BOARD FOR PROFESSIONAL AND OCCUPATIONAL REGULATION

Report on the Need to Regulate Estheticians

November 18, 2002

Board Members

Morris A. Nunes, Chairman

Raynard Jackson, Vice Chairman

Keela Boose-Jackson

Susan T. Ferguson

Maxime A. Frias

Ronald E. Lushbaugh

Dana Martin

Thomas J. Meany, Jr.

Leroy O. Pfeiffer, Sr.

COMMONWEALTH OF VIRGINIA

DEPARTMENT OF PROFESSIONAL AND OCCUPATIONAL REGULATION

3600 West Broad Street, Richmond, Virginia 23230-4917
Telephone: (804) 367-8500 TDD: (804) 367-9753
http://www.state.va.us/dpor

MEMORANDUM

TO: The Honorable Mark R. Warner
Governor, Commonwealth of Virginia

The Honorable Bruce F. Jamerson
Clerk of the House of Delegates, Virginia House of Delegates

The Honorable Susan Clarke Schaar
Clerk of the Senate, Senate of Virginia

FROM: Louise Fontaine Ware
Director

PHONE: 397-8519

DATE: November 27, 2002

RE: Report on the Need to Regulate Estheticians
Report on the Need to Regulate Electrologists

The Board for Professional and Occupational Regulation (Board), in response a request by the Board for Barbers and Cosmetology, conducted a study to determine the need for regulation of estheticians. The Board recommended that further coordinated study be done with the Department of Health Professions to determine the appropriate regulation of this and related occupations such as electrology. Based on research and public comment, the Board has found convincing evidence to support regulation by mandatory licensure of Estheticians and Electrologists through the Board for Barbers and Cosmetology with appropriate exemptions. By reason of the evidence presented and duty to the protection of the health, safety, and welfare of the citizens of the Commonwealth, the Board for Professional and Occupational Regulation, after collaboration with the Department of Health Professions, hereby refers these reports to the Governor and General Assembly. I am pleased to submit the results of these studies to you.

The Board conducted the studies in accordance with Section 54.1-310 of the *Code of Virginia*, which gives authority to study and make recommendations to the General Assembly on the need to regulate professions or occupations and, if so, the degree of

regulation that should be imposed. Section 54.1-311 B. of the *Code of Virginia*, states that whenever the Board determines that a profession or occupation should be regulated, it shall consider degrees of regulation and shall regulate only to the degree necessary to fulfill the need for regulation and only upon approval of the General Assembly.

These reports, approved by the Board on November 18, 2002, outline the findings, conclusions and recommendations of the Board. Members of the Board for Professional and Occupational Regulation would be pleased to answer any questions you may have regarding these studies. Please send any questions that you may have to:

Karen O'Neal
Deputy Director, Regulatory Programs
Department of Professional and Occupational Regulation
3600 West Broad Street
Richmond, Virginia 23230
(804) 367-8537
oneal@dpor.state.va.us

c: The Honorable Michael J. Schewel
Secretary of Commerce and Trade

The Honorable Jane H. Woods
Secretary of Health and Human Resources

The Honorable John S. Reid
Chairman, House General Laws Committee

The Honorable Walter A. Stosch
Chairman, Senate General Laws Committee

The Honorable Phillip A. Hamilton
Chairman, House Health, Welfare and Institutions Committee

The Honorable H. Russell Potts, Jr.
Chairman, Senate Education and Health Committee

The Honorable E. M. Miller
Director, Division of Legislative Services

The Honorable Robert A. Nebiker
Director, Department of Health Professionals

Board Members
Board for Barbers and Cosmetology

Report on the Need to Regulate Estheticians

TABLE OF CONTENTS

I. SUMMARY

The Board for Barbers and Cosmetology voted on March 5, 2001, to request the Board for Professional and Occupational Regulation (Board) to conduct a study to determine the need for regulation of estheticians. On November 13, 2001, the Board recommended that further coordinated study be done with the Department of Health Professions to determine the appropriate regulation of this and related occupations.

The Board conducted the study in accordance with Section 54.1-310 of the *Code of Virginia* which gives authority to study and make recommendations to the General Assembly on the need to regulate professions or occupations and, if so, the degree of regulation that should be imposed. Section 54.1-311 B. of the *Code of Virginia*, states that whenever the Board determines that a profession or occupation should be regulated, it shall consider degrees of regulation and shall regulate only to the degree necessary to fulfill the need for regulation and only upon approval of the General Assembly. In April 2002, the General Assembly established separate licensing categories for wax technicians, tattooists and body piercers under the Board for Barbers and Cosmetology.

The Board reviewed the competencies and standards of practice for estheticians in the Commonwealth and other jurisdictions. The study's objectives were to determine specialized skills and training, independent judgment required, actual harm and potential risk for harm to the consumer, the scope of practice, the economic impact of regulation, other alternatives than state regulation, and the least restrictive level of regulation that is consistent with the protection of the public's health, safety and welfare.

The Board conducted reviews of general policy literature, federal and states' laws and regulations, the definition and scope of practice for estheticians, and malpractice insurance coverage data. In addition three public hearings were conducted to receive comments from the public on the issue of state regulation.

Public comment supported regulation of estheticians but indicated that several license categories may be needed to encompass the different services provided and the training and education required to perform these services in a manner that protects the health, safety, and welfare of the citizens of the Commonwealth.

Based on research and public comment, the Board has found convincing evidence to support regulation by mandatory licensure of Estheticians through the Board for Barbers and Cosmetology with appropriate exemptions. By reason of the evidence presented and duty to the protection of the health, safety, and welfare of the citizens of the Commonwealth, the Board for Professional and Occupational Regulation, after collaboration with the Department of Health Professions, hereby refers this report to the General Assembly and the Governor with copies to the Department of Health Professions and Board for Barbers and Cosmetology.

II. INTRODUCTION

A. Background

As directed by the 1988 General Assembly, the Board of Commerce (predecessor to the Board for Professional and Occupational Regulation) studied the need for licensing estheticians. After conducting public hearings and reviewing written comments, the Board of Commerce concluded that the potential for harm necessitated close monitoring, but recommended no regulatory program be implemented at that time.

Upon consideration of the statutory and regulatory changes resulting from the merger of the Board for Barbers and the Board of Cosmetology, on December 4, 2000, the new Board for Barbers and Cosmetology revisited the issue of licensing individuals who only administer skin or cosmetic treatments and moved to seek advice from the Office of the Attorney General.

Legal advice from the Assistant Attorney General stated that there is no indication that, with its 2000 amendments to § 54.1-700 of *Code of Virginia*, the General Assembly intended to impose a new licensure requirement for those who only administer skin or cosmetic treatments separate and apart from the traditional professional practices associated with barbering, cosmetology, or nail care. On further advice from the Attorney General's Office, the Board for Barbers and Cosmetology voted on March 5, 2001, to request the Board to conduct a study to determine the need for regulation of estheticians. In April 2002, the General Assembly established separate licensing categories for wax technicians, tattooists and body piercers under the Board for Barbers and Cosmetology.

On November 13, 2001, the Board recommended that further coordinated study be done with the Department of Health Professions to determine the appropriate regulation of this and related occupations.

B. Statutory Authority for Study

Section 54.1-310 of the *Code of Virginia* provides the statutory authority for the Board to study and make recommendations to the General Assembly on the need to regulate professions or occupations and, if so, the degree of regulation that should be imposed.

Pursuant to § 54.1-311 B. of the *Code of Virginia*, whenever the Board determines that a profession or occupation should be regulated, it shall consider the following degrees of regulation and shall regulate only to the degree necessary to fulfill the need for regulation and only upon approval of the General Assembly:

1. Whether the practitioner, if unregulated, performs a service for individuals involving a hazard to the public health, safety or welfare.

2. The opinion of a substantial portion of the people who do not practice the particular profession, trade or occupation on the need for regulation.

3. The number of states which have regulatory provisions similar to those proposed.

4. Whether there is sufficient demand for the service for which there is no regulated substitute and this service is required by a substantial portion of the population.

5. Whether the profession or occupation requires high standards of public responsibility, character and performance of each individual engaged in the profession or occupation, as evidenced by established and published codes of ethics.

6. Whether the profession or occupation requires such skill that the public generally is not qualified to select a competent practitioner without some assurance that he has met minimum qualifications.

7. Whether the professional or occupational associations do not adequately protect the public from incompetent, unscrupulous or irresponsible members of the profession or occupation.

8. Whether current laws which pertain to public health, safety and welfare generally are ineffective or inadequate.

9. Whether the characteristics of the profession or occupation make it impractical or impossible to prohibit those practices of the profession or occupation which are detrimental to the public health, safety and welfare.

10. Whether the practitioner performs a service for others which may have a detrimental effect on third parties relying on the expert knowledge of the practitioner.

Section 54.1-2510, of the *Code of Virginia* provides the statutory authority for the Board of Health Professions to advise the Governor, General Assembly and the Director of the Department of Health Professions on matters relating to the regulation or deregulation of health care professions and occupations.

C. Methodology

The general methodology of this study was to review the competencies and standards of practice for estheticians in the Commonwealth and other jurisdictions. Since resources were not available to conduct criticality scaling, the Board focused its efforts in determining the answers to the following key questions:

1. What specialized skills and training do estheticians possess?

2. To what degree is independent judgment required in their practice?

3. What is the documented actual harm and potential risk for harm to the consumer resulting from the tasks performed and judgments made by these practitioners?

4. Is the scope of practice distinguishable from other regulated occupations or professions?

5. What would be the economic impact to the public if this group was regulated?

6. Are there alternatives other than state regulation of this occupation that would adequately protect the public?

7. If the Board determines that this profession requires state regulation, what is the least restrictive level that is consistent with the protection of the public's health, safety and welfare?

To answer the key questions, the following methods were used:

1. A review of the general policy literature related to the regulation of estheticians was conducted.

2. A review of the current relevant federal and states' laws and regulations was conducted.

3. A review of the definition and scope of practice for estheticians was conducted to determine all facets of the knowledge, skills, abilities, and tasks involved in the practice of this occupation in order to assess the risk of harm to the consumer.

4. Malpractice insurance coverage data was reviewed for individuals, salons, and schools engaged in offering esthetic services or training in conjunction with other data, to address risk of harm to the consumer and the economic impact on the practitioner.

5. Three public hearings were conducted to receive comments from the public on the issue of the state regulation of this occupation, including any public health and safety issues germane to current practices. Relevant health professional constituents were notified of all hearings and opportunities for public comment.

III. FINDINGS

A. The Practice of Esthetics

As defined in *Milady's Standard Comprehensive Training for Estheticians (2002)*, a leading educational resource for the esthetics profession, *esthetics (aesthetics) is a branch of anatomical science that deals with the overall health and well-being of the skin, the largest organ in the human body.*

In establishing regulations and licensing programs for esthetics, the definition and scope of practice for an esthetician varies somewhat from state to state. As an example, listed below are the definitions for the states of Maryland, Illinois, and Arkansas:

> **Maryland** – To provide an individual for compensation the service of: (1) cleansing, exercising, massaging, stimulating, or performing any other similar procedure on the skin or scalp by electrical, mechanical, or any other means; (2) applying to the face an alcohol, cream, lotion, astringent, or cosmetic preparation; or (3) removing superfluous hair by the use of a depilatory, tweezers, or wax.
>
> **Illinois** – Any person who for compensation, whether direct or indirect, including tips, engages in the following practices: (1) beautifying, massaging, cleansing, exfoliating the stratum corneum of the epidermis or stimulating the skin of the human body, except the scalp, by use of cosmetic preparations, body treatments, body wraps, the use of hydrotherapy, antiseptics, tonics, lotions or creams or any device, electrical or otherwise, for the care of the skin; (2) applying make-up or eyelashes to any person, tinting eyelashes and eyebrows and lightening hair on the body except the scalp; and (3) removing superfluous hair from the body of any person by the use of depilatories, waxing or tweezers. However, esthetics does not include services provided by a cosmetologist or electrologist. Estheticians are prohibited from performing any procedure which may puncture or abrade the skin below the stratum corneum of the epidermis or remove closed milia (whiteheads), which may draw blood or serous body fluid. The term esthetics includes rendering advice on what is cosmetically appealing, but no person licensed under this Act shall render advice on what is appropriate medical treatment for diseases of the skin.
>
> **Arkansas** – Any combination of the following practices: (1) massaging, cleaning, or stimulating the face, neck, arms, bust, or upper part of the human body by means of the hands, devices, apparatus, or appliances, with or without the use of cosmetic preparations, antiseptics, tonics, lotions, and creams; (2) beautifying the face, neck, arm, bust or upper part of the human body, by use of cosmetic preparations, antiseptics, tonics, lotions, or creams; (3) removing, temporarily, superfluous hair from the body of any person by the use of depilatories or by the use of tweezers, chemical, or preparations or by the use of devices or appliances of any kind or description, except by the use of light waves, commonly known as rays.

Nationally, estheticians primarily operate in salons, day spas, and skin care centers, however, it is also common for estheticians to work within the practices of dermatologists and plastic surgeons. The Lam School of Advanced Asthetics, an international leader in the area of training estheticians, refers to the following three job titles to delineate the scope of practice for estheticians working in these various settings:

Medical Estheticians – Work together with medical professionals and focus on pre- and post-operative care for the doctor's patients. They concentrate on skin problems such as acne scarring and the preparation as well as after-effects of cosmetic surgery of the skin. They work primarily with dermatologists and cosmetic surgeons;

Clinical Estheticians – Work independently within a clinical setting such as a skin care clinic or salon. Although they also perform spa services, they concentrate mainly on clinical aspects of skin care to produce results for particular skin concerns such as acne and wrinkled, aging skin;

Spa or Salon Estheticians – Cater primarily for the rejuvenation or relaxation and focus on the pampering aspect of esthetics.

B. Education and Training

The procedures and modalities that are fairly consistent in the definition and scope of practice for an esthetician are indicative of the education and training required to demonstrate minimal competence and proficiency in order to provide esthetic services in a manner that protects the public health, safety, and welfare.

The regulations for all of the states that currently have a licensing program for estheticians consist of curriculum requirements that must be met by their licensed schools and successfully completed by individuals seeking licensure. The following is a list of the standard subject matter content for the esthetician curriculum mandated by state licensing boards:

- Laws, rules and regulations governing the profession
- Anatomy, physiology, and analysis of the skin
- Bacteriology
- Conditions of the skin
- Facials
- Skin resurfacing
- Laser therapy

- Mask therapy
- Nutrition for skin and body care
- Dermatology and cosmetic surgery – basic exposure
- Scar treatments
- Chemistry pertaining to the practice of esthetics
- Body treatments – wraps and masks
- Health and Safety – (client and practitioner) infectious diseases and viruses (AIDS, HIV, and Hepatitis B) and hazardous chemicals
- Disinfection and Sanitation
- Aromatherapy
- Electric modalities
- Face and body waxing and depilatories
- Makeup application
- Professional ethics
- Business marketing
- Salon management

In addition to satisfactory completion of education and training in theory, some states, such as Ohio, require that an individual desiring a skin care (esthetician) license also complete an internship program mandating hours of technical instruction and practical operation (performances).

There are currently nine proprietary schools in Virginia that offer an esthetician training program. These schools are certified and monitored by the Proprietary Division of the Department of Education. The certification process includes curriculum review, assessment of staff qualifications, and the adequacy of the school's facility and equipment. Three of these schools, Yvonne De Vilar Scientific Skin Care, Ltd, Ana Visage Institute, and The Skin Care Center, all located in the Northern Virginia area, are currently licensed by Maryland to offer their required 600 hour training program to individuals seeking licensure in that state. Listed below are the costs for the esthetic programs, including books and materials, provided by these three schools:

1. Yvonne De Vilar Scientific Skin Care, Ltd.

600 hours	$9,000.00

2. Ana Visage Institute

600 hours	$6,500.00
300 hours	$4,000.00

3. The Skin Care Center

600 hours	$6,150.00
300 hours	$4,150.00
150 hours (refresher)	$2,950.00

Training and educational opportunities are also made available to estheticians by professional associations such as the National Coalition of Esthetic & Related Professional Associations (NCEA) which publishes *The Medical Journal for Skin Care Professionals (PCI)*. The American Estheticians Education Association publishes *Skin Inc.*, a monthly magazine dedicated to current issues, trends, and challenges in the skin care industry. These and other professional associations related to the practice of esthetics also set standards, and codes of ethics for the industry, however, membership and adherence to these standards are voluntary.

C. Profile of Industry

The skin care industry has experienced significant growth during the past decade. Evidence of this growth is apparent in the increasing number of specialty salons, day spas, and skin care centers that employ estheticians to perform a variety of skin care services. Such services may include, but are not limited to:

- Microdermabrasion – mechanical exfoliation of the skin
- Chemical Peel – chemical exfoliation of the skin using glycolic acids
- Laser Resurfacing – use of lasers to vaporize a thin layer of skin and give new skin a smoother appearance
- Waxing – use of depilatory wax for the removal of hair from the face, arm, underarm, leg, back, bikini area, and full body
- Skin Analysis – use of methods of skin typing based on appearance, reactions to external and topical substances, medications, and environment
- Facials – extraction, hydration, and massage
- Makeup Application

- Holistic Therapy – aromatherapy, Shiodara, herbalism, Reiki, Lomi Lomi, Shiatsu, craniosacral massage, reflexology, and polarity therapy
- Cellulite Treatments – stimulation of circulation to eliminate built up cellulite
- Back Treatments – back facials or back deep cleansing
- Body Wraps and Body Masks – conditioning the skin using remineralizing and detoxifying wraps and masks consisting of ingredients such as seaweed
- Body Exfoliation – use of dry brushing, salt glow, scrubs, and gommage to exfoliate the body
- Metabolic Stimulation – applying specialized products to encourage metabolic stimulation

Of the first two services listed, microdermabrasion and chemical peels, it is necessary to point out that both of these exfoliation procedures have often been the subject of controversy between the esthetic and medical professions. The Esthetics Manufacturers and Distributors Alliance (EMDA) of the American Beauty Association has recommended that all exfoliation procedures performed by estheticians be referred to as exfoliations, rather than peels in order to clarify the domain of the esthetician verses that of the physician. During an exfoliation procedure, also known as a superficial peeling, performed by an esthetician, only the stratum corneum (the outermost layer of the epidermis) is affected. Any procedure that removes cells beyond the stratum corneum is considered a medical peel and should only be performed by a dermatologist or plastic surgeon.

The delineation between these two exfoliation procedures, the use of certain levels of glycolic acids, and the use of instruments associated with the practice, often described as "sandblasting" equipment for the skin, are some of the issues that the industry and regulatory agencies have had to closely examine in order to ensure consumer safety.

In advancing its goal to enhance the professional treatment of clients of the professional beauty industry, EMDA has published "Guidelines for Professional Cosmetic Resurfacing Exfoliating Procedures" that have been endorsed by the National Interstate Council of State Boards of Cosmetology (NIC). The Ohio Board of Cosmetology has adopted these same guidelines and requires all of its licensees providing microdermabrasion services to adhere to the guidelines in providing these services.

In addition to endorsing the EMDA guidelines referenced above, the NIC has published Health and Safety Standards for the industry, based on the potential risks to clients, practitioners, and students. These standards address blood spill procedures, infection control, wet disinfection and storage standards.

Many estheticians also provide laser and light-based hair removal except, where prohibited by law. Alabama, for example, will only allow estheticians certified by the manufacturer of a device, or under the supervision of a physician, to operate laser and intense-pulsed light devices. *Milady's Standard Comprehensive Training for Estheticians* textbook provides the following definitions for Laser and light-based hair removal:

- Laser hair removal – (*The acronym derived from Light Amplification by Stimulated Emission of Radiation.*) A direct beam of radiation that penetrates the epidermis creating a photochemical destruction of hair follicles (photothermolysis).

- Pulsed Light hair removal – The use of energy pulsed light (or photo light) at intervals of a thousandth to almost a billionth of a second to destroy the vein of the hair bulb.

Since Virginia does not regulate estheticians, the use of these devices and the risk to consumers can not be monitored.

Another aspect of the esthetics profession which borders on a practice often regulated under medical boards, as is the case in Virginia, is body massage services. The body massage services are frequently offered by day spas as part of their "Body Services" package along other services such as body wraps and body masks. One of the leading educational resources for the esthetics profession, *Milady's Standard Comprehensive Training for Estheticians*, points out that licensure for body massage varies from state to state and that a massage therapist license may be required to offer this service.

According to Robert N. Kretzmer, CIC, Vice President of Inner Harbour Insurance, Inc., a major provider of insurance coverage for the skin care industry, including estheticians, esthetic schools, and facilities providing esthetic services since 1980, the following claims and incidents have been filed against estheticians:

- Skin peels – burns, discoloration and bruising

- Microdermabrasion – burns and bruising

- Waxing – burns and scarring

- Medications – applying chemicals without asking if medications are being taken

- Skin Care Products – applying without knowing about earlier adverse reactions to skin care products

- (this is only a limited example of claims reported)

Referring to his handling of numerous claims related to the esthetics industry, Mr. Kretzmer states that many of the claims stem from untrained, under trained and unregulated individuals practicing esthetics. In addition, Kretzmer states that it has and continues to be his direct experience to find many Virginia Esthetic salons, spas, and schools without the proper esthetic malpractice liability or those that are performing services for which there is simply no malpractice coverage under their current policies. Kretzmer points out that this is a very serious situation because if a claim or incident occurs where a consumer is injured, there may be no or limited insurance coverage available to assist the injured.

Mr. Kretzmer advised that the current minimum annual premium for general and malpractice insurance offered by Inner Harbour Insurance for estheticians and esthetic salons offering standard skin care services (not including microdermabrasion and chemical peels) is $350.00. This premium provides for coverage in the amount of one million dollars per occurrence, and one million dollars aggregate for the practitioner or the salon. Kretzmer advised that since estheticians operate as sole proprietors they are only required to pay $350.00. For those estheticians and esthetic salons that do offer microdermabrasion and chemical peel services, or any additional specialty services such as electric steam baths, electrolysis, and aromatherapy, for example, there is an additional charge per service based on gross receipts. Mr. Kretzmer advises that the minimum annual premium for general and malpractice coverage for esthetic schools is $50.00 per student which provides the school with the same coverage as estheticians and esthetic salons.

D. Regulation of Estheticians in Other States

At this time, Virginia, Connecticut, Kentucky, and South Dakota are the only states that do not regulate estheticians.

Since the time of the previous study in 2001, the state of North Carolina has increased its hours of education from 450 to the national standard of 600. Utah, the most recent state to enact laws requiring licensure, established a two tier license (1) a basic esthetics license which requires 600 hours of training and (2) a master esthetics license which requires an additional 600 hours with a minimum of 200 in lympathic training and 100 in anatomy and physiology.

In Maryland, an esthetician must complete 600 hours of instruction or a twelve month apprenticeship in licensed salon, and effective March 2002, use or possession of lasers or microdermabrasion machines in any salon or by any practitioner is prohibited. South Carolina requires 450 hours of training for estheticians and an esthetic license is not recognized in a medical practice. The District of Columbia requires 350 hours of training to be eligible for an estheticians license, and the state of West Virginia requires 600 hours.

Listed below are the mandated training hours, licensing fees, and renewal requirements for seven states surrounding Virginia:

1.	District of Columbia 350 hours	$305.00	Biennial
2.	Maryland 600 hours or 12 month apprenticeship	$25.00	Biennial
3.	Delaware 600 hours	$28.20	Biennial
4.	North Carolina 600 hours	$10.00	Annual
5.	Pennsylvania 300 hours	$21.00	Biennial
6.	South Carolina 450 hours	$15.00	Annual
7.	West Virginia 600 hours	$25.00	Annual

According to Marian Raney, Editor, Skin, Inc., magazine, there are an estimated 40,000 practicing estheticians nationwide (taken from Cosmetology state boards) and approximately 7,000 day spas nationwide (information taken from Price Waterhouse Coopers International Spa Association (ISPA) study).

The Board's inquiry into the number of complaints filed with other state boards pertaining to estheticians does not indicate any significant number of consumer complaints prior to, or after, the enactment of their esthetician licensing programs. However, based on interviews with various state board administrators, the risks of harm to consumers of esthetic services such as chemical peels, microdermabrasion, and waxing, was a major factor in development of their regulatory programs.

E. Federal Laws Affecting the Practice of Esthetics

The U.S. Food and Drug Administration (FDA) determined that microdermabrasion equipment was a Class I exempt device in 1998. This means that the FDA has no control over who uses these devices, however, individual states may impose regulations regarding use of microdermabrasion equipment.

In 1993, The Occupational Safety and Health Act (OSHA), in its federal oversight of workplace safety for employees developed guidelines for the safe handling of bloodborne materials instruments and equipment. These voluntary guidelines are designed to reduce the occupational risk and exposure to the HIV (AIDS) virus and hepatitis B virus (HBV).

Another OSHA requirement that affects the practice of esthetics is the mandatory use of a Material Safety Data Sheet (MSDS) due to the use of chemicals in the workplace. These forms include information about flammability, toxicity, how to handle spills, and other information pertaining to the use of chemicals in the workplace.

F. Public Comment

Public comment supported licensure of estheticians. Several comments gave evidence that there is a large spectrum of services provided by estheticians and the education and training needed to be proficient in these services varies as well. If estheticians are regulated, public comment indicated that several license categories may be needed to encompass the different services provided and the training and education required to perform these services in a manner that protects the health, safety, and welfare of the citizens of the Commonwealth.

The Board for Professional and Occupational Regulation received written public comment and conducted public hearings on the following dates and locations:

September 20, 2002, 1:30 p.m.
Newport News City Council Chamber
City Hall Building
2400 Washington Avenue
Newport News, Virginia 23607

September 23, 2002, 1:30 p.m.
Department of Professional and Occupational Regulation
3600 West Broad Street
Richmond, Virginia 23230

October 4, 2002, 10:00 a.m.
Roanoke City Council Chamber
Noel C. Taylor Municipal Building
215 Church Avenue SW
Roanoke, Virginia 24011

IV. Conclusion

Based on research and public comment, the Board has found convincing evidence to support regulation by mandatory licensure of Estheticians through the Board for Barbers and Cosmetology with appropriate exemptions. By reason of the evidence presented and duty to the protection of the health, safety, and welfare of the citizens of the Commonwealth, the Board for Professional and Occupational Regulation, after collaboration with the Department of Health Professions, hereby refers this report to the

General Assembly and the Governor with copies to the Department of Health Professions and Board for Barbers and Cosmetology.

APPENDIX A

Notice and Flyer

COMMONWEALTH OF VIRGINIA

DEPARTMENT OF PROFESSIONAL AND OCCUPATIONAL REGULATION
3600 West Broad Street, Richmond, Virginia 23230-4917
Telephone: (804) 367-8500 TDD: (804) 367-9753
http://www.state.va.us/dpor

LOUISE FONTAINE WARE
DIRECTOR

SANDRA WHITLEY RYALS
CHIEF DEPUTY

DEPUTY DIRECTORS:
JAMES L. GUFFEY
Enforcement
STEVEN L. ARTHUR
Administration & Finance
KAREN W O'NEAL
Regulatory Programs

MEMORANDUM

TO: Board for Barbers and Cosmetology Public Participation List
And Interested Parties

FROM: William H. Ferguson, II
Assistant Director
Board for Barbers and Cosmetology

DATE: August 29, 2002

PHONE: 804-367-8590

SUBJECT: Board for Barbers and Cosmetology Emergency Regulations
Board for Barbers and Cosmetology Proposed Regulations
Board for Barbers and Cosmetology Proposed Public Participation Guidelines
Wax Technician Regulations
Tattooing and Body-piercing Regulations
Board for Professional and Occupational Regulation Estheticians Study
Board for Professional and Occupational Regulation Electrologists Study

The Board for Barbers and Cosmetology would like to notify you of the following seven regulatory actions:

1. **Board for Barbers and Cosmetology Emergency Regulations:** Board for Barbers and Cosmetology Emergency Regulations became effective July 2, 2002. These regulations are available on our website, www.state.va.us/dpor or, you may make a written request or contact us by phone at (804) 367-8509, to request a copy of the regulations.

   To access the Board for Barbers and Cosmetology Emergency Regulations on the DPOR Internet Site, please follow the following instructions:

   On the internet, go to www.state.va.us/dpor
   Select 'Boards and Regulations' from the menu on the left side
   Select either 'Barbers' or 'Cosmetology" from the menu that appears below Boards and Regulations
   Select 'Barbers and Cosmetology Regulations and Statutes' from the Board's page

   Current forms may be accessed at the same site.

2. **Board for Barbers and Cosmetology Proposed Regulations:** The Board for Barbers and Cosmetology is conducting regulatory review of its regulations. Board for Barbers and Cosmetology Proposed Regulations are being promulgated and consists of changes necessary to ensure the health, safety, and welfare of the public and effective administration of the Board's programs. The proposed regulatory changes will promulgate regulations for the newly combined Board for Barbers and Cosmetology clarify and standardize requirements for licensure; provide for and ensure that health, sanitation standards, and safety are adequate in facilities where barbering and cosmetology are practiced; and extend the temporary work permit period from 30 to 45 days to allow sufficient time for posting examination scores and avoid interruption of employment, and adjust licensing fees.

   The text of the proposed regulations may be accessed electronically on the Virginia Town Hall internet site, www.townhall.state.va.us or requested from the Board for Barbers and Cosmetology.

   Public Comments may be submitted to the Board until September 27, 2002. A Public Hearing is scheduled on September 10, 2002, 9:30 a.m., at the Department of Professional and Occupational Regulation, 3600 West Broad Street, Richmond, VA, 23230.

3. **Board for Barbers and Cosmetology Proposed Public Participation Guidelines:** The Board for Barbers and Cosmetology is conducting regulatory review of its public participations guidelines. Board for Barbers and Cosmetology Proposed Public Participation Guidelines are also being promulgated to establish Public Participation Guidelines for the newly combined Board for Barbers and Cosmetology to ensure that the Board is meeting its statutory mandate without burdensome requirements and to ensure that the public has knowledge and opportunity to participate in the formation and development of regulations and are being changed to provide access to information through electronic notification to listed participants.

   The text of the proposed public participation guidelines may be accessed electronically on the Virginia Town Hall internet site, www.townhall.state.va.us or requested from the Board for Barbers and Cosmetology.

   Public Comments may be submitted to the Board until September 27, 2002. A Public Hearing is scheduled on September 10, 2002, 9:30 a.m., at the Department of Professional and Occupational Regulation, 3600 West Broad Street, Richmond, VA, 23230.

4. **Wax Technician Regulations:** The Board for Barbers and Cosmetology is promulgating Wax Technician Regulations governing the licensure and practice of waxing as directed by Acts 2002, c. 797. These regulations will establish the licensing requirements and applicable fees for individuals, salons, instructors, and schools offering waxing services.

   Public Comments may be submitted to the Board until September 25, 2002.

5. **Tattooing and Body-piercing Regulations:** The Board for Barbers and Cosmetology is promulgating Tattooing and Body-piercing Regulations governing the licensure and practice of tattooing and body-piercing as directed by Acts 2002, c. 869. These Regulations will establish the licensing requirements and applicable fees for individuals, salons, instructors, and schools offering tattooing and body-piercing services or training programs.

   Public Comments may be submitted to the Board until September 25, 2002.

6. **Board for Professional and Occupational Regulation Estheticians Study:** The Board for Professional and Occupational Regulation within the Department of Professional and Occupational Regulation is conducting a study to examine the appropriateness of regulating estheticians in Virginia.

   Public Hearings are scheduled for the following dates and locations:

   September 20, 2002, 1:30 p.m.
   Newport News City Council Chamber
   City Hall Building
   2400 Washington Avenue
   Newport News, Virginia 23607

   September 23, 2002, 1:30 p.m.
   Department of Professional and Occupational Regulation
   3600 West Broad Street
   Richmond, Virginia 23230

   October 4, 2002, 10:00 a.m.
   Roanoke City Council Chamber
   Noel C. Taylor Municipal Building
   215 Church Avenue SW
   Roanoke, Virginia 24011

7. **Board for Professional and Occupational Regulation Electrologists Study:** The Board for Professional and Occupational Regulation within the Department of Professional and Occupational Regulation is conducting a study to examine the appropriateness of regulating electrologists in Virginia.

   Public Hearings are scheduled for the same dates and locations listed for estheticians in number 6 on previous page.

You may submit comments to the Board for Barbers and Cosmetology by:

Mail	3600 West Broad Street Richmond, Virginia 23230
E-mail	barbercosmo@dpor.state.va.us
FAX:	804-367-9265

Public Hearing
We want to hear from YOU!

The Department of Professional and Occupational Regulation (DPOR), in collaboration with the Department of Health Professions (DHP), is conducting a study to examine the appropriateness of regulating estheticians and electrologists in Virginia.

Public Hearings are scheduled for the following dates and locations:

September 20, 2002, 1:30 p.m.
Newport News City Council Chamber
City Hall Building
2400 Washington Avenue
Newport News, Virginia 23607

September 23, 2002, 1:30 p.m.
Department of Professional and Occupational Regulation
3600 West Broad Street
Richmond, Virginia 23230

October 4, 2002, 10:00 a.m.
Roanoke City Council Chamber
Noel C. Taylor Municipal Building
215 Church Avenue SW
Roanoke, Virginia 24011

Appointments are not required. If you prefer to provide written comments, they may be sent to: Department of Professional and Occupational Regulation, 3600 W. Broad St., Richmond, Virginia, 23230; ATTN: Board for Cosmetology. Persons desiring to attend a meeting and requiring special accommodations/interpretive services should contact DPOR at (804) 367-8590/TDD (804) 367-9753 as soon as possible so that suitable arrangements can be made. DPOR fully complies with the Americans with Disabilities Act.

APPENDIX B

OSHA

OSHA MANUAL

ON

BLOODBORNE

PATHOGENS

OSHA MANUAL
ON BLOODBORNE PATHOGENS

OSHA MANUAL ON BLOODBORNE PATHOGENS

Publisher: Paramedical Consultants, Inc.
Susanne S. Warfield, President

1998 EDITION

Revision Information Provided By:

Dame Practice Management
Health Care Consultants
3853 Serubi Avenue
Lake Worth, FL 33461-4021
(561) 967-6565
(561) 967-7885 fax

Printed in the United States.

Paramedical Consultants, Inc.
40 Dean Street
Glen Rock, NJ 07452-1409
(201) 670-4100
(201) 670-4265 Fax
www.pcijournal.com

Table of Contents

PAGE

INTRODUCTION

The Occupational Safety and Health Act (OSHA) of 1970 (29 U.S.C. 651 ET SEQ) was created within the U.S. Department of Labor to encourage employers and employees to implement safer work and health practices in an effort to reduce on the job hazards. The Act also requires the development and implementation of training programs to increase competency of safety and health personnel. Mandatory provisions are evaluated through analysis and are continually redefined to more specific standards, as proves necessary over time.

The purpose of the Act is...to assure so far as possible every working man and woman in the Nation safe and healthful working conditions and to preserve our human resources." It is OSHA's responsibility to see that working conditions meet standards established by the Occupational Safety and Health Act. This extends to all employers and employees in the 50 states, the District of Columbia, Puerto Rico and all other territories under federal government jurisdiction.

An employer, as defined by the act, is "any person engaged in a business affecting commerce who has employees, but does not include the United States or any state or political subdivision of a state. The act does not cover self-employed persons; farms at which only immediate members of the farm employer's are employed; and working conditions regulated by other federal agencies under other federal statutes."

PURPOSE OF THE BLOODBORNE PATHOGEN ACT

In 1983, OSHA issued a set of voluntary guidelines designed to reduce the occupational risk or exposure to the Hepatitis B Virus (HBV). The voluntary guidelines, which were sent to employers in the healthcare industry, included a description of the disease, recommended work practices and recommendations for use of immune globulins and the Hepatitis B vaccine.

On November 27, 1987, OSHA published in the *Federal Register* an ANPR announcing the initiation of the rule-making process. On March 6,1992, they issued new regulations on the protection of employees from infection with bloodborne pathogens.

Although there were various compliance dates, the exposure control plans were required by May 5, 1992 and came into effect on July 6, 1992. These legally enforceable standards for workplace safety authorizes OSHA to conduct workplace inspections. After presenting proper credentials, an OSHA compliance officer (industrial hygienist) can enter any "workplace, or environment, where work is performed by an employee of an employer." Most inspections are conducted without advance notice and any and all findings will be cited and penalties for noncompliance will be imposed on the employer. It is through this system of inspection and issuance of citation and fines that OSHA ensures compliance with the Occupational Safety and Health Act and other standards.

UNIVERSAL PRECAUTIONS

"Universal Precautions" is the name for the Center for Disease Control's recommended policy for workers regarding blood and body fluids.

The general rule is to protect yourself from the transmission of bloodborne pathogens:

Wear gloves and other protective barriers to reduce the risk of exposure. HBV and HIV and other infectious diseases are spread by direct contact through skin or mucous membranes. Preexisting lesions on hands or from injuries incurred at the workplace, at home or from dermatitis may provide a route of entry.

HEPATITIS B VACCINATION

The recommendations of the Immunization Practices Advisory Committee, *Protection Against Viral Hepatitis*, published by the U.S. Public Health Services in 1990, support the OSHA recommendations that, "persons at substantial risk of HBV who are demonstrated or judged likely to be susceptible should be vaccinated."

Exposure determination must be based on the definition of occupational exposure **without regard to personal protective clothing and equipment.** The exposure determination is made by reviewing job classifications and listing exposures.

Employers must make the Hepatitis B vaccine available to all employees within 10 working days of initial assignment where they may have occupational exposure. [1]A Healthcare Professional (MDRN) must evaluate the employee for contradictions of administering the HBV prior to vaccination. This must be well documented in their employee file. Post-exposure evaluation and follow up: employees who experience an exposure incident must be provided and documented.

[2]All vaccinated employee's must have surface antibodies drawn (HBsAb) to ensure coverage from the vaccine. This result must be part of their employee personnel file. Employee's refusing to receive vaccine may change their mind at anytime and reconsider. At which time the employer is responsible to provide vaccination.

An employer is **not** required to make the Hepatitis B vaccine available if;

(1) the employee has been previously vaccinated,
(2) an employee is already immune according to antibody testing or,
(3) when the vaccine is contraindicated due to medical reasons,
(4) employee has no exposure risk.

If an employee for whatever reason chooses not to accept the vaccine, the following declination form (provided on page 10) must be signed and kept in the employees records. By far the best way of ensuring employee safety from Hepatitis B infection is by education of the employee about their occupational risk and the safety of having the vaccine. Through vaccination, the vast majority of employees will receive durable immunity to the virus.

1 Provided by Dame Practice Management.
2 Provided by Dame Practice Management.

POSTEXPOSURE EVALUATION AND FOLLOW-UP

All medical evaluations and procedures, including the vaccine and vaccination series, must be made available at no cost to the employee. These procedures must be available within a reasonable time and place and be performed by, or under the supervision of a licensed physician or other licensed health care professional.

The employer must also ensure that all laboratory tests are conducted at an accredited laboratory at no cost to the employee if an bloodborne incident or exposure occurs.

Documentation of the exposure incident in the employees chart must contain the following information;

(1) Document the route of entry and how it occurred,
(2) Identify and document the source or individual, if possible,
(3) Obtain confidential consent from both the individual source and employer to determine HIV or HBV infectivity,
(4) Provide the employee with serologic testing, if source individual is not available,
(5) Provide any necessary counseling and safe, effective postexposure prophylaxis accord ing to the U.S. Public Health Service guidelines.

A written evaluation must be provided to the exposed employee within 15 days of the exposure incident and must include documentation for postexposure evaluation and documentation that the employee has been informed of the results of the medical evaluation and that any medical conditions resulting from the exposure incident may require further evaluation or treatment.

[3]Employers must be aware of the fact that exposure incidents must be reported to Workers Compensation within 24 hours. Most workers compensation carriers require specific treatment for the exposed employee (i.e. go to specific doctor or clinic).

3 Provided by Dame Practice Management.

STERILIZATION AND DISINFECTION FOR THE SKIN CARE SPECIALIST

In the skin care industry, following strict sterilization techniques is important not only for our clients, but for our own protection.Every client must be treated as though they could be carrying some kind of infection. The most threatening agents are not even the most publicized, such as mycobacterium tuberculosis or the Hepatitis B virus. The implements used by a skin are specialist should be at best disposable æ one-time use items. These would include facial sponges/cloths, extraction tissue/cotton, brushes, lancets and gloves.

There is a distinct difference between sterilization and disinfection. Sterilization is the destruction of all forms of microbial life, in or about an object, by heat (steam or hot air), chemical sterilant (sodium hypochlorite, gluteraldehyde, phenolic, idophor), or gas (ethylene oxide). Disinfection is the process that eliminates many pathogenic microorganisms on inanimate objects with the exception of bacterial spores.

The disposable combine roll is an inexpensive alternative to sponges/cloths and provides enough absorbency to clean and remove products. Lancets should be individually wrapped and sterile. Disposable gloves can be non-sterile and are available in three types. Latex gloves are composed of natural rubber derived from petroleum. This type of glove provides better touch accuracy, however, latex breaks down when exposed to cream and oil products. During the course of a facial treatment this type of glove will be compromised.

Vinyl or polyvinyl chloride (PVC) gloves provide optimum protection during the course of a facial treatment. Gloves must be worn throughout the facial treatment procedure in order to provide protection. Polyethylene gloves also provide optimum protection and tend to allow for better feel but are generally more costly.

The issue of creating a "latex-safe environment" is also of increasing importance, due to the increased signs of latex allergies. Current data suggest that about 10% of workers have latex-specific IgE antibodies in their bloodstream and another 2.5% already experience type I mediated allergic responses to the material. (Johns Hopkins Medical Institution Study). The availability of nonlatex materials–polyvinyl chloride, nitrile, neoprene, and other forms of synthetic rubber can block infectious pathogens as well as standard gloves. However, nitrile gloves have been shown to contain allergenic ingredients such as mercaptobenzothiazole, thiurams, and carbamates. For more information you can contact the Web site of the nonprofit ELASTIC Coalition, a latex allergy patient advocacy group at http://www.netcom.com/~nam1/latex_allergy.html.

The more expensive implements such as comedone extractors, epilating needles, tweezers, high frequency electrodes, and galvanic electrodes require following rigid guidelines to prevent contamination. (See Table A.1)

Providing an antiseptic environment does not stop here however. It should include countertops, machinery, chairs, magnifying lamps, and any other objects that you or your client may touch. To simplify the process of disinfecting these items, use only stainless steel bowls and hard, non-porous materials if possible. When it comes to gowns, towels, and sheets, it may be easier to use a laundry service. If you do, ask about their procedure and if they use a detergent with bleach. All laundry facilities are required by OSHA to follow proper washing procedures and a surcharge may be applied to your invoice.

The skin care specialist must also follow strict rules of hygiene, including washing their hands

every time they leave the client's face and touch another object. Wearing gloves outside of the treatment room is strictly prohibited. Upon removal of gloves, the employee must be provided with hand washing facility to immediately wash their hands, in case the gloves were compromised. An antibacterial soap can accomplish this level of sanitization. If you are suffering from a cold and are coughing, a face mask is mandatory. It should also be used when performing acne surgery(extractions) on a pilosebaceous client to protect yourself from accidentally getting fluids on your face.

In conclusion, it is evident that if the skin care specialist comes into contact with five mucous membranes, possible body fluids and blood. The following of strict sterilization procedures to prevent the spread of infectious agents is now law and not just a matter of good professional conduct. The Center for Disease Control in Atlanta, Georgia and your local OSHA office may be a source of continuous information to update these guidelines. Also please be aware the OSHA is a nationally governed act under the Department of Labor and these laws supersede any state cosmetology board guidelines.

METHODS OF STERILIZATION AND DISINFECTION

Classification of Object	Sterilization		Disinfection	
	Procedure	Time	Procedure	Time
1. Critical Objects				
Enters tissue or comes in contact with blood/body fluids	A	MR		
	B	MR		
	C*	MR		
	D	6 Hrs.		
Smooth, hard surface i.e., epilating needles, comedone extractors	E*	6 Hrs.		
2. Semi-critical Objects				
Comes in contact with mucous membranes or non-intact skin	A	MR		
	B	MR		
	C*	MR		
	D*	6 Hrs.		
	E*	6 Hrs.		
Smooth, hard surface l.e.,HF/Galvanic electrodes, tweezers	F*	30 min.		
	G*	20 min.		
3. Non-critical Objects				
Could come into contact with intact skin			G*	
			I*	
			J*	
			K*	
Smooth, hard surface i.e., countertops, machine, magnifying loop			L*	

Modified from Rutolo, Washington, Guidelines for Infection Control Practice, Association for Practitioners in Infection Control, Inc. January 1990.

KEY TO STERILIZATION AND DISINFECTION METHODS

A Heat sterilization (steam or hot air æ see manufacturer's recommendations)

B Ethylene oxide gas (see manufacturer's recommendations)

C Glutaraldehyde-based formulations (2 percent),used at full strength has been shown to sterilize items if they are soaked for about seven hours.

D Demand-release chlorine dioxide. Will corrode aluminum, copper, brass, series 400 stainless steel, and chrome with prolonged exposure.

E Stabilized hydrogen peroxide 6 percent. Will corrode copper, zinc, and brass.

F Wet pasteurization at 75 degrees Centigrade for 30 minutes after detergent cleansing.

G Sodium hypochlorite (1,000 ppm available chlorine). Will corrode metal instruments.

H Ethyl or Isopropyl alcohol (70 to 90 percents)

I Sodium Hypochlorite (100 ppm available chlorine)

J Phenolic germicidal detergent solution (follow manufacturer's recommendations)

K Iodophor germicidal detergent solution (follow manufacturer's recommendations)

L Quatemary ammonium germicidal detergent solution (follow manufacturer's recommen dations)

**Note: Scientific literature has been used to augment the manufacturer's label claims because these claims are not consistently verifiable. Variations in chemical sterilant efficacy is evident when subjected to conditions such as dilution age, temperature, pH, and the presence of organic matter. The Environmental Protection Agency registration claims are based only on efficacy data submitted by the manufacturer. Post-registration efficacy testing is not performed by the EPA.*

A HEAT STERILIZATION

Dual purpose autoclaves/sterilizers can be used for steam or dry heat. Requires distilled water to operate, depending on manufacturer's recommendations. Takes approximately 30 minutes to sterilize. Only for use with hard, non-porous implements, it has a tendency to dull sharp points.

B ETHYLENE OXIDE GAS STERILIZATION

Ideal for porous or difficult to clean, narrow, channeled implements. Refer to manufacturer's recommendations for operation and sterilization time.

C GLUTARALDEHYDE-BASED FORMULATIONS - (2 PERCENT)

Lower percentages of glutaraldehyde phenate are no longer considered high level disinfectants and must be used at 2 percent. Time requirements have also been updated by the Center for Disease Control to 20 minutes for disinfection. Once activated by alkaline solution, it has a limited shelf life of 14 days.

[4]Gluteraldehyde products (i.e. CidexPlus) have a shelf life of 28 days. You must verify efficacy with gluteraldehyde test strips.

D DEMAND-RELEASE CHLORINE DIOXIDE

A relatively new sterilant which sterilizes after six hours. Refer to manufacturer's recommendations for restrictions and directions.

E STABILIZED HYDROGEN PEROXIDE - (6 PERCENT)

Scientific literature contains limited accounts of the properties of hydrogen peroxide, although it has been found to be antibacterial, anti-viral, anti-sporicidal, and anti-fungal. Commercially available 3 percent hydrogen peroxide is a stable and effective disinfectant when used on inanimate surfaces.

F WET PASTEURIZATION

Some scientific data challenges the efficacy of this method of disinfection and doesn't consider it for high level use.

G SODIUM HYPOCHLORITE

Sodium hypochlorite, or household bleach has a broad spectrum of antimicrobial activity and is inexpensive and fast-acting (20 minutes). Unfortunately its use is limited due to corrosiveness, inactivation by organic matter and instability. Chlorine stability is dependent on pH, and as the pH rises due to prolonged shelf life so the number of hypochlorite ions, which reduce the anti-microbial efficiency. Alternative compounds that release chlorine and have more stability are demand-release chlorine dioxide and Chloramine-T.

H ETHYL OR ISOPROPYL ALCOHOL (70 - 90 PERCENT)

These alcohols are rapidly anti-bacterial, anti-tuberculous, anti-fungal, and anti-viral, but they do not destroy bacterial spores. Not recommended for high-level disinfection because of their inability to inactivate bacterial spores and isopropyl's inability to inactivate hydrophilic viruses.

I SODIUM HYPOCHLORITE

Refer to G

4. Provided by Dame Practice Management.

J PHENOLIC GERMICIDAL DETERGENT SOLUTION

Phenol (carbolic acid) may be used with numerous other derivatives such as ortho-phenylphenol or ortho-benzyl-para-chlorophenol. The CDC has deleted 3 percent phenolics and iodophors as high-level disinfectants due to their inactivity against bacterial spores, mycobacterium tuberculosis and fungi.

K IODOPHOR GERMICIDAL DETERGENT SOLUTION

Iodine solution or tinctures have long been used by health care professionals. The most widely used is povidone-iodine and is generally found to be free of skin irritation. However, antiseptic iodophors are not suitable as disinfectants due to their varying concentration difference. See above for CDC ruling.

L QUATERNARY AMMONIUM GERMICIDAL DETERGENT SOLUTION

Quaternaries that are sold as disinfectants are anti-fungal, antibacterial, and anti-viral against lipophilic viruses, but they are not anti-sporicidal, anti-tuberculous, or anti-viral against hydrophilic viruses. The CDC recommends quaternaries [5] be used only for ordinary environmental sanitation of non-critical surfaces such as floors, furniture and walls.

[5]All sterilization processes must be thoroughly documented. Documentation must be updated every two years.

5 Provided by Dame Practice Management.

ENGINEERING AND WORK CONTROL PRACTICES

Engineering and work practice controls are the primary methods used to prevent occupational transmission of HBV and HIV. Engineering controls reduce employee exposure in the workplace by either removing or isolating the hazard. These controls need to be examined and maintained on a regular schedule to ensure their effectiveness. Proper work controls alter the manner in which a task is performed. This would include the restriction of eating, drinking, smoking, applying cosmetics or lip balms, and handling of contact lenses around work areas. The storage of food and/or drink in refrigerators or other locations of possible infectivity need also be monitored.

Employees are required to wash their hands immediately or as soon as feasible after removal of gloves or other protective equipment as well as when there has been possible contact with a potentially infectious material. Hand washing facilities must therefore be accessible to all employees in order for safe and proper performance of their tasks.

Equipment should also be routinely checked which might have become contaminated with blood or potentially infectious materials and decontaminated. Equipment in need of repair, should also be checked and, if necessary, decontaminated prior to servicing or shipping.

"Contaminated sharps" (means any contaminated object that may have come in contact with a bloodborne pathogen) must be disposed of in the proper fashion, as regulated. A sharps container must be used for any objects that can penetrate the skin, including but not limited to, broken glass, needles and lancets. The Environmental Protection Agency (EPA), in its standards for the tracking and management of hazardous waste, has a much broader definition of sharps, but OSHA deals with the concern of the presence of potentially infectious materials.

PERSONAL PROTECTIVE EQUIPMENT

Personal protective equipment must be used if exposure to bloodborne pathogens is a possibility even after instituting engineering and work practice controls, or if those controls are not feasible.

An employer is required to provide and ensure that an employee uses appropriate personal protective equipment when there is a risk of occupational exposure.

"Appropriate personal protective equipment means that the equipment does not permit blood or other potentially infectious materials to pass through or reach the employee's work clothes, street clothes, undergarments, hands(skin), eyes, mouth or other mucous membranes under normal conditions of use and for the duration of time when the protective equipment will be used."

Personal protective equipment that must be provided includes, but is not limited to, gloves, fluid resistant gowns, laboratory coats, face shield or mask and eye protection. Appropriate sizes must be accessible at the work site or issued to employees at no cost to the employees.

Hypoallergenic gloves or a similar alternative must be made available to any employees who are allergic to the gloves normally provided. If the employee's responsibility is to provide cleaning, laundering or disposal of contaminated material, the employer must provide the appropriate protective clothing for this task.

Also, all protective equipment must be removed before an employee leaves a work area and should be placed in an appropriate container or area for storage, washing, decontaminating or disposal.

[6]Please note that employees performing decontaminating of surgical instruments must wear eye protection/face mask or full face shield, fluid resistant gown that comes down to waist (fully covers clothing/arms) and utility gloves must be worn. Employee non-compliance must be fully documented.

6 Provided by Dame Practice Management.

HOUSEKEEPING

The OSHA Standard on Bloodborne Pathogens requires each employer to assure that the workplace is maintained in a clean and sanitary condition. The employer must determine and implement a written schedule for cleaning and provide methods of decontamination. The method is based upon the location, type of surface to be cleaned, type of soil present and the tasks and procedures being carried out in the work area. A checklist of housekeeping chores should be maintained at each work site and completed at the end of each work shift.

Sample Checklist

_____ All work surfaces have been cleaned with an appropriate disinfectant.

_____ Protective coverings on equipment have been replaced such as plastic wrap, or aluminum foil.

_____ All bins, pails or other receptacles intended for reuse have been properly disinfected.

_____ All handling of laundry is done as if it is potentially contaminated.

_____ All contaminated sharps have been properly disposed of in a sharps container.

LABELING

The standard requires that fluorescent orange or orange-red warning labels be attached to containers of regulated waste. The BIOHAZARD label must be in a contrasting color and be attached to the container to prevent unintentional removal.

A regulated waste container such as a sharps container requires a red container as well as a Biohazard label. Reusable contaminated sharps container such as a sterilizing tray also requires use of a Biohazard label.

[7]Corrugated boxes/red bags (not removed daily) must also be labeled with name and address of facility as well as dated when the first piece of waste is disposed. All paper/gauze products must be removed off- site within 30 days.

[8]The sharp box label must also include the above, however, a date is not warranted unless paper gauze products are in the box. Sharp boxes may be used till 3/4 full as long as there's no paper. It's not cost effective to place paper in sharp boxes.

7. Provided by Dame Practice Management.
8. Provided by Dame Practice Management.

RECORDKEEPING

Employers must preserve and maintain for each employee an accurate record of occupational exposure, Title 29 Code of Federal Regulations, Part 1910.20.

The Bloodborne Pathogens Standard also requires employers to maintain and to keep accurate training records on each employee at risk of occupational exposure.

These records should include;

(1) Dates of training and by whom, must be maintained every 3 years;

(2) Summary of OSHA Regulations for Bloodborne Pathogens,

(3) Epidemiology and Symptoms of Bloodborne Diseases,

(4) Modes of Transmission of Bloodborne Pathogens,

(5) Exposure Control Plans,

(6) HBV Vaccination Form/ Declination,

(7) Occupational Exposure including Postexposure Evaluation and Follow-Up,

(8) OSHA Publications,

(9) [9]Your Exposure Plan of Action.

9. Provided by Dame Practice Management.

OSHA CONSULTATION PROJECT DIRECTORY

Consultation programs provide free services to employers who request information on identifying hazards or want to improve their safety programs and/or need further assistance in training and education. Funded by OSHA and administered by well-trained professional staff of state governments, consultation services are comprehensive and include an appraisal of all workplace hazards, practices, job safety and health programs; conferences and agreements with management assistance in implementing recommendations and a follow up appraisal to ensure that any required corrections are made.

For more information on consultation programs, contact the appropriate office in your state.

**Please note that the above consultation program does not guarantee that you will not be fined for noncompliance.

For more information on risk management, you may contact: Dame Practice Management Health Care Consultants, (561) 967-6565 or fax (561) 967-7885.

STATES WITH APPROVED PLANS

ALASKA
Alaska Department of Labor

Business Address:
1111 West Eighth Street
Juneau, AK 99801
(907) 465-4855

Mailing Address:
PO. Box 21149
Juneau, AK 99802

ARIZONA
Industrial Commission of Arizona

Business Address:
800 W Washington
Phoenix, AZ 85007
(602) 542-5795

Mailing Address:
P.O. Box 19070
Phoenix, AZ 85005-9070

CALIFORNIA
California Department of Industrial Relations
1390 Market Street
Room 718
San Francisco, CA 94102
(415) 557-8640

CONNECTICUT
Connecticut Department of Labor

Business Address:
38 Wolcott Hill Road
Wethersfield, CT 06109
(860) 566-4550

Mailing Address:
200 Folly Brook Blvd.
Wethersfield, CT 06109-

HAWAII
Hawaii Department of Labor and Industrial Relations
830 Punchbowl Street
Room 423
Honolulu, HI 96813
(808) 586-9100

INDIANA
Indiana Department of Labor
402 West Washington Street
Indianapolis, IN 46204-2751
(317) 232-2665

IOWA
Iowa Division of Labor Services
1000 E. Grand Avenue
Des Moines, IA 50319
(515) 281-3447

KENTUCKY
Commissioner for Workplace Standards
Kentucky Labor Cabinet
1047 U.S. Highway 127 South
Frankfort, KY 40601-4381
(502) 564-3070

MARYLAND
Maryland Division of Labor
Department of Licensing and Regulation
312 Marshall Avenue,
Laurel, MD 20707
(301) 483-8406

MICHIGAN
Michigan Department of Safety and Regulation
State Secondary Complex
P.O. Box 30643
Lansing, MI 48909-8143
(517) 322-1814

MINNESOTA
Minnesota Department of Labor and Industry
443 Lafayette Road
St. Paul, MN 55155
(612) 296-2342

NEVADA
Nevada Department of Industrial Relations
Division of Occupational Safety and Health
Capitol Complex
400 West King Street
Carson City, NV 89710
(702) 687-3032

NEW MEXICO
New Mexico Environment Department
Occupational Health and Safety Bureau
1 Civic Plaza Northwest
Albuquerque, NM 87103
(505) 768-4510

NEW YORK
New York Department of Labor
State Campus Building 12
Albany, NY 12240
(518) 457-2741

NORTH CAROLINA
North Carolina Department of Labor
319 Chapanoke Road
Suite 105
Raleigh, NC 27603
(919) 733-7426

OREGON
Oregon Occupational Safety and Health Administration
Department of Consumer and Business Services
530 Winter Street N. E.
Room 430
Salem OR 97310
(503) 378-3272

PUERTO RICO
Puerto Rico Department of Labor and Human Resources
Prudencio Rivera
Martinez Building
505 Munoz Rivera Avenue
Hata Rey, PR 00918
(809) 754-2119

SOUTH CAROLINA
South Carolina Department of Labor
3600 Forest Drive
P.O. Box 11329
Columbia. SC 29211-1329
(803) 734-9606

TENNESSEE
Tennessee Department of Labor
710 James Robertson Parkway
Andrew Johnson Tower, 3rd Floor
Nashville, TN 37243-0659
(615) 741-2582

UTAH
Utah Occupational Safety and Health Administration
1781 South 300 West
Salt Lake City, UT 84115-1802
(801) 487-0267

VERMONT
Vermont Department of Labor and Industry
National Life Insurance Building
Drawer 20
Montpelier, VT 05620-3401
(802)828-2765

VIRGIN ISLANDS
Virgin Islands Department of Labor
2131 Hospital Street, Box 890
Christiansted
St. Croix, VI 00840-4666
(809) 773-1994

VIRGINIA
Virginia Department of Labor and Industry
Occupational Safety and Health Administration
Powers-Taylor Building
13 S. 13th Street
Richmond, VA 23219-4101
(804) 786-8707

WASHINGTON
Washington Safety and Health Act
300 West Harrison Street Room 301
Seattle, WA 98119-4081
(206) 281-5470

WYOMING
Department of Employment
Division of Employment Affairs
Occupational Safety and Health Administration
Herschler Building 2nd Floor East
122 West 25th Street
Cheyenne, WY 82002
(307) 777-7786

ADDITIONAL PUBLICATIONS

A single free copy of the following material may be obtained from OSHA Field Offices or the OSHA Publications Office, 200 Constitution Avenue, N.W., Room N3101, Washington, DC 20210, (202) 219-4667. Enclose a self-addressed label with request.

OSHA 2056 - All about OSHA

OSHA 3021 - Employee Workplace Rights
OSHA 3047 - Personal Protective Equipment
OSHA 3088 - How to Prepare for Workplace Emergencies
OSHA 3110 - Access to Medical and Exposure Records

Other available publications are subject to fees and checks are to be made payable to the Superintendent of Documents. The Government Printing Office gives a 25% discount for orders of 100 or more copies. Credit cards; Visa and MasterCard are accepted.

Chemical Hazard Communication Guidelines (OSHA 3111)
Order No. 029-016-00127. Cost $1.00

Ergonomics: The Study of Work (OSHA 3125)
Order No. 029-016-00124-7. Cost $1.00

GLOSSARY

A

B

Biohazard
A danger to life.

Bloodborne Pathogen
Pathogenic microorganism that is present in human blood and that can infect and cause disease in persons who are exposed to blood containing such pathogens, including, but not limited to, HBV and the human immunodeficiency virus (HIV).

C

Compliance
To act in accordance with.

Contaminated
The presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

Contaminated Laundry
Laundry which has been soiled with blood or other potentially infectious material and may contain sharps.

Contaminated Sharps
Any contaminated object that can penetrate the skin, including, but not limited to, needles, scalpels, broken glass and lancets.

D

Decontamination
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.

E

Efficacy
Effectiveness.

Engineering Controls
Controls (e.g., sharps disposal containers) that isolate or remove the bloodborne pathogens hazard from the workplace.

Epidemiology
The study of the relationships of the various factors determining the frequency, distribution and causation of disease in a human community.

Exposure Control Plan
A plan designed to minimize or reduce employee exposure to bloodborne pathogens and other infectious materials.

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

H

HBV
Hepatitis B virus.

HIV
Human immunodeficiency virus.

Hand Washing Facilities
A facility providing an adequate supply of running potable water, soap and single-use towels or hot drying machines.

N

NIOSH
National Institute for Occupational Safety and Health, U.S. Department of Health and Human Services.

O

Occupational Exposure
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.

OSHA
Occupational Safety and Health Administration.

P

Parenteral
Piercing mucous membranes or the skin barrier through such events as needle sticks, human bites, cuts and abrasions.

Personal Protective Equipment
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.

Prophylaxis
A measure to prevent or protect from disease.

R

Regulated Waste
Liquid or semi-liquid blood or other potentially infectious material; contaminated items that would release blood or other potentially infectious material; contaminated sharps; and pathological and microbiological wastes containing blood or other potentially infectious material.

S

Source Individual
Any individual, living or dead, whose blood or other potentially infectious material may be a source of occupational exposure to an employee.

Sterile
The use of a physical or chemical procedure to destroy all microbial life, including highly resistant bacterial endospores.

U

Universal Precautions
An approach to infection control whereby all human blood and certain human body fluids are treated as if known to be infectious for HIV, HBV and other bloodborne pathogens.

V

Vaccination Declination
The right of an employee to refuse vaccination for HBV.

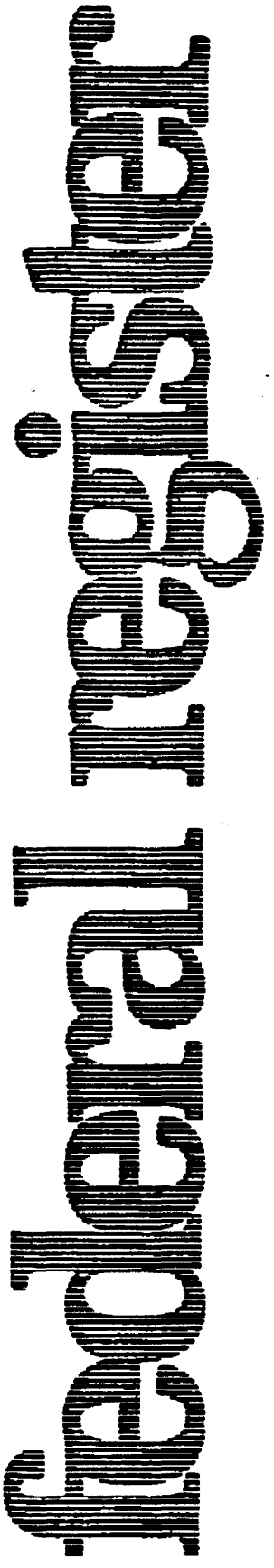
Vaccine
Any preparation of killed microorganisms, living weakened organisms, etc., introduced into the body to produce immunity to a specific disease by causing antibodies to be formed.

W

Work Practice Controls
Controls that reduce the likelihood of exposure by altering the manner in which a task is performed.

REFERENCES

1. *Federal Registrar* 56(235):64175, December 6,1991



Friday
December 6, 1991

Part II (Excerpts)

Pages 64175 thru 64182

Department of Labor

Occupational Safety and Health Administration

29 CFR Part 1910.1030

Occupational Exposure to Bloodborne Pathogens; Final Rule

XI. The Standard

General Industry

Part 1910 of title 29 of the Code of Federal Regulations is amended as follows:

PART 1910—[AMENDED]

Subpart Z—[Amended]

1. The general authority citation for subpart Z of 29 CFR part 1910 continues to read as follows and a new citation for § 1910.1030 is added:

Authority: Secs. 6 and 8, Occupational Safety and Health Act, 29 U.S.C. 655, 657, Secretary of Labor's Orders Nos. 12–71 [36 FR 8754], 8–76 [41 FR 25059], or 9–83 [48 FR 35736], as applicable; and 29 CFR part 1911.

* * * * *

Section 1910.1030 also issued under 29 U.S.C. 653.

* * * * *

2. Section 1910.1030 is added to read as follows:

§ 1910.1030 Bloodborne Pathogens.

(a) *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.

(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) 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.

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.

[illegible] HIV or HBV research [illegible] HIV or HBV [illegible] [illegible] means conducting the [illegible]

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.

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).

(c) *Exposure control*—(1) *Exposure Control Plan.* (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 [illegible]

eliminate or minimize employee exposure.

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

(A) The exposure determination required by paragraph(c)(2).

(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

(C) The procedure for the evaluation of circumstances surrounding exposure incidents as required by paragraph (f)(3)(i) of this standard.

(iii) Each employer shall ensure that a copy of the Exposure Control Plan is accessible to employees in accordance with 29 CFR 1910.20(e).

(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.

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

(2) *Exposure determination.* (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:

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

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

(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.

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

(d) *Methods of compliance*—(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.

(2) *Engineering and work practice controls.* (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.

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

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

(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.

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

(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.

(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.

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

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

(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:

(A) Puncture resistant;

(B) Labeled or color-coded in accordance with this standard;

(C) Leakproof on the sides and bottom; and

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

(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.

(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.

(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.

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

(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.

(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.

(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.

(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.

(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.

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

(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.

(3) Personal protective equipment—(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.

(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 occurences in the future.

(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.

(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.

(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.

(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.

(vii) All personal protective equipment shall be removed prior to leaving the work area.

(viii) When personal protective equipment is removed it shall be placed in an appropriately designated area or container for storage, washing, decontamination or disposal.

(ix) 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.

(A) 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.

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

(C) 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.

(D) 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

(*4*) Require that gloves be used for phlebotomy in the following circumstances:

(*i*) When the employee has cuts, scratches, or other breaks in his or her skin;

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

(*iii*) When the employee is receiving training in phlebotomy.

(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.

(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.

(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).

(4) *Housekeeping.* (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.

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

(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.

(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.

(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.

(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.

(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.

(iii) Regulated Waste.

(A) Contaminated Sharps Discarding and Containment. (*1*) Contaminated sharps shall be discarded immediately or as soon as feasible in containers that are:

(*i*) Closable;

(*ii*) Puncture resistant;

(*iii*) Leakproof on sides and bottom; and

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

(*2*) During use, containers for contaminated sharps shall be:

(*i*) 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);

(*ii*) Maintained upright throughout use; and

(*iii*) Replaced routinely and not be allowed to overfill.

(*3*) When moving containers of contaminated sharps from the area of use, the containers shall be:

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

(*ii*) Placed in a secondary container if leakage is possible. The second container shall be:

(*A*) Closable;

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

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

(*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.

(B) Other Regulated Waste Containment.(*1*) Regulated waste shall be placed in containers which are:

(*i*) Closable;

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

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

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

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

(*i*) Closable;

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

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

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

(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.

(iv) Laundry.

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

(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.

(3) 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.

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

(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).

(e) *HIV and HBV Research Laboratories and Production Facilities.* (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.

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

(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.

(ii) Special practices.

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

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(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.

(L) A spill or accident that results in an exposure incident shall be immediately reported to the laboratory director or other responsible person.

(M) 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.

(iii) Containment equipment. (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.

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

(3) HIV and HBV research laboratories shall meet the following criteria:

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

(ii) An autoclave for decontamination of regulated waste shall be available.

(4) HIV and HBV production facilities shall meet the following criteria:

(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.

(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.

(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.

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

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

(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).

(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).

(f) *Hepatitis B vaccination and post-exposure evaluation and follow-up—(1) General.* (i) 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.

(ii) 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:

(A) Made available at no cost to the employee:

(B) Made available to the employee at a reasonable time and place:

(C) Performed by or under the supervision of a licensed physician or by or under the supervision of another licensed healthcare professional: and

(D) 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).

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

(2) *Hepatitis B Vaccination.* (i) 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.

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

(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.

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

(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).

(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:

(i) Documentation of the route(s) of exposure. and the circumstances under which the exposure incident occurred:

(ii) Identification and documentation of the source individual. unless the employer can establish that identification is infeasible or prohibited by state or local law:

(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.

(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.

(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.

(iii) Collection and testing of blood for HBV and HIV serological status:

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

(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.

(iv) Post-exposure prophylaxis, when medically indicated, as recommended by the U.S. Public Health Service:

(v) Counseling; and

(vi) Evaluation of reported illnesses.

(4) *Information Provided to the Healthcare Professional.* (i) The employer shall ensure that the healthcare professional responsible for the employee's Hepatitis B vaccination is provided a copy of this regulation.

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

(A) A copy of this regulation;

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

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

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

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

(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.

(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.

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

(A) That the employee has been informed of the results of the evaluation; and

(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.

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

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

(g) *Communication of hazards to employees*— (1) *Labels and signs.* (i) Labels. (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).

(B) Labels required by this section shall include the following legend:

BIOHAZARD

BIOHAZARD

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

(D) Labels required by affixed as close as feasible to the container by string, wire, adhesive, or other method that prevents their loss or unintentional removal.

(E) Red bags or red containers may be substituted for labels.

(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).

(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.

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

(I) Regulated waste that has been decontaminated need not be labeled or color-coded.

(ii) Signs. (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:

BIOHAZARD

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

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

(2) *Information and Training.* (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.

(ii) Training shall be provided as follows:

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

(B) Within 90 days after the effective date of the standard; and

(C) At least annually thereafter.

(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.

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

(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.

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

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

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

(B) A general explanation of the epidemiology and symptoms of bloodborne diseases;

(C) An explanation of the modes of transmission of bloodborne pathogens;

(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;

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

(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;

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

(H) An explanation of the basis for selection of personal protective equipment;

(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;

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

(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;

(L) Information on the post-exposure evaluation and follow-up that the employer is required to provide for the employee following an exposure incident;

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

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

(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.

(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.

(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.

(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.

(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.

(h) *Recordkeeping—(1) Medical Records.* (i) The employer shall establish and maintain an accurate record for each employee with occupational exposure, in accordance with 29 CFR 1910.20.

(ii) This record shall include:

(A) The name and social security number of the employee;

(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);

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

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

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

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

(A) Kept confidential; and

(B) Are 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.

(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 1910.20.

(2) *Training Records. (i) Training records shall include the following information:*

(A) The dates of the training sessions;

(B) The contents or a summary of the training sessions;

(C) The names and qualifications of persons conducting the training; and

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

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

(3) *Availability.* (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.

(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 in accordance with 29 CFR 1910.20.

(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 1910.20.

(4) *Transfer of Records.* (i) The employer shall comply with the requirements involving transfer of records set forth in 29 CFR 1910.20(h).

(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.

(i) *Dates—(1) Effective Date.* The standard shall become effective on March 6, 1992.

(2) The Exposure Control Plan required by paragraph (c)(2) of this section shall be completed on or before May 5, 1992.

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

(4) Paragraphs (d)(2) Engineering and Work Practice Controls, (d)(3) Personal Protective Equipment, (d)(4) Housekeeping, (e) HIV and HBV Research Laboratories and Production Facilities, (f) Hepatitis B Vaccination and Post-Exposure Evaluation and Follow-up, and (g) (1) Labels and Signs, shall take effect July 6, 1992.

Appendix A to Section 1910.1030—Hepatitis B Vaccine Declination (Mandatory)

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 vaccine series at no charge to me.

[FR Doc. 91-28886 Filed 12-3-91; 8:45 am]

BILLING CODE 4510-26-M

U.S. Department of Labor
Program Highlights

Fact Sheet No. OSHA 92-46

Bloodborne Pathogens Final Standard: Summary of Key Provisions

PURPOSE: 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 handwashing 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. Gloves are not necessarily required for routine phlebotomies in volunteer blood donation centers but must be made available to employees who want them.

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.

HIV AND HBV RESEARCH LABORATORIES AND PRODUCTION FACILITIES: Calls for these facilities to follow standard microbiological practices and specifies additional practices intended to minimize exposures of employees working with concentrated viruses and reduce the risk of accidental exposure for other employees at the facility. These facilities must include required containment equipment and an autoclave for decontamination of regulated waste and must be constructed to limit risks and enable easy clean up. Additional training and experience requirements apply to workers in these facilities.

HEPATITIS B VACCINATION: 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 which 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 labelled. 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: Mandates training within 90 days of 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.

DATES: Effective date: March 6, 1992. Exposure control plan: May 5, 1992. Information and training requirements and recordkeeping: June 4, 1992. And the following other provisions take effect on July 6, 1992: engineering and work practice controls, personal protective equipment, housekeeping, special provisions covering HIV and HBV research laboratories and production facilities, hepatitis B vaccination and post-exposure evaluation and follow-up and labels and signs.

# # #

U.S. Department of Labor
Program Highlights

Fact Sheet No. OSHA 83-26

HAZARD COMMUNICATION STANDARD

SUMMARY

Protection under OSHA's Hazard Communication Standard (HCS) includes all workers exposed to hazardous chemicals in all industrial sectors. This standard is based on a simple concept - that employees have both a need and a right to know the hazards and the identities of the chemicals they are exposed to when working. They also need to know what protective measures are available to prevent adverse effects from occurring.

SCOPE OF COVERAGE

More than 30 million workers are potentially exposed to one or more chemical hazards. There are an estimated 650,000 existing hazardous chemical products, and hundreds of new ones are being introduced annually. This poses a serious problem for exposed workers and their employers.

BENEFITS

The HCS covers both physical hazards (such as flammability or the potential for explosions), and health hazards (including both acute and chronic effects). By making information available to employers and employees about these hazards, and recommended precautions for safe use, proper implementation of the HCS will result in a reduction of illnesses and injuries caused by chemicals. Employers will have the information they need to design an appropriate protective program. Employees will be better able to participate in these programs effectively when they understand the hazards involved, and to take steps to protect themselves. Together, these employer and employee actions will prevent the occurrence of adverse effects caused by the use of chemicals in the workplace.

REQUIREMENTS

The HCS established uniform requirements to make sure that the hazards of all chemicals imported into, produced, or used in U.S. workplaces are evaluated and that this hazard information is transmitted to affected employers and exposed employees.

Chemical manufacturers and importers must convey the hazard information they learn from their evaluations to downstream employers by means of labels on containers and material safety data sheets (MSDS's). In addition, all covered employers must have a hazard communication program to get this information to their employees through labels on containers, MSDS's, and training.

This program ensures that all employers receive the information they need to inform and train their employees properly and to design and put in place employee protection programs. It also provides necessary hazard information to employees so they can participate in, and support, the protective measures in place at their workplaces.

All employers in addition to those in manufacturing and importing are responsible for informing and training workers about the hazards in their workplaces, retaining warning labels, and making available MSDS's with hazardous chemicals.

Some employees deal with chemicals in sealed containers under normal conditions of use (such as in the retail trades, warehousing and truck and marine cargo handling). Employers of these employees must assure that labels affixed to incoming containers of hazardous chemicals are kept in place. They must maintain and provide access to MSDS's received, or

obtain MSDS's if requested by an employee. And they must train workers on what to do in the event of a spill or leak. However, written hazard communication programs will not be required for this type of operation.

All workplaces where employees are exposed to hazardous chemicals must have a written plan which describes how the standard will be implemented in that facility. The only work operations which do not have to comply with the written plan requirements are laboratories and work operations where employees only handle chemicals in sealed containers.

The written program must reflect what employees are doing in a particular workplace. For example, the written plan must list the chemicals present at the site, indicate who is responsible for the various aspects of the program in that facility and where written materials will be made available to employees.

The written program must describe how the requirements for labels and other forms of warning, material safety data sheets, and employee information and training are going to be met in the facility..

EFFECT ON STATE RIGHT-TO-KNOW LAWS

The HCS pre-empts all state (in states without OSHA-approved job safety and health programs) or local laws which relate to an issue covered by HCS without regard to whether the state law would conflict with, complement, or supplement the federal standard, and without regard to whether the state law appears to be "at least as effective as" the federal standard.

The only state worker right-to-know laws authorized would be those established in states and jurisdictions that have OSHA-approved state programs.

These states and jurisdictions include: Alaska, Arizona, California, Connecticut (state and municipal employees only), Hawaii, Indiana, Iowa, Kentucky, Maryland, Michigan, Minnesota, Nevada, New Mexico, New York (state and municipal employees only), North Carolina, Oregon, Puerto Rico, South Carolina, Tennessee, Utah, Vermont, Virgin Islands, Virginia, Washington, and Wyoming.

FEDERAL WORKERS

Under the hazard communication standard federal workers are covered by executive order.

*U.S. GPO: 1993-0-49-526/72000

****New Publication****

Chapters include:

- Examining your Career Options
- Procedures in a Medical Practice
- Approaching Physicians
- Interviewing Process
- Employment Agreement
- Insurance and Liability Issues
- Practice Administration
- Business in the Physicians Office
- How to Promote your Medical Skin Care Practice
- Professional Associations
- Directory of Consulting Services
- Professional Journals

LASER SAFETY FOR THE SALON & SPA

By Judi Nicholson RN BS
Susanne S. Warfield BS

Chapters include:

- What are They?
- Classes of Lasers
- How Do They Fit in the Salon/Spa Environment?
- Types of Lasers for Skin Care

Laser Safety

- Licensing/Regulatory Agencies
- OSHA General Duty Clause
- ANSI Laser Standards
- Glossary of Laser Terms

P C I 2000 YearBook™

The Medical Journal for Skin Care Professionals®

All the years abstracts indexed for easy reference

- Acne-Aging-Rosacea
- Complementary Therapies
- Cosmetic Ingredients
- Plastic Surgery Procedures

Physician's Guide to In-Office Dispensing

By Inga Elizey MPA,RRA & Susanne S. Warfield

- Why it Makes Sense
- Which Products Should You Dispense
- Selection of the Product
- Product Liability
- The Business of Dispensing
- Gearing Up with Staff and Space
- Inventory Control
- In-office Marketing
- Patient Education

OSHA Manual on Bloodborne Pathogens By Susanne S. Warfield

Chapters include:

- Purpose of the Act
- Preventative Measures
- Universal Precautions
- Hepatitis B Vaccine
- Sterilization and Disinfection
- Methods of Control
- Engineering & Work Control Practices
- Personal Protective Equipment
- Housekeeping, Labeling, Recordkeeping

Guide to Building a Medical Esthetic Practice

By Susanne S. Warfield

Chapters include:

- Benefits for the Physician
- Skin Care Services Beneficial in a Medical Setting
- Legal and Liability Considerations
- OSHA Requirements for the Medical Esthetic Practice
- Product and Service Proforma
- Medical Esthetic Marketing
- Physical Plant
- Front End Set-up
- Hiring an Esthetician
- Employment Contract

The Medical Journal for Skin Care Professionals®

P C I Journal™

www.pcijournal.com

Subscription—Bi-monthly

The PCI Journal reviews over 80 Medical Journals. We pull out articles that would be of educational value to a Skin Care Professional. Whether you work in a salon, spa or medical practice, PCI Journal will keep you informed on the latest medical literature.

Each issue includes:

- Scientific Abstracts
- Current Licensing/Legal Issues
- Management/Marketing Tips
- Clinical Reviews

YES—Send me the following: (10% Discount for Participating Associations)

____	PCI Journal™ (One-year Subscription) - (20% Student Discount with I.D. card)	$60.00 ____
____	PCI Journal™ (Two-year Subscription)	$108.00 ____
____	Foreign One-year Subscription (US funds drawn on US Bank)	$80.00 ____
____	PCI YearBook© 2000 $24.95 plus ($5.00 s & h)	$29.95 ____
____	Esthetician's Guide to Working with Physicians $54.95 + ($5.00 s&h)	$59.95 ____
____	Guide to Building a Medical Esthetic Practice $99.95 + ($6.00 s&h)	$105.95 ____
____	Physician's Guide to In-Office Dispensing $79.95 + ($6.00 s&h)	$85.95 ____
____	OSHA Manual on Bloodborne Pathogens $42.95 + ($5.00 s&h)	$47.95 ____
____	Laser Safety for the Salon & Spa $34.95 + ($5.00 s&h)	$39.95 ____

**Allow 2-4 weeks delivery. Prices are Subject to Change.* TOTAL $____

SAVE $$ Order Online - Most books available as e-books.

Payment Method: Check #: _____ Amex/Discover/Visa/MC#: _____

Expiration Date: ____ /____ /____ Name on Card: _____ Signature: _____

Name: _____ Company: _____

Specialty: Do work in Dermatology____ Plastic Surgery ____ Salon____ Spa____ Other_____

Address: _____ Suite/Apt. # _____

City _____ State _____ Zip _____(+4)_____

E-Mail Address: _____ Website: _____

Telephone: Day (____)_____ Night (____)_____ Fax (____)_____

ORDER ONLINE AT WWW.PCIJOURNAL.COM

Mail to Paramedical Consultants, Inc.: 40 Dean Street, Glen Rock, NJ 07452-1409

(201) 670-4100 or FAX (201) 670-4265

APPENDIX C

FDA

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2002]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR878.4820]

[Page 378]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN
SERVICES (CONTINUED)

PART 878--GENERAL AND PLASTIC SURGERY DEVICES--Table of Contents

Subpart E--Surgical Devices

Sec. 878.4820 Surgical instrument motors and accessories/attachments.

(a) Identification. Surgical instrument motors and accessories are AC-powered, battery-powered, or air-powered devices intended for use during surgical procedures to provide power to operate various accessories or attachments to cut hard tissue or bone and soft tissue. Accessories or attachments may include a bur, chisel (osteotome), dermabrasion brush, dermatome, drill bit, hammerhead, pin driver, and saw blade.

(b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to Sec. 878.9.

[55 FR 48440, Nov. 20, 1990, as amended at 65 FR 2318, 2000]

510(k) Premarket Notification Database

Device Classification Name	DERMATOME
Regulation Number	878.4820
510(k) Number	K965256
Device Name	DMS-1000C DERMOABRADER
Applicant	MATTIOLI ENGINEERING, SRL VIALE MACHIAVELLI, 2/A FLORENCE, IT 50125
Contact	GIAN FRANCO BERNABE
Product Code	GFD
Date Received	08/16/1996
Decision Date	12/09/1996
Decision	SUBSTANTIALLY EQUIVALENT (SE)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Statement/purged 510(k)
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No

Database Updated 10/6/2002

510(k) Number (if known): K965256

Device Name: Dermoabrader

Indications For Use:

THE MAIN INDICATION FOR DERMOABRADERS DEVICES ARE THE FOLLOWING:

1. SCAR REVISION

2. GENERAL DERMOABRASION

3. TATTOO

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K965256

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

APPENDIX D

Guidelines for Professional Resurfacing Exfoliating Procedures

The Esthetics Manufacturers and Distributors Alliance
of the
American Beauty Association

Guidelines for Professional Cosmetic Resurfacing Exfoliating Procedures

I. Introduction

The Esthetics Manufacturers and Distributors Alliance (EMDA) of the American Beauty Association (ABA) represents manufacturers and distributors of personal care products within the professional beauty industry. EMDA serves the interests of its members within the professional beauty industry and seeks to enhance the professional treatment of clients of the professional beauty industry. To advance these goals, EMDA developed these Guidelines for Professional Cosmetic Resurfacing Exfoliating Procedures for cosmetologists, estheticians and/or skin care specialists licensed to practice skin care within their state. EMDA's Guideline Committee[1] drafted the Guidelines with input and advice from industry participants. Before publication, the draft Guidelines were reviewed and approved by EMDA's Review Committee.[2]

II. Objectives for the Guidelines

The Guidelines are intended to enhance the safe and efficacious application of Professional Cosmetic Resurfacing Exfoliating Substances. The Guidelines recommend procedures for the application of Cosmetic Resurfacing Exfoliating Substances by licensed practitioners. The Guidelines exclude all chemicals and mechanical products that are not specifically included in the Definitions. EMDA has prepared these Guidelines as a service to the professional beauty industry and its clientele. Because the circumstances of each particular application may vary, adherence to the Guidelines does not ensure safe or satisfactory application of Cosmetic Resurfacing Exfoliating Substances under all circumstances. **CAREFULLY REVIEW SECTION IX: LIMITATIONS AND DISCLAIMERS.**

---

[1] Guideline Committee: Paul Scott Premo, Committee Chair/ Executive Vice President of Marketing & Education, Ph.D., Formulations/Bioceutix Inc. and Charles Mizelle, Regional Operations Director, Sothys Paris.

[2] Review Committee: Mark Lees, PhD, President, Mark Less Skin Care, Howard Murad, M.D., Assistant Clinical Professor of Dermatology UCLA, CEO, Murad Inc., Paul Dykstra, Executive Director, American Beauty Association (ABA), Robert Posner, CEO, ABBE Cosmetic Group, William Althen, Attorney, Heenan, Althen & Roles.

III. Cosmetic Use of Resurfacing Exfoliating Procedures

Exfoliation is derived from the Latin word "exfoliatus" defined as "to strip of leaves". Cosmetic Resurfacing Exfoliating Procedures have been used throughout history as a means to cleanse, smooth and improve the appearance of the skin. Today, Cosmetic Resurfacing Exfoliating Procedures utilize a variety of chemical substances and/or mechanical equipment intended to remove the stratum corneum of the epidermis thereby improving the aesthetic appearance of the skin. Cosmetic Resurfacing Exfoliating Procedures are not intended to cause viable epidermal and/or dermal wounding or injury and therefore differ from medical resurfacing procedures administered by physicians.

IV. Definitions

A. Cosmetic Resurfacing Exfoliating Substances and Equipment: "Cosmetic Resurfacing Exfoliating Substance and Equipment" includes cosmetic-use AHAs (Glycolic & Lactic Acids), BHAs (salicylic acid), Jessner's solutions (14% salicylic acid, lactic acid and resorcinol) or modifications thereof, and proteolytic enzymes (papain, bromelain). The term also includes mechanical instruments and instruments that mechanically administer substances, including brushing machines, polyethylene granular scrubs, loofah or textured sponges, gommage and microdermabrasion instruments, provided the manufacturer has established and substantiated product and equipment safety. The term excludes all other chemical and mechanical exfoliation/peeling procedures and substances including, but not limited to Trichloroacetic Acid (TCA), Carbolic Acid (phenol), or combinations thereof and further excludes all adulterated chemical exfoliating/peeling substances.

B. Cosmetic Resurfacing Exfoliating Procedures: "Cosmetic Resurfacing Exfoliating Procedures" means the application of Cosmetic Resurfacing Exfoliating Substances by Licensed Practitioners for the purpose of improving the aesthetic appearance of the skin.

C. Cosmetic Use AHAs: "Cosmetic Use AHAs" means Alpha Hydroxy Acid exfoliation preparations that do not exceed a 30% concentration with a pH value not lower than pH 3.0 as established and recommended by the Cosmetic Ingredient Review Expert Panel. (See reference in appendix)

D. Licensed Practitioner: "Licensed Practitioner" means a cosmetologist, esthetician or other person licensed or otherwise authorized by an appropriate state government regulatory agency to administer Cosmetic Resurfacing Exfoliating Substances who is practicing in a cosmetology establishment as regulated by local or state ordinances or laws.

E. **Microdermabrasion Equipment:** The Federal Food and Drug Administration (FDA) lists Microdermabrasion equipment as Class I devices intended for use by Licensed Practitioners trained in the appropriate use of such equipment. For purposes of these Guidelines, microdermabrasion equipment is considered a Cosmetic Resurfacing Exfoliating Substance only if they are used in a manner that is not intended to remove viable (living) skin below the stratum corneum.

V. Professional Use

Cosmetic Resurfacing Exfoliation Substances and Procedures are intended for "professional use only". Only Licensed Practitioners should administer Cosmetic Resurfacing Exfoliating Substances. These products and procedures are not intended for consumer resale or use. Licensed Practitioners must not use any equipment or practice intended to remove viable (living) skin below the stratum corneum.

VI. Compliance with State Requirements

Licensed Practitioners must comply with all rules and regulations established by their respective State Boards of Cosmetology or other governmental regulatory agency regarding Cosmetic Resurfacing Exfoliating Substances and Procedures.

VII. Recommendations for Manufacturer Instructional Material and Training

A. **Manufacturer Training Materials:** EMDA recommends that manufacturers marketing and distributing Cosmetic Resurfacing Exfoliating Substances for professional uses shall provide instructional procedure and product use training materials for Licensed Practitioners. Manufacturer sponsored training programs are independent of the training requirements established by individual State Boards of Cosmetology in professional skin care. It is the responsibility of the manufacturer to provide procedural guidelines, practical training, video and/or written instructional materials with the initial purchase of its products or equipment by or for Licensed Practitioners.

B. **Training of Licensed Practitioners:** It is extremely important that Licensed Practitioners of Cosmetic Resurfacing Exfoliation Substances receive adequate training regarding safe application procedures. Manufacturer instructional training should cover theoretical and practical application of Cosmetic Resurfacing

Exfoliating Substances and Procedures. Licensed Practitioners must check and follow state board requirements and training and safety data and information supplied by the manufacturer.

C. Recommended Training Programs: EMDA recommends the following training programs:

1. Theoretical overview, scientific and safety data;
2. Clinical indications vs. cosmetic applications;
3. Client general history, skin evaluation, realistic expectations;
4. Contraindications/Precautions;
5. Predisposition patch testing;
6. Client pre-application care;
7. Application procedure;
8. Post application care; and
9. Client follow-up.

VIII. Cosmetic Resurfacing Exfoliating Procedures

A. Basic Procedures: In order to provide safe and efficacious application of Cosmetic Resurfacing Exfoliating Procedures, Licensed Practitioners should provide for:

1. Appropriate disinfection and sanitation as established by respective State Boards of Cosmetology; as regulated by local or state ordinances or laws.
2. Proper client selection and general health profile procedures before application of the product;
3. A thorough skin evaluation and consultation for each client to determine if the procedure is appropriate before application of product;
4. Verification by the client of the receipt of appropriate information; and
5. Use of proper procedures in applying product.

B. Disinfection and Sanitation Procedures: Licensed Practitioners should only apply Cosmetic Resurfacing Exfoliation Substances in establishments licensed or practicing in a cosmetology establishment as regulated by local or state ordinances or laws. They must follow disinfection and sanitation procedures required by the State Boards of Cosmetology and recommended by manufacturers.

C. Client Selection and Health Profile Procedures:

1. Client History: The Licensed Practitioner should take a client history of conditions related to the application of Cosmetic Resurfacing Exfoliation Substances. Relevant topics include cosmetic related irritant/allergic reactions, HSV (cold sores) predisposition, frequency of sun exposure or tanning bed use, topical and/or oral medications, all of which may increase an individual's susceptibility to adverse reactions.

2. Sample Questions for Client History: The following are a partial list of questions to aid in determining if the procedure is appropriate:

- Female clients currently pregnant;
- History of sun exposure and/or tanning bed use;
- History of cosmetic related irritant/allergic reactions;
- History of oral and/or topical medications, i.e. tretinoin (Retin-A, Renova), isotretinoin (Accutane) [3]and others;
- HSV (herpes simplex virus) predisposition;
- Previous facial plastic/reconstructive surgery;
- Previous chemical peel or other resurfacing procedures and outcome;
- Previous Cosmetic Resurfacing Exfoliating Procedure-type and outcome;
- Current skin care regimen; and
- Client's expectations.

3. Cautions regarding Use:

a. EMDA does not recommend the use of multiple cosmetic resurfacing exfoliating services, chemical and/or mechanical, during the same procedure;

b. Cosmetic Resurfacing Exfoliating Substances are not recommended when a client is under the supervision of a physician for skin related disorders, pregnancy, post chemical peel, laser treatments or plastic/reconstructive surgery without the approval of the physician.

[3] Retin A and Renova are registered trademarks of Johnson & Johnson/Ortho Pharmaceuticals. Accutane is a registered trademark of Roche.

c. If client history reveals cosmetic related irritant/allergic reactions, HSV (cold sores) predisposition, frequency of sun exposure or tanning bed use, or topical and/or oral medications, these factors may increase a client's susceptibility to adverse reactions. EMDA recommends, as appropriate, a predisposition patch test 24 hours before the procedure or physician advice.

d. EMDA recommends that a pregnant client receive approval from her attending physician before the procedure is administered.

D. Skin Evaluation Procedures:

1. The Licensed Practitioner should perform a physical examination and evaluation of client's skin.

   a. Check for degree of sebaceous activity (skin oiliness), acne, telangiectasias (broken capillaries) and degree of photodamage;

   b. Check for open cuts, sores, lesions or apparent skin irritation or sensitivity

2. EMDA recommends Cosmetic Resurfacing Exfoliating Substances not be administered to skin exhibiting open cuts, sores, sunburn, chemical or thermal burns, apparent skin irritation or sensitivity.

3. Sensitivity to chemical exfoliating products can only be determined by administering a predisposition patch test. EMDA recommends such procedure 24 hours before the application of chemical exfoliating substances.

4. After the appropriate client evaluation, the Licensed Practitioner should discuss and outline realistic expectations with the client. EMDA recommends client photo-documentation at baseline and upon conclusion of each procedure

E. Verification by Client of Receipt of Information: EMDA recommends that Licensed Practitioners maintain written documentation signed by the client that the Licensed Practitioner has taken a client history, performed a skin evaluation and discussed the planned procedures with the client. The informed client should approve the planned procedures.

F. Proper Application Procedures: EMDA recommends the following procedures in applying Cosmetic Resurfacing Exfoliation Substances:

1. Thoroughly wash and disinfect hands. The use of sterile latex gloves is recommended during the procedure. The Licensed Practitioner should wear protective face and eye guards and protective gloves and should protect the client's eyes when administering microdermabrasion treatments.
2. Prepare, drape and protect client appropriately in accordance with local or state ordinances or laws.
3. Conduct client skin evaluation and inspection.
4. Cleanse client's skin according to manufacturer's directions.
5. Apply protective eye pads or guards.
6. Apply cosmetic resurfacing exfoliation preparation or procedure according to the manufacturer directions. **Manufacturers' directions may vary. Always read carefully and follow complete directions.**
7. EMDA recommends the use of disposable implements.
8. Always follow manufacturer's directions regarding exposure time and skin contact.
9. Remove preparation after the appropriate exposure time with cool, damp gauze or cotton pads or as directed by the manufacturer.
10. Conclude procedure with recommended skin care products including the use of UVA/UVB SPF 15 (or higher) sunscreen.
11. Instruct client on appropriate post care.
12. Have client report any adverse reactions. Seek medical assistance if necessary.
13. Follow the manufacturer recommendation on the number of successive treatments depending on the client's skin type, condition and treatment results.
14. EMDA recommends client photo-documentation at baseline and upon conclusion of each procedure

IX. Limitations and Disclaimers

A. Disclaimer regarding Aluminum Oxide Particulate: EMDA is not aware of any long-term scientific studies to support the safety of aluminum oxide particulates in cosmetic microdermabrasion resurfacing treatments. Therefore, EMDA recommends that Practitioners and their clients use protective wear to reduce any potential risk factors that may be associated with this substance.

B. Requirement for Individual Responsibility: Undetermined variables may influence the outcome of any procedure, and specific consideration must be given to each client and procedure on an individual basis. Although EMDA intends these Guidelines to be generally useful, compliance with these Guidelines does not

guarantee the client a successful procedure or eliminate other potential risk factors to individual clients. It is the responsibility of the Licensed Practitioner and the client to assure the safety and efficacy of any substance and/or procedure.

C. **NO WARRANTIES: ABA AND EMDA, AND THEIR RESPECTIVE DIRECTORS, OFFICERS, COMMITTEE MEMBERS, AND AGENTS MAKE NO WARRANTIES FOR THESE GUIDELINES, INCLUDING (BUT NOT LIMITED TO) ANY EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE. ABA AND EMDA ARE NOT RESPONSIBLE FOR ANY ERRORS, DEFICIENCES, OR OMISSIONS AND SPECIFICALLY DISCLAIM ANY OBLIGATION TO REVISE, MODIFY, OR UPDATE THESE GUIDELINES.**

D. **DISCLAIMER OF LIABILITY: IN NO EVENT WILL ABA OR EMDA, OR THEIR RESPECTIVE DIRECTORS, OFFICERS, COMMITTEE MEMBERS, OR AGENTS BE LIABLE TO ANY PERSON FOR ANY DIRECT, INDIRECT, SPECIAL OR OTHER DAMAGES ARISING FROM ANY USE OF THESE GUIDELINES OR ANY INFORMATION IN THE GUIDELINES, INCLUDING WITHOUT LIMITATION ANY LOST PROFITS, LOST OPPORTUNITIES, BUSINESS INTERRUPTION OR PHSYSICAL OR EMOTIONAL INJURIES, EVEN IF THEY ARE EXPRESSLY ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.**

E. **GOVERNMENT REGULATIONS: THESE GUIDELINES DO NOT SUPERCEDE ANY RULES OR REGULATIONS ESTABLISHED BY INDIVIDUAL STATE BOARDS OF COSMETOLOGY OR OTHER GOVERNMENTAL AGENCIES.**

APPENDIX

Cosmetic Ingredient Review Conclusion on AHAs

Based on the available information included in this report, the CIR Expert Panel concludes that Glycolic and Lactic Acid, their common salts and their simple esters, are safe for use in cosmetic products at concentrations ≤ 10%, at final formulation pH ≥ 3.5, when formulated to avoid increasing sun sensitivity or when directions for use include the daily use of sun protection. These ingredients are safe for use in

salon products at concentrations ≤ 30%, at final formulation pH ≥ 3.0, in products designed for brief, discontinuous use followed by through rinsing from the skin, when applied by trained professionals, and when application is accompanied by directions for the daily use of sun protection.

For the full CIR Decision, please contact the Esthetics Manufacturers and Distributors Alliance on 312.245.1595