

10-144

Chapter 223

**STATE OF MAINE RULES
RELATING TO TANNING FACILITIES**



**DEPARTMENT OF HEALTH & HUMAN SERVICES
MAINE CENTER FOR DISEASE CONTROL & PREVENTION
DIVISION OF ENVIRONMENTAL HEALTH
11 STATE HOUSE STATION
AUGUSTA, MAINE 04333**

LAST AMENDED: April 30, 2013

STATE OF MAINE RULES RELATING TO TANNING FACILITIES
10-144 CMR, CHAPTER 223

SUMMARY

These rules describe the requirements for tanning facilities using ultraviolet lamps and regulates the maintenance and operation of tanning facilities.

BASIS STATEMENT:

These Rules provide minimum State requirements for tanning facilities to protect public health.

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Department of Health & Human Services
Maine Center for Disease Control and Prevention
Division of Environmental Health
Radiation Control Program
11 State House Station
Augusta, Maine 04333-0011

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SECTION 1. PURPOSE AND SCOPE

- A.** These rules, formerly established at 10-144 CMR, Chapter 220, Part T, 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 section, all facilities are subject to the applicable provisions of other sections of these regulations.

- C.** Nothing in this section 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.

SECTION 2. DEFINITIONS

The following terms are defined for purposes of these rules ~~this part~~:

- A. “Act” means 22 M.R.S. Chapter 160.
- B. “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.
- C. “CFR” means Code of Federal Regulations.
- D. “Department” means the Department of Health and Human Services.
- E. “FDA” means the Food and Drug Administration of the United States Government.
- F. “Formal operator training” means a course of instruction pre-approved by the Department 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 the issues listed in Section 7(D)(4).
- G. “Healing arts” means any discipline which involves the diagnosis or treatment of individuals by a practitioner who is licensed for that purpose by the State of Maine, and which discipline, prior to the effective date of these regulations, included the intentional exposure of individuals to sources of radiation for diagnosis or treatment.
- H. “Individual” means any human being.
- I. “Informal Operator Training” means training by a formally trained operator of the same facility as described in Section 7(D)(5).
- J. “Injury” means physical damage or negative effects to the body, resulting from the use of tanning equipment.

K. "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.

L. "Minor" means any individual who is under 18 years of age.

M. "Mobile facilities" means any tanning equipment not used in a permanent facility.

N. "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. Under this definition, the term "operator" means any formally or informally trained individual who conducts one or more of the following activities:

- 1) Determine customer's skin type;
- 2) Determine the suitability for the use of a piece of tanning equipment by prospective customers;
- 3) Inform the customer of the dangers of ultraviolet radiation exposure, including photoallergic reactions and photosensitizing agents;
- 4) Assure that the customer reads and properly signs all forms required by these rules;
- 5) Maintain required customer exposure records;
- 6) Recognize and report customer injuries or alleged injuries to the Department;
- 7) Determine the customers' exposure schedule;
- 8) Set timers which control the duration of exposure; and
- 9) Instruct the customer in the proper use of protective eyewear.

N. "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.

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

P. "Protective eyewear" means suitable devices that safeguard the eyes from ultraviolet radiation and allows adequate vision.

Q. "Radiation" for the purpose of this part means ultraviolet radiation.

R. "Radiation machine" means any device capable of producing radiation.

- S.** "Registrant" means any person who obtains a registration from the Agency upon payment of the registration fee, and who is obligated to obtain such registration from the Department pursuant to these regulations and the Act.
- T.** "Registration" means registration with the Department in accordance with regulations adopted by the Department.
- U.** "Sanitize" means the effective bactericidal treatment of surfaces of equipment and devices "to reduce bacterial count to a safe level. Sanitizers must be used at recommended dilutions and for recommended durations stated in the sanitizer instructions."
- V.** "Tanning equipment" means ultraviolet lamps and equipment containing ultraviolet lamps intended to induce skin tanning through the irradiation of any part of the living human body.
- W.** "Tanning facility" means any location, place, area, structure or business which provides consumers access to tanning equipment.
- X.** "These regulations" or "these rules" mean the Maine Rules Relating to Tanning Facilities, 10-144 CMR 223.
- Y.** "Ultraviolet radiation" means electromagnetic radiation with wavelengths in air between two hundred (200) nanometers and four hundred (400) nanometers.

SECTION 3. EXEMPTIONS

- A.** General. The Department 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 the 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 these rules.
- C.** Equipment used for the intentional exposure of patients to ultraviolet radiation for the purpose of treatment or use commensurate with a licensed practitioner's use of a healing art are exempt from these rules.
- D.** Equipment intended for personal use and not employed in a profit making venture are exempt from these rules.
- E.** Radiation machines while in transit or storage incidental thereto are exempt from provisions of these rules.

SECTION 4. APPLICATION FOR REGISTRATION OF TANNING FACILITIES

- A.** All newly established tanning facilities shall submit the necessary registration to the Department within 30 days after the start of business. Applications for registration shall be completed on forms provided by the Department.
- B.** The application must be signed and dated, certifying that the applicant has read and understands the requirements of these regulations.
- C.** The Department requires the following information on the Application for Registration of Tanning Facilities Form for new tanning facilities or renewal of an existing tanning facility:
 - (1) Name, address and telephone number of the following:
 - (a) the tanning facility; and
 - (b) the owner(s) and manager(s) of the tanning facility;
 - (2) The manufacturer, model number, and serial number for each piece of tanning equipment located within the facility, as well as the type of each ultraviolet lamp for each piece of equipment;
 - (3) Name of the tanning equipment supplier, installer, and service agent;
 - (4) A copy of the following documents must be included in the application;
 - (a) Operator training materials. (Manufacturer's information may be referenced);
 - (b) Operating and safety instructions or procedures developed for the facility;
 - (c) Information and/or instructions provided to consumers;
 - (d) Any posted warning signs or notices, if other than that specified in Section 7(A)(1)(2).
 - (e) Method of maintaining records.
 - (5) Mobile facilities shall provide the following additional information:
 - (a) Region of the state in which the facility will operate;
 - (b) Locations and schedule at which the facility will operate; and
 - (c) Contact person at each location.

- E.** Each applicant shall provide such additional information as the Department may reasonably require, to protect public health.
- F.** Each application shall include the yearly registration fee, as stated in Section 9.

SECTION 5. CERTIFICATE OF REGISTRATION

- A. Issuance of Certificate of Registration.** Upon determination that an applicant meets the requirements of Section 4, the Department shall issue a certificate of registration, which is valid for one year.
- (1) 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 to protect the public health.
 - (2) Except as provided in Section 4(A), no person shall operate a tanning facility until the Department has issued the certificate of registration, pursuant to these rules.
- B. Expiration of Certificate of Registration.** Except as provided in Section 5(C)(2), each certificate of registration shall expire after 12 months of issuance, or upon an expiration date to be determined by the Department.
- C. Renewal of Existing Certificate of Registration.**
- (1) Application for renewal of a certificate of registration shall be filed in accordance with Section 4.
 - (2) In any case in which a registrant has filed a renewal application in proper form no later than 30 days prior to the expiration of its existing registration, such existing registration shall remain in effect until the Department has taken final action on its renewal application.
- D. Report of Changes.**
- (1) The registrant shall notify the Department in writing within 30 days of making any change which would render the information reported pursuant to Section 4(D) no longer accurate.
 - (2) In addition to the requirement of 5(D)(1), mobile facilities will notify the Department by telephone within 5 days of any changes to the information provided under Section 4(C)(5).
 - (3) 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" lamps.
- E. Transfer** No certificate of registration shall be transferable A person purchasing an existing tanning facility must submit a new application.
- F. Approval Not Implied.** No person, in any advertisement, shall refer to the fact that a facility is registered with the Department pursuant to the provisions of Section 4, and no

person shall state or imply that any activity under such registration has been approved by the Department.

SECTION 6. DENIAL, SUSPENSION OR REVOCATION OF A REGISTRATION.

- A.** The Department may, for good cause shown, deny, seek to suspend or revoke a registration sought or issued, pursuant to these regulations, for any of the following reasons:
- (1) Submission of incorrect, false or misleading information in the application and reports;
 - (2) Failure to operate or maintain the tanning facility, in accordance with the application, approved by the Department, except as such maintenance may involve the replacement of lamps by "equivalent" lamps which have been defined in Section 5(D)(3);
 - (3) Operation of the tanning facility in a way that causes or creates a nuisance or hazard to the public health or safety;
 - (4) Violation of any rules, regulations, standards, or requirements adopted by the Department;
 - (5) Violation of any condition upon which the registration was issued;
 - (6) Failure to allow duly authorized agents of the Department to conduct inspections at reasonable hours and in a reasonable manner; and
 - (7) Failure to pay any registration or inspection fees.
- B. Notice of Violation:** Before instituting any proceeding to modify, suspend or revoke a certificate of registration or to take other action for alleged violations of any provision of these rules, the Department will serve on the registrant a written notice of violation. The notice of violation will state the alleged violation and will require that the registrant submit a written explanation or statement in reply within 20 working which includes the following:
- (1) Corrective steps which have been taken to date;
 - (2) Schedule of corrective steps which will be taken; and
 - (3) The date when full compliance will be achieved.
- C. Hearing:** If any certificate of registration is conditioned, denied, suspended, or revoked, the applicant or registrant may request a hearing within 10 working days of receipt of the written decision, in accordance with the Maine Administrative Procedures Act, 5 M.R.S., Chapter 375, Sub-chapter 4 and the Department's Administrative Procedures Manual, 10-144 C.M.R., Chapter 1. A request for an administrative fair hearing should be made in writing and addressed to the Manager, Radiation Control Program, Division of Environmental Health, Department of Health and Human Services.

- D. **Informal Review:** In addition to recourse to an administrative hearing, an aggrieved applicant or registrant may request an informal review of the Department's decision by writing to the Manager, Radiation Control Program. Such a request must be made within 10 working days of receipt of the decision. If an applicant or registrant is dissatisfied with the decision of the informal review, an administrative fair hearing may be requested within 10 days of receipt of the informal review decision.

SECTION 7. OPERATION OF TANNING FACILITIES

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

A. Physical facilities.

- (1) A warning sign (with the exact text shown in Section 7(A)(2) below) shall be posted conspicuously near the 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;
- (2) The lettering on each warning sign shall be at least ten (10) millimeters high for all words shown in capital letters, and at least five (5) millimeters high for all lower case letters.

DANGER - ULTRAVIOLET RADIATION

-Follow instructions.

-Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may 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 your physician before using sun lamp if you are using medications or have a history of skin problems or believe yourself especially sensitive to sunlight.

-Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult your physician before using sun lamp 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.

- (3) Only tanning equipment labeled as required by FDA regulations and manufactured and certified to comply with 21CFR Part 1040, Section 1040.20, "Sunlamp products and ultraviolet lamps intended for use in sunlamp products," shall be used in tanning facilities. Use of tanning equipment that has not been approved by the FDA is prohibited. A copy of 21 CFR Part 1040.20, revised as of April 1, 2012 is attached to this rule as Appendix A and incorporated herein by reference.
- (4) Each tanning equipment shall have a timer which complies with the requirements of 21 CFR Part 1040, Section 1040.20(c)(2).
 - a. The timer shall be incorporated in the tanning device.

- b. The maximum timer interval shall not exceed the manufacturer's maximum recommended exposure time.
 - c. No timer interval shall have an error greater than + 10% of the maximum timer interval for the product.
 - d. 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 equipment has been interrupted.
- (5) Each piece of tanning equipment 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).
- (6) Each piece of tanning equipment shall have labels, as provided in 21 CFR 1040.20(d)(1)(i-vi).
- (7) Only tanning equipment which is labeled as meeting the National Fire Protection Association's National Electrical Code may be used.
- (8) There shall be physical barriers to protect consumers from injury induced by touching or breaking the lamps.
- (9) Additional requirements for stand-up booths:
- a. 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.
 - b. The construction of the booth shall be such that it will withstand the stress of use and the impact of a falling person.
 - c. Access to the booth shall be of rigid construction; doors shall open outwardly. Handrails and non-slip floors shall be provided.

B. Protective Eyewear.

- (1) Protective eyewear must be worn while using tanning equipment.
- (2) Each consumer shall be provided with protective eyewear and instructions for their use. Selling eyewear or allowing use of properly sanitized eyewear satisfies the meaning of "provided". Consumers may provide their own eyewear.

- (3) Protective eyewear, whether provided by the facility operator or the consumer, shall meet the requirements of 21 CFR Part 1040, Section 1040.20(c)(4).
- (4) Protective eyewear shall be properly sanitized before each use by a trained facility operator. A sanitizing agent recommended by the product manufacturer shall be used. Exposure to the ultraviolet radiation produced by the tanning equipment itself is not considered a sanitizing agent.

C. Operation.

- (1) A tanning registrant shall allow operation of tanning equipment only by those who have successfully completed a formal or informal operator training course.
- (2) Tanning equipment shall be operated only when a trained operator is present at a tanning facility.
- (3) Prior to initial exposure, each consumer shall be provided the opportunity to read a copy of the warning sign's statement, which must satisfy the requirements of Section 7 (A)(1)(2). The operator shall request that the consumer sign a statement that that warning sign information, as well as any other information required by the facility, has been read and understood. For illiterate or visually handicapped persons, the warning statement shall be read by the operator in the presence of a witness. Both the witness and the operator shall sign the statement.
- (4) A record shall be kept by the facility operator of each consumer's total number of tanning visits and tanning times. The records shall be maintained for 12 months after the last tanning visit. The consumer must initial the tanning visit and tanning time to validate the entry.
- (5) A written report of any tanning injury shall be forwarded to the Department within 5 working days of its occurrence or knowledge thereof. The report shall include:
 - (a) the name of the affected individual;
 - (b) the name and location of the tanning facility involved;
 - (c) the nature of the injury;
 - (d) name and address of health care provider, if any; and
 - (e) any other information considered relevant to the situation.
- (6) No minor under the age of 14 shall be allowed to use the tanning equipment. For minors 14 years of age and older:
 - (a) The tanning facility operator must obtain written consent of the minor's parent or legal guardian and written acknowledgment by the minor and the parent or legal guardian that they have read and understood the information required by Section 7(A)(2) of these rules. Written consent and written acknowledgment must be executed in the presence of the operator of the tanning facility.

- (b) The tanning facility operator must confirm the identification of the minor and the minor's parent or legal guardian.
 - (c) The parent's or legal guardian's written consent is effective for one year from the date of signature and may be revoked by the parent or legal guardian at any time.
 - (d) The parent or legal guardian must be present when minors 14 and 15 years of age are using the tanning equipment.
- (7) Defective or burned-out lamps or filters shall be replaced with a type intended for use in that piece of tanning equipment, as specified on the product label on the tanning equipment, or, with lamps or filters that are "equivalent" under the FDA regulations as described in Section 5(D)(3).
- (8) Tanning beds and stand up booths shall be cleaned and sanitized after each use with an approved sanitizer by the facility operator. A list of approved sanitizers will be maintained by the Department. The operator shall use a sanitizer that sanitizes to a safe level of microorganisms, as required by these rules. A clean paper towel shall be used each time the tanning equipment is used and sanitized. The ultraviolet light produced by the tanning equipment itself is not considered an adequate sanitizer.

D. Training.

- (1) The registrant shall ensure that all tanning equipment operators are adequately trained by formal and/or informal training.
- (2) At least one tanning equipment operator for each tanning facility must be adequately trained by a pre-approved formal training course. Formal training is obtained by successfully attending a classroom course, completing a correspondence course, or online course, and receiving a certificate.
- (3) The Department shall maintain a list of pre-approved formal training courses.
- (4) Formal and Informal Training shall include the following items listed below:
 - (a) The requirements of these regulations;
 - (b) Procedures for correct operation of the facility;
 - (c) Recognition of injury or overexposure;
 - (d) Manufacturer's procedures for operation and maintenance of tanning equipment;
 - (e) Emergency procedures in case of injury or overexposure;
 - (f) Procedures for correct cleaning, sanitizing, maintenance, and operation of the tanning equipment. This training includes proper care and use of protective eyewear;

- (g) Eye protection, 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 affixed by the manufacturer to the equipment;
- (h) Review and explanation of the lamp compatibility for tanning equipment; and
- (i) Courses will include written material which covers the required subjects, such as a training manual, audio-visual presentations on the required subjects (such as videos or slides), copies of Maine's Rules Relating to Tanning Facility rules and 21 CFR Section 1040.20, and a question/answer period for trainees.

(5) A list or log of operators trained in accordance with Section 7(D)(4) above shall be maintained and available at the facility. Inclusion of an individual as an operator on this list will be considered proof of training.

E. The Department or its duly authorized representatives may enter at all reasonable time upon any private or public property for the purpose of inspecting any tanning facility whether registered or not, for the purposes of inspecting the premises, reviewing any records required under these Rules and determining whether there is compliance with or violation of these rules and the Act. 22 MRS §682.

SECTION 8. ENFORCEMENT AND PENALTIES

- A. **Civil Penalties.** In addition to the procedures in Section 6, and in accordance with 22 M.R.S. § 690 (2), a civil penalty shall be assessed and enforced, as follows:
- (1) Any person who violates any licensing or registration provision of the Radiation Protection Act (“this Act”), or any rule or order issued under this Act, any term, condition or limitation of any license or registration certificate issued under this Act, or any person who commits any violation for which a license or registration certificate may be revoked, suspended or modified under these rules, is subject to a civil penalty.
 - (2) A civil penalty shall be imposed by the Department, in the amount of \$200, for each violation. If any violation is a continuing violation, each day of the violation shall constitute a separate violation for the purpose of computing the applicable civil penalty. The Department may compromise, mitigate or remit the penalties. The maximum amount of a civil penalty may not exceed \$10,000 for each violation.
 - (3) When the Department has reason to believe that a person has become subject to the imposition of a civil penalty under the provisions of 22 M.R.S. § 690 (2), the Department may notify the Attorney General or hold a public hearing. If a hearing is scheduled, the commissioner shall give at least 30 days' written notice to the alleged violator of the date, time and place of that hearing. The notice shall specify the act done or omitted to be done which is claimed to be in violation of law; identify the particular provisions of the section, rule, order or license involved in the violation; and advising of each penalty which the Department proposes to impose and its amount. The notice shall be sent by registered or certified mail by the Department to the last known address of the person.
 - (4) Any hearing conducted under the authority of this subsection shall be in accordance with the provisions of the Maine Administrative Procedure Act, Title 5, chapter 375. At the hearing, the alleged violator may appear in person or by attorney and answer the allegations of violation and file a statement of the facts, including the methods, practices and procedures, if any, adopted or used by him/her to comply with 22 M.R.S., Chapter 160 and these rules, and present such evidence as may be pertinent and relevant to the alleged violation.
 - (5) After a notice of violation is served, a follow-up inspection will be conducted to confirm and/or assess corrective actions specified in the registrant's written explanation or statement have been fulfilled.
 - (6) A penalty or penalties may be imposed for a violation or violations that are found to be uncorrected after a notice of violation has been served, and sufficient time has been allowed for correction.
 - (7) A civil penalty may be immediately administered for non-payment of a registration fee, after 6 months of non-payment, and where repeated notices of late payment have been received by the facility. The penalty amount is in addition to the registration fee.

(8) On the request of the Department, the Attorney General may institute a civil action to collect a penalty imposed pursuant to this subsection. Only the Attorney General may compromise, mitigate or remit such civil penalties as are referred to him for collection.

(9) All money collected from civil penalties shall be paid to the Treasurer of State for deposit in the General Fund. Money collected from civil penalties shall not be used for normal operating expenses of the Department, except as appropriations made from the General Fund in the normal budgetary process.

B. **Criminal Penalties.** In accordance with 22 M.R.S. § 690(1), criminal penalties may be assessed for:

(1) intentional or knowing violation of the Radiation Protection Act, or a rule or order of the Department in effect, pursuant to the Radiation Protection Act, is a criminal violation Class D crime;

(2) violation of a term, condition or limitation of a license or registration certificate issued under the Radiation Protection Act, is a criminal violation Class D crime;
or

(3) a violation for which a license or registration certificate may be revoked under these Rules, is a criminal violation Class D crime.

SECTION 9. FEES

- A. Yearly registration fees of \$40.00 per tanning facility shall be submitted with the initial application for registration or renewal of a tanning facility's registration. Starting in calendar year 2015, the yearly registration fee becomes \$50.00 per tanning facility, plus an equipment surcharge of \$20 per unit of tanning equipment.
- B. No fee will be assessed for routine inspections or for the first follow-up inspection, to confirm corrective actions were taken in response to a notice of violation.
- C. A fee of \$25.00 per visit may be assessed for follow-up inspections, due to a failure to respond to a notice of violation, as authorized by Section (B).
- D. A fee of \$25.00 per visit may be assessed for any additional inspections to insure compliance, notwithstanding the provisions of Sections (A) and (B).

SECTION 10. 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.

LAST AMENDED 2012

EFFECTIVE DATE (ELECTRONIC CONVERSION): May 5, 1996;

APPENDIX A

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2012]
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TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER J--RADIOLOGICAL HEALTH

PART 1040 -- PERFORMANCE STANDARDS FOR LIGHT-EMITTING PRODUCTS Sec. 1040.20 Sunlamp products and ultraviolet lamps intended for use in sunlamp products.

- i. Applicability.
 - (1) The provisions of this section, as amended, are applicable as specified herein to the following products manufactured on or after September 8, 1986.
 - (i) Any sunlamp product.
 - (ii) Any ultraviolet lamp intended for use in any sunlamp product.
 - (2) Sunlamp products and ultraviolet lamps manufactured on or after May 7, 1980, but before September 8, 1986, are subject to the provisions of this section as published in the Federal Register of November 9, 1979 (44 FR 65357).
- ii. Definitions. As used in this section the following definitions apply:
 - (1) Exposure position means any position, distance, orientation, or location relative to the radiating surfaces of the sunlamp product at which the user is intended to be exposed to ultraviolet radiation from the product, as recommended by the manufacturer.
 - (2) Intended means the same as "intended uses" in 801.4.
 - (3) Irradiance means the radiant power incident on a surface at a specified location and orientation relative to the radiating surface divided by the area of the surface, as the area becomes vanishingly small, expressed in units of watts per square centimeter (W/cm²).
 - (4) Maximum exposure time means the greatest continuous exposure time interval recommended by the manufacturer of the product.
 - (5) Maximum timer interval means the greatest time interval setting on the timer of a product.
 - (6) Protective eyewear means any device designed to be worn by users of a product to reduce exposure of the eyes to radiation emitted by the product.

- (7) Spectral irradiance means the irradiance resulting from radiation within a wavelength range divided by the wavelength range as the range becomes vanishingly small, expressed in units of watts per square centimeter per nanometer ($W/(cm^2/nm)$).
- (8) Spectral transmittance means the spectral irradiance transmitted through protective eyewear divided by the spectral irradiance incident on the protective eyewear.
- (9) 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 200 and 400 nanometers, to induce skin tanning.
- (10) Timer means any device incorporated into a product that terminates radiation emission after a preset time interval.
- (11) Ultraviolet lamp means any lamp that produces ultraviolet radiation in the wavelength interval of 200 to 400 nanometers in air and that is intended for use in any sunlamp product.

iii. Performance requirements.

- (1) Irradiance ratio limits. For each sunlamp product and ultraviolet lamp, the ratio of the irradiance within the wavelength range of greater than 200 nanometers through 260 nanometers to the irradiance within the wavelength range of greater than 260 nanometers through 320 nanometers may not exceed 0.003 at any distance and direction from the product or lamp.
- (2) Timer system.
 - (i) Each sunlamp product shall incorporate a timer system with multiple timer settings adequate for the recommended exposure time intervals for different exposure positions and expected results of the products as specified in the label required by paragraph (d) of this section.
 - (ii) The maximum timer interval(s) may not exceed the manufacturer's recommended maximum exposure time(s) that is indicated on the label required by paragraph (d)(1)(iv) of this section.
 - (iii) No timer interval may have an error greater than 10 percent of the maximum timer interval of the product.
 - (iv) 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 sunlamp product has been terminated.
 - (v) The timer requirements do not preclude a product from allowing a user to reset the timer before the end of the preset time interval.

(3) Control for termination of radiation emission. Each sunlamp product shall incorporate 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.

(4) Protective eyewear.

(i) Each sunlamp product shall be accompanied by the number of sets of protective eyewear that is equal to the maximum number of persons that the instructions provided under paragraph (e)(1)(ii) of this section recommend to be exposed simultaneously to radiation from such product.

(ii) The spectral transmittance to the eye of the protective eyewear required by paragraph (c)(4)(i) of this section shall not exceed a value of 0.001 over the wavelength range of greater than 200 nanometers 320 nanometers and a value of 0.01 over the wavelength range of greater than 320 nanometers through 400 nanometers, and shall be sufficient over the wavelength greater than 400 nanometers to enable the user to see clearly enough to reset the timer.

(5) Compatibility of lamps. An ultraviolet lamp may not be capable of insertion and operation in either the "single-contact medium screw" or the "double-contact medium screw" lampholders described in American National Standard C81.10-1976, Specifications for Electric Lamp Bases and Holders--Screw-Shell Types, which is incorporated by reference. Copies are available from the American National Standards Institute, 1430 Broadway, New York, NY 10018, or available for inspection at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to:http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html.

iv. Label requirements. In addition to the labeling requirements in part 801 and the certification and identification requirements of 1010.2 and 1010.3, each sunlamp product and ultraviolet lamp shall be subject to the labeling requirements prescribed in this paragraph and paragraph (e) of this section.

(1) Labels for sunlamp products. Each sunlamp product shall have a label(s) which contains:

(i) A warning statement with the words "DANGER--Ultraviolet radiation. Follow instructions. Avoid overexposure. As with natural sunlight, overexposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin and skin cancer. WEAR PROTECTIVE EYEWEAR; FAILURE TO MAY RESULT IN SEVERE BURNS OR LONG-TERM INJURY TO THE EYES. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult 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."

(ii) Recommended exposure position(s). Any exposure position may be expressed either in terms of a distance specified both in meters and in feet (or in inches) or through the use of markings or other means to indicate clearly the recommended exposure position.

(iii) Directions for achieving the recommended exposure position(s) and a warning that the use of other positions may result in overexposure.

(iv) A recommended exposure schedule including duration and spacing of sequential exposures and maximum exposure time(s) in minutes.

(v) A statement of the time it may take before the expected results appear.

(vi) Designation of the ultraviolet lamp type to be used in the product.

(2) Labels for ultraviolet lamps. Each ultraviolet lamp shall have a label which contains:

(i) The words "Sunlamp--DANGER--Ultraviolet radiation. Follow instructions."

(ii) The model identification.

(iii) The words "Use ONLY in fixture equipped with a timer."

(3) Label specifications.

(i) Any label prescribed in this paragraph for sunlamp products shall be permanently affixed or inscribed on an exterior surface of the product when fully assembled for use so as to be legible and readily accessible to view by the person being exposed immediately before the use of the product.

(ii) Any label prescribed in this paragraph for ultraviolet lamps shall be permanently affixed or inscribed on the product so as to be legible and readily accessible to view.

(iii) If the size, configuration, design, or function of the sunlamp product or ultraviolet lamp would preclude compliance with the requirements for any required label or would render the required wording of such label inappropriate or ineffective, or would render the required label unnecessary, the Director, Office of Communication, Education, and Radiation Programs 10903 New Hampshire Ave., Bldg. 66, rm. 4312, Silver Spring, MD 20993-0002, Center for Devices and Radiological Health, on the center's own initiative or upon written application by the manufacturer, may approve alternate means of providing such label(s), alternate wording for such label(s), or deletion, as applicable.

(iv) In lieu of permanently affixing or inscribing tags or labels on the ultraviolet lamp as required by 1010.2(b) and 1010.3(a), the manufacturer of the ultraviolet lamp may permanently affix or inscribe such required tags or labels on the lamp packaging uniquely associated with the lamp, if the name of the manufacturer and month and year of manufacture are permanently affixed or inscribed on the exterior surface of the ultraviolet lamp so as to be legible and readily accessible to view. The name of the manufacturer and month and year of manufacture affixed or inscribed on the exterior surface of the lamp may be expressed in code or symbols, if the manufacturer has previously supplied the

Director, Office of Compliance (HFZ-300), Center for Devices and Radiological Health, with the key to such code or symbols and the location of the coded information or symbols on the ultraviolet lamp. The label or tag affixed or inscribed on the lamp packaging may provide either the month and year of manufacture without abbreviation, or information to allow the date to be readily decoded.

(v) A label may contain statements or illustrations in addition to those required by this paragraph if the additional statements are not false or misleading in any particular; e.g., if they do not diminish the impact of the required statements; and are not prohibited by this chapter.

(e) Instructions to be provided to users. Each manufacturer of a sunlamp product and ultraviolet lamp shall provide or cause to be provided to purchasers and, upon request, to others at a cost not to exceed the cost of publication and distribution, adequate instructions for use to avoid or to minimize potential injury to the user, including the following technical and safety information as applicable:

(1) Sunlamp products. The users' instructions for a sunlamp product shall contain:

(i) A reproduction of the label(s) required in paragraph (d)(1) of this section prominently displayed at the beginning of the instructions.

(ii) A statement of the maximum number of people who may be exposed to the product at the same time and a warning that only that number of protective eyewear has been provided.

(iii) Instructions for the proper operation of the product including the function, use, and setting of the timer and other controls, and the use of protective eyewear.

(iv) Instructions for determining the correct exposure time and schedule for persons according to skin type.

(v) Instructions for obtaining repairs and recommended replacement components and accessories which are compatible with the product, including compatible protective eyewear, ultraviolet lamps, timers, reflectors, and filters, and which will, if installed or used as instructed, result in continued compliance with the standard.

(2) Ultraviolet lamps. The users' instructions for an ultraviolet lamp not accompanying a sunlamp product shall contain:

(i) A reproduction of the label(s) required in paragraphs (d)(1)(i) and (2) of this section, prominently displayed at the beginning of the instructions.

(ii) A warning that the instructions accompanying the sunlamp product should always be followed to avoid or to minimize potential injury.

(iii) A clear identification by brand and model designation of all lamp models for which replacement lamps are promoted, if applicable.

- (f) Test for determination of compliance. Tests on which certification pursuant to 1010.2 is based shall account for all errors and statistical uncertainties in the process and, wherever applicable, for changes in radiation emission or degradation in radiation safety with age of the product. Measurements for certification purposes shall be made under those operational conditions, lamp voltage, current, and position as recommended by the manufacturer. For these measurements, the measuring instrument shall be positioned at the recommended exposure position and so oriented as to result in the maximum detection of the radiation by the instrument.

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