
# E-LIQUID MANUFACTURING STANDARDS

**AEMSA advocates electronic cigarette products for ADULT USE ONLY. AEMSA supports ban on sales to minors.**

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# PURPOSE

The purpose of these Standards is to create a responsible and sustainable practices and process for the safe manufacturing of “eliquids” used in electronic cigarettes. Our members believe we have a responsibility to self--regulate the e-liquid manufacturing process based on professional criteria. AEMSA aims to accomplish this by creating, implementing and upholding standards for the manufacture of e-liquids. One of AEMSA’s primary goals is to provide consumers with higher degrees of confidence our members’ products are manufactured with professionalism, accuracy and safety **AEMSA standards are established based on the following Core Beliefs:**

- We have a responsibility to verify the accuracy of any nicotine content in the products we distribute.
- We have a responsibility to ensure the quality of all ingredients in our e-liquids.
- We have a responsibility to prepare our products in a clean, sanitary and safe environment.
- We have a responsibility to ensure our products are packaged and delivered in a safe manner.
- We have a responsibility to provide a level of transparency into the monitoring and verification process.

The 2017 AEMSA Standards are living documents and subject to changes according to the AEMSA corporate structure and procedures.

# SCOPE

These standards apply to all AEMSA general members that engage in the manufacturing or processing of E-liquids. 2017 E-Liquid Manufacturing Standard will be used as a basis for:

- Evaluating compliance for membership acceptance
- Confirming compliance of existing membership

# CONTENTS

# Article I. Verifying the accuracy of the nicotine content in products

## Section 1.01 Accuracy of nicotine

(a) All manufactures must confirm the accuracy of nicotine content upon receipt from supplier

## Section 1.02 Titrated/verified after dilution

(a) All nicotine must be titrated/verified for content accuracy after dilution to working level

## Section 1.03 Measuring Nicotine

(a) All equipment used in measuring nicotine from working level to final product must be either

(i) NIST traceable

(ii) Calibrated by an accredited provider (ISO 17025 or NVLAP)

## Section 1.04 Tolerance level

(a) All products produced will be within the tolerance level of +/-10% nicotine content in final product

## Section 1.05 Maximum allowable nicotine content

(a) The maximum allowable nicotine content in final flavored product will be no greater than 24 mg / ml

## Section 1.06 Retail nicotine sold for unflavored/DIY nicotine

(a) Will follow the same criteria for verifying the nicotine content and quality on all batches when received and titrated after dilution at various sales levels

(b) Is not subject to maximum allowable nicotine content in final flavored product

# Article II. Ensure the quality of the all ingredients of in e-liquid

## Section 2.01 Nicotine Sources

(a) All manufacturers must purchase and comply with at least one of the following:

(i) USP CERTIFIED nicotine (with evidentiary documentation from a certified lab)

(ii) Free-base nicotine from suppliers who can provide source evidentiary documentation from a certified lab confirming (batched) nicotine conforms to the Nicotine Quality Standard (see Section 2.02)

(iii) Purchase from nicotine suppliers who can provide evidentiary documentation from a certified lab confirming the incoming (batched) free-base nicotine conforms to the Nicotine Quality Standard (see Section 2.02)

## Section 2.02 Nicotine Quality Standard

(a) All nicotine used in manufacturing must meet the following nicotine quality standards:

(i) Nicotine purity greater than or equal to 99%*

(ii) Total combined of all other possible contaminants less than or equal to 1.0%

(iii) Per existence of any solvent must not exceed 0.06%

(iv) Per existence nicotine oxide less than or equal to 1%

(v) Per existence nicotine-N-oxides less than or equal to 1%

(vi) Cumulative heavy metals *content* cannot exceed 10ppm

(vii) Cumulative Arsenic *content* cannot exceed 1ppm

(viii) All diluents after source pure must be USP certified thru chain of custody

## Section 2.03 Base liquid ingredients

(a) Base liquid diluent ingredients such as Propylene Glycol, Vegetable Glycerin, Glycerol, or any other e-liquid bases (either regularly or exclusively) will be at a minimum level of USP (US Pharmacopoeia) grade certified

(i) Material must maintain full certification throughout chain of custody on raw materials used in manufacturing process

(ii) Manufacturer must exclusively use certified base products throughout the manufacturing process

## Section 2.04 Ingredients/ Components other than base liquids

(a) Ingredients/ Components other than base liquids will contain only the highest grade base materials

(i) Flavorings (including menthol) used will be at a minimum of food grade and/or Generally Recognized as Safe (GRAS) standard certifications whenever the ingredient is produced at those standards

(ii) Flavorings containing artificial food coloring will identify food coloring information to include coloring number in advertising and product descriptions

(iii) Finished product must conform to AEMSA Compliance Guidelines for Finished Product Analysis

(iv) Water used (if any) will be either deionized or distilled

(v) Alcohol and additional additives (if any) will be:

1) Used in the purest form commercially available and safe for human consumption

2) Minimum of US Food grade standards

## Section 2.05 The following will not be added or used in the creation of eliquids

(a) Including but not limited to:

(i) WTA (whole tobacco alkaloids)

(ii) Medicinal - or prescription medicinal

(iii) Illegal or controlled substances

(iv) Caffeine

(v) Vitamins or Dietary supplements (other than for preservative purposes)

(vi) Artificial Food Coloring

1. AEMSA members will not add any artificial coloring or dyes during the e-liquid manufacturing process. Non vendor manufactured flavorings containing artificial food coloring will identify food coloring information to include coloring number in advertising and product descriptions

(vii) AEMSA reserves the right to review, evaluate and deny/approve any potential substance used in the creation of e- liquids at any given time

(viii) Prohibited compounds per local, state, or federal agencies (if applicable)

### Section 2.06 Process / Records / Traceability

(a) Manufactures will maintain sufficient process and records to enable the manufacturer to trace any individual product distributed to the test results for nicotine content to include source nicotine (see section 2.02)

## Article III. Clean, Sanitary and Safe Preparation of Products

### Section 3.01 General

(a) All Lab/Mixing employees are required to be fully familiar with all AEMSA standards

(i) There will be a special emphasis placed on nicotine handling, storage and clean-up

(b) Each member will create and maintain written lab/mixing protocol and make accessible to all lab/mixing employees

(c) All Persons allowed in process area must comply with applicable protection/ safety and standards

(d) All products will be created and/or bottled in dedicated manufacturing space reserved exclusively for e-liquid

### Section 3.02 Manufacturing Environment

(a) Manufacturing processes will meet food preparation standards to include

(i) Non-porous sanitized preparation work surface

(ii) Ceiling constructed of non-porous material

(b) All surfaces in lab/mixing area (floors, counters, etc.) shall be cleaned with anti-bacterial agents at least once each day and after any spill of any mixing ingredient or any possible-contaminants

(c) Equipment will be cleaned by FDA Approved Chemical Sanitation or autoclave

(d) All supplies and material will be disposed of in a manner that is appropriate to component disposal -- proper disposal of production material. Disposal of manufacturing materials must comply with all local, state, and federal requirements (if applicable).

(e) There shall be no open fans, dusty boxes and/or other potential sources of airborne contaminants etc. in dedicated space

(f) All bottles and materials unpacked outside of dedicated lab/mixing space

## Section 3.03 Hand washing / sanitation

(a) Not in sink used for cleaning mixing utensils, and/or other e-liquid materials

(b) Minimum 20 seconds with commercial (food handler's grade) antibacterial hand washing agent and warm water

(c) Hands washed each and every time entering mixing room

(d) After bathroom use, coughing, sneezing, eating and/or drinking, engaging in any other activities which potentially expose hands to any form of potential contaminants

(e) During mixing as often as necessary to remove any mixing products on hands

(f) Before proceeding to a subsequent mixing session -> to prevent any cross contamination from one batch to the next

## Section 3.04 Health / Illness

(a) All open wounds or abrasion will be properly covered

(b) Any/All mixing employees report any illness/abrasion(s)/lesions to person in charge before entering the process

(c) Employees must report to person in charge if exposed to any contagion or infection - viral or bacterial - from anywhere (including others in their homes, other work environments, other domiciles, etc.) before entering lab/mixing area

(i) Such exposure/conditions excludes said individual from entering mixing room for a period of three (3) asymptomatic days have passed and/or cleared with medical documentation (equivalent to commercial food handling)

(ii) Discharge from eyes, nose and/or mouth:

(iii) Report to business any persistent discharge from eyes, nose, and/or mouth. Any employee exhibiting such symptoms shall not enter the mixing room until such symptoms cease

## Section 3.05 Eating / Drinking

(a) No eating, drinking, vaping and/or smoking in the lab/mixing area at any time

## Section 3.06 Hair Restraints

(a) Each member must establish written hair and beard standards

## Section 3.07 Animals

(a) No animals shall be permitted in the mixing room at any time for any reason

## Section 3.08 POISONOUS OR TOXIC MATERIALS

(a) POISONOUS OR TOXIC MATERIALS shall be stored so they cannot contaminate PRODUCT COMPONENT, EQUIPMENT, UTENSILS, and SINGLE-USE ARTICLES by:

(i) Separating the POISONOUS OR TOXIC MATERIALS by spacing or partitioning

(ii) Locating the POISONOUS OR TOXIC MATERIALS in an area that is not above PRODUCT COMPONENTS, EQUIPMENT, UTENSILS, or SINGLE-USE ARTICLES

(iii) This does not apply to EQUIPMENT and UTENSIL cleaners and SANITIZERS that are stored in WAREWASHING areas for availability and convenience if the materials are stored to prevent contamination of PRODUCT COMPONENT, EQUIPMENT, UTENSILS, LINENS, and SINGLE-SERVICE and SINGLE-USE ARTICLES

(iv) All POISONOUS OR TOXIC MATERIALS will be disposed of in a safe manner

(v) Only those POISONOUS OR TOXIC MATERIALS that are required for the operation and maintenance of a lab/mixing area, such as for the cleaning and SANITIZING of EQUIPMENT and UTENSILS and the control of insects and rodents, shall be allowed in a lab/mixing area (kept sealed and separate - never above - from any/all mixing supplies)

(vi) A container previously used to store POISONOUS OR TOXIC MATERIALS may not be used to store, transport, or dispense any other substance

## Section 3.09 Employee Safety

(a) Employers MUST provide their employees with a workplace that does not have serious hazards and follow all relevant local, state, and federal requirements including - but not limited to - the following mandatory personal protective equipment (P.P.E.):

(i) Eye protection must meet or exceed ANSI Z87.1 standards and must be worn at all times in process areas of the manufacturing environment.

(ii) Lab Coat / Apron

(i) Long sleeves required. If apron is chosen for PPE, appropriate long sleeve undergarments must be chosen so that the entire arm is covered from environmental hazards during the manufacturing process.

(iii) Full coverage pant / leg attire

(i) Garment(s) must not be torn or contain opening(s) that may expose worker to environmental hazards during the manufacturing process.

(iv) Fully covered footwear

(v) Chemical-resistant / liquid-resistant gloves

(vi) All manufacturing spaces must have easily accessible

1) First aid kit

2) Emergency eye wash kit

3) Chemical containment spill kit

# Article IV. Safe Packaging and delivery of products

## Section 4.01 Child proof caps

(a) Child proof caps required for all consumer level e-liquid products

(b) Zero Nicotine Products do not require child proof caps

## Section 4.02 Tamper Evident packaging

(a) All Products require tamper evident packaging once leaving vendor chain of custody

## Section 4.03 Labeling

(a) Smear Resistant Labeling is required on all e-liquid products

(i) Must pass “30 second submerged” test for all required elements

(b) Nicotine content must be clearly displayed

(c) Safety and health Warning must be clearly displayed

(i) Contains Nicotine

(ii) Keep away from Children and Pets

(d) Nicotine Traceability elements (i.e. Batch ID or nicotine batch ID or production date)

## Section 4.04 Delivery

(a) All shipped liquid must be bagged or wrapped to provide waterproof barrier between packaging and product for spill protection

(b) Safe handling information must be included in all packaging

(c) All business to business shipments must include General Certificates of Conformity per 16 C.F.R § 1700.15, Poison Prevention Packaging Standards (16 C.F.R. § 1700.20, Testing Procedure for Special Packaging)

## Section 4.05 Active Age Verification

(a) All Vendors must use Active age verification for all sales (retail and/or online)

(b) AEMSA Members will not knowingly sell products to any persons under the legal smoking age

# Article IV. Transparency into the monitoring and verification process

## Section 5.01 Within the organization

(a) Members must provide information to applications and compliance committees required to establish compliance including:

(i) Documented evidence of compliance

1) Photographic and Video evidence

2) Unfettered access to facilities for inspection (scheduled and/or unscheduled)

3) Process and records

(b) Member to member profiles will contain only minimal information for the identification and communication amongst and between members

(i) Current status of compliance - by facility

(ii) Contact Information

1) Name

2) DBA

3) Email

4) Phone

5) Location(s)/ Facilities of production

## Section 5.02 To the consumer

- **Note: Subsections (a) and (b) are already posted on AEMSA website. Subsections (c) and (d) are intended for specific information warranted situations ONLY; these may include - but not limited to - allergy sensitivities, other specific medical conditions/sensitivities, etc. Subsection (e) shall be available on member's web site**

(a) A substantive version of the AEMSA Standards be published on Website

(b) AEMSA Membership Status

(c) **Members will provide consumers tracking nicotine test results as far back as the source nicotine**

(i) **Information on the supplier may be redacted to protect intellectual property and trade secrets**

(ii) **The member may charge a reasonable and fair fee for said tracing requests**

(d) Members will provide answers to consumers on ingredients of products

(i) Yes/No answers to specific questions as pertains to specific customer sensitivity questions

(ii) No intellectual property or trade secrets of the e-liquid ingredient has to be revealed

1) This includes revealing the source supplier and trademarked/brand name ingredient

(e) Clearly identified products that are not manufactured by AEMSA Members

1) If the member sells liquid that is manufactured in a non AEMSA compliant facility it must:

2) Clearly identify/ differentiate products that are AEMSA compliant and those that are not AEMSA compliant on a product by product basis

### Section 5.03 To potential regulators

(a) To be decided on case by case basis

# APPENDIX A: TERMS AND DEFINITIONS

**Active Age Verification:** Taking active measures to ensure that all customers are of legal age. Can be accomplished in many ways including Photo Identification and 3rd party verification systems. Note: Having pop up box asking the person to indicate they are over a specified age is not Active Age Verification

**ASTM - American Society for Testing and Materials:** An international standards organization that develops and publishes voluntary consensus technical standards for a wide range of materials, products, systems, and services

**Chain of custody:** The chronological documentation or, showing the custody, control, transfer, analysis, and disposition of physical component; tracking a product along the supply chain to the point of sale

**Components:** A part or element of a larger whole; a substance that forms part of a mixture. Any substance, material or the tangible substance that goes into the manufacturing of e- liquid

**Contaminants:** An impurity or foreign substance present in a material or environment that affects one or more properties of the material

**Custard Notes:** Flavor compounds that impart a buttery, creamy, or custard taste or sensation. Most commonly used are acetoin, acetyl propionate and diacetyl

**Dedicated Manufacturing Space:** A clean safe environment that is used exclusively for the manufacturing of e-liquid

**Diacetyl:** A natural byproduct of fermentation. It is a vicinal diketone (two C=O groups, side-by-side) with the molecular formula C4H6O2. Diacetyl occurs naturally in alcoholic beverages, other natural sources and is added to some foods to impart a buttery flavor. Diacetyl, while not problematic for ingestion via digestion, has been identified as a potential inhalation risk and has been reported in some flavorings. As a preventative and good product stewardship measure, many e-liquid manufacturers are now testing, reformulating and/or removing identified flavors from inventory to avoid potential inhalation risks.

**Direct Operation:** A facility or process where Full time employees for an organization directly supervise and oversee production and process

**DIY:** Do it Yourself

**Electronic cigarette:** Also known as an e-cigarette (e-cig) is an electrical inhaler that vaporizes a propylene glycol and/or glycerin-based liquid solution into an aerosol mist simulating the act of tobacco smoking

**E-liquid:** Liquid for producing vapor in electronic cigarettes, known as e-juice or e-liquid

**E-liquid manufacturing:** Fabrication: the act of making something (a product) from raw materials; to include all processes from supply acceptance to the point of customer delivery

**Free-base:** An amine or nitrogen-containing organic compound, such as nicotine, in its basic (high pH) form, in contrast to its acidic (low pH) form, which is often called the “salt” form. Unless an acid has been added to nicotine, or it is purchased as the salt, it is in the freebase form. Free-base describes the form of the compound, not its purity

**Generally Recognized as Safe (GRaS):** Generally recognized as safe (GRAS) is an American Food and Drug Administration (FDA) designation that a chemical or substance added to food is considered safe by experts, and so is exempted from the usual Federal Food, Drug, and Cosmetic Act (FFDCA) food additive tolerance requirements

**Indirect Operation:** A facility or process where supervision and/or oversight of production and/or process for an organization is conducted by a 3rd party or contractor (subcontractor)

**Mg / ml:** Milligrams per Milliliter – a scale (or ratio) for measuring an ingredient component, in liquid form, where accuracy is measured in mg per ml - or a percentage equivalent

**Nicotine:** Nicotine is an alkaloid found in the nightshade family of plants (Solanaceae) that acts as a nicotinic acetylcholine agonist. The biosynthesis takes place in the roots and accumulation occurs in the leaves of the Solanaceae. It constitutes approximately 0.6–3.0% of the dry weight of tobacco and is present in the range of 2–7 µg/kg of various edible plants

**NIST -The National Institute of Standards and Technology:** A non-regulatory agency of the United States Department of Commerce. The institute's official mission is to: Promote U.S. innovation and industrial competitiveness by advancing measurement science, standards, and technology in ways that enhance economic security and improve our quality of life

**OSHA:** The United States Occupational Safety and Health Administration (OSHA) is an agency of the United States Department of Labor. Congress established the agency under the Occupational Safety and Health Act, was signed into law on December 29, 1970. OSHA's mission is to "assure safe and healthful working conditions for working men and women by setting and enforcing standards and by providing training, outreach, education and assistance". The agency is also charged with enforcing a variety of whistleblower statutes and regulations

**PPM:** Parts Per Million

**SINGLE-USE ARTICLES:** Utensils, containers and tools designed and constructed to be used once and discarded

**Tamper Evident:** Tamper-evident describes a device or process that makes unauthorized access to the protected object easily detected. Seals, markings or other techniques may be tamper indicating

**Titration:** Also known as titrimetry, is a common laboratory method of quantitative chemical analysis that is used to determine the concentration of an identified component; the determination of rank or concentration of a solution with respect to water with a pH of 7 (the pH of pure H2O under standard conditions)

**USP (US Pharmacopoeia):** The United States Pharmacopeia (USP) is the official pharmacopeia of the United States, published dually with the National Formulary as the USP-NF. The United States Pharmacopeial Convention (usually also called the USP) is the nonprofit organization that owns the trademark and copyright to the USP-NF and publishes it every year. Prescription and over–the–counter medicines and other health care products sold in the United States are required to follow the standards in the USP- NF. USP also sets standards for food ingredients and dietary supplements

**WTA (whole tobacco alkaloids):** A full-spectrum mixture of all alkaloids extracted from whole tobacco. WTA can contain, in addition to nicotine, anabasine, cotinine, myosmine, anatabine, and/or nornicotine, in varying compositions, largely dependent on the tobacco species

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