

PART T
TANNING FACILITIES

1. Purpose and Scope.

A. 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.

2. Definitions. The following terms are defined for purposes of this part:

A. "Act" means 22 MRSA c. 160.

B. "Agency" means the Department of Human Services.

C. "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.

D. "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.

E. "Individual" means any human being.

F. "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.

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

H. "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.

I. "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.

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

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

L. "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 Agency pursuant to these regulations and the Act.

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

M. "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.

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

O. "These regulations" means all parts of Maine Rules Relating to Radiation Protection, 10-144A CMR 220.

P. "Ultraviolet radiation" means electromagnetic radiation with wavelengths in air between two hundred (200) nanometers and four hundred (400) nanometers.

3. Exemptions.

A. General. The Agency may, upon application, therefore, 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 this Part.

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 this part.

D. Equipment intended for home use and not employed in a profit making venture are exempt from this part.

E. Radiation machines while in transit or storage incidental thereto are exempt from provisions of this Part.

4. Application for Registration of Tanning Facilities.

A. Each person operating a tanning facility shall apply for a registration of such facility with the Agency within ninety (90) days following the effective date of these regulations.

B. Beginning April 1, 1991, all newly established tanning facilities shall submit the necessary registration to the Agency within 30 days after the start of business.

C. Application for registration shall be completed on forms provided for by the Agency. The application will be signed and dated certifying that the applicant has read and understands the requirements of these Regulations;

D. The Agency shall require the following information on the Application for Registration of Tanning Facilities form:

- (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 type of each ultraviolet lamp or tanning equipment located within the facility;
- (3) Name of the tanning equipment supplier, installer, and service agent;
- (4) A copy of the following documents will be included in the application;
- (a) Operator training materials. Manufacturers information may be referenced.
 - (b) Operating and safety instructions or procedures developed for the facility
 - (c) Information and/or instructions provided to users
 - (d) Any posted warning signs or notices if other than that specified in section 12.A.(1)
- (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
 - (c) Contact person at each location
 - (d) Method of maintaining records

E. Each applicant shall provide such additional information as the Agency may reasonably require to protect the public health.

F. Each application shall include the yearly registration fee as stated in section 14.

5. Issuance of a Certificate of Registration.

A. Upon determination that an applicant meets the requirements of Section 4 the Agency shall issue a certificate of registration.

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 to protect the public health.

C. Except as provided in Section 4.A and 4.B, No person shall operate a tanning facility until the Agency has issued the certificate of registration pursuant to 22 MRSA.

6. Expiration of the Certificate of Registration.

A. Except as provided in Section 7.B, each certificate of registration shall expire at the end of the specified day in the month and year stated therein.

7. Renewal of a Certificate of Registration.

A. Application for renewal of a certificate of registration shall be filed in accordance with Section 4.

B. In any case in which a registrant not less than 30 days prior to the expiration of his existing registration has

filed an application in proper form for renewal, such existing registration shall not expire until the application status has been finally determined by the Agency.

8. Report of Changes.

A. The registrant shall notify the Agency in writing within 30 days of making any change which would render the information reported pursuant to Section 4.D. no longer accurate.

B. In addition to the requirement of 8.A., mobile facilities will notify the Agency by telephone within 5 days of any changes to the information provided under section 4.B.(6).

B. 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 under the FDA regulations and policies applicable at the time of replacement of the lamps. The facility owner shall maintain manufacturer's literature demonstrating the equivalency of any replacement lamps.

9. Transfer of Certificate of a Registration.

A. No certificate of registration shall be transferable from one person to another or from one tanning facility to another.

10. Approval Not Implied.

A. No person, in any advertisement, shall refer to the fact that a facility is registered with the Agency 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 Agency.

11. Denial, Suspension, or Revocation of a Registration.

A. The Agency 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 Agency except as such maintenance may involve the replacement of lamps by "equivalent" lamps which have been defined in Section 8.B;

- (4) Operation of the tanning facility in a way that causes or creates a nuisance or hazard to the public health or safety;
- (5) Violation of any rules, regulations, standards, or requirements adopted by the Agency;
- (6) Violation of any condition upon which the registration was issued;
- (7) Failure to allow duly authorized agents of the Agency to conduct inspections at reasonable hours and in a reasonable manner; and
- (8) 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 Agency 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 within 20 working days a written explanation or statement in reply including the following;

- (1) Corrective steps which have been taken to date,
- (2) Schedule of corrective steps which will be taken,
- (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 and the Department's Administrative Procedures Manual. Such a request should be made in writing and addressed to the Manager, Radiation Control Program.

Any applicant or registrant who may request a hearing as set forth above may also request an informal review of the 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 a hearing may be requested within 10 days.

12. Operation of Tanning Facilities.

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

- (1) Physical facilities.
 - (a) A warning sign (shown below) shall be posted on 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 ultraviolet light generating equipment;

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.

-If you do not tan in the sun, you are unlikely to tan from the use of this product.

(b) Only tanning equipment manufactured and certified to comply with 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.

(c) Each tanning equipment shall have a timer which complies with the requirements of 21 CFR Part 1040, Section 1040.20(c)(2). The timer shall be incorporated in the tanning device. 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.

(d) Tanning equipment shall meet the National Fire Protection Association's National Electrical Code.

(e) There shall be physical barriers to protect consumers from injury induced by touching or breaking the lamps.

(f) 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.
T.12.A(2)

(2) Protective goggles.

- (a) Each consumer shall be provided with protective goggles and instructions for their use. Protective goggles provided by the consumer must meet the requirements of 12.A.(2) (c),
- (b) Each consumer will be required to wear the protective goggles during tanning,
- (c) Protective goggles shall meet the requirements of 21 CFR Part 1040, Section 1040.20(c)(4).
- (d) Protective goggles shall be properly sanitized before each use. 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.

(3) Operation.

- (a) An operator must be present when tanning equipment is operated.
- (b) Prior to initial exposure each consumer shall be provided the following information;
 - (1) A copy of the warning specified in Section 12.A.(1)(a).
 - (2) Information on photosensitizing drugs
 - (3) A recommended tanning schedule for that individual
- (c) Prior to the initial exposure the operator shall then request that the consumer sign a statement that the information required under 12.A.(3) 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.
- (d) 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.
- (e) A copy of any written report of any tanning injury submitted to the facilities insurer shall be forwarded to the Agency within five (5) working days of its occurrence or knowledge thereof. The report shall include:
 - (1) the name of the affected individual;
 - (2) the name and location of the tanning facility involved;
 - (3) the nature of the injury;
 - (4) name and address of health care provider, if any; and

(5) any other information considered relevant to the situation.

(f) No minor shall be allowed to use the tanning facility unless the minor provides a consent form signed by the parent or legal guardian. The parent or guardian shall have been provided with the basic information required under Section 12.A.(1).

(g) Defective or burned-out lamps or filters shall 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 "equivalent" under the FDA regulations and policies applicable at the time of lamp manufacture.

(h) Each operator must be adequately trained. Proof of training must be maintained in the facility and available for inspection. Training shall include:

- (1) The requirements of these Regulations;
- (2) Manufacturer's procedures for operation and maintenance of tanning equipment;
- (3) Procedures for correct operation of the facility;
- (4) An understanding of and the ability to recognize skin types;
- (5) An understanding of the effects of photosensitizing drugs and the possible adverse effects which may arise from tanning while taking such drugs;
- (6) An understanding of exposure times and frequency;
- (7) Recognition of injury or overexposure;
- (8) Emergency procedures in case of injury.

(i) A list of operators trained in accordance with Section 12.A.(3)(g) shall be maintained and available at the facility. Inclusion of an individual as an operator on this list will be considered proof of training.

(j) Tanning beds and stand up booths shall be cleaned after each use with a disinfectant recommended by the manufacturer of the tanning device

13. Enforcement and Penalties. Fines may be levied in accordance with 22 MRSA subsection 690.

14. Fees.

A. Yearly registration fees of \$40.00 per tanning facility shall be submitted with the initial application for registration or renewal. After the effective date of these rules for facilities not registered previously, who were in existence yet did not obtain a registration, past fees will be assessed.

B. No fee will be assessed for routine inspections or for the first follow up inspection to confirm corrective actions 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 required under section 11.B.

D. A fee of \$25.00 per visit may be assessed for any additional inspections to insure compliance, notwithstanding the provisions of sections 14.A. and B.

15. 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.

16. Effective Date. These rules become effective on March 1, 1991

Basis Statement. These rules were adopted to provide necessary guidance to tanning facilities using ultraviolet lamps, dealing with the maintenance and safe operation of tanning facilities.