

PART BB
TANNING FACILITIES

Sec. BB.1 - Purpose and Scope.

- a. This Part provides for [the registration of tanning facilities using ultraviolet lamps and] regulation of the maintenance and operation of tanning facilities.
- b. In addition to the requirements of this Part, all facilities are subject to the applicable provisions of other Parts of these regulations.
- c. Nothing in this Part shall be interpreted as limiting the intentional exposure of patients to ultraviolet radiation for the purpose of treatment or use commensurate with the licensed practitioner's use of a healing art.

Sec. BB.2 - Definitions.

"Act" means [cite State Radiation Control Act].

"Agency" means [cite appropriate State Agency].

"CFR" means Code of Federal Regulations.

"Consumer" means any member of the public who is provided access to a tanning facility 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 facility as a condition or benefit of membership or access.

"EPA" means Environmental Protection Agency.

"FDA" means Food and Drug Administration.

"FTC" means Federal Trade Commission.

"Formal operator training" means a course of instruction pre-approved by the Agency conducted or presented under formal classroom conditions, a correspondence program, or through a computer based program by a person possessing adequate knowledge and experience to offer the curriculum, associated training, and certification testing pertaining to and associated with the safe use of tanning equipment. Training shall cover ultraviolet radiation and effects on the skin, photosensitivity, eye protection, equipment maintenance, FDA regulations and the provisions of these rules [insert appropriate rules or regulations].

"Individual" means any human being.

"Inspection" means an official examination or observation including but not limited to tests, surveys, and monitoring to determine compliance with rules, regulations, orders, requirements and conditions of the Agency.

"License" means a license issued by the Agency in accordance with regulations issued by the Agency.

"Medical Lamps" means any lamp that is specifically designed and labeled for medical use only.

"Minor" means any individual less than eighteen (18) years of age.

"Operator" means an individual designated by the registrant to control operation of the tanning facility and to instruct and assist the consumer in the proper operation of the tanning equipment.

"Person" means any individual, corporation, partnership, firm, association, trust, estate, public or private institution, group, agency, political subdivision of this State, any other State or political subdivision or agency thereof; and any legal successor, representative, agent, or agency of the foregoing.

"Personal use" means operating a single tanning unit for individual purpose of cosmetic tanning. Personal use implies that the unit will not be used for any business purpose. Multiple tanning units can not be used as personal use.

"Registrant" means any person who obtains a registration, permit or other entitlement from the Agency, and who is under obligation by such registration, permit or other entitlement from the Agency pursuant to these regulations and the Act.

"Registration" means registration with the Agency in accordance with regulations adopted by the Agency.

"Tanning device" means any equipment used during the process of skin tanning with a sun lamp 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.

"Tanning facility" means any location, place, area, structure or business which provides consumers access to tanning equipment.

"These regulations" means all parts of [cite appropriate rules or regulations].

"Ultraviolet radiation" means electromagnetic radiation with wavelength in air between 200 nanometers and 400 nanometers.

Sec. BB.3 - Exemptions.

- a. General: The Agency may, upon application or upon its own initiative, grant such exemptions or exceptions from the requirements of these regulations as it determines are authorized by law and will not result in undue hazard to public health and safety.

- b. Equipment intended for purposes other than deliberate exposure of parts of the living human body to ultraviolet radiation, and which produce or emit ultraviolet radiation incidental to its proper operation, are exempt from the provisions of this Part.
- c. Radiation machines while in transit or storage incidental thereto are exempt from provisions of this Part.
- d. Any individual is exempt from the provisions of these rules to the extent that such individual owns a tanning device exclusively for personal use.

Sec. BB.4 - Application for Registration of Tanning Facilities.

- a. Each person having a tanning facility shall apply for registration of such facility with the Agency within [30] days following the effective date of these regulations or thereafter prior to the operation of a tanning facility. Application for registration shall be completed on forms satisfactory to the Agency and shall contain all the information required by the form and the accompanying instructions.
- b. The Agency shall require at least the following information on the application for registration of tanning facilities form:
 - i. The name, address and telephone number of the following:
 - (1) The tanning facility;
 - (2) The owner(s) of the tanning facility;
 - ii. The manufacturer, model number, and type of each lamp or tanning equipment located within the facility;
 - iii. The geographic areas within the State where the tanning equipment will be operated under this registration if the facility is mobile;
 - iv. The name address and telephone number of the tanning equipment supplier, installer, and service agent;
 - v. A signed and dated certification that the applicant has read and understands the requirements of these regulations;
 - vi. A copy of operating and safety procedures unique to facility operation;
 - vii. A copy of the certificate from a state approved training program showing satisfactory completion of Formal Operator Training.
- c. Each applicant shall provide such additional information as the Agency may reasonably require.

Sec. BB.5 - Issuance of Certificate of Registration.

- a. Upon determination that an applicant meets the requirements of BB.4, the Agency shall issue a certificate of registration. The Certificate of Registration shall be displayed in a conspicuous location that is visible to the customer and on the premises of the tanning facility.
- b. The Agency may incorporate in the certificate of registration at the time of issuance or thereafter by appropriate rule, regulation or order, such additional requirements and conditions with respect to the registrant’s receipt, possession, use and transfer of tanning facilities as it deems appropriate or necessary.
- c. No person shall operate a tanning facility until the Agency has issued the certificate of registration [here insert reference to the relevant administrative procedures for response by the Agency.]

Sec. BB.6 - Expiration of Certificate of Registration. Except as provided in BB.7b., each certificate of registration shall expire at the end of the specified day in the month and year stated therein.

Sec. BB.7 - Renewal Certificate of Registration.

- a. Application for renewal of registration shall be filed in accordance with BB.4.
- b. In any case in which a registrant not less than 30 days prior to the expiration of his existing certificate of registration has filed an application in proper form for renewal, such existing certificate of registration shall not expire until the application status has been finally determined by the Agency.

Sec. BB.8 - Report of Changes. The registrant shall notify the Agency in writing before making any change which would render the information reported pursuant to BB.4b.i., ii., iii., and vi., contained in the application for registration or certificate 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 Food and Drug Administration as “equivalent” replacement of the lamps. The facility owner shall maintain manufacturer’s literature demonstrating the equivalency of any replacement lamps.

Sec. BB.9 - Transfer of Certificate of Registration. No certificate of registration shall be transferable from one person to another or from one tanning facility to another.

Sec. BB.10 - Approval Not Implied. No person, in any advertisement, shall refer to the fact that their facility is registered with the Agency pursuant to the provisions of BB.5, and no person shall state or imply that any activity under such registration has been approved by the Agency.

Sec. BB.11 - Denial, Suspension, or Revocation of Certificate of Registration.

- a. The Agency may, for good cause shown, deny, suspend or revoke a certificate of registration sought or issued pursuant to these regulations for any of the following reasons:

- i. Failure to have reports, plans or specifications to show that the tanning facility will be constructed, operated or maintained in accordance with the requirements of these regulations;
 - ii. Submission of incorrect, false or misleading information in the application, reports, plans, or specifications;
 - iii. Failure to construct, operate or maintain the tanning facility in accordance with the application, plans and specifications approved by the Agency except as such maintenance may involve the replacement of lamps by “equivalent” lamps which have been defined in BB.8 above;
 - iv. Operation of the tanning facility in a way that causes or creates a nuisance or hazard to the public health or safety;
 - v. Violation of any rules, regulations, standards, or requirements adopted by the Agency;
 - vi. Violation of any condition upon which the certificate of registration was issued;
 - vii. Failure to allow duly authorized agents of the Agency to conduct inspections within facility’s hours of operation and in a proper protocol[;
 - vii. Failure to pay any registration or inspection fees within Agency specified time limit].
- b. Hearing: If any certificate of registration is denied, suspended, or revoked, the applicant or registrant may request a hearing in accordance with [here insert reference to applicable administrative procedures act, hearing rules, etc].

Sec. BB.12 - Construction and Operation of Tanning Facilities. Unless otherwise ordered or approved by the Agency, each tanning facility shall be constructed, operated, and maintained to meet the following minimum requirements:

- a. Physical Facilities.
 - i. The following warning sign shall be in the immediate proximity (within 1 meter) of each piece of tanning equipment; 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 energizing the-tanning equipment:

WARNING – ULTRAVIOLET RADIATION

- Follow instructions
- 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 indoor tanning beds or booths 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 [insert the name, address, and telephone number of state agency governing the tanning facilities].

The lettering on each warning sign shall be at least 10 millimeters high for all words shown in capital letters and at least 5 millimeters high for all lower case letters. A Consumer Notification providing the consumer the name and address of the state agency governing the tanning facilities, so that in case of an injury the consumer can contact the Agency.

- ii. Only tanning equipment manufactured and certified to comply with the 21 CFR Part 1040, Section 1040.20, “Sunlamp products and ultraviolet lamps intended for use in sunlamp products,” shall be used in tanning facilities. 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, Section 1010.3.
- iii. Each tanning equipment shall have a timer which complies with the requirements of 21 CFR Part 1040, Section 1040.20(c)(2). The maximum timer interval shall not exceed the manufacturer’s maximum recommended exposure time. No timer interval shall have an error greater than 10% of the maximum timer interval for the product.
- iv. The timer 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.
- v. Each tanning device shall be equipped with a user or consumer accessible on/off switch and an emergency shut-off mechanism to allow manual termination of the UV exposure as required by 21 CFR 1040.20 (c)(3).
- vi. Each tanning device shall have labels as noted in 21 CFR 1040.20(d)(1)(i-vi).
- vii.. Tanning equipment shall meet the National Fire Protection Association’s National Electrical Code.
- viii. There shall be physical barriers to protect consumers from injury induced by touching or breaking the lamps.

- ix. Additional requirements for stand-up booths:
 - (1) There shall be 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;
 - (2) The construction of the booth shall be such that it will withstand the stress of use and the impact of a falling person;
 - (3) Access to the booth shall be of rigid construction; doors shall open outwardly. Handrails and non-slip floors shall be provided.
- [x. Here insert reference to other appropriate regulations dealing with health, hygiene, safety standards, including electrical standards such as Underwriters Laboratories, etc.]
- b. Protective Eyewear.
 - i. Each consumer shall be provided with protective eyewear and instructions for their use.
 - ii. Protective eyewear shall meet the requirements of 21 CFR Part 1040.20 (c)(4).
 - iii. Protective eyewear shall be properly sanitized before each use with a sanitizing agent which is registered by the EPA, mixed to the appropriate concentration. Exposure to the ultraviolet radiation produced by the tanning equipment itself is not a sanitizing agent.
 - iv. Tanning facility operators shall instruct the consumer in the proper utilization of the protective eyewear required by this Section.
- c. Operation and Training.
 - i. A tanning registrant shall only allow operation of tanning equipment by those who have successfully completed a formal operator training course that has been pre-approved by the Agency.
 - ii. Tanning equipment shall only be operated when a trained tanning operator is present at the tanning facility.
 - iii. Prior to initial exposure, each consumer shall be provided the opportunity to read a copy of the warning specified in BB.12a.i. The operator shall then request that the consumer sign a statement that the information has been read and understood. For illiterate or visually handicapped persons, the warning sign shall be read by the operator in the presence of a witness. Both the witness and the operator shall sign the statement.

- iv. A record shall be kept by the facility operator of each consumer's total number of tanning visits and total accumulated exposure times.
- v. A written report of any alleged tanning injury shall be forwarded to the Agency within 5 working days of its occurrence or knowledge thereof. The report shall include:
 - (1) The name of affected individual;
 - (2) The name and location of the tanning facility involved;
 - (3) The nature and circumstance of the alleged injury;
 - (4) Name and address of health care provider, if any;
 - (5) Any other information considered relevant to the situation.
- vi. No minor shall be allowed to use the tanning device equipment unless the minor provides a consent signed by the parent or legal guardian and the consent statement must be witnessed by an operator. The parent or legal guardian shall have been provided with the basic information required under BB.12a.i. A tanning facility may not allow a minor between the ages of 14 and 18 to use a tanning device unless it has on file a statement signed by the minor's parent or legal guardian stating that the parent and legal guardian has read and understands the warnings given by the tanning facility, consents to the minor's use of the tanning device, and agrees that the minor will use federally compliant protective eyewear.
 - (1) A minor under the age of 14 must be accompanied by a parent or legal guardian when using a tanning device.
- vii. Each assembly of tanning equipment shall be designed for use by only one consumer at a time.
- viii. Defective, nonlighting, or filters or lamps at the end of their useful UV emitting life should be replaced with a type intended for use in that device as specified on the product label on the tanning equipment, or, with lamps or filters that are registered with the Food and Drug Administration as compatible to the original lamp and according to the regulations and policies at the time of lamp manufacture.
- ix. Each tanning equipment operator must be adequately trained by a pre-approved formal training course as required by the Agency. Proof of training must be maintained in the facility and available for inspection. Each formal training course shall meet the following requirements
 - (1) The requirements of these regulations;
 - (2) Procedures for correct operation of the facility;

- (3) Recognition of injury or overexposure;
 - (4) Manufacturer's procedures for operation and maintenance of tanning equipment;
 - (5) Emergency procedures in case of overexposure or injury;
 - (6) Each course shall include written material which covers the required subjects, such as a training manual; audio-visual presentations which cover the required subjects, such as slides or videos; copies of the state's rules and copies of Title 21, Code of Federal Regulations, Section 1040.20; and a question and answer period for trainees;
 - (7) Procedures for correct cleaning, sanitizing, and operation of the tanning device. This includes proper care and use of protective eyewear;
 - (8) Biological effects of ultraviolet radiation, maximum allowable time of exposure, photosensitivity, and determination of human skin types as it relates to compliant use of the FDA recommended exposure schedule;
 - (9) Review and explain the lamp compatibility for tanning equipment.
- x. A list of operators trained in accordance with BB.12c.ix. shall be maintained and available at the facility.
- xi. A list of photosensitizing agents shall be posted in each area where tanning equipment is located and shall be explained to the consumer on their initial visit and periodically.

Sec. BB.13 - Enforcement and Penalties. [here insert reference to relevant statutory authority to inspect, cite violations, and compel compliance and assess penalties.]

Sec. BB.14 - Severability. If any provision, clause, section, sentence or paragraph of these regulations or the application thereof to any person shall be held to be invalid, such invalidity shall not affect the remaining provisions or applications of the regulations. The valid part of any provision, clause, section, sentence or paragraph shall be given independence from the invalid provisions or applications, and to this end these regulations are hereby declared to be severable.

Sec. BB.15 - Effective Date. [here insert relevant effective date.]

2007 RATIONALE

PART BB TANNING FACILITIES

Sec. BB.2 - Definitions.

A number of definitions were added to BB.2 for purposes of greater clarification. This included defining common acronyms for ease of reading. New definitions include: Code of Federal Regulations, Environmental Protection Agency, Food and Drug Administration, and Federal Trade Commission.

Definitions for Formal Operator Training, Medical Lamps, Minor were added, and the definition for Tanning equipment services was deleted for clarification purposes only.

Sec. BB.3 - Exemptions.

Section BB.3d. was added to make clear that the regulations are intended for commercial tanning purposes only.

Sec. BB.4 - Application for Registration of Tanning Facilities.

Section BB.4b.vii. was added to require training certificates for all trained operators prior to registering with the Agency.

Sec. BB.5 - Issuance of Certificate of Registration.

Section BB.5a. was amended so that patrons will be made aware that the facility is properly registered.

Sec. BB.8 - Report of Changes.

Notification requirements were changed under this section to eliminate the need for the tanning facility to notify the Agency each time lamps are replaced. This was accomplished by eliminating the reference to Section BB.4b.ii.

Sec. BB.12 - Construction and Operation of Tanning Facilities.

The warning sign defined under section BB.12a.i. will remain as original until FDA make changes to update the language. If the FDA rule changes then the States can make noted changes. The committee does request that Agency name, address and telephone number remain on warning signs to assist in reporting injuries due to tanning equipment and ensure that the Agency is notified of any injury at a tanning facility.

Section BB.12a.iii. remote timers was removed by committee at this time due to peer review and discussion.

In addition, Section BB.12a.iv. was added to avoid overexposure to ultraviolet once the time on the tanning equipment has been interrupted.

Section BB.12a.v. reinforces the requirements of 21 CFR 1040.20 (c)(3). This addition also ensures a safety mechanism for the consumer.

Section BB.12a.vi. is also required by the CFR (21 CFR 1040.20(1)(i-vi) but also provides needed information to the consumer.

Throughout Section BB.12b., the term "Eyewear" was substituted for "Goggles" because several types of eye protection are available. Also, BB.12b.iii. and BB.12b.iv. were added to ensure that each consumer has protective eyewear and has been instructed on proper usage.

Section BB.12c. was changed to provide safety to the consumer by requiring that operators be formally trained.

Section BB.12c.vi. was expanded to provide safety on the part of the minor and to ensure that the guardian is aware of the warnings associated with the use of tanning equipment.

Section BB.12c.ix. provides the tanning operators with training courses that have only been approved by the Agency. Subsections (5) and (6) were added both for purposes of clarification and to ensure that the operator is trained with the appropriate materials.

Section BB.12c.ix.(8) was added for additional safety for the consumer.

Section BB.12c.ix.(9) reinforces the importance of lamp compatibility.

Section BB.12c.xi. was added for safety on the part of the consumer.

Matters for Future Consideration

A copy of the Federal Statutes to accompany the SSR rules as an appendix.

The committee removed any reference to professional insurance policy as it is not required. A footnote mentions it as a state option.

The committee would suggest further discussion of the remote timer component of the rule between the committee and FDA and future changes to Part BB may incorporate these findings.

Addition of a reference list for EPA approved sanitizer agents.

**1996
RATIONALE**

**PART BB
REGULATIONS FOR TANNING FACILITIES**

Introduction

The use of ultraviolet tanning equipment for cosmetic purposes has been a growing industry for a number of years, to the point where several million citizens, young and old, receive tanning sessions each year.

Concern over the health effects of ultraviolet exposure to these sources has caused the Food and Drug Administration to promulgate a performance standard for sunlamp products, which became effective May 7, 1980. This performance standard is chiefly a manufacturing standard.

While there is still an active home purchase market for ultraviolet tanning machines, a sizable commercial tanning industry has also grown up. This market is not confined to commercial tanning salons alone. Rather, units can be found in, beauty parlors, health clubs, apartment complexes, nail shops, resorts, bars, etc.

Training of operators, instructions to clients, even time of exposure is left entirely to the whim of the unit owner or employee. This includes the crucial instructions on eye protection.

The Food and Drug Administration, the American Dermatology Association, and the U.S. Surgeon General's Office are but a few groups that recognize the hazard of ultraviolet tanning and support its control and regulations.

Part BB is concerned with the issuance of license/registration authorizing the exposure of the general population to artificial ultraviolet tanning sources, i.e., tanning beds, stand-up booths, and facial units.

This Part is needed to provide specific standards and performance objectives for facilities offering nonmedical or unintentional exposure to ultraviolet radiation to the public; in other words, facilities offering cosmetic exposure. These objectives include recordkeeping, equipment performance, safety posting, training of operators, and knowledgeable consent of the user.

Currently only Food and Drug Administration regulations are available and only cover manufacturing standards of commercial tanning equipment, and as such do not concern themselves with numerous safety aspects of the units once in the field, or how the licensee complies with those standards.