



Rhode Island Department of Health

NOTICE OF PUBLIC HEARING

The Director of the Rhode Island Department of Health has under consideration proposed amendments to the *Rules and Regulations Pertaining to Rules and Regulations for the Registration of Tanning Facilities [R23-68-TAN]* pursuant to the authority conferred under Chapters 23-68 and 42-35 of the Rhode Island General Laws, as amended. The purpose of the proposed amendments is to update minimum standards for the registration and operation of tanning facilities in Rhode Island. These specific amendments implement recent changes to RIGL Chapter 23-68, 21 CFR Part 1040.20, and also address several needed “housekeeping” revisions.

Notice is hereby given in accordance with the provisions of Chapter 42-35 of the Rhode Island General Laws, as amended, that the Director will hold a public hearing on the above mentioned matters, in the **AUDITORIUM** of the Rhode Island Department of Health (on the lower level of the Cannon Building), Three Capitol Hill, Providence, Rhode Island on **THURSDAY, 12 JUNE 2014 AT 11:30 AM** at which time and place all persons interested therein will be heard. The seating capacity of the room will be enforced and therefore the number of persons participating in the hearing may be limited at any given time by the hearing officer, in order to comply with safety and fire codes.

In the development of the rules and regulations, consideration was given to the following: (1) alternative approaches; (2) overlap or duplication with other statutory and regulatory provisions and (3) financial impact on small business. No alternative approach, duplication, or overlap was identified based upon available information.

For the sake of accuracy, it is requested that statements to be made relative to any aspect of the regulations, including alternative approaches or overlap, be submitted in writing at the time of the hearing or in electronic format prior to the hearing date to: Raymond Rusin, Chief, Office of Facilities Regulation: e-mail to OFR@health.ri.gov or by calling 401-222-2566.

Copies of the regulations are available for public inspection in the Cannon Building, Room #201, Rhode Island Department of Health, 3 Capitol Hill, Providence, Rhode Island, on the Secretary of State’s website: <http://www.sos.ri.gov/ProposedRules/>, by calling 401-222-7767 or by e-mail to Bill.Dundulis@health.ri.gov.

The Department of Health is accessible to the handicapped. If communication assistance (readers/ interpreters/captioners) is needed, or any other accommodation to ensure equal participation, please call 401-222-7767 or RI Relay 711 at least three (3) business days prior to the meeting so arrangements can be made to provide such assistance at no cost to the person requesting.

Signed this 25th day of April 2014

Original signed by Michael Fine, MD

Michael Fine, M.D., Director of Health

**RULES AND REGULATIONS FOR THE
REGISTRATION OF TANNING FACILITIES**

[R23-68-TAN]



STATE OF RHODE ISLAND AND PROVIDENCE PLANTATIONS

DEPARTMENT OF HEALTH

December 1998

AS AMENDED

January 2002 (re-filing in accordance with the provisions of §42-35-4.1 of the Rhode Island General Laws, as amended)

January 2007 (re-filing in accordance with the provisions of §42-35-4.1 of the Rhode Island General Laws, as amended)

June 2007

September 2007

January 2012 (re-filing in accordance with the provisions of §42-35-4.1 of the Rhode Island General Laws, as amended)

September 2012

May 2014 (Proposed)

COMPILER'S NOTES:

Additions: Underlined

Proposed Deletions: ~~Strikeouts~~

INTRODUCTION

These amended *Rules and Regulations for the Registration of Tanning Facilities* [R23-68-TAN] are promulgated pursuant to the authority conferred under ~~section~~ RIGL §23-68-8 ~~of the General Laws of Rhode Island, as amended,~~ for the purpose of adopting minimum standards for the registration and operation of tanning facilities in Rhode Island ~~this state~~. These specific amendments implement recent changes to RIGL Chapter 23-68, 21 CFR Part 1040.20, and also address several needed “housekeeping” revisions.

Pursuant to the provisions of ~~section 42-35-3(e) of the General Laws of Rhode Island, as amended~~ RIGL §42-35-3(a)(3) and §42-35.1-4, ~~the following were given consideration in arriving at the amended regulations~~ consideration was given to:: (1) alternative approaches to the regulations; ~~and~~ (2) duplication or overlap with other state regulations; and (3) significant economic impact on small business. Based on the available information, no known alternative approach, overlap or duplication was identified ~~based on available information~~.

Upon promulgation of these amendments, these amended Regulations shall supersede all previous *Rules and Regulations for the Registration of Tanning Facilities* promulgated by the Rhode Island Department of Health and filed with the Secretary of State.

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PART I PURPOSE AND DEFINITIONS

Section 1.0 *PURPOSE AND SCOPE*

- 1.1 The purpose of these Regulations is to regulate tanning facilities to minimize the risks associated with tanning by artificial ultraviolet light. These risks include, but may not be limited to:
- 1.1.1 Sunburn;
 - 1.1.2 Premature aging of the skin;
 - 1.1.3 Skin cancer;
 - 1.1.4 Retinal damage;
 - 1.1.5 Formation of cataracts;
 - 1.1.6 Suppression of the immune system;
 - 1.1.7 Damage to the vascular system; and
 - 1.1.8 Communication of disease due to improper sanitation of tanning devices.

Section 2.0 *DEFINITIONS*¹

Wherever used in these Regulations, these terms shall be construed as follows:

- 2.1 ~~The "Act" refers to RIGL Chapter 23-68 of the General Laws of Rhode Island, as amended, entitled, "Tanning Facility Safety Standard Act."~~
- 2.2 *"Department"* means the Rhode Island Department of Health.
- 2.3 *"Director"* means the Director of the Rhode Island Department of Health.
- 2.4 *"EPA"* means the United States Environmental Protection Agency.
- 2.5 *"FDA"* means the United States Food and Drug Administration.
- 2.6 *"Minor"* means any individual under the age of eighteen.
- 2.7 *"Other compensation"* means the payment or exchange of goods, services or anything of value for use of the tanning device or devices.
- 2.8 *"Patron"* means any member of the public who is provided access to a tanning device in exchange for a fee or other compensation, or any individual who, in exchange for a fee or other compensation, is afforded use of a tanning device as a condition or benefit of membership or access.
- 2.9 *"Person"* means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this state, any other

¹ [Compiler's Note: The proposed May 2014 amendments add some additional definitions, thus renumbering most of the definitions. To minimize confusion, these changes in numbering are not annotated. Only actual text changes have been annotated.](#)

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state or political subdivision or agency thereof, and any legal successor, representative, agent or agency of these entities.

- 2.10 **"Protective eyewear"** means suitable eyewear that protects the eye from ultraviolet radiation and allows adequate vision.
- 2.11 **"Registrant"** means any person who is registered with the Department as required by provisions of these Regulations.
- 2.12 **"Registration"** means registration with the Department in accordance with provisions of these Regulations.
- 2.13 **"RIGL"** means the General Laws of Rhode Island, as amended.
- 2.14 **"Safe level"** means not more than fifty (50) colonies of microorganisms per four (4) square inches of equipment surface.
- 2.15 **"Sanitization"** means the effective bactericidal treatment of surfaces of equipment and devices by an EPA or FDA registered product which provides a sufficient concentration of chemicals, allowing enough time to reduce the bacterial count, including pathogens, to a safe level. Chemical germicides that are registered with the EPA as hospital disinfectants, when used at recommended dilutions and directions, may be approved for sanitizing tanning devices.
- 2.16 **"Sunlamp product"** means any electronic product designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the living human body, by ultraviolet radiation with wavelengths in air between two hundred (200) nanometers and four hundred (400) nanometers, to induce skin tanning, equipment used for tanning of the skin that emits electromagnetic radiation with wavelengths in the air between 200 and 400 nanometers including, but not limited to, a sunlamp, ultraviolet lamp, tanning booth, facial unit, UVA wand, or tanning bed.
- 2.17 **"Tanning device"** means any equipment used during the process of skin tanning with a sunlamp product, such as any sunlamp product and any accompanying equipment, including, but not limited to, timers, ballasts, starters, lamps, reflectors, cooling fans, acrylics, comfort pillows and handrails.
- 2.18 **"Tanning facility"** means any location, place, area, structure, or business that either as a sole service or in conjunction with other services, provides patrons with access to sunlamps, ultraviolet lamps or other equipment intended to induce skin tanning through the irradiation of any part of the human body for cosmetic or non-medical purposes.
- 2.19 **"These Regulations"** mean all parts of Rhode Island Rules and Regulations for the Registration of Tanning Facilities [R23-68-TAN].
- 2.20 **"Timer"** means a device provided to terminate the exposure at a preset time interval.
- 2.21 **"Ultraviolet radiation lamp"** means any lamp that produces ultraviolet radiation in the wavelength interval of two hundred (200) nanometers to four hundred (400) nanometers in air and that is intended for use in any sunlamp product. radiation that has a wavelength between two hundred nanometers and four hundred nanometers.

PART II REGISTRATION

Section 3.0 ***REQUIREMENTS. APPLICATION AND REGISTRATION FEE***

- 3.1 It shall be unlawful for any person, corporation, or other entity to own, maintain, conduct, or operate a tanning facility in ~~the state~~ Rhode Island without having been registered with the ~~Rhode Island~~ Department of Health pursuant to the provisions of ~~section~~ §23-68-6 of the Act and these ~~rules and~~ Regulations ~~herein~~.
- 3.2 Each tanning facility shall be registered prior to operation. The registrant shall file an application with the Department and pay applicable fee(s) specified in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* to register each tanning facility.
 - 3.2.1 If the registrant owns or operates more than one such tanning facility, the registrant shall file a separate application for each tanning facility owned or operated.
- 3.3 Registrations are issued to one person for one tanning facility and are non-transferable.
- 3.4 As a requirement for registration, each tanning facility shall maintain evidence of holding liability insurance.
- 3.5 Registration application shall be made on forms furnished by the Department and shall contain all the information required by the form and accompanying instructions.
- 3.6 A certificate of registration will be issued by the Department upon a determination that the applicant has provided all of the information required by the application, meets the requirements of the Act and ~~these~~ Regulations herein, and has paid the application fee as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health*.
 - 3.6.1 The certificate of registration expires annually on the date shown on the registration.
 - 3.6.2 ~~Except as provided in section §3.8 of these Regulations~~, No person shall operate or maintain a tanning facility without a current and valid certificate of registration.
 - 3.6.3 The certificate shall be displayed in a conspicuous place on the premises of the tanning facility.
- 3.7 The registrant shall notify the Department in writing before making any change which would render the information contained in the application for registration or the validation of registration no longer accurate. This requirement shall not apply for changes involving replacement of designated original equipment lamp types with lamps which have been certified with the FDA as “equivalent” replacement of the lamps. The registrant shall maintain manufacturer’s literature demonstrating the equivalency of any replacement lamps.

- 3.8 ~~[DELETED] Any tanning facility already in existence at the time of the effective date of these regulations may continue to operate, provided that a valid registration application is filed as required by this section and the registration fee is remitted with the application.~~
- ~~3.8.1 Any existing tanning facility that does not meet the requirements of these regulations may be prohibited from continuing to operate until the Department determines that the requirements have been met.~~

Section 4.0 **RENEWAL OF REGISTRATION**

- 4.1 All registrations issued under the provisions of these ~~rules and~~ Regulations shall be required to be renewed annually by the registrants.
- 4.1.1 A registration, unless sooner suspended or revoked, shall expire by limitation one (1) year following its issuance. Said registration may be renewed from year to year after approval by the Department, provided the applicant meets the appropriate ~~statutory and regulatory requirements herein~~ requirements of the Act and these Regulations.
- 4.2 Registration renewal application shall be made on forms furnished by the Department and shall contain all the information required by the form and accompanying instructions.
- 4.3 An annual tanning facility registration renewal fee as set forth in the *Rules and Regulations Pertaining to the Fee Structure for Licensing, Laboratory and Administrative Services Provided by the Department of Health* shall accompany the application renewal form provided by the Department.
- 4.4 The application for registration renewals and renewal fees shall be received by the Department on or before the expiration date of said registration.

Section 5.0 **INSPECTIONS**

- 5.1 The Department shall make, or cause to be made, such inspections and investigations as it deems necessary in accordance with ~~Section §23-68-5 of the Act reference 1 and these Regulations herein.~~
- 5.2 (a) ~~Every tanning facility shall be given prompt notice by the Department of all deficiencies reported as a result of an inspection or investigation. The Department shall notify the registrant of violations of individual standards through a statement of deficiencies (SOD) which shall be forwarded to the tanning facility within fifteen (15) days of the inspection team formally exiting the tanning facility unless the Director determines that immediate action is necessary to protect the health, welfare, or safety of the public or any member thereof through the issuance of an immediate compliance order in accordance with RIGL §23-1-21.~~
- (b) A tanning facility which received a statement of deficiencies (SOD) report must submit a plan of corrections, signed by an authorized representative of the registrant's management, to the Department within fifteen (15) days of the date of the notice of deficiencies.

- 5.3 ~~All written reports and recommendations of inspections~~ All written reports, statements of deficiencies and plans of correction shall be maintained on file in each tanning facility for a period of no less than five (5) years.

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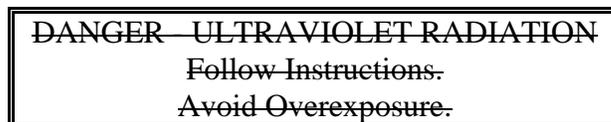
PART III: PROTECTION OF PATRONS

Section 6.0 **WARNING STATEMENT**

- 6.1 At each patron's initial visit to a tanning facility, and at ~~least annually~~ intervals not to exceed twelve (12) months thereafter, the patron shall be provided a written statement containing the following information to review and sign:
- 6.1.1 Not wearing protective eyewear while tanning may cause injury to the eyes;
 - 6.1.2 Overexposure to the tanning process may cause burns;
 - 6.1.3 Repeated exposure to the tanning process may cause skin cancer or premature aging of the skin or both;
 - 6.1.4 Abnormal skin sensitivity or burning may result from the tanning process if the patron is also consuming or using certain:
 - (a) Foods;
 - (b) Cosmetics; or
 - (c) Medications, such as tranquilizers, antibiotics, diuretics, high blood pressure medication, antineoplastic or birth control pills;
 - 6.1.5 Any person taking a prescription or over-the-counter drug should consult a physician or a registered pharmacist before using a sunlamp product; and
 - 6.1.6 During pregnancy a woman should consult with her health care provider before tanning.
- 6.2 A copy of this signed statement shall be maintained in the patron's record, as described in ~~section §14.0 of these Regulations herein.~~
- 6.3 The registrant shall be responsible for complying with the requirements of ~~section §6.0 of these Regulations herein.~~

Section 7.0 **WARNING SIGN**

- 7.1 Pursuant to ~~section §23-68-4(4) of the Act,~~ the registrant shall conspicuously post the warning sign described in ~~section §7.2 of these Regulations below~~ within one meter (39.37 inches) of each sunlamp product and in such a manner that the sign is clearly visible, not obstructed by any barrier, equipment or other object, and can be easily viewed by the patron before operating the sunlamp product.
- 7.1.1 A similar sign containing at least the information listed in ~~section §7.2 of these Regulations below~~ that complies with all other applicable state and federal laws, codes and regulations may be used instead.
- 7.2 This warning sign shall use upper and lower case letters which are at least ten millimeters (0.39 inches) and five millimeters (0.20 inches) in height, as follows:



DANGER – Ultraviolet Radiation

- Follow instructions
- Avoid overexposure
- As with natural sunlight, overexposure may cause eye and skin injury and allergic reactions.
- Repeated overexposure may cause premature aging of the skin and skin cancer.
- **WEAR FDA COMPLIANT 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.
- If you believe that you have been injured by this tanning equipment, you should contact RI Department of Health, Radiation Control Program, 3 Capitol Hill, Room 305, Providence, RI 02908-5097

PROTECTIVE EYEWEAR

- 7.3 The registrant shall require that each patron wear protective eyewear during the use of sunlamp products.
- 7.3.1 The registrant shall provide such protective eyewear, unless the patron furnishes his or her own protective eyewear which meets the requirements of these Regulations herein.
- 7.3.2 Tanning facility operators shall instruct the consumer in the proper utilization of the protective eyewear required by §8.0 of these Regulations.
- 7.4 The tanning facility registrant shall be responsible to ensure that patrons have the protective eyewear required by ~~this section~~ §8.0 of these Regulations before each tanning session and shall make a reasonable effort to ensure that this eyewear is worn during tanning.
- 7.5 The protective eyewear required by ~~this rule~~ §8.0 of these Regulations shall meet the requirements of 21 CFR Part 1040.20(c)(4)(i). [Reference 1]
- 7.6 Any reusable protective eyewear furnished by the registrant shall be sanitized in accordance with ~~section~~ §10.2 of these Regulations herein.

Section 8.0 ***POLICY AND PROCEDURAL REQUIREMENTS RELATED TO PATRON SAFETY***

- 8.1 The registrant shall maintain a list of the common photosensitizing agents as provided by the FDA, or other appropriate authorities, available for review by patrons.
- 8.2 At each tanning facility, the registrant shall keep a list of emergency contact numbers appropriate for the community in which the facility is located. This list shall be easily accessible and shall include, but not be limited to, contact numbers for:
- 8.2.1 The nearest hospital;
 - 8.2.2 The nearest fire department; and
 - 8.2.3 Emergency 911 service.
- 8.3 At least one trained staff member is required on-site at all times when the tanning facility is in operation.
- 8.4 Only one patron may be in a tanning room at one time, with the following exceptions:
- (a) If two (2) or more sunlamp products are used in the same room, in which case only those patrons using sunlamp products may be present in the room; and
 - (b) If a patron using a sunlamp product needs aid or assistance from another person, in which case that individual shall also be provided with and wear protective eyewear.

Exposure of Minors

- 8.5 No patron under the age of eighteen (18) shall be allowed to use a sunlamp product without written consent from a parent or legal guardian.
- 8.5.1 ~~Written consent shall be provided at the facility in the presence of a facility staff member, with the parent or legal guardian understanding the potential risks involved in overexposure. For every two (2) uses of a tanning facility, the parent or legal guardian of such person shall sign and date a written consent form on-site and in the presence of a tanning facility staff member. The written consent form shall contain, at a minimum, the following language: "I understand that the World Health Organization has classified the ultraviolet radiation used in tanning facilities as a Class 1 carcinogen, the same category as tobacco products. By exposing my child to ultraviolet radiation in this tanning facility, the possibility of my child developing melanoma (skin cancer) will increase. I also understand that there are safe alternatives available to achieve the same cosmetic effect as exposing my child's skin to ultraviolet radiation, such as spray tanning or bronzing creams.~~
- 8.5.2 A sign shall be posted in clear view at or near the reception area with the following text: "INDIVIDUALS UNDER AGE 18 ARE REQUIRED TO HAVE PARENT OR LEGAL GUARDIAN SIGN AUTHORIZATION IN THE PRESENCE OF TANNING FACILITY STAFF FOR PERMISSION TO TAN."

- 8.5.3 The minor child and his or her parent or legal guardian shall each submit proof of his or her identity by producing a government-issued photo identification.
 - 8.5.4 A tanning facility shall only accept one (1) written consent form at a time from a parent or guardian. A minor patron is not allowed to have more than one written consent form active at the same time.
- 8.6 Infants and other minors are not permitted to be in the sunlamp product room during exposure of parents or guardians.

Exposure Limits and Other Controls Against Overexposure

- 8.7 The registrant shall ensure that each patron using a sunlamp product shall be instructed on the maximum exposure time and proper exposure distance, as recommended by the manufacturer of the product.
- 8.8 The registrant shall ensure that each patron does not exceed the maximum exposure time indicated by the sunlamp product manufacturer.
- 8.8.1 The registrant shall limit exposure time to the recommended maximum exposure time provided by the product manufacturer on the sunlamp product or in the product operating manual. The maximum exposure time recommended by the manufacturer of the product shall not be exceeded in any twenty-four (24)-hour period.
 - 8.8.2 Initial tanning sessions (three to five) are limited to one tanning session per forty-eight (48)-hour period or as recommended by the sunlamp product manufacturer, whichever is less frequent, to allow adequate time for melanin activation and transit to occur prior to subsequent exposures. Patrons shall be advised of the manufacturer's recommended exposure schedule as posted on the sunlamp product or listed in the operating manual for the product prior to the initial tanning sessions.
 - 8.8.3 After the initial (three to five) tanning exposures, tanning sessions are limited to one tanning session per twenty-four (24)-hour period or as recommended by the sunlamp product manufacturer, whichever is less frequent. Patrons shall be advised of the manufacturer's exposure schedule as posted on the sunlamp product or listed in the operating manual for the sunlamp product prior to tanning.
 - 8.8.4 For patrons with annual tanning packages, package maximums shall not exceed the maximum amount of exposure recommended by the product manufacturer.
- 8.9 Tanning facilities are prohibited from controlling the use of sunlamp products solely with token timer control systems, in the absence of trained staff.
- 8.10 ~~**[DELETED]** Tanning facilities using token timer control systems shall ensure that the patron is not provided with a number of tokens such that overexposure may occur, based on the patron's skin type.~~
- 8.11 The registrant shall ensure the patron is instructed as to the location and proper operation of the sunlamp product's emergency shut-off switch.

- 8.12 The registrant shall establish and use a procedure manual that will aid in the protection of the patron from excessive or unnecessary exposure to ultraviolet light.
- 8.12.1 This manual shall be specific to the facility and shall include at least documentation of the requirements detailed in these ~~rules and~~ Regulations.
- 8.12.2 A copy of this manual shall be kept on-site and readily available at all times when the tanning facility is in operation.
- 8.12.3 This procedure manual may be developed as part of the training manual described in ~~section~~ §13.2 of these Regulations ~~herein~~, provided the above requirements are met.

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PART IV: PHYSICAL PLANT AND EQUIPMENT

Section 9.0 ***CONSTRUCTION, SANITATION AND MAINTENANCE OF TANNING FACILITIES***

- 9.1 Each tanning facility shall be constructed to meet the following minimum requirements:
- 9.1.1 All tanning facilities shall be equipped with convenient toilet facilities and dressing rooms. At a minimum, such toilet facilities shall include a water closet, a hand-washing sink and a safe and sanitary supply of water. Such toilet and dressing rooms shall be properly maintained, as well as meet all federal, state and local laws, codes and regulations.
 - 9.1.2 The sunlamp products shall meet the requirements of ~~section~~ §10.0 of these Regulations herein and all other applicable federal and state requirements.
 - 9.1.3 The physical facility shall be constructed such that:
 - (a) All areas of the tanning facility shall be ventilated with at least six (6) air changes per hour or as otherwise required by local code; and
 - (b) Tanning booth temperature shall be maintained below 100 degrees Fahrenheit (38 degrees Centigrade) during sunlamp product operation.
 - 9.1.4 Except as otherwise required by these Regulations, each tanning facility shall be constructed in accordance with all applicable local and state codes.
- 9.2 Each tanning facility shall be cleaned and maintained to meet the following minimum requirements:
- 9.2.1 All areas of the tanning facility, including tanning devices, equipment and apparatus, shall be maintained in a clean and sanitary manner and in accordance with manufacturer's instructions.
 - 9.2.2 The tanning device(s) and protective eyewear shall be cleaned with an EPA-approved sanitizer after each use, unless the facility provides sanitary disposable clear plastic sheets for application and disposal after each patron use of a tanning device. Suitable written instructions shall be posted to provide adequate guidance to patrons using sanitary sheets.
 - (a) Facilities using disposable clear plastic sheets to cover the surface of a tanning device shall be required to clean and sanitize those tanning devices periodically throughout each day the tanning devices are being used by patrons
 - (b) Disposable eyewear designed for one use only are exempt from this requirement provided that they are disposed of and not reused by any other patron.
 - (c) Tanning devices shall be cleaned and sanitized according to the following minimum provisions:
 - (1) A clean paper or cloth towel shall be used each time the tanning device is cleaned and sanitized;

- (2) The sanitizer used shall be one specifically manufactured for sanitizing ultraviolet light-emitting equipment and protective eyewear and that does not damage the acrylic lamp covers of the sunlamp product.
 - (3) The ultraviolet light produced by a sunlamp product itself is not considered an adequate sanitizing agent.
- 9.2.3 A test kit or other device that accurately measures the concentration of the sanitizing solution in parts per million (ppm) shall be used to measure the strength of the sanitizing solution when the concentrate and water dilution is initially prepared and at least weekly thereafter to ensure sufficient strength of the sanitizing solution.
- (a) If a suitable test kit is not available for an approved sanitizer, the laboratory analysis data shall be provided by the product manufacturer, and a copy shall be on file with the Department.
- 9.2.4 Written procedures maintained at the facility shall include proper mixing and handling instructions for each sanitizer used, so as to ensure proper concentration of the sanitizer.
- 9.2.5 Except as otherwise required by these Regulations, each tanning facility shall be cleaned and maintained in accordance with all applicable local and state codes.
- 9.3 Clean sanitary towels shall be available to all patrons using tanning facilities.
- 9.4 A hamper or other receptacle shall be provided for all soiled towels and linen.
- 9.5 No pets or other animals shall be permitted in tanning rooms at any time, other than seeing eye dogs or hearing assistance dogs.

Section 10.0 ***EQUIPMENT***

- 10.1 The registrant shall use only sunlamp products manufactured in accordance with the specifications set forth in 21 CFR Part 1040.20, "Sunlamp products and ultraviolet lamps intended for use in sunlamp products." [Reference 1], Sunlamp products which do not meet the provisions of 21 CFR Part 1040.20 shall not be operated.
- 10.1.1 The sunlamp products shall meet the National Fire Protection Association's National Electrical Code, or be approved by the Underwriter Laboratories (UL) or Electrical Testing Laboratories (ETL). Compliance shall be based on the standard in effect at the time of manufacture as shown on the device identification label required by 21 CFR Part 1010.3.
- 10.2 Each sunlamp product or ultraviolet lamp used in tanning facilities shall not emit measurable ultraviolet C radiation.
- 10.3 Each ultraviolet lamp contained within the sunlamp product shall be shielded so as to not come into contact with the patron.

- 10.4 The construction of the sunlamp product shall be such that it will have the strength to withstand the stress of use and the impact of a falling person.
- 10.4.1 Entry to stand-up sunlamp products shall be of rigid construction with doors which are non-locking and open outwardly.
- 10.5 The appropriate position the patron is to assume prior to operation shall be clearly marked on each sunlamp product.
- 10.6 Each sunlamp product shall prominently display ~~the following~~ a label which contains the information required by §7.2 of these Regulations or an equivalent warning/information label:

~~**DANGER – ULTRAVIOLET RADIATION
FOLLOW INSTRUCTIONS CAREFULLY
DO NOT ENTER WITHOUT PROTECTIVE EYEWEAR**~~

- 10.7 Reasonable means shall be provided to enable a patron to summon assistance from the exposure position.
- 10.8 Original Equipment Manufacturer (OEM) replacement parts (or their equivalent) shall be used, if available, to prevent UL/ETL de-listing of sunlamp products. All local, state and national electrical codes shall be observed during installation.
- 10.9 Defective or ~~burned-out tanning lamps or bulbs~~ non-lighting filters or lamps at the end of their useful UV-emitting life shall be replaced with a type intended for use in the sunlamp product, shall be of the same ultraviolet range (A or B) as specified by the manufacturer, and shall be the original lamp type as specified by the manufacturer, or shall be certified as an equivalent lamp per 21 CFR 1040.20(c)(5). [Reference 1]
- 10.9.1 If equivalent lamps are used instead of the required OEM lamps, a copy of the equivalency certification provided by the lamp supplier shall be maintained on file for review by the Department.
- 10.10 Defective or burned out tanning lamps and tanning lamps which have been operated in a sunlamp product for the manufacturer's maximum rated lamp hour life shall be disposed of in a safe and proper manner to prevent unauthorized and unsafe use as lighting devices. Used tanning lamps are prohibited from being resold for any purpose.
- 10.11 Each sunlamp product shall have a timer which complies with the requirements of 21 CFR Part 1040.20(c)(2). [Reference 1]
- 10.11.1 The maximum timer interval shall not exceed the manufacturer's maximum recommended exposure time.
- 10.11.2 Each timer shall be functional and accurate to within $\pm 10\%$ of the maximum timer interval of the product as required by 21 CFR Part 1040.20 (c)(2)(iii). [Reference 1]

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- 10.11.3 The registrant shall ensure that the timer is tested ~~annually~~ for accuracy at intervals not to exceed twelve (12) calendar months.
- 10.11.4 Sunlamp product timers shall be controlled by properly trained staff.
- 10.11.5 ~~New~~ Tanning facilities ~~(including existing facilities with change of ownership)~~ shall install remote timer controls prior to the operation of sunlamp products. ~~Existing sunlamp products not equipped with a remote timer control system are required to have remote timer controls (outside of sunlamp product room) installed no later than May 1, 2000.~~
- 10.11.6 The time shall 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 interrupted.
- 10.12 In addition to a timer, each sunlamp product shall be equipped with ~~an emergency shut-off mechanism to allow manual termination of the UV exposure by the patron~~ a control on the product to enable the person being exposed to terminate manually radiation emission from the product at any time without disconnecting the electrical plug or removing the ultraviolet lamp, as required by 21 CFR Part 1040.20(c)(3). [Reference 1]
- 10.13 The minimum requirements of the manufacturer shall be maintained for all sunlamp products.
- 10.14 Each sunlamp product shall be equipped with an hour meter to accurately determine lamp hour use.
- 10.14.1 Lamp hour use as indicated by the hour meter shall be recorded at each episode of maintenance service for each product, as specified in ~~section~~ §14.10.3 of these Regulations.
- ~~10.15 Sunlamp products which do not meet the provisions of this section shall not be operated.~~

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PART V: ADMINISTRATIVE REQUIREMENTS

Section 11.0 *GENERAL ADMINISTRATIVE REQUIREMENTS*

- 11.1 The registrant shall be responsible for directing the operation of the tanning facility which has been registered with the Department. That registrant shall assure that the provisions of these Regulations are met in the operation of a tanning facility.
- 11.2 The registrant shall ensure that the tanning facility complies with all applicable federal, state and local codes, laws and regulations.
- 11.3 Each registrant shall establish and maintain a tanning facility specific electronic mail address (i.e., e-mail address) to be provided to the Department for the purposes of contacting the registrant with both routine communications and emergency notices. The registrant shall be responsible for providing notice to the Department at any time that the tanning facility's specific electronic mail address is changed or updated.

Section 12.0 *TRAINING OF PERSONNEL*

- 12.1 ~~DELETED Prior to July 1, 1999, all registered tanning facilities in the state of Rhode Island shall have completed the staff training requirements listed in section 13.2 below.~~
- 12.2 The registrant shall certify that all tanning facility staff are adequately trained and have been issued a training manual established for that facility. This training and manual shall include, but not be limited to, coverage of the following provisions:
 - 12.2.1 The requirements of these Regulations;
 - 12.2.2 Procedures for correct operation of the tanning facility and sunlamp products;
 - 12.2.3 Guidelines for the recognition of injury or overexposure to ultraviolet radiation;
 - 12.2.4 The sunlamp product manufacturer's procedures for operation and maintenance of the sunlamp products;
 - 12.2.5 Guidelines for the determination of skin type of customers and appropriate determination of duration of exposure to sunlamp products;
 - 12.2.6 Procedures for the use of minor and patron consent forms;
 - 12.2.7 Emergency procedures to be followed in case of injury;
 - 12.2.8 Potential photosensitizing foods, cosmetics, and medications;
 - 12.2.9 Requirements for the proper use of protective eyewear; ~~and~~
 - 12.2.10 Proper sanitizing procedures for eyewear, facility, and devices; and
 - 12.2.11 Instructions for use of sunlamp product to avoid or to minimize potential injury to the patron, as required by 21 CFR Part 1040.20(e). [Reference 1].
- 12.3 The registrant may use vendor-provided information in establishing the facility's training manual, provided that this material contains all of the above information.

- 12.4 Staff training shall be documented by the registrant. Such documentation shall include the dates and times of the training, as well as the subjects covered in each training session
- 12.5 Tanning equipment shall only be operated when a trained tanning operator is present at the tanning facility.

Section 13.0 ***RECORDS AND REPORTS***

- 13.1 The registrant shall be responsible ~~to maintain~~ for maintaining all records as described in these Regulations herein.
- 13.2 All required records shall be maintained at the tanning facility for a minimum of three (3) years and shall be available for review by the Department.
- 13.3 All required records may also be completed, transmitted, and stored in electronic media with the capability for producing legible, accurate, and complete copies of the records. If records are stored electronically, they shall be maintained in a manner that will allow retrieval of records for any specified time period. All records shall be maintained in either an electronic format or a printed format.

Patron Records

- 13.4 The registrant shall maintain a record of each patron's total number of tanning visits, dates and durations of tanning exposures.
- 13.5 The registrant shall maintain a record of each patron's signature and acknowledgment that he/she understands the potential risks involved with exposure and overexposure to ultraviolet radiation and he/she has reviewed a photosensitizing drug list.
- 13.6 The registrant shall maintain all records of parental consent regarding minors, as required by §9.5 of these Regulations, including a copy of the government-issued photo identification used by the minor child and his or her parent or legal guardian to document compliance with §9.5.3 of these Regulations.
- 13.7 Within five (5) working days after occurrence or knowledge thereof, the registrant shall submit to the Department a written or electronic report of each actual or alleged accident or injury that results from the use of registered sunlamp products for which medical attention was sought or obtained. The report shall include:
- 13.7.1 The name of the ~~injured~~ affected individual(s);
- 13.7.2 The name, location and phone number of the tanning facility involved;
- 13.7.3 The nature of the actual or alleged injury(ies); and
- 13.7.4 Any other information relevant to the actual or alleged injury(ies) to include the date and duration of exposure and any documentation of medical attention sought or obtained.
- 13.7.5 All reports are to be forwarded to RI Department of Health, Radiation Control Program, 3 Capitol Hill, Room 305, Providence, RI 02908-5097 or electronically to ofr@health.ri.gov.

Training and Equipment Records

- 13.8 The registrant shall maintain a record of staff training as required in ~~section~~ §12.0 of these Regulations herein.
- 13.9 The registrant shall maintain records showing the results of ~~annual~~ timer tests required by §10.11.3 of these Regulations.
- 13.10 The registrant shall maintain the following information for each sunlamp product:
- 13.10.1 Manufacturer's equipment manual and any other service-related material or instruction;
 - 13.10.2 The exposure schedule provided by the manufacturer; and
 - 13.10.3 Records of surveys, inspections, maintenance and modifications performed on the sunlamp product, including the names of persons performing such services, the date of service and the hour meter reading of the product serviced.
- 13.11 The registrant shall maintain records showing the receipt, transfer, repair and disposal of all sunlamp products and lamps.

Section 14.0 ***ADVERTISING AND PROMOTION***

- 14.1 No person or establishment registered under the Act and these Regulations ~~statutory and regulatory provisions herein~~ shall use or cause or promote the use of any advertising, promotional literature, testimonial, guarantee, warranty, label, brand, insignia or any other representation, however disseminated or published, which is misleading, deceptive or untruthful.
- 14.2 No person or facility shall advertise or promote tanning packages labeled as "unlimited" unless information regarding maximum exposure schedules is included in such advertisements.
- 14.2.1 Promotion of annual tanning packages shall include a written statement listing the total number of sessions allowed per person per year, as listed in ~~section~~ §9.8 of these Regulations herein.

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PART VI: PENALTIES, PRACTICES AND PROCEDURES AND SEVERABILITY

Section 15.0 ***DENIAL, REVOCATION OR SUSPENSION OF REGISTRATION***

- 15.1 The Department is authorized to deny an application for the issuance of a registration or to revoke or suspend any registration issued if the ~~statutory and regulatory~~ provisions of the Act and these Regulations ~~herein~~ are not met.
- 15.2 Whenever an action shall be proposed to deny, revoke or suspend a registration, the Department shall notify the applicant by certified mail, setting forth reasons for the proposed action. The applicant shall be given an opportunity for a prompt and fair hearing, in accordance with the ~~*Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP)*~~ of reference ~~3~~ *Rules and Regulations Pertaining to Practices and Procedures Before the Rhode Island Department of Health [R42-35-PP]. [Reference 2]*
- 15.3 If the Department finds that the public health, safety or welfare of the public requires emergency action and incorporates a finding to that effect in its order, the Department may order summary suspension of a registration pending proceedings for revocation or other action in accordance with ~~sections~~ RIGL §42-35-14(c) and ~~section~~ §23-1-21 ~~of the General Laws of Rhode Island, as amended.~~

Section 16.0 ***VIOLATIONS AND PENALTIES***

- 16.1 In accordance with ~~section~~ §23-68-7 of the Act, any person, firm or corporation who violates the provisions of the Act or these Regulations shall be punished by a fine not to exceed five hundred dollars (\$500) for the first offense and by a fine not more than one thousand dollars (\$1000) for each subsequent offense.

Section 17.0 ***SEVERABILITY***

- 17.1 If any provision of these ~~rules and~~ Regulations or the application thereof to any individual or circumstance shall be held invalid, such invalidity shall not affect the provisions or application of these Regulations which can be given effect, and to this end the provisions of these Regulations are declared to be severable.

REFERENCES

1. ~~"Tanning Facility Safety Standard Act," Chapter 23-68 of the Rhode Island General Laws, as amended.~~
2. ~~"Sunlamp products and ultraviolet lamps intended for use in sunlamp products," Department of Health and Human Services, Food and Drug Administration (FDA): 21 CFR Part 1040.20. Available online: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=1040.20>
<http://www.ecfr.gov/cgi-bin/text-idx?SID=36133bee3466e5d38063e419e5f22fde&node=21:8:0.1.3.45&rgn=div5#21:8:0.1.3.45.0.1.3>~~
2. *Rules and Regulations Pertaining to Practices and Procedures Before the Rhode Island Department of Health [R42-35-PP]*, Rhode Island Department of Health, July 2013.
3. ~~*Rules and Regulations of the Rhode Island Department of Health Regarding Practices and Procedures Before the Department of Health and Access to Public Records of the Department of Health (R42-35-PP)*, Rhode Island Department of Health, May 1997.~~

The revision dates of all regulations cited above were current when these amended regulations were filed with the Secretary of State. Current copies of all regulations issued by the RI Department of Health may be downloaded at no charge from the RI Secretary of State's Final Rules and Regulations Database website: <http://www.sos.ri.gov/rules/>