secondary container if leakage is possible. The second container shall be:


Closable;


Constructed to contain all contents and prevent leakage during handling, storage, transport, or shipping; and


Labeled or color-coded according to paragraph (g)(1)(i) of this standard.

1910.1030(d)(4)(iii)(A)(4)

Reusable containers shall not be opened, emptied, or cleaned manually or in any other manner which would expose employees to the risk of percutaneous injury.

1910.1030(d)(4)(iii)(B)

Other Regulated Waste Containment --

1910.1030(d)(4)(iii)(B)(1)

Regulated waste shall be placed in containers which are:


Closable;


Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

1910.1030(d)(4)(iii)(B)(1)(iii)
Labeled or color-coded in accordance with paragraph (g)(1)(i) this standard; and


Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

1910.1030(d)(4)(iii)(B)(2)

If outside contamination of the regulated waste container occurs, it shall be placed in a second container. The second container shall be:


Closable;


Constructed to contain all contents and prevent leakage of fluids during handling, storage, transport or shipping;

1910.1030(d)(4)(iii)(B)(2)(iii)

Labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard; and


Closed prior to removal to prevent spillage or protrusion of contents during handling, storage, transport, or shipping.

1910.1030(d)(4)(iii)(C)

Disposal of all regulated waste shall be in accordance with applicable regulations of the United States, States and Territories, and political subdivisions of States and Territories.

1910.1030(d)(4)(iv)

Laundry.

1910.1030(d)(4)(iv)(A)

Contaminated laundry shall be handled as little as possible with a minimum of agitation.

1910.1030(d)(4)(iv)(A)(1)
Contaminated laundry shall be bagged or containerized at the location where it was used and shall not be sorted or rinsed in the location of use.

1910.1030(d)(4)(iv)(A)(2)

Contaminated laundry shall be placed and transported in bags or containers labeled or color-coded in accordance with paragraph (g)(1)(i) of this standard. When a facility utilizes Universal Precautions in the handling of all soiled laundry, alternative labeling or color-coding is sufficient if it permits all employees to recognize the containers as requiring compliance with Universal Precautions.


Whenever contaminated laundry is wet and presents a reasonable likelihood of soak-through of or leakage from the bag or container, the laundry shall be placed and transported in bags or containers which prevent soak-through and/or leakage of fluids to the exterior.

1910.1030(d)(4)(iv)(B)

The employer shall ensure that employees who have contact with contaminated laundry wear protective gloves and other appropriate personal protective equipment.

1910.1030(d)(4)(iv)(C)

When a facility ships contaminated laundry off-site to a second facility which does not utilize Universal Precautions in the handling of all laundry, the facility generating the contaminated laundry must place such laundry in bags or containers which are labeled or color-coded in accordance with paragraph (g)(1)(i).

1910.1030(e)

HIV and HBV Research Laboratories and Production Facilities.

1910.1030(e)(1)

This paragraph applies to research laboratories and production facilities engaged in the culture, production, concentration, experimentation, and manipulation of HIV and HBV. It does not apply to clinical or diagnostic laboratories engaged solely in the analysis of blood, tissues, or organs. These requirements apply in addition to the other requirements of the standard.

1910.1030(e)(2)

Research laboratories and production facilities shall meet the following criteria:
1910.1030(e)(2)(i)

**Standard Microbiological Practices.** All regulated waste shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)

**Special Practices.**

1910.1030(e)(2)(ii)(A)

Laboratory doors shall be kept closed when work involving HIV or HBV is in progress.

1910.1030(e)(2)(ii)(B)

Contaminated materials that are to be decontaminated at a site away from the work area shall be placed in a durable, leakproof, labeled or color-coded container that is closed before being removed from the work area.

1910.1030(e)(2)(ii)(C)

Access to the work area shall be limited to authorized persons. Written policies and procedures shall be established whereby only persons who have been advised of the potential biohazard, who meet any specific entry requirements, and who comply with all entry and exit procedures shall be allowed to enter the work areas and animal rooms.

1910.1030(e)(2)(ii)(D)

When other potentially infectious materials or infected animals are present in the work area or containment module, a hazard warning sign incorporating the universal biohazard symbol shall be posted on all access doors. The hazard warning sign shall comply with paragraph (g)(1)(ii) of this standard.

1910.1030(e)(2)(ii)(E)

All activities involving other potentially infectious materials shall be conducted in biological safety cabinets or other physical-containment devices within the containment module. No work with these other potentially infectious materials shall be conducted on the open bench.

1910.1030(e)(2)(ii)(F)
Laboratory coats, gowns, smocks, uniforms, or other appropriate protective clothing shall be used in the work area and animal rooms. Protective clothing shall not be worn outside of the work area and shall be decontaminated before being laundered.

1910.1030(e)(2)(ii)(G)

Special care shall be taken to avoid skin contact with other potentially infectious materials. Gloves shall be worn when handling infected animals and when making hand contact with other potentially infectious materials is unavoidable.

1910.1030(e)(2)(ii)(H)

Before disposal all waste from work areas and from animal rooms shall either be incinerated or decontaminated by a method such as autoclaving known to effectively destroy bloodborne pathogens.

1910.1030(e)(2)(ii)(I)

Vacuum lines shall be protected with liquid disinfectant traps and high-efficiency particulate air (HEPA) filters or filters of equivalent or superior efficiency and which are checked routinely and maintained or replaced as necessary.

1910.1030(e)(2)(ii)(J)

Hypodermic needles and syringes shall be used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., the needle is integral to the syringe) shall be used for the injection or aspiration of other potentially infectious materials. Extreme caution shall be used when handling needles and syringes. A needle shall not be bent, sheared, replaced in the sheath or guard, or removed from the syringe following use. The needle and syringe shall be promptly placed in a puncture-resistant container and autoclaved or decontaminated before reuse or disposal.

1910.1030(e)(2)(ii)(K)

All spills shall be immediately contained and cleaned up by appropriate professional staff or others properly trained and equipped to work with potentially concentrated infectious materials.

1910.1030(e)(2)(ii)(L)

A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.
A biosafety manual shall be prepared or adopted and periodically reviewed and updated at least annually or more often if necessary. Personnel shall be advised of potential hazards, shall be required to read instructions on practices and procedures, and shall be required to follow them.

1910.1030(e)(2)(iii)

**Containment Equipment.**

1910.1030(e)(2)(iii)(A)

Certified biological safety cabinets (Class I, II, or III) or other appropriate combinations of personal protection or physical containment devices, such as special protective clothing, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals, shall be used for all activities with other potentially infectious materials that pose a threat of exposure to droplets, splashes, spills, or aerosols.

1910.1030(e)(2)(iii)(B)

Biological safety cabinets shall be certified when installed, whenever they are moved and at least annually.

1910.1030(e)(3)

HIV and HBV research laboratories shall meet the following criteria:

1910.1030(e)(3)(i)

Each laboratory shall contain a facility for hand washing and an eye wash facility which is readily available within the work area.

1910.1030(e)(3)(ii)

An autoclave for decontamination of regulated waste shall be available.

1910.1030(e)(4)

HIV and HBV production facilities shall meet the following criteria:

1910.1030(e)(4)(i)

The work areas shall be separated from areas that are open to unrestricted traffic flow within the building. Passage through two sets of doors shall be the basic requirement for entry into the work area from access corridors or other contiguous areas. Physical separation of the high-containment work area from access corridors or other areas or activities may also be provided by a double-doored clothes-change room (showers may
be included), airlock, or other access facility that requires passing through two sets of doors before entering the work area.

1910.1030(e)(4)(ii)

The surfaces of doors, walls, floors and ceilings in the work area shall be water resistant so that they can be easily cleaned. Penetrations in these surfaces shall be sealed or capable of being sealed to facilitate decontamination.

1910.1030(e)(4)(iii)

Each work area shall contain a sink for washing hands and a readily available eye wash facility. The sink shall be foot, elbow, or automatically operated and shall be located near the exit door of the work area.

1910.1030(e)(4)(iv)

Access doors to the work area or containment module shall be self-closing.

1910.1030(e)(4)(v)

An autoclave for decontamination of regulated waste shall be available within or as near as possible to the work area.

1910.1030(e)(4)(vi)

A ducted exhaust-air ventilation system shall be provided. This system shall create directional airflow that draws air into the work area through the entry area. The exhaust air shall not be recirculated to any other area of the building, shall be discharged to the outside, and shall be dispersed away from occupied areas and air intakes. The proper direction of the airflow shall be verified (i.e., into the work area).

1910.1030(e)(5)

Training Requirements. Additional training requirements for employees in HIV and HBV research laboratories and HIV and HBV production facilities are specified in paragraph (g)(2)(ix).

1910.1030(f)

Hepatitis B Vaccination and Post-exposure Evaluation and Follow-up --

1910.1030(f)(1)

General.
The employer shall make available the hepatitis B vaccine and vaccination series to all employees who have occupational exposure, and post-exposure evaluation and follow-up to all employees who have had an exposure incident.

The employer shall ensure that all medical evaluations and procedures including the hepatitis B vaccine and vaccination series and post-exposure evaluation and follow-up, including prophylaxis, are:

Made available at no cost to the employee;

Made available to the employee at a reasonable time and place;

Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional; and

Provided according to recommendations of the U.S. Public Health Service current at the time these evaluations and procedures take place, except as specified by this paragraph (f).

The employer shall ensure that all laboratory tests are conducted by an accredited laboratory at no cost to the employee.

Hepatitis B Vaccination.

Hepatitis B vaccination shall be made available after the employee has received the training required in paragraph (g)(2)(vii)(I) and within 10 working days of initial assignment to all employees who have occupational exposure unless the employee has previously received the complete hepatitis B vaccination series, antibody testing has
revealed that the employee is immune, or the vaccine is contraindicated for medical reasons.

1910.1030(f)(2)(ii)

The employer shall not make participation in a prescreening program a prerequisite for receiving hepatitis B vaccination.

1910.1030(f)(2)(iii)

If the employee initially declines hepatitis B vaccination but at a later date while still covered under the standard decides to accept the vaccination, the employer shall make available hepatitis B vaccination at that time.

1910.1030(f)(2)(iv)

The employer shall assure that employees who decline to accept hepatitis B vaccination offered by the employer sign the statement in Appendix A.

1910.1030(f)(2)(v)

If a routine booster dose(s) of hepatitis B vaccine is recommended by the U.S. Public Health Service at a future date, such booster dose(s) shall be made available in accordance with section (f)(1)(ii).

1910.1030(f)(3)

Post-exposure Evaluation and Follow-up. Following a report of an exposure incident, the employer shall make immediately available to the exposed employee a confidential medical evaluation and follow-up, including at least the following elements:

1910.1030(f)(3)(i)

Documentation of the route(s) of exposure, and the circumstances under which the exposure incident occurred;

1910.1030(f)(3)(ii)

Identification and documentation of the source individual, unless the employer can establish that identification is infeasible or prohibited by state or local law;

1910.1030(f)(3)(ii)(A)

The source individual's blood shall be tested as soon as feasible and after consent is obtained in order to determine HBV and HIV infectivity. If consent is not obtained, the employer shall establish that legally required consent cannot be obtained. When the
source individual's consent is not required by law, the source individual's blood, if available, shall be tested and the results documented.

1910.1030(f)(3)(ii)(B)

When the source individual is already known to be infected with HBV or HIV, testing for the source individual's known HBV or HIV status need not be repeated.

1910.1030(f)(3)(ii)(C)

Results of the source individual's testing shall be made available to the exposed employee, and the employee shall be informed of applicable laws and regulations concerning disclosure of the identity and infectious status of the source individual.

1910.1030(f)(3)(iii)

Collection and testing of blood for HBV and HIV serological status;

1910.1030(f)(3)(iii)(A)

The exposed employee's blood shall be collected as soon as feasible and tested after consent is obtained.

1910.1030(f)(3)(iii)(B)

If the employee consents to baseline blood collection, but does not give consent at that time for HIV serologic testing, the sample shall be preserved for at least 90 days. If, within 90 days of the exposure incident, the employee elects to have the baseline sample tested, such testing shall be done as soon as feasible.

1910.1030(f)(3)(iv)

Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service;

1910.1030(f)(3)(v)

Counseling; and

1910.1030(f)(3)(vi)

Evaluation of reported illnesses.

1910.1030(f)(4)

Information Provided to the Healthcare Professional.
1910.1030(f)(4)(i)

The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

1910.1030(f)(4)(ii)

The employer shall ensure that the healthcare professional evaluating an employee after an exposure incident is provided the following information:

1910.1030(f)(4)(ii)(A)

A copy of this regulation;

1910.1030(f)(4)(ii)(B)

A description of the exposed employee's duties as they relate to the exposure incident;

1910.1030(f)(4)(ii)(C)

Documentation of the route(s) of exposure and circumstances under which exposure occurred;

1910.1030(f)(4)(ii)(D)

Results of the source individual's blood testing, if available; and

1910.1030(f)(4)(ii)(E)

All medical records relevant to the appropriate treatment of the employee including vaccination status which are the employer's responsibility to maintain.

1910.1030(f)(5)

Healthcare Professional's Written Opinion. The employer shall obtain and provide the employee with a copy of the evaluating healthcare professional's written opinion within 15 days of the completion of the evaluation.

1910.1030(f)(5)(i)

The healthcare professional's written opinion for Hepatitis B vaccination shall be limited to whether Hepatitis B vaccination is indicated for an employee, and if the employee has received such vaccination.

1910.1030(f)(5)(ii)
The healthcare professional's written opinion for post-exposure evaluation and follow-up shall be limited to the following information:

1910.1030(f)(5)(ii)(A)
That the employee has been informed of the results of the evaluation; and

1910.1030(f)(5)(ii)(B)
That the employee has been told about any medical conditions resulting from exposure to blood or other potentially infectious materials which require further evaluation or treatment.

1910.1030(f)(5)(iii)
All other findings or diagnoses shall remain confidential and shall not be included in the written report.

1910.1030(f)(6)

Medical Recordkeeping. Medical records required by this standard shall be maintained in accordance with paragraph (h)(1) of this section.

1910.1030(g)

Communication of Hazards to Employees --

1910.1030(g)(1)

Labels and Signs --

1910.1030(g)(1)(i)

Labels.

1910.1030(g)(1)(i)(A)

Warning labels shall be affixed to containers of regulated waste, refrigerators and freezers containing blood or other potentially infectious material; and other containers used to store, transport or ship blood or other potentially infectious materials, except as provided in paragraph (g)(1)(i)(E), (F) and (G).

1910.1030(g)(1)(i)(B)

Labels required by this section shall include the following legend:
1910.1030(g)(1)(i)(C)

These labels shall be fluorescent orange or orange-red or predominantly so, with lettering and symbols in a contrasting color.

1910.1030(g)(1)(i)(D)

Labels shall be affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

1910.1030(g)(1)(i)(E)

Red bags or red containers may be substituted for labels.

1910.1030(g)(1)(i)(F)

Containers of blood, blood components, or blood products that are labeled as to their contents and have been released for transfusion or other clinical use are exempted from the labeling requirements of paragraph (g).

1910.1030(g)(1)(i)(G)

Individual containers of blood or other potentially infectious materials that are placed in a labeled container during storage, transport, shipment or disposal are exempted from the labeling requirement.

1910.1030(g)(1)(i)(H)

Labels required for contaminated equipment shall be in accordance with this paragraph and shall also state which portions of the equipment remain contaminated.

1910.1030(g)(1)(i)(I)

Regulated waste that has been decontaminated need not be labeled or color-coded.
1910.1030(g)(1)(ii)

Signs.

1910.1030(g)(1)(ii)(A)

The employer shall post signs at the entrance to work areas specified in paragraph (e), HIV and HBV Research Laboratory and Production Facilities, which shall bear the following legend:

(Name of the Infectious Agent)
(Special requirements for entering the area)
(Name, telephone number of the laboratory director or other responsible person.)

1910.1030(g)(1)(ii)(B)

These signs shall be fluorescent orange-red or predominantly so, with lettering and symbols in a contrasting color.

1910.1030(g)(2)

Information and Training.

1910.1030(g)(2)(i)

Employers shall ensure that all employees with occupational exposure participate in a training program which must be provided at no cost to the employee and during working hours.

1910.1030(g)(2)(ii)

Training shall be provided as follows:

1910.1030(g)(2)(ii)(A)
At the time of initial assignment to tasks where occupational exposure may take place;

1910.1030(g)(2)(ii)(B)

Within 90 days after the effective date of the standard; and

1910.1030(g)(2)(ii)(C)

At least annually thereafter.

1910.1030(g)(2)(iii)

For employees who have received training on bloodborne pathogens in the year preceding the effective date of the standard, only training with respect to the provisions of the standard which were not included need be provided.

1910.1030(g)(2)(iv)

Annual training for all employees shall be provided within one year of their previous training.

1910.1030(g)(2)(v)

Employers shall provide additional training when changes such as modification of tasks or procedures or institution of new tasks or procedures affect the employee's occupational exposure. The additional training may be limited to addressing the new exposures created.

1910.1030(g)(2)(vi)

Material appropriate in content and vocabulary to educational level, literacy, and language of employees shall be used.

1910.1030(g)(2)(vii)

The training program shall contain at a minimum the following elements:

1910.1030(g)(2)(vii)(A)

An accessible copy of the regulatory text of this standard and an explanation of its contents;

1910.1030(g)(2)(vii)(B)

A general explanation of the epidemiology and symptoms of bloodborne diseases;
1910.1030(g)(2)(vii)(C)

An explanation of the modes of transmission of bloodborne pathogens;

1910.1030(g)(2)(vii)(D)

An explanation of the employer's exposure control plan and the means by which the employee can obtain a copy of the written plan;

1910.1030(g)(2)(vii)(E)

An explanation of the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials;

1910.1030(g)(2)(vii)(F)

An explanation of the use and limitations of methods that will prevent or reduce exposure including appropriate engineering controls, work practices, and personal protective equipment;

1910.1030(g)(2)(vii)(G)

Information on the types, proper use, location, removal, handling, decontamination and disposal of personal protective equipment;

1910.1030(g)(2)(vii)(H)

An explanation of the basis for selection of personal protective equipment;

1910.1030(g)(2)(vii)(I)

Information on the hepatitis B vaccine, including information on its efficacy, safety, method of administration, the benefits of being vaccinated, and that the vaccine and vaccination will be offered free of charge;

1910.1030(g)(2)(vii)(J)

Information on the appropriate actions to take and persons to contact in an emergency involving blood or other potentially infectious materials;

1910.1030(g)(2)(vii)(K)

An explanation of the procedure to follow if an exposure incident occurs, including the method of reporting the incident and the medical follow-up that will be made available;
Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

1910.1030(g)(2)(vii)(M)

An explanation of the signs and labels and/or color coding required by paragraph (g)(1); and

1910.1030(g)(2)(vii)(N)

An opportunity for interactive questions and answers with the person conducting the training session.

1910.1030(g)(2)(viii)

The person conducting the training shall be knowledgeable in the subject matter covered by the elements contained in the training program as it relates to the workplace that the training will address.

1910.1030(g)(2)(ix)

Additional Initial Training for Employees in HIV and HBV Laboratories and Production Facilities. Employees in HIV or HBV research laboratories and HIV or HBV production facilities shall receive the following initial training in addition to the above training requirements.

1910.1030(g)(2)(ix)(A)

The employer shall assure that employees demonstrate proficiency in standard microbiological practices and techniques and in the practices and operations specific to the facility before being allowed to work with HIV or HBV.

1910.1030(g)(2)(ix)(B)

The employer shall assure that employees have prior experience in the handling of human pathogens or tissue cultures before working with HIV or HBV.

1910.1030(g)(2)(ix)(C)

The employer shall provide a training program to employees who have no prior experience in handling human pathogens. Initial work activities shall not include the handling of infectious agents. A progression of work activities shall be assigned as techniques are learned and proficiency is developed. The employer shall assure that employees participate in work activities involving infectious agents only after proficiency has been demonstrated.
1910.1030(h)

Recordkeeping --

1910.1030(h)(1)

Medical Records.

1910.1030(h)(1)(i)

The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.1020.

1910.1030(h)(1)(ii)

This record shall include:

1910.1030(h)(1)(ii)(A)

The name and social security number of the employee;

1910.1030(h)(1)(ii)(B)

A copy of the employee's hepatitis B vaccination status including the dates of all the hepatitis B vaccinations and any medical records relative to the employee's ability to receive vaccination as required by paragraph (f)(2);

1910.1030(h)(1)(ii)(C)

A copy of all results of examinations, medical testing, and follow-up procedures as required by paragraph (f)(3);

1910.1030(h)(1)(ii)(D)

The employer's copy of the healthcare professional's written opinion as required by paragraph (f)(5); and

1910.1030(h)(1)(ii)(E)

A copy of the information provided to the healthcare professional as required by paragraphs (f)(4)(ii)(B)(C) and (D).

1910.1030(h)(1)(iii)

Confidentiality. The employer shall ensure that employee medical records required by paragraph (h)(1) are:
1910.1030(h)(1)(iii)(A)

Kept confidential; and

1910.1030(h)(1)(iii)(B)

Not disclosed or reported without the employee's express written consent to any person within or outside the workplace except as required by this section or as may be required by law.

1910.1030(h)(1)(iv)

The employer shall maintain the records required by paragraph (h) for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020.

1910.1030(h)(2)

Training Records.

1910.1030(h)(2)(i)

Training records shall include the following information:

1910.1030(h)(2)(i)(A)

The dates of the training sessions;

1910.1030(h)(2)(i)(B)

The contents or a summary of the training sessions;

1910.1030(h)(2)(i)(C)

The names and qualifications of persons conducting the training; and

1910.1030(h)(2)(i)(D)

The names and job titles of all persons attending the training sessions.

1910.1030(h)(2)(ii)

Training records shall be maintained for 3 years from the date on which the training occurred.

1910.1030(h)(3)
Availability.

1910.1030(h)(3)(i)

The employer shall ensure that all records required to be maintained by this section shall be made available upon request to the Assistant Secretary and the Director for examination and copying.

1910.1030(h)(3)(ii)

Employee training records required by this paragraph shall be provided upon request for examination and copying to employees, to employee representatives, to the Director, and to the Assistant Secretary.

1910.1030(h)(3)(iii)

Employee medical records required by this paragraph shall be provided upon request for examination and copying to the subject employee, to anyone having written consent of the subject employee, to the Director, and to the Assistant Secretary in accordance with 29 CFR 1910.1020.

1910.1030(h)(4)

Transfer of Records.

1910.1030(h)(4)(i)

The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.1020(h).

1910.1030(h)(4)(ii)

If the employer ceases to do business and there is no successor employer to receive and retain the records for the prescribed period, the employer shall notify the Director, at least three months prior to their disposal and transmit them to the Director, if required by the Director to do so, within that three month period.

1910.1030(h)(5)

Sharps injury log.

1910.1030(h)(5)(i)

The employer shall establish and maintain a sharps injury log for the recording of percutaneous injuries from contaminated sharps. The information in the sharps injury log
shall be recorded and maintained in such manner as to protect the confidentiality of the injured employee. The sharps injury log shall contain, at a minimum:

1910.1030(h)(5)(i)(A)

The type and brand of device involved in the incident,

1910.1030(h)(5)(i)(B)

The department or work area where the exposure incident occurred, and

1910.1030(h)(5)(i)(C)

An explanation of how the incident occurred.

1910.1030(h)(5)(ii)

The requirement to establish and maintain a sharps injury log shall apply to any employer who is required to maintain a log of occupational injuries and illnesses under 29 CFR 1904.

1910.1030(h)(5)(iii)

The sharps injury log shall be maintained for the period required by 29 CFR 1904.6.

1910.1030(i)

Dates --

1910.1030(i)(1)

Effective Date. The standard shall become effective on March 6, 1992.

1910.1030(i)(2)

The Exposure Control Plan required by paragraph (c) of this section shall be completed on or before May 5, 1992.

1910.1030(i)(3)

Paragraph (g)(2) Information and Training and (h) Recordkeeping shall take effect on or before June 4, 1992.

1910.1030(i)(4)


Appendix A

I understand that due to my occupational exposure to blood or other potentially infectious materials I may be at risk of acquiring hepatitis B virus (HBV) infection. I have been given the opportunity to be vaccinated with hepatitis B vaccine, at no charge to myself. However, I decline hepatitis B vaccination at this time. I understand that by declining this vaccine, I continue to be at risk of acquiring hepatitis B, a serious disease. If in the future I continue to have occupational exposure to blood or other potentially infectious materials and I want to be vaccinated with hepatitis B vaccine, I can receive the vaccination series at no charge to me.
Food and Drug Administration Fact Sheet

The following Fact Sheet was published by the U. S. Food and Drug Administration Center for Food Safety and Applied Nutrition Office on November 29, 2000:

TATTOOS AND PERMANENT MAKEUP

The inks used in tattoos and permanent makeup (also known as micropigmentation) and the pigments in these inks are subject to FDA regulation as cosmetics and color additives. However, FDA has not attempted to regulate the use of tattoo inks and the pigments used in them and does not control the actual practice of tattooing. Rather, such matters have been handled through local laws and by local jurisdictions.

But with the growth in popularity of tattooing and permanent makeup, FDA has begun taking a closer look at related safety questions. Among the issues under consideration are tattoo removal, adverse reactions to tattoo colors, and infections that result from tattooing.

Another concern is the increasing variety of pigments and diluents being used in tattooing -- more than fifty different pigments and shades, and the list continues to grow. Although a number of color additives are approved for use in cosmetics, none is approved for injection into the skin. Using an unapproved color additive in a tattoo ink makes the ink adulterated. Many pigments used in tattoo inks are not approved for skin contact at all. Some are industrial grade colors that are suitable for printers' ink or automobile paint.

Nevertheless, many individuals choose to undergo tattooing in its various forms. For some, it is an aesthetic choice or an initiation rite. Some choose permanent makeup as a time saver or because they have physical difficulty applying regular, temporary makeup. For others, tattooing is an adjunct to reconstructive surgery, particularly of the face or breast, to simulate natural pigmentation. People who have lost their eyebrows due to alopecia (a form of hair loss) may choose to have "eyebrows" tattooed on, while people with vitiligo (a lack of pigmentation in areas of the skin) may try tattooing to help camouflage the condition.
Whatever their reason, consumers should be aware of the risks involved in order to make an informed decision.

What Risks Are Involved in Tattooing?

The following are the primary complications that can result from tattooing:

- **Infection.** Unsterile tattooing equipment and needles can transmit infectious diseases, such as hepatitis. The risk of infection is the reason the American Association of Blood Banks requires a one-year wait between getting a tattoo and donating blood.

  It is extremely important to make sure that all tattooing equipment is clean and sterilized before use. Even if the needles are sterilized or never have been used, it is important to understand that in some cases the equipment that holds the needles cannot be sterilized reliably due to its design. In addition, the person who receives a tattoo must be sure to care for the tattooed area properly during the first week or so after the pigments are injected.

- **Removal problems.** Despite advances in laser technology, removing a tattoo is a painstaking process, usually involving several treatments and considerable expense. Complete removal without scarring may be impossible. See "The Most Common Problem: Dissatisfaction" and "Removal Techniques," below.

- **Allergic reactions.** Although allergic reactions to tattoo pigments are rare, when they happen they may be particularly troublesome because the pigments can be hard to remove. Occasionally, people may develop an allergic reaction to tattoos they have had for years.

- **Granulomas.** These are nodules that may form around material that the body perceives as foreign, such as particles of tattoo pigment.

- **Keloid formation.** If you are prone to developing keloids -- scars that grow beyond normal boundaries -- you are at risk of keloid formation from a tattoo. Keloids may form any time you injure or traumatize your skin, and according to Office of Cosmetics and Colors (OCAC) dermatologist Ella Toombs, M.D., tattooing or micropigmentation is a form of trauma. *Micropigmentation: State of the Art*, a book written by Charles Zwerling, M.D., Annette Walker, R.N., and Norman Goldstein, M.D., states that keloids occur more frequently as a consequence of tattoo removal.

- **MRI complications.** There have been reports of people with tattoos or permanent makeup who experienced swelling or burning in the affected areas when they underwent magnetic resonance imaging (MRI). This seems to occur only rarely and apparently without lasting effects.

  There also have been reports of tattoo pigments interfering with the quality of the image. This seems to occur mainly when a person with permanent eyeliner undergoes MRI of the eyes. Mascara may produce a similar effect. The difference is that mascara is easily removable.
The cause of these complications is uncertain. Some have theorized that they result from an interaction with the metallic components of some pigments.

However, the risks of avoiding an MRI when your doctor has recommended one are likely to be much greater than the risks of complications from an interaction between the MRI and tattoo or permanent makeup. Instead of avoiding an MRI, individuals who have tattoos or permanent makeup should inform the radiologist or technician of this fact in order to take appropriate precautions, avoid complications, and assure the best results.

The Most Common Problem: Dissatisfaction

According to the FDA Fact Sheet, the most common problem that develops with tattoos is the desire to remove them. Removing tattoos and permanent makeup can be very difficult.

Skill levels vary widely among people who perform tattooing. According to an article by J.K. Chiang, S. Barsky, and D.M. Bronson in the June 1999 issue of the Journal of the American Academy of Dermatology, the main complication with eyelid tattooing is improperly placed pigment. You may want to ask the person performing the procedure for references and ask yourself how willing you are to risk permanently wearing someone else's mistake.

Although tattoos may be satisfactory at first, they sometimes fade. Also, if the tattooist injects the pigments too deeply into the skin, the pigments may migrate beyond the original sites, resulting in a blurred appearance.

Another cause of dissatisfaction is that the human body changes over time, and styles change with the season. The permanent makeup that may have looked flattering when first injected may later clash with changing skin tones and facial or body contours. People who plan to have facial cosmetic surgery are advised that the appearance of their permanent makeup may become distorted. The tattoo that seemed stylish at first may become dated and embarrassing. And changing tattoos or permanent makeup is not as easy as changing your mind.

Removal Techniques

Methods for removing tattoos include laser treatments, abrasion, scarification, and surgery. Some people attempt to camouflage an objectionable tattoo with a new one. Each approach has drawbacks:

- **Laser treatments** can lighten many tattoos, some more easily and effectively than others. Generally, several visits are necessary over a span of weeks or months, and the treatments can be expensive. Some individuals experience hypopigmentation -- a lightening of the natural skin coloring -- in the affected...
Laser treatments also can cause some tattoo pigments to change to a less desirable shade.

Unfortunately, knowing what pigments are in your tattoo or permanent makeup has always been difficult and has become more so as the variety of tattoo inks has multiplied. Inks are often sold by brand name only, not by chemical composition. Because the pigments are sold to tattoo parlors and salons, not on a retail basis to consumers, manufacturers are not required by law to list the ingredients on the labels. Furthermore, because manufacturers may consider the identity and grade of their pigments "proprietary," neither the tattooist nor the customer may be able to obtain this information.

There also have been reports of individuals suffering allergic reactions after laser treatments to remove tattoos, apparently because the laser caused allergenic substances in the tattoo ink to be released into the body.

- **Dermabrasion** involves abrading layers of skin with a wire brush or diamond fraise (a type of sanding disc). This process itself may leave a scar.
- **Salabrasion**, in which a salt solution is used to remove the pigment, is sometimes used in conjunction with dermabrasion, but has become less common.
- **Scarification** involves removing the tattoo with an acid solution and creating a scar in its place.
- **Surgical removal** sometimes involves the use of tissue expanders (balloons inserted under the skin, so that when the tattoo is cut away, there is less scarring). Larger tattoos may require repeated surgery for complete removal.
- **Camouflaging** a tattoo entails the injection of new pigments either to form a new pattern or cover a tattoo with skin-toned pigments. Dr. Toombs notes, however, that injected pigments tend not to look natural because they lack the skin's natural translucency.

**What About Temporary Tattoos?**

Temporary tattoos, such as those applied to the skin with a moistened wad of cotton, fade several days after application. Most contain color additives approved for cosmetic use on the skin. However, the agency has issued an import alert for several foreign-made temporary tattoos.

According to OCAC Consumer Safety Officer Allen Halper, the temporary tattoos subject to the import alert are not allowed into the United States because they don't carry the FDA-mandated ingredient labels or they contain colors not permitted by FDA for use in cosmetics applied to the skin. FDA has received reports of allergic reactions to temporary tattoos.

In a similar action, FDA has issued an import alert for henna intended for use on the skin. Henna is approved only for use as a hair dye, not for direct application to the skin. Also, henna typically produces a reddish brown tint, raising questions about what
ingredients are added to produce the varieties of colors labeled as "henna," such as "black henna" and "blue henna."

**Reporting Adverse Reactions**

FDA urges consumers and healthcare providers to report adverse reactions to tattoos and permanent makeup, problems with removal, or adverse reactions to temporary tattoos. The agency operates the **Cosmetics Adverse Reaction Monitoring (CARM)** system to monitor problems consumers experience with cosmetic products and ingredients, including color additives. Consumers and healthcare providers can register complaints by contacting their FDA district office (see the blue pages of your local phone directory) or by sending written reports of adverse reactions to:

Office of Cosmetics and Colors  
HFS-106  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740-3835

You also can contact CARM by telephone at (202) 401-9725.

In addition, healthcare professionals and consumers may submit information about adverse events to MedWatch, the FDA Medical Products Reporting Program, as follows:

- **By phone:** 1-800-FDA-1088  
- **By fax:** 1-800-FDA-0178  
- **By Internet:** MedWatch

Consumers may obtain MedWatch reporting forms by calling the following FDA toll-free number: (888) 463-6332 [888-INFO-FDA]
State and Local Regulatory Offices

State Authorities

The following is a list of summarized regulatory guidelines at the state and local level. Due to ongoing changes in regulatory requirements in many states, it is strongly suggested that your local Board of Health be contacted for the most up-to-date copy of state or local regulations governing tattooing.

<table>
<thead>
<tr>
<th>STATE</th>
<th>REGS</th>
<th>SPECIFICS</th>
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</table>
| Alabama    | Regulated | Licensing and Facility Inspection Under Department of Health Services - HB 324 (1/98) Disclosure statement required  
Training program for blood borne pathogens is required. Tattooing of minors is prohibited.  
[http://www.alapubhealth.org/environmental/BodyArtFAQs.PDF](http://www.alapubhealth.org/environmental/BodyArtFAQs.PDF) |
| Alaska     | Regulated | CSSB#4 (FIN) passed 4/03/00 under Board of Barbers and Hairdressers, license required -  
[http://www.state.ak.us/dec/press/2001/rel_0625.htm](http://www.state.ak.us/dec/press/2001/rel_0625.htm) |
| Arizona    | Regulated | HB2124 - 431R - H Ver Unlawful for a person to engage in the business of tattooing out of a home. Tattooing of minors is prohibited. 13-3721  
[http://www.azleg.state.az.us/ars/13/03721.htm](http://www.azleg.state.az.us/ars/13/03721.htm) |
| Arkansas   | Regulated | Regulated separately for body tattooing - Apprenticeship & Testing required - Tattooing of minors prohibited -  
[http://www.healthyarkansas.com/faq/faq_tattoos.htm](http://www.healthyarkansas.com/faq/faq_tattoos.htm) |
<table>
<thead>
<tr>
<th>State</th>
<th>Regulated/Deregulated</th>
<th>Regulations</th>
</tr>
</thead>
<tbody>
<tr>
<td>California</td>
<td>Regulated</td>
<td>AB 186 requires registration with county health dept and facility inspection. Complete regulations going through legal channels before Public Hearing. Tattooing of minors prohibited <a href="http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=4081827662+0+0+0&amp;WAISaction=retrieve">http://www.leginfo.ca.gov/cgi-bin/waisgate?WAISdocID=4081827662+0+0+0&amp;WAISaction=retrieve</a></td>
</tr>
<tr>
<td>Colorado</td>
<td>Regulated</td>
<td>Licensing with the State Board of Cosmetology - Permanent Make-up is separated from <a href="http://www.dora.state.co.us/Barbers_Cosmetologists/Laws_2000.htm">http://www.dora.state.co.us/Barbers_Cosmetologists/Laws_2000.htm</a></td>
</tr>
<tr>
<td>Conn.</td>
<td>Regulated</td>
<td>Adopted by Dept. of health - tattooing allowed only under direct supervision of MD, DDS or DC. PA 94-105, SHB 5388. tattooing an unemancipated minor under 18 years of age without the permission of the parent or guardian prohibited</td>
</tr>
<tr>
<td>Delaware</td>
<td>Regulated</td>
<td>Tattooing of minors prohibited</td>
</tr>
<tr>
<td>Florida</td>
<td>Regulated</td>
<td>Allowed under general endorsement of MD, DDS or Osteopathic Physician. 877.04 (1998) - Tattooing of minors under 16 is prohibited</td>
</tr>
<tr>
<td>Georgia</td>
<td>Regulated</td>
<td>Unlawful to tattoo any person within one inch of the eye - Tattooing of a minor is prohibited except under direct supervision of a physician or osteopath</td>
</tr>
<tr>
<td>Hawaii</td>
<td>Regulated</td>
<td>8/2000 revised statutes (HRS) 321-376 Application of facial tattoos must be under the general (not requiring presence of) supervision of a physician. Must have a written statement to Dept. of Health verifying work relationship. Tattooing of minors is prohibited.</td>
</tr>
<tr>
<td>Idaho</td>
<td>Regulated</td>
<td>Facility inspection required. Amending definitions (3/99) Tattooing of minor is prohibited</td>
</tr>
<tr>
<td>Illinois</td>
<td>Regulated</td>
<td>Tattooing of minors is illegal</td>
</tr>
<tr>
<td>Indiana</td>
<td>Regulated</td>
<td>Senate Enrolled Act 13</td>
</tr>
<tr>
<td>Iowa</td>
<td>Regulated</td>
<td>Regulated by the State Department of Health</td>
</tr>
<tr>
<td>Kansas</td>
<td>Regulated</td>
<td>H2529 1999 revised bill licensed and regulated by state board of Cosmetology. Must demonstrate safety, sanitation and sterilization techniques by means of an inspection conducted. Tattooing of</td>
</tr>
</tbody>
</table>
minors is prohibited. Requires 1250 hr internship with tattoo artist. Exempt if licensed electrologist or working under direct supervision of MD or DDS. Statute 65-1940-46

<table>
<thead>
<tr>
<th>State</th>
<th>Status</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kentucky</td>
<td>Regulated</td>
<td>Tattooing of minors prohibited</td>
</tr>
<tr>
<td>Louisiana</td>
<td>Regulated</td>
<td>Licensed, monitored by the State Department of Health</td>
</tr>
<tr>
<td>Maine</td>
<td>Regulated</td>
<td>Regulated separately from body tattooing</td>
</tr>
<tr>
<td>Maryland</td>
<td>Regulated</td>
<td>licensed by the state Board of Barbers and Cosmetologists:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1. Expressly prohibits any licensee (i.e.: cosmetologists, nail technician, esthetician, etc.) from performing permanent cosmetic tattooing.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Expressly prohibits permanent cosmetic tattooing inside any licensed salon or limited licensed salon.</td>
</tr>
<tr>
<td>Mass.</td>
<td>Regulated by County</td>
<td>ban on tattooing has been lifted. Legalized tattooing, body art (permanent cosmetics) - each county is regulated separately by the Board of Health - Tattooing of minors prohibited - Contact Marie Eileen O'Neil 617-624-5280</td>
</tr>
<tr>
<td>Michigan</td>
<td>Regulated</td>
<td>State Department of Health requires facility license. - Tattooing of minors is illegal</td>
</tr>
<tr>
<td>Minnesota</td>
<td>Regulated</td>
<td>Tattooing of minors prohibited</td>
</tr>
<tr>
<td>Mississippi</td>
<td>Regulated</td>
<td>State Department of Health requires registration and license.</td>
</tr>
<tr>
<td>Missouri</td>
<td>Regulated</td>
<td>HB 343 - License required - Tattooing of minors is prohibited</td>
</tr>
<tr>
<td>Montana</td>
<td>Regulated</td>
<td>Regulated by the State Board of Health - Tattooing of minors is prohibited</td>
</tr>
<tr>
<td>Nebraska</td>
<td>Un-Regulated</td>
<td></td>
</tr>
<tr>
<td>Nevada</td>
<td>Regulated by County</td>
<td>Clark County (Las Vegas) regulated by Health Department - must obtain Health permit and work in a permitted facility</td>
</tr>
<tr>
<td>New Jersey</td>
<td>Regulated</td>
<td>New legislation passed - regulated by the Board of Health</td>
</tr>
<tr>
<td>State</td>
<td>Regulation Status</td>
<td>Regulations</td>
</tr>
<tr>
<td>-------------</td>
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<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>New Mexico</td>
<td>Un-Regulated</td>
<td>Current regulations for tattooing - Permanent Cosmetics not defined.</td>
</tr>
<tr>
<td>New Hampshire</td>
<td>Regulated</td>
<td>State Regulations have been proposed. Some locales restricted - Must be licensed by the Board of Health - Legislation under review at present time - Tattooing of minors is prohibited - <a href="http://assembly.state.ny.us/leg/?bn=07900">http://assembly.state.ny.us/leg/?bn=07900</a></td>
</tr>
<tr>
<td>New York</td>
<td>Pending Legislation for State Regulation</td>
<td>Requires annual permit, tattoo removal prohibited. Some local prohibition (Wake Co.); tattooing of minors prohibited &amp; considered a felony 130A-283 Part II <a href="http://www.ncga.state.nc.us/statutes/generalstatutes/html/bychapter/chapter%5F130a.html">http://www.ncga.state.nc.us/statutes/generalstatutes/html/bychapter/chapter%5F130a.html</a></td>
</tr>
<tr>
<td>North Carolina</td>
<td>Regulated</td>
<td>Requires training by state approved trainers registered with State Board of Health or apprenticeship program. Prohibits removal. Tattooing of minors is prohibited - Inspection of facility required - <a href="http://onlinedocs.andersonpublishing.com/revisedcode/">http://onlinedocs.andersonpublishing.com/revisedcode/</a></td>
</tr>
<tr>
<td>North Dakota</td>
<td>Un-Regulated</td>
<td>only regulations on tattoo equipment</td>
</tr>
<tr>
<td>Ohio</td>
<td>Regulated</td>
<td>Requires 368 hrs. Training at state approved school, written exam. DDS authorized to give anesthesia injections for lip procedures. <a href="http://www.hdlp.hr.state.or.us/etreg2.htm">http://www.hdlp.hr.state.or.us/etreg2.htm</a> - <a href="http://www.hdlp.hr.state.or.us/etreg2.htm">http://www.hdlp.hr.state.or.us/etreg2.htm</a></td>
</tr>
<tr>
<td>Oklahoma</td>
<td>Pending Legislation</td>
<td>HB 1964 temporary legislation (Oklahoma Medical Micropigmentation Regulation Act) Tattooing by licensed medical physician, or RN certified by State Commission of Health</td>
</tr>
<tr>
<td>Oregon</td>
<td>Regulated</td>
<td>Requires 368 hrs. Training at state approved school, written exam. DDS authorized to give anesthesia injections for lip procedures. <a href="http://www.hdlp.hr.state.or.us/etreg2.htm">http://www.hdlp.hr.state.or.us/etreg2.htm</a> - <a href="http://www.hdlp.hr.state.or.us/etreg2.htm">http://www.hdlp.hr.state.or.us/etreg2.htm</a></td>
</tr>
<tr>
<td>Rhode Island</td>
<td>Regulated</td>
<td>Regulated by State health Dept. - Registration required - Tattooing of minors is prohibited</td>
</tr>
<tr>
<td>State</td>
<td>Regulation Type</td>
<td>Requirements</td>
</tr>
<tr>
<td>-------------</td>
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<td>-------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>South Carolina</td>
<td>Regulated</td>
<td>A physician may not delegate procedures to an employee - prohibited under age 21 - Allowed only by MD in course of practice</td>
</tr>
<tr>
<td>South Dakota</td>
<td>Regulated</td>
<td>Tattooing of minors is prohibited</td>
</tr>
<tr>
<td>Tennessee</td>
<td>Regulated</td>
<td>Requires 1 yr. Apprenticeship with tattoo artist that has been licensed with the state for min. 3 yrs., registration with local health dept., inspection, and permit. Tattoo removal prohibited - Tattooing of minors is prohibited</td>
</tr>
<tr>
<td>Texas</td>
<td>Regulated</td>
<td>Sterilization Standards under the Health Department. SB 1812 - Tattooing of minors is prohibited</td>
</tr>
<tr>
<td>Utah</td>
<td>Regulated by County</td>
<td>regulated by local county Health Departments - for sanitation and sterilization and some for training</td>
</tr>
<tr>
<td>Vermont</td>
<td>Regulated</td>
<td>Must register with the office of regulation - Tattooing of minors is illegal</td>
</tr>
<tr>
<td>Virginia</td>
<td>Regulated</td>
<td>Tattooing of minors prohibited - Resolution #375 requesting Dept. of Health to study appropriate level of regulation to ensure that participants use proper infection control techniques. Must submit findings and recommendations to Governor for 2002 session legislatures</td>
</tr>
<tr>
<td>Washington</td>
<td>Regulated</td>
<td>House Bill 1042 New Standards for tattooing</td>
</tr>
<tr>
<td>West Virginia</td>
<td>Regulated by Locale</td>
<td>Registration and Region Certificate required by Board of Health - Tattooing of minors prohibited</td>
</tr>
<tr>
<td>Wisconsin</td>
<td>Regulated</td>
<td>Regulated by the State Department of Health - Tattooing of minors prohibited</td>
</tr>
<tr>
<td>Wyoming</td>
<td>Regulated</td>
<td></td>
</tr>
</tbody>
</table>