

# DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT Consumer Protection Division 6 CCR 1010-20 STATE BOARD OF HEALTH ARTIFICIAL TANNING DEVICES

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#### ARTIFICIAL TANNING DEVICE REGULATIONS

1-101 <u>Purpose</u>. These rules and regulations provide for the registration and regulation of facilities and equipment which employ ultraviolet and other lamps for the purpose of artificially tanning the human skin through the application of ultraviolet radiation.

#### 1-102 Definitions:

- (a) <u>Approved</u> shall mean acceptable to the Colorado Department of Health, or its authorized agents, or employees based on determination of conformance with applicable documented standards and good public health practices.
- (b) <u>Artificial Tanning Device</u> shall mean any equipment that as defined in Section 25-5-1003(1), C.R.S. 1989, as amended.
- (c) <u>Board</u> shall mean the State Board of Health as defined in Section 25-5-1003(2), C.R.S. 1989, as amended.
- (d) <u>Consumer</u> shall mean any individual who is provided access to a tanning facility which is required to be registered as provided in Section 25-5-1004(1), C.R.S. 1989, as amended.
- (e) <u>Department</u> shall mean the Colorado Department of Health, or its authorized agents, or employees.
- (f) <u>Inspection</u> shall mean an official examination or observation by the Department including, but not limited to, tests, surveys, and monitoring of artificial tanning devices and tanning facilities.
- (g) Operator shall mean any individual designated by the registrant to operate or to assist and instruct the consumer in the correct operation and use of artificial tanning device(s).
- (h) Owner shall mean a person in possession and in charge of an artificial tanning

- facility, and/or tanning device(s), except as exempted in 1-103 of these regulations.
- (i) <u>Person</u> shall mean a natural person, partnership, association, company, corporation, or organization or a manager, agent, servant, officer, or employee thereof.
- (j) <u>Phototherapy Device</u> shall mean a piece of equipment as defined in Section 25-5-1003(5), C.R.S. 1989, as amended.
- (k) <u>Registrant</u> shall mean any person who is registered with the Department as provided in Section 25-5-1004(1), C.R.S. 1989, as amended.
- (l) <u>Registration</u> shall mean registration with the Department in accordance with the provisions of Section 25-5-1004(1), C.R.S. 1989, as amended.
- (m) <u>Tanning equipment</u> shall mean ultraviolet or other lamps and equipment containing such lamps intended to induce skin tanning through the irradiation of any part of the living human body.
- (n) <u>Tanning Facility</u> shall mean any location, premises, place, area, structure, or business, as defined in Section 25-5-1003(6), C.R.S. 1989, as amended.
- (o) <u>Ultraviolet radiation</u> shall mean electromagnetic radiation as defined in Section 25-5-103(7), C.R.S. 1989, as amended.
- 1-103 <u>Exemptions</u>. Exemptions shall be as provided in Section 25-5-1005(1)(a)(b) and (c), C.R.S. 1989, as amended.

# 2-201 <u>Application for Registration of Artificial Tanning Facilities:</u>

- (a) Each person having an artificial tanning facility on January 1, 1993 shall apply for registration of such facility no later than thirty (30) days from January 1, 1993.
- (b) Each person establishing or acquiring a tanning facility after January 1, 1993, shall apply for registration of each location for such facility prior to beginning operation of such a facility.
- (c) The application required in 2-202(a) and 2-202(b) of this regulation shall be completed on forms provided by the Department and shall contain all the information required by such forms.
- (d) The Department shall require at least the following information on the forms provided when applying for registration of each tanning facility:
  - (1) Name, mailing address, location if different than mailing address, and telephone number of the tanning facility;
  - (2) Name(s), mailing address(es) and telephone number(s) of the owner(s) of the tanning facility;
  - (3) The manufacturer(s), model number(s), and type(s) of ultraviolet lamp(s) or tanning equipment located within the facility;
  - (4) The geographic areas within the State to be covered, if the facility is mobile.
  - (5) A signed and dated application for registration that the applicant will comply with the requirements of these regulations.

#### 2-202 Duration of Registration:

- (a) Registration is valid for a period of one calendar year. Applications for registration shall be made during the month of December of each year.
- (b) All registrations shall expire at midnight on December thirty-first of the year for which issued.
- (c) The annual registration fee shall be prorated on a monthly basis for any initial registration received after January 1 of any year.
- (d) A registration shall not be granted without prior payment of the tanning equipment fee required in 25-5-1004(2), C.R.S.

# 2-203 <u>Transfer of Registration</u>:

Registration is not transferable from one person to another person or from one tanning facility to another tanning facility.

#### 2-204 Report of Change:

- (a) The registrant shall notify the Department in writing before making any change which would render the information contained in the application for registration no longer accurate.
- (b) Any new or additional tanning equipment which was not previously reported to the Department, shall be reported at the time of annual registration.

#### 2-205 Termination of Registration.

The Department may terminate a registration upon receipt of a written request for termination from the registrant. Once a tanning facility is registered and the fee has

been paid for the year, no portion of the fee will be refunded.

#### 2-206 <u>Prohibited Advertisement:</u>

- (a) No person, in any advertisement or promotion, shall state or imply that because such person or person's tanning facility is registered with the Department pursuant to the provisions of Section 25-5-1004(1), C.R.S. 1989, as amended, and these regulations, that any activity under such registration has been approved by the Department.
- (b) No person, in any advertisement or promotion, shall indicate that such person's artificial tanning device(s) is safe or free of hazards from ultraviolet radiation, nor imply use as a medical device or treatment.

#### 3-301 <u>Construction and Operation of Tanning Facilities:</u>

Unless otherwise ordered or approved by the Department, each tanning facility shall be constructed, operated and maintained to meet the following minimum requirements:

#### (a) <u>Warning Signs</u>:

(1) The following warning sign shall be posted in the immediate proximity (within one meter) of each tanning station; it shall be readily legible, clearly visible, and not obstructed by any barrier, equipment, or other item present so that the user can easily view the warning sign before activating the tanning equipment.

#### DANGER--ULTRAVIOLET RADIATION

- Follow instructions.
- Avoid overexposure. As with natural sunlight, exposure can cause premature aging of the skin and skin cancer.
- Wear protective eyewear. FAILURE TO USE PROTECTIVE EYEWEAR MAY RESULT IN SEVERE BURNS OR LONG TERM INJURY TO THE EYES.
- Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult a physician before using sunlamp if you are using medications or have a history of skin problems, or believe yourself especially sensitive to sunlight.
- If you do not tan in the sun, you are unlikely to tan from the use of this product.

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(2) The lettering on each warning sign shall be at least ten millimeters high for all words shown in capital letters and at least five millimeters high for all lower case letters.

#### (b) <u>Physical Facilities</u>:

- (1) Only tanning equipment manufactured in accordance with the specifications set forth in 1991 21 CFR Part 1040, Section 1040.20, "Sunlamp products and ultraviolet lamps intended for use in sunlamp products", shall be used in tanning facilities. The exact nature of compliance shall be based on the standard in effect at the time of manufacture as shown on the device identification label required by 1991 21 CFR Part 1010, Section 1010.3.
- (2) Each assembly of tanning equipment shall be equipped with a timer which complies with the requirements of 1991 21 CFR 1040.20 (c) (2). The maximum timer interval shall not exceed the manufacture's maximum recommended exposure time. No timer interval shall have an error exceeding plus or minus 10 percent of the maximum timer interval for the product. The registrant shall ensure that tests are preformed on each assembly of tanning equipment, at least annually, and documented in writing to ensure the timer is accurate to within 10% of the maximum exposure time. A record of timer testing results shall be kept at each tanning facility location.
- (3) The timer intervals shall be numerically indicated, at ten (10) minute intervals to a maximum of thirty (30) minutes.
- (4) The timer may not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle, when emission from the tanning device has been terminated.
- (5) The timer requirements do not preclude a product from allowing a user to reset the timer before the end of the preset time interval.
- (6) Each assembly of tanning equipment shall be provided with a control on the equipment to enable the consumer to terminate manually radiation emission from the equipment at any time without disconnecting the electrical plug or removing any ultraviolet lamp.

- (7) Tanning equipment shall be provided with ground fault protection on the electrical circuit, or other methods for preventing shock.
- (8) Tanning equipment shall include physical barriers to protect consumers from injury induced by touching or breaking the lamps.
- (9) Each tanning device shall be operated to preclude any thermal burns to human skin or cause heat prostration.

# (c) Additional Requirements for Stand-Up Booths and any Cabinet or Vertical Tanning Device:

- (1) Tanning booths and cabinets or vertical tanning device(s) designated for stand-up use shall also comply with the following additional requirements:
- (2) Booths shall have physical barriers or other means, such as handrails or floor markings, to indicate the proper exposure distance between ultraviolet lamps and the consumer's skin;
- (3) Booths shall be constructed with sufficient strength and rigidity to withstand the stress of use and the impact of a falling person;
- (4) Access to booths shall be rigid construction with doors which are non-latching and open outwardly;
- (5) Booths shall be equipped with handrails and non-slip floors.

### (d) <u>Protective Eyewear</u>:

- (1) Registrants are responsible to provide protective eyewear to each consumer during use of tanning equipment however, consumers may use their own protective eyewear if approved by the registrant.
- (2) The protective eyewear in this regulation shall meet the requirements

of 1991 21 CFR 1040.20 (c) (4).

- (3) Tanning facility operators shall instruct the consumer in the proper utilization of the protective eyewear. Eyewear must be worn when the lamps are energized. The eyepiece must be in place, and must cover the eye sockets of the user.
- (4) Tanning facility operators shall ensure all protective eyewear is clean and sanitized, the eyewear has no defects, the frames and lenses contain no cracks, abrasions and that the lenses are not clouded.

#### (e) Sanitation:

- (1) The registrant shall ensure that an operator properly sanitizes the tanning equipment and the protective eyewear between every use by a consumer. Exposure to the ultraviolet radiation produced by tanning equipment is not adequate sanitization. The sanitizer used shall be one registered for such use by the U.S. Environmental Protection Agency or the Colorado Department of Agriculture.
- (2) The floors, walls and fixtures in tanning facilities shall be kept clean and in good repair at all times.
- (3) If towels or linens are provided to consumers, they shall be clean and sanitary. Towels and linens shall be washed between each use. Towels shall be stored in a clean place. Soiled towels and linens shall be stored in nonabsorbent containers or washable laundry bags.

#### (f) <u>Consumer Warning</u>:

(1) Prior to initial exposure to ultraviolet radiation at a tanning facility, the consumer shall be given a copy of the warning statements and must be supplied with at least the following information:

- (a) A representative list of potential photosensitizing drugs and agents. This list should at least include drugs or agents in the product classes of acne treatment, antibacterials, antibiotics, anticonvulsants, antidepressants, antibacterials, antihypertensive, dye, estrogen and progesterones, melanogenics, perfumes and toilet articles, tranquilizers, antihistamines and antimicrobials/antinfectious agents.
- (b) Information regarding potential negative health effects related to ultraviolet exposure, including:
  - (1) The increased risk of skin cancer later in life; and potential detrimental health risks including skin cancer; a significant increased risk of skin cancer/melanoma, when a painful blistering sunburn has occurred prior to the age of eighteen (18).
  - (2) The increased risk of skin thickening and premature aging;
  - (3) The possible activation of some viral conditions (cold sores); and
  - (4) The possibility of skin burning or rashes, especially if using any of the potential photosensitizing drugs and agents. Potential clients who are using photosensitizing medication, have a history of sun sensitivity or have a history of sun related skin problems should be advised not to use the tanning device
- (c) Basic information on how different skin types respond to tanning.

- (d) An explanation of the need to use protective eyewear with both ultraviolet-A (UVA) and ultraviolet-B (UVB) systems, and that closing the eyes is not sufficient to prevent possible eye damage.
- (e) Information that tanning may be inadvisable during pregnancy and information that tanning is inadvisable for persons with photosensitizing diseases, melanoma or other skin cancers.

#### 4-401 Records.

- (a) The registrant shall maintain records ensuring that the requirements of 3-301(b)(1) and (2), have been met.
- (b) Each registrant shall keep records showing receipt, transfer, and disposal of all tanning equipment.

#### 5-501 Report of Accident or Adverse Reaction:

- (a) The registrant shall submit to the Department a written report, as provided in Section 25-5-1007(6) C.R.S. 1989, as amended, of any accident or adverse reaction to the use of any artificial tanning device within fifteen days after discovery of the event;
- (b) The report shall include:
  - (1) The name, address, telephone number of the affected individual;
  - (2) The name, address, telephone number of tanning facility, and identification of the specific tanning device involved;
  - (3) The nature of the actual or alleged accident or adverse reaction, and

- any other information relevant to the actual or alleged accident or adverse reaction including duration of exposure;
- (4) Name of attending physician, if applicable, medical attention sought and treatment.

# 6-601 Replacement of Ultraviolet Lamps, Bulbs or Filters:

- (a) The registrant shall only use lamps which have been certified with the Food and Drug Administration (FDA) as "equivalent" lamps under the FDA regulations and policies applicable at the time of replacement of the lamps.
- (b) The registrant shall replace defective or burned out lamps, bulbs or filters with a type intended for use in the affected tanning equipment as specified on the product label and having the same spectral distribution.
- (c) The registrant shall maintain manufacturer's literature demonstrating the equivalency of any replacement lamps.
- (d) Defective or burned-out lamps or filters shall be replaced before further use of the tanning equipment.
- (e) Lamps and bulbs designated for medical use only shall not be used.

#### 7-701 Inspections.

- (a) Agents of the Department, after proper identification, shall be permitted to enter any tanning facility during business hours for the purpose of making inspections, investigating complaints and to determine compliance with these regulations. Agents of the Department shall not inspect any tanning device while in use by consumers.
- (b) Each registrant shall make available to the Department records and documents, upon reasonable notice, maintained pursuant to the requirements

# of these regulations.

Copies of "Code of Federal Regulations" (CFR) are available for reference from the Director, Consumer Protection Division, Colorado Department of Health, 4300 Cherry Creek Drive South, Denver, Colorado 80222-1530. This reference does not include later amendments to or editions of the incorporated material.

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