WEBER-MORGAN
HEALTH DEPARTMENT

Weber-Morgan Health Department

Regulation for

Manufacturing of E-Liquid

Adopted by the Weber-Morgan Board of Health

October 27, 2014
Amended Oct 23, 2017

Under Authority of Section 26A-1-121
Utah Code Annotated, 1953, as amended

Certified Official Copy
Weber-Morgan Health Department

By _____
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By _____
Ken Johnson, Chair, Weber-Morgan Board of Health

Manufacturing of E-Liquid

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1.0 TITLE AND PURPOSE

These standards shall be known as the Manufacturing of E-Liquid Regulation, hereinafter referred to as "this Regulation".

It is the purpose of this Regulation to protect the public health, safety and welfare of Weber and Morgan County residents and employees, by establishing requirements and provisions for the manufacturing of E-liquid components.

2.0 AUTHORITY AND JURISDICTION OF THE DEPARTMENT

The Weber-Morgan Board of Health is authorized to make standards and regulations pursuant to Section 26A-1-121(1) of the Utah Code Annotated, 1953 as amended.

2.1 The Weber-Morgan Board of Health is authorized to establish and collect fees pursuant to Section 26A-1-114 and Section 26-38-1 et. seq. of the Utah Code Annotated, 1953 as amended.

2.2 All fees shall be set by the Board of Health. The Department may charge additional fees for enforcement and follow-up inspections as set by the Board of Health.

3.0 DEFINITIONS

For the purpose of this Regulation, the following words and phrases, when used herein, except as otherwise required by the context, have the following meanings.

3.1 **"Board of Health"** means the Weber-Morgan Board of Health.

3.2 **"Business"** means any sole proprietorship, partnership, joint venture, corporation, association, or other entity formed for purposes that include profit-making.

3.3 **"Department"** means the Weber-Morgan Health Department.

3.4 **"Electronic-Cigarette"** means any electronic oral devise that provides a vapor of nicotine or other substance and stimulates smoking through its use or through inhalation of the device. An oral devise is composed of a heating element, battery, or electronic circuit and is marketed, manufactured, distributed, or sold as an e-cigarette, e-cigar, e-pipe, or any other product name or descriptor.

3.5 **"E-Liquid"** means any substance, including liquid containing nicotine, used or intended for use in an electronic-cigarette.

3.6 **"E-Liquid Components"** means the ingredients used in making E-Liquid including, but not limited to: propylene glycol (PG), vegetable glycerin (VG), nicotine, and flavorings.

3.7 **"Employee"** means any Person who is employed or retained as an independent contractor by any Employer or Nonprofit Entity in consideration for direct or indirect monetary wages or profit, or any Person who volunteers his or her services for an Employer or Nonprofit Entity.

3.8 **"Employer"** means any Business or Nonprofit Entity that retains the service of one or more Employees.

3.9 **"Good Hygienic Practices"** means the activities to prevent the transmission of disease and contamination of work spaces that include, but are not limited to: washing hands, covering open wounds or abrasions, not working when experiencing signs or symptoms of an illness, keeping work areas clean and free from food and drink, etc.

3.10 **"Good Manufacturing Practices"** means applying manufacturing restrictions to tobacco, prescribe regulations (which may differ based on the type of tobacco product involved) requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a tobacco product), packing, and storage of a tobacco product conform to current good manufacturing practice, or hazard analysis and critical control point methodology, as prescribed in such regulations to assure that the public health is protected and that the tobacco product is in compliance with this Regulation. Such regulations may provide for the testing of raw tobacco for pesticide chemical residues regardless of whether a tolerance for such chemical residues has been established.

3.11 **"Health Officer"** means and includes the Health Officer of the Weber-Morgan Health Department, his/her deputy, or other designated officer.

3.12 **"Inspection"** means a procedure performed by Department personnel that includes but is not limited to: inspection of a facility's retail and preparation areas, review of required records, review of personnel working knowledge and training, and taking samples of E-liquid. The Inspection procedures are intended to ensure compliance with this Regulation and Department policies and procedures.

3.13 **"Manufacturer"** means any business that is involved in the manufacturing of E-Liquid

3.14 **"Manufacturing"** means the process that includes, but is not limited to, mixing, re-packaging, and/or re-sizing E-Liquid.

3.15 **"Manufacturing Facility"** means any business within Weber or Morgan counties that manufactures, repackages, or resizes E-Liquid for sale or for resale.

3.16 **"Nicotine"** means an alkaloid derived of tobacco and other plants, or produced synthetically which has addictive and other physiological effects when ingested or inhaled.

3.17 **"Nonprofit Entity"** means any entity that meets the requirements of Section 16-6a-102 of the Utah Code, as well as any corporation, unincorporated association or other entity created for charitable, religious, philanthropic, educational, political, social or similar purposes, the net proceeds of which are committed to the promotion of the objectives or purposes of the entity and not to private gain. A government agency is not a Nonprofit Entity within the meaning of this Regulation.

3.18 **"Permit"** means the document issued by the Weber-Morgan Health Department that authorizes a Person to operate a business that manufactures E-Liquid.

3.19 **"Person"** means any natural person, Business, cooperative association, Employer, Nonprofit Entity, personal representative, receiver, trustee, assignee, or any other legal entity including a government agency.

3.20 **"Preparation Area"** means the physical location in which E-Liquid Components are mixed, repackaged, or resized for sale to the consumer.

3.21 **"Safety Precautions"** mean the activities that prevent or limit the risk of harm or injury to an Employee that include but are not limited to, wearing gloves, wearing eye protection, using equipment that is in good repair, cleaning up spills, access to a first aid kit, fire extinguisher, etc.

3.22 **"United States Pharmacopeia (USP) Standards"** means the written standards for medicines, food ingredients, dietary supplement products and ingredients. These standards are used by regulatory agencies and manufacturers to help ensure products are of the appropriate identity, as well as strength, quality, purity, and consistency.

4.0 SCOPE

This Regulation applies to E-Liquid manufactured in incorporated and unincorporated areas of Weber and Morgan Counties.

5.0 POWERS AND DUTIES

General Powers and Duties. The Department shall be responsible for the enforcement and administration of this Regulation and any other powers vested in it by law and shall:

5.1 Require the submission of information reports, plans, and specifications as necessary to implement the provisions and requirements of this Regulation.

5.2 Issue permits, and charge fees as necessary to implement this Regulation.

5.3 Perform Inspections of any facility and issue orders and/or notices, hold hearings, levy administrative penalties and negotiate monetary penalties as necessary to effect the purposes of this Regulation.

5.4 When necessary take samples and make analysis to ensure that the provisions of this Regulation are met; and

5.5 Adopt policies and procedures necessary to ensure that the provisions of this Regulation are met and that the purposes of this Regulation are accomplished.

5.6 Suspension, Revocation, or Denial of Permits. The Department may suspend, revoke, deny or require the surrender of the Permit as a result of violations of this Regulation.

5.7 The Department shall respond according to its policies, procedures, this Regulation, and to public complaints regarding this Regulation.

6.0 PROHIBITIONS

6.1 No person shall engage in Manufacturing if the person's age is below the minimum age allowed by state law for selling or possessing any tobacco product.

7.0 E-LIQUID MANUFACTURING FACILITIES PERMIT REQUIREMENTS

7.1 No person shall act as a Manufacturer without having first obtained, for each location at which manufacturing is to occur or otherwise, a manufacturer permit as provided in this Regulation, as well as a business license and, if applicable, a Cigarette and Tobacco License from the Utah Tax Commission.

7.1.1 No permit will be issued to authorize manufacturing at any place other than the fixed location approved on the application. Manufacturing by persons on foot, at events or from vehicles is prohibited.

7.1.2 A person desiring to operate as a Manufacturer shall submit to the Department a written application for a permit on a form provided by the Department.

7.1.3 Be an owner of the proposed facility or an officer of the Business.

7.1.4 Comply with the requirements of this Regulation.

7.1.5 Agree to allow Department access to the facility and to provide required information.

7.1.6 Pay the permit application fee at the time the application is submitted.

7.1.7 Present a copy of a current business license relating to the facility; and

7.1.8 Other information required by the Department for purposes of the enforcement of this Regulation.

7.2 Manufacturing Application

7.2.1 Any person desiring a manufacturing permit to engage in manufacturing as provided by this Regulation shall make a written application to, and upon forms furnished by, the Department, which shall be signed by applicant or his/her duly authorized agent. Any person signing the application as an agent shall furnish a written authorization executed by the applicant designating the person signing the permit as the applicant's duly authorized agent for such purpose. Such authorization will remain in full force and effect until revoked by a written document signed by the applicant and filed with the Department.

7.2.1.1 Such application shall be verified and include the following:

7.2.1.1.1 The name, mailing address and telephone number of the applicant and signature of the person applying for the permit.

7.2.1.1.2 The business name, address and telephone number of each fixed location for which a Manufacturing permit is being sought.

7.2.1.1.3 The name, title, address, and telephone number of the person directly responsible for the facility.

7.2.1.1.4 A statement signed by the applicant that attests to the accuracy of the information provided in the application, and affirms that the applicant will comply with this Regulation, and allow the Department access to the facility.

7.2.1.1.5 If applicable, proof of Cigarette and Tobacco License from the Utah Tax Commission.

7.2.1.1.6 Such other information pertaining to public health and safety as may be required by the Department, consistent with the purpose of this Regulation and other applicable laws.

7.2.1.2 The Department shall issue the Manufacturing Permit to the applicant unless such application is incomplete or inaccurate, the application seeks authorization for Manufacturing by a person or location for which a suspension is in effect under this Regulation.

7.2.1.3 No permit shall be issued unless the Department finds that the facilities, tools, and equipment of the applicant comply with the requirements of this Regulation.

7.3 Manufacturing Permit Issuance

7.3.1 The Department shall conduct an inspection of the place of business where manufacturing is to occur, and if it is found that all provisions of this Regulation and all applicable laws have been and will be complied with, the Department shall issue the permit; otherwise, the application for permit shall be denied.

7.3.2 The Manufacturing Permit shall clearly state the following on its face:

7.3.2.1 The legal owner(s) of the permitted premises.

7.3.2.2 Doing Business As (dba), if any.

7.3.2.3 The business and mailing address of the owner of the permitted premises.

7.3.2.4 The date the license was issued.

7.3.2.5 The permit number.

7.3.3 The Permit shall not be transferable or assignable from one person or proprietor to another or from one location to another location. If the information required in the permit application changes, a new permit is required before the Business or Person may continue to act as a manufacturer. For example, if a proprietor to whom a permit has been issued changes a business location, that proprietor must apply for a new permit prior to acting as a manufacturer at the new location. Or if the business is sold, the new owner must apply for a permit for that location before acting as a manufacturer.

7.3.4 Possession of a valid Permit under this Regulation does not entitle the holder to engage in an activity which is otherwise prohibited by law.

8.0 GENERAL PROVISIONS – PERMIT TERMS AND RENEWALS

8.1 No person shall in any way represent any place as a permitted facility unless the facility is operated under a valid Permit issued by the Department.

8.2 The Department is authorized to issue, suspend, revoke, deny or require the surrender of a Permit.

8.3 A Permit may not be transferred from one person to another person, from one facility to another facility or from one type of operation to another.

8.4 The Permit shall be posted in a conspicuous place within public view on the premises.

8.5 The Department may renew a Permit for an existing facility or may issue a Permit to a new owner of an existing facility after a properly completed

renewal form is submitted, reviewed, and approved, the fees are paid, and a review shows that the facility is in compliance with this Regulation.

8.5.1 The Department shall not approve any application for issuance or renewal of a Permit for an existing facility that is under suspension until the date that the suspension has expired.

8.5.2 The Department shall not issue a Permit to a new owner of any facility where a Permit has been revoked prior to twelve months from the date of revocation.

8.5.3 If the property referenced in sections 8.5.1 or 8.5.2 is sold or leased to a new Person that is requesting a Permit, that Person may request a waiver to sections 8.5.1 or 8.5.2 from the Board of Health.

8.5.3.1. The waiver may be issued upon demonstrating that no association exists between the Person requesting the Permit and the owner/operator currently suspended or revoked, and all monetary penalties have been paid.

8.5.4 No Permit shall be issued unless the Department finds that the facilities, tools, and equipment of the applicant comply with the requirements of this Regulation and that competent personnel are employed and available, and the operation thereof will be properly conducted in accordance with this Regulation.

8.6 Permit Duration and Renewal.

8.6.1 The Permit shall be issued annually and shall expire on December 31st of each year. The Permit is renewable within sixty (60) days prior to the date of expiration.

8.6.2 It is the responsibility of the owner/operator to pursue the Permit renewal through appropriate channels.

8.6.3 The Permit fee shall be paid annually to the Department by the billing due date set by the Department.

8.6.4 Permits that have expired for more than 90 days are not renewable.

8.6.5 Prior to the date on which the Permit fee is due the Department shall attempt to notify each regulated facility of the amount of the fee.

Fees unpaid after the billing due date will be assessed a late fee which shall be added to the original fee amount.

8.7 Permit Revocation and Suspension

8.7.1 Permits may be suspended by the Department for violations of this Regulation or any violation of applicable state and federal laws.

8.7.2 Permits may be revoked by the Department for severe and/or repeated violations of this Regulation.

8.7.3 Permits are and remain the property of the Department, only their use and the license they represent is tendered.

8.7.4 A Permit may be suspended or revoked by the Department because of returned checks and may not be reinstated until repayment is confirmed. All returned checks will be charged a returned check handling fee (referenced in Appendix B).

8.7.5 A Permit may be suspended or revoked by the Department for failure to allow access to authorized Department representatives for inspections.

8.8 Failure to pay the Permit fee and any additional charges after the due date may result in suspension and/or revocation of the Permit and the right to operate.

8.9 The permit applicant shall hold the Department harmless in making application for a Permit or for its renewal; such action shall constitute a declaration by the applicant that the Department shall be held harmless from liability incurred due to action or inaction of the owner or their employees.

8.10 The permit fees shall be determined according to a fee schedule adopted by the Board of Health. Fees are subject to change and may be amended as deemed necessary by the Board of Health to accomplish the purposes of this Regulation.

8.11 The Department has the authority to perform inspections, reviews or other similar actions as necessary to promulgate this Regulation. No person shall refuse to allow, or hinder the activity of the authorized representatives of the department while conducting inspections of permitted facilities.

8.12 Violations of any tobacco-related laws shall constitute violations of the manufacturing permit issued pursuant to this Regulation.

9.0 MANUFACTURING REQUIREMENTS – SANITATION AND SAFETY

9.1 General Provisions. A permit holder with a manufacturing endorsement shall comply with the following requirements.

9.1.1 E-Liquid preparation surfaces must be smooth, non-absorbent and easily cleanable.

9.1.2 Floors, walls and ceilings in the Preparation Area must be smooth, non-absorbent and easily cleanable.

9.1.3 All E-Liquid preparation equipment shall be maintained clean and in good repair.

9.1.4 Individuals preparing E-Liquid shall use Good Hygienic Practices, follow Good Manufacturing Practices, and take proper Safety Precautions. Preparation area access restricted to employees only.

9.1.5 Work surfaces shall be cleaned and sanitized before, between preparation of batches with different nicotine concentrations, and upon completion of any manufacturing procedures.

9.1.6 Drinking, eating, vaping or smoking is not permitted in the Preparation Area.

9.1.7 No animals shall be permitted in the Preparation Area.

9.1.8 E-Liquid Components shall be stored to prevent contamination and/or spillage.

9.1.9 Nicotine shall be stored in a manner to prevent contamination of Preparation Areas, equipment, supplies and other E-Liquid Components.

9.1.10 Material Data Safety Sheets shall be kept on premises for all E-Liquid components.

9.1.11 Chemicals not involved in the preparation of E-Liquid shall not be stored in preparation or ingredient storage areas.

9.2 Operating Procedures

9.2.1 Standard Operating Procedures (SOPs) for manufacturing E-Liquids shall be written and must incorporate Good Hygienic Practices, Good

Manufacturing Practices, and Safety Precautions. SOPs shall be made available to the Department upon request.

9.2.2 Standard Operating Procedures shall include, but are not limited to;

9.2.2.1 A system for recalling any batch of product from sale or supply.

9.2.2.2 A procedure for receiving and investigating complaints.

9.2.2.3 A procedure for investigating causes of quality defects and the corrective action taken to prevent recurrence.

9.2.3 Employees shall be trained on all SOPs and training logs shall be maintained. Logs shall be made available to the Department upon request.

9.3 Quality and Safety of E-Liquid Components

9.3.1 E-Liquid Components including, but not limited to: propylene glycol (PG), vegetable glycerin (VG), nicotine, and flavoring must be at a minimum US Pharmacopeia (USP) grade certified, food grade, FDA approved, or equivalent.

9.3.1.1 Documentation must be available for all E-Liquid Components showing certification, approval, grade, or equivalency and shall be submitted at the time of application and annually with the permit renewal. Documentation must also be made available to the Department upon request.

9.3.2 All nicotine used in manufacturing must be USP certified and meet the following nicotine quality standards:

9.3.2.1 Nicotine purity greater than or equal to 99.0%. Total combine of all other possible contaminants less than or equal to 1.0%.

9.3.2.2 Cumulative heavy metals content cannot exceed 10ppm.

9.3.2.3 Cumulative Arsenic content cannot exceed 1ppm.

9.3.2.4 All diluents after source pure must be USP certified thru chain of custody.

9.3.2.5 Manufacturers will maintain records that enable the manufacturer or the department to trace any individual product distributed, to the test results for nicotine content. These records shall include source nicotine content.

10.0 E-LIQUID FOR SALE IN WEBER OR MORGAN COUNTY

10.1 Failure to meet testing standard for nicotine may result in further sample testing at the owner's expense, recall and disposal of product, or both.

10.2 Manufacturers must have information readily available for the consumer explaining the difference between mg/mL and percent by volume of nicotine.

11.0 PENALTY

11.1 Any person who is found guilty of violating any of the provisions of this Regulation, either by failing to do those acts required herein or by doing a prohibited act, shall be guilty of a class B misdemeanor pursuant to Section 26a-1-123, Utah Code Annotated, 1953, as amended. If a person is found guilty of a subsequent similar violation within two years, he shall be guilty of a class A misdemeanor pursuant to Section 26a-1-123, Utah Code annotated, 1953, as amended.

11.2 Each day that a violation is committed or permitted to continue shall constitute a separate violation.

11.3 The County Attorney may initiate legal action, civil or criminal, requested by the Department to abate any condition that exists in violation of this Regulation.

11.4 In addition to other penalties imposed by a court of competent jurisdiction, any person(s) found guilty of violating any of this Regulation shall be liable for all expenses incurred by the Department in prosecuting and/or abating the violation.

11.5 Violations of this Regulation shall be subject to the Department's Adjudicative Hearing Procedures and may result in permit suspension or revocation, and/or monetary penalties.

11.6 Enforcement of any criminal penalties does not preclude imposition of administrative or civil penalties and vise-versa.

12.0 SEVERABILITY

If any provision, clause, sentence, or paragraph of this Regulation or the application thereof to any person or circumstances shall be held to be invalid, such invalidity shall not affect the other provisions or applications of this Regulation. The valid part of any clause, sentence, or paragraph of this Regulation shall be given independence from the invalid provisions or application and to this end the provisions of this Regulation are hereby declared to be severable.

13.0 EFFECTIVE DATE

This Regulation shall become effective the day of its adoption by the Board of Health.
Adopted by the Weber-Morgan Board of Health (October 23, 2017)