

STATE OF MAINE
TANNING FACILITIES RULE
10-144 CODE OF MAINE RULES
Chapter 223



Department Of Health & Human Services
Maine Center For Disease Control & Prevention
11 State House Station
Augusta, Maine 04333

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SECTION 1. PURPOSE AND DEFINITIONS

- A. Purpose.** This rule governs any tanning facilities using ultraviolet lamps by including maintenance and operation requirements. 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.
- B. Definitions.** The definitions in this rule supplement the definitions in the applicable statutes.
1. **Act** means 22 MRS Chapter 160, Radiation Protection Act.
 2. **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.
 3. **CFR** means Code of Federal Regulations.
 4. **Department** means the Maine Department of Health and Human Services, Maine Center for Disease Control and Prevention.
 5. **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 ultraviolet radiation and effects on the skin, photosensitivity, eye protection, equipment maintenance, the United States Food and Drug Administration (FDA) regulations and the provisions of this rule.
 6. **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.
 7. **Individual** means any human being.
 8. **Informal Training** means an operator trained by a formally trained operator of the same facility.
 9. **Injury** means physical damage or negative effects to the body, resulting from the use of tanning equipment.
 10. **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 Department.
 11. **Minor** means any individual who is under 18 years of age.
 12. **Mobile facilities** means any tanning equipment not used in a permanent facility.
 13. **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 individual who is formally or informally trained to conduct one or more of the following activities, to:

- a. Determine a customer's skin type;
 - b. Determine the suitability for the use of a piece of tanning equipment by prospective customers;
 - c. Inform the customer of the dangers of ultraviolet radiation exposure, including photoallergic reactions and photosensitizing agents;
 - d. Ensure that the customer reads and properly signs all forms required by this rule;
 - e. Maintain required customer exposure records;
 - f. Recognize and report customer injuries or alleged injuries to the Department;
 - g. Determine the customers' exposure schedule;
 - h. Set timers which control the duration of exposure; and
 - i. Instruct the customer in the proper use of protective eyewear.
14. **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.
 15. **Personal use** means operating a single tanning unit for the individual purpose of cosmetic tanning. Personal use implies that the unit will not be used for any business purpose. Multiple tanning units cannot be used as personal use.
 16. **Phototherapy device** means equipment that emits ultraviolet radiation and is used in the diagnosis or treatment of disease or injury.
 17. **Protective eyewear** means suitable devices that safeguard the eyes from ultraviolet radiation and allow adequate vision.
 18. **Radiation** means ultraviolet radiation.
 19. **Radiation machine** means any device capable of producing radiation.
 20. **Registrant** means any person who obtains a registration from the Department upon payment of the registration fee, and who is obligated to obtain such registration from the Department pursuant to this rule and the Act.
 21. **Registration** means registration with the Department in accordance with this rule and the Act.
 22. **Sanitize** means the effective bactericidal treatment of surfaces of equipment and devices by an Environmental Protection Agency (EPA) or FDA-registered product that provides a sufficient concentration of chemicals and enough time to reduce the bacterial count, including pathogens, to a safe level. Chemical germicides that are registered with EPA as hospital disinfectants when

used at recommended dilutions and directions may be approved for sanitizing tanning equipment. The Department maintains a list of approved sanitizers.

23. **Tanning equipment or tanning device** means ultraviolet lamps and equipment containing ultraviolet lamps intended to induce skin tanning through the irradiation of any part of the living human body and any equipment used with such device, including but not limited to protective eyewear, timers, and handrails. "Tanning device" includes a sunlamp, tanning booth, or tanning bed, but does not include a phototherapy device used or prescribed for use by a physician.
24. **Tanning facility** means any location, place, area, structure or business which provides consumers access to tanning equipment, including tanning salons, health clubs, apartments and condominiums, regardless of whether a fee is charged for access to the tanning equipment.
- .25. **Ultraviolet radiation** means electromagnetic radiation with wavelengths in air between two hundred (200) nanometers and four hundred (400) nanometers.

SECTION 2. EXEMPTIONS

- A. **General.** The Department may, upon application, or upon its own initiative, grant such exemptions or exceptions from the requirements of this rule, 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 rule.
- 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 rule.
- D. Equipment intended for home use and not employed in a profit-making venture are exempt from this rule.
- E. Radiation machines while in transit or storage incidental thereto are exempt from provisions of this rule.

SECTION 3. APPLICATION FOR REGISTRATION OF TANNING FACILITIES

- A.** All newly established tanning facilities must submit the necessary registration application to the Department within 30 calendar 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 this rule
- 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. Copies of each of the following documents:
 - 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 users; and
 - d. Any posted warning signs or notices, if other than that specified in Section 6(A)(1) and (2).
 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; and
 - d. Method of maintaining records.
- D.** Each applicant must provide such additional information as the Department may reasonably require, to protect public health.
- E.** Each application must include the yearly registration fee, as stated in Section 8.

SECTION 4. CERTIFICATE OF REGISTRATION

- A. Issuance of New Certificate of Registration.** Upon determination that an applicant meets the requirements of Section 3, the Department will issue a certificate of registration, which is valid for one year.
1. The Department 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 3(A), no person shall operate a tanning facility until the Department has issued the certificate of registration, pursuant to 22 MRS §677(2).
 3. The registrant must display the certificate of registration in a conspicuous place visible to customers at the tanning facility.
- B. Expiration of Certificate of Registration.** Except as provided in Section 4(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 must be filed in accordance with Section 3.
 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 calendar days of making any change which would render the information reported pursuant to Section 3(D) no longer accurate.
 2. In addition to the requirement of Section 4(D)(1), mobile facilities must notify the Department by telephone within five days of any changes to the information provided under Section 3(C)(5).
 3. This requirement does not apply to 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 must maintain manufacturer's literature demonstrating the equivalency of any replacement lamps.
- E. Transfer** No certificate of registration shall be transferable. A person purchasing an existing business 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 3, and no person shall state or imply that any activity under such registration has been approved by the Department.

SECTION 5. DENIAL, SUSPENSION OR REVOCATION OF A REGISTRATION

A. Department Actions. The Department may deny an application or renewal, or suspend or revoke an existing registration, pursuant to this rule and the *Radiation Protection Rule* (10-144 CMR Ch. 220), 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 4(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 this rule, the Department will issue 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 days, which includes the following:

1. Corrective steps already completed by the registrant;
2. Schedule of corrective steps planned; and
3. The date when full compliance will be achieved.

C. Hearing: If any certificate of registration is conditioned, denied, suspended, or revoked, then the applicant or registrant may request an administrative hearing within 30 calendar days of receipt of the written decision, in accordance with the Maine Administrative Procedure Act, 5 MRS Chapter 375, Sub-chapter 4 and the Department's *Administrative Hearings Regulations* (10-144 CMR Ch. 1). A request for an administrative hearing must be made in writing and addressed to the Department's Maine CDC Radiation Control Program Manager.

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 Department's Radiation Control Program Manager. 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 30 calendar days of receipt of the informal review decision.

SECTION 6. 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 6(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 10 millimeters high for all words shown in capital letters, and at least 5 millimeters high for all lower-case letters.
3. Only tanning equipment manufactured and certified to comply with federal Performance Standards for Light-Emitting Products (21 CFR Part 1040, § 1040.20), which states the following: "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."

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.

4. Each piece of tanning equipment must have a timer which complies with the federal Performance Standards for Light-Emitting Products (21 CFR Part 1040, Section 1040.20(c)(2)).

- a. The timer must be incorporated in the tanning device.
 - b. The maximum timer interval is not allowed to exceed the manufacturer's maximum recommended exposure time.
 - c. No timer interval is allowed to have an error greater than 10% of any selected timer interval for the product. The timer must be remotely located, so customers cannot set their own exposure time.
 - d. The timer must be prevented from an automatic reset, in order to avoid radiation emission from resuming 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 must 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) in Performance Standards for Light-Emitting Products.
 6. Each piece of tanning equipment must have labels, as provided in Performance Standards for Light-Emitting Products at 21 CFR §1040.20(d)(1)(i-vi).
 7. Tanning equipment must meet the National Fire Protection Association's National Electrical Code.
 8. Physical barriers must be in place to protect consumers from injury induced by touching or breaking the lamps.
 9. Additional requirements for stand-up booths:
 - a. Physical barriers or other means, such as handrails or floor markings, must be in place to indicate the proper exposure distance between ultraviolet lamps and the consumer's skin.
 - b. The construction of the booth must be such that it will withstand the stress of use and the impact of a falling person.
 - c. Access to the booth must be of rigid construction; doors must open outwardly. Handrails and non-slip floors must be provided.
 10. The owner or lessee of a tanning facility or device must post a notice in a conspicuous place in the tanning facility (with the exact text shown in Section 6(A)(11) below). This notice must be readily legible, clearly visible, and not obstructed by any barrier, equipment, or other item present, so that the user can easily view the notice before energizing the tanning equipment.
 11. The lettering on each warning sign must 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.

TANNING FACILITY NOTICE

- It is unlawful for a tanning facility, a lessee of a tanning device, or an operator to allow an individual under 18 years of age to use a tanning device.
- A tanning facility, a lessee of a tanning device, or an operator that violates the provisions of *State of Maine Tanning Facilities Rule* is subject to penalties.
- An individual may report a violation of the *State of Maine Tanning Facilities Rule* to the local law enforcement agency or Radiation Control Program of the Maine Center for Disease Control and Prevention (207) 287-5676.
- The health risks associated with tanning include but are not limited to skin cancer, premature aging of skin, burns to the skin and adverse reactions to certain medications, food, and cosmetics.

12. The customer is limited to the maximum exposure time recommended by the manufacturer for that customer's skin type.
13. The customer is not allowed to use a tanning device more than once every 24 hours.
14. The interior temperature of the tanning facility does not exceed 100 degrees Fahrenheit.

B. Protective Eyewear

1. While using tanning equipment, each consumer must wear protective eyewear that is either provided by the tanning facility or the consumer.
- (2) Each consumer must be offered at no cost, protective eyewear and instructions for their use. Consumers may decline the offer and use their own eyewear.
- (3) Protective eyewear, whether provided by the facility operator or worn by the consumer, must meet the requirements of Performance Standards for Light-Emitting Products at 21 CFR Part 1040, Section 1040.20(c)(4).
4. Protective eyewear must be properly sanitized before each use by a trained facility operator. A sanitizing agent recommended by the product manufacturer must 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 may only allow operation of tanning equipment by those who have successfully completed a formal or informal operator training course.
2. Tanning equipment must be operated only when a trained operator is present at a tanning facility.

3. Prior to the first exposure in each calendar year, each consumer must be required to sign a consent form. For illiterate or visually handicapped persons, the warning statement and tanning facility notice must be read by the operator in the presence of a witness. Both the witness and the operator must sign the statement. The warning statement must include language that the consumer:
 - a. Understands the warning sign's statement and the tanning facility notice which must satisfy the requirements of Section 6(A)(1) and (2) as well as Section 6(A)(10) and (11) of this rule;
 - b. Agrees to use protective eyewear; and
 - c. Has been properly trained for the use of the tanning device and physical aids, including handrails and markings on the floor to maintain a proper exposure distance from the tanning device as recommended by the manufacturer.
4. The facility operator must keep a record of each consumer's consent forms, total number of tanning visits and dates and tanning duration. The records must be maintained for three years after the last tanning visit. The consumer must initial the tanning visit and tanning duration to validate the entry.
5. A copy of any written report of any tanning injury submitted to the facility's insurer must be forwarded to the Department within five 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. The name and address of health care provider, if any; and
 - e. Any other information considered relevant to the situation.
6. No individual under the age of 18 is allowed to use the tanning equipment. Proof of age may be satisfied with a driver's license or other government-issued identification containing the date of birth and a photograph of the individual, in accordance with 22 MRS § 689-A (2).
7. Defective or burned-out lamps or filters must 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 and policies applicable at the time of the lamp's manufacturing date.
8. Tanning beds and stand-up booths must be cleaned after each use with an approved sanitizer by the facility operator. A list of approved sanitizers will be maintained by the Department. The operator must use a sanitizer that sanitizes to a safe level of microorganisms, as required by this rule. A clean paper towel must be used each time that 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 must ensure that all tanning equipment operators are adequately trained by formal and/or informal training.
2. At least one tanning equipment operator 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 will maintain a list of pre-approved formal training course vendors.
4. Training must include the following items listed below:
 - a. A copy of this rule (informal training only);
 - b. Procedures for correct operation of the facility (informal training only);
 - c. Recognition of injury or overexposure;
 - d. Manufacturer's procedures for operation and maintenance of tanning equipment (informal training only);
 - e. Emergency procedures in case of injury or overexposure;
 - f. Procedures for correct cleaning, sanitizing, and operation of the tanning equipment. This training includes proper care and use of protective eyewear;
 - g. 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;
 - h. Review and explanation of the lamp compatibility for tanning equipment; and
 - i. Courses which 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 Tanning Facility rule and Performance Standards for Light-Emitting Products at 21 CFR Section 1040.20, and a question/answer period for trainees.
5. A list or log of operators trained in accordance with Section 6(D)(4) above must be maintained and available at the facility. Inclusion of an individual as an operator on this list will be considered proof of training.

SECTION 7. ENFORCEMENT AND PENALTIES

- A. Civil Penalties.** In accordance with 22 MRS §690 (2), a civil penalty may 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 this rule, is subject to a civil penalty.
 2. A civil penalty may be imposed by the Department, in the amount of \$200, for each violation. If any violation is a continuing violation, the Department is authorized to deem each day of the violation as constituting 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 MRS §690 (2), the Department may notify the Office of the Attorney General or hold a public hearing. If a hearing is scheduled, the commissioner will give at least 30 calendar days written notice to the alleged violator of the date, time, and place of that hearing. The notice will 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 advise of each penalty which the Department proposes to impose and its amount. The notice will 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 will be managed in accordance with the provisions of the Maine Administrative Procedure Act, 5 MRS Chapter 375. At the hearing, the operator 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 the operator to comply with 22 MRS, Chapter 160, 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 six 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 will 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.

SECTION 8. FEES

- A.** Yearly registration fee payments of \$50.00 per tanning facility must be submitted with the initial application for registration or renewal of a tanning facility's registration, plus an equipment surcharge of \$20 per tanning equipment device.
- 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 required, as a result of failure to respond to a notice of violation, as authorized by Section 5(B).
- D.** A fee of \$25.00 per visit may be assessed for any additional inspections necessary to ensure compliance, notwithstanding the provisions of Sections 8(A) and (B).

SECTION 9. 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.

STATUTORY AUTHORITY AND HISTORY

STATUTORY AUTHORITY: 22 MRS §§ 674(4)(D), 677, 680, 682, 683, 689-A & 690

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