

Emergency Rule
LSA Document #16-145(E)

DIGEST

Temporarily adds noncode provisions for licensing requirements for e-liquid manufacturers. Statutory authority: [IC 4-22-2-37.1](#); [IC 7.1-7-3-3](#). Effective March 31, 2016.

SECTION 1. (a) The purpose of this document is, in the absence of federal regulations, to protect public health and safety by:

- (1) ensuring the safety and security of e-liquid manufactured for sale in Indiana;
- (2) ensuring that e-liquid manufactured or sold in Indiana conforms to appropriate standards of identity, strength, quality, and purity; and
- (3) ensuring that e-liquid is not contaminated or adulterated by the inclusion of ingredients or other substances that might pose unreasonable threats to public health and safety.

(b) This document applies to the commercial manufacturing, bottling, selling, bartering, or importing of e-liquid products in Indiana and the sale, possession, and use of e-liquid products in Indiana.

SECTION 2. Any e-liquid or nicotine product, including nonrefillable sealed cartridge electronic cigarettes, sold for use in Indiana may not be sold to anyone less than eighteen (18) years of age.

SECTION 3. (a) The definitions in [IC 7.1-7-2](#) and this SECTION apply throughout this document.

(b) "Commission" or "ATC" means the Indiana Alcohol and Tobacco Commission.

(c) "Packaging" means the process by which e-liquid is bottled in a tamper evident package with a child resistant cap and labeled in compliance with [IC 7.1-7](#). The term does not include the process of preparing to ship or distribute already manufactured and packaged e-liquid.

SECTION 4. (a) Anyone involved in manufacturing an e-liquid for sale to retailers or distributors of e-liquid in Indiana must first obtain an e-liquid manufacturer's permit from the commission.

(b) The commission shall accept initial applications and issue manufacturing permits until June 30, 2016.

(c) The application must include the following:

- (1) Name, address, and telephone number of the applicant.
- (2) Name, telephone number, and address of the manufacturing facility.
- (3) Full legal name, address, date of birth, Social Security number, and primary telephone contact number for each owner.
- (4) Full legal name, telephone number, date of birth, Social Security number, title, and address of the facility managers responsible for the manufacturing facility.
- (5) The projected output in liters per year of e-liquid of the manufacturing facility.
- (6) Floor plans, marked as confidential under [IC 7.1-7-3-2](#), of the manufacturing facility that show the layout of the entire manufacturing facility including the following:
 - (A) The clean room.
 - (B) The storage room where sample bottles are stored as required by [IC 7.1-7-4-6](#).
 - (C) All entrances, exits, and interior doors.
 - (D) All areas open to the public, including areas used for sales or distribution of e-liquids.
- (7) An executed security agreement showing compliance with the requirements of [IC 7.1-7-4-1\(d\)\(3\)](#) and [IC 7.1-7-4-6\(b\)\(10\)](#) through [IC 7.1-7-4-6\(b\)\(15\)](#). A security agreement will be treated as confidential and only be released pursuant to a court order.
- (8) A verified statement from the security firm that includes the following:
 - (A) Name of at least one employee of the security firm who is accredited or certified by the Door and Hardware Institute as an architectural hardware consultant.
 - (B) Name of at least one employee of the security firm who is accredited or certified as a certified rolling steal *[sic]* fire door technician by the International Door Association or the Institute of Door Dealer Education and Accreditation.

(C) Name of the employee of the security firm who is a locksmith.

(D) Statement that the security firm has at least one (1) year of commercial experience, in the preceding year, with the following:

(i) Video surveillance system design and installation with remote viewing capability from a secure facility.

(ii) Owning and operating a security monitoring station with ownership control and use of a redundant offsite backup security monitoring station.

(iii) Operating a facility that modifies commercial hollow metal doors, frames, and borrowed lights with authorization to apply the Underwriters Laboratories label.

(9) Statement that no individuals, corporations, limited liability companies, limited liability partnerships, partnerships or stock owners, members, or partners of such entities with an interest, either directly or indirectly, in the security company have any interest, either directly or indirectly, in any e-liquid manufacturer, distributor, or retailer.

(10) A verified statement that all products manufactured for distribution in Indiana contain only the ingredients listed in [IC 7.1-7-5-1\(a\)](#).

(11) An addendum, marked as confidential, that provides a product listing that complies with SECTION 8 of this document.

(12) A verified statement that the facility will comply with manufacturing processes required by [IC 7.1-7](#) and this document.

(13) A verified statement that equipment used is easily cleanable as defined in [410 IAC 7-24-27\(a\)](#).

(14) Written consent allow law enforcement officer to conduct a state or national criminal history background check on any person listed on the application.

(15) Written consent allowing the commission, or its duly appointed agents, after a permit is issued to the applicant, to enter during normal business hours the premises where the e-liquid [*sic*] is manufactured to conduct physical inspections, sample the product to ensure the e-liquid meets the requirements for e-liquid set forth in this article, and perform and audit.

(16) A nonrefundable application fee of one thousand dollars (\$1,000).

(17) Any other information as deemed appropriate by the commission to complete review of the application.

(d) The applicant is responsible for notifying the commission within ten (10) business days if any information in the initial application changes. Failure to make a timely and accurate notification about information changes may result in the denial or revocation of the application.

SECTION 5. (a) The commission shall complete its review and take final action upon the application within sixty (60) days after receiving all information and documentation required by [IC 7.1-7](#) and this document, including, but not limited to, the following:

(1) The completed application form.

(2) The certification by the security firm that the manufacturing facility is in compliance with the requirements of [IC 7.1-7-4-1\(d\)\(3\)](#) and [IC 7.1-7-4-6\(b\)\(10\)](#) through [IC 7.1-7-4-6\(b\)\(15\)](#).

(3) A fully compliant service security agreement is executed with the final copy submitted to commission.

(4) Product listing that complies with SECTION 8 of this rule [*document*].

(5) Payment of the application fee.

(6) Floor plan.

(7) Any other outstanding matters required by the commission are satisfied.

(b) An approved manufacturer's permit will not be required for renewal until five (5) years after the date of the initial application's approval or the last renewal.

(c) For an out of state or out of country manufacturing facility that the commission is unable to physically inspect, arrangements may be made for an independent provider approved by the commission to perform such inspection. The out of state approved inspection provider will be required to submit the results of the inspection directly to the commission via first class mail.

(d) All costs associated with the inspection and reporting may be assessed to the applicant.

SECTION 6. (a) Applications for renewals of existing permits must be submitted to the commission on an application form prescribed by the commission at least sixty (60) days before the expiration date of the existing permit and must include the following:

(1) The name, address, and telephone number of the applicant.

- (2) The name, address, and telephone number of the manufacturing facility.
- (3) The full legal name, address, and primary telephone contact number for each owner.
- (4) The full legal name, address, and primary telephone contact number for each facility manager responsible for the manufacturing facility.
- (5) The annual output in liters of e-liquid of the manufacturing facility for the five (5) years preceding the year of the application.
- (6) Certification by the applicant that the applicant will continue to use the security protocol approved by the commission with the applicant's initial application. However, if the applicant desires to change the previously approved security protocol, the applicant shall submit the suggested changes to the commission for approval.
- (7) Evidence that the security firm complies with the requirements of [IC 7.1-7](#) by either:
 - (A) a verified statement by the security company that the information provided in the initial application or most recent renewal applicant continues to be correct; or
 - (B) a verified statement as required by SECTION 4(a)(7) of this document that includes any changes to the security company.
- (8) A verified statement that all products manufactured for distribution in Indiana contain only the ingredients listed in [IC 7.1-7-5-1\(a\)](#).
- (9) A verified statement that the manufacturing process used by the applicant complies with the requirements of [IC 7.1](#) and this document.
- (10) Written consent allowing law enforcement to conduct a state or national criminal history background check on any person listed on the application.
- (11) Written consent allowing the commission, if a permit is renewed to the applicant, to enter the premises where the e-liquid is manufactured to conduct physical inspections, sample the product to ensure the e-liquid meets the requirements of e-liquid set forth in [IC 7.1-7](#), and perform an audit.
- (12) A nonrefundable application fee in the amount of five hundred dollars (\$500).
- (13) Any other information as deemed appropriate by the commission that is relevant to the renewal application.

(b) The applicant is responsible for notifying the commission within ten (10) business days if any information in the initial application changes. Failure to make a timely and accurate notification about information changes may result in the denial of the application.

SECTION 7. (a) As used in this SECTION, "sample" means the three (3) ten (10) milliliter sample bottles from each production batch of more than two (2) liters required to be stored or maintained by [IC 7.1-7-4-6\(b\)\(15\)](#).

(b) Permits are transferable to another person or location only with commission approval.

(c) Permits shall be transferable upon a showing to the commission that:

- (1) the permit has not been suspended or revoked and is in good standing; and
- (2) the new permit holder and location meet all of the requirements as required by this document.

(d) An e-liquid manufacturer transferring the location of the permit shall maintain the samples in a secure, limited access area during the transfer of location by complying with the following:

- (1) The e-liquid manufacturer must notify the commission of the anticipated date the samples will be removed from the original location and the anticipated date the samples will be moved into the new location.
- (2) Samples may only be removed from the secure, limited access area with recorded video surveillance at the original location by designated employees of the e-liquid manufacturer.
- (3) Samples removed from the secure, limited access area with recorded video surveillance at the original location must be placed immediately in a secure, limited access container or vehicle for transporting to the new permit location.
- (4) Video surveillance may not be removed or disconnected from the secure, limited access area until all samples are removed to the secure, limited access container or vehicle.
- (5) The secure, limited access area for the storage of samples at the new location must have operational video surveillance before samples may be placed in the area.
- (6) The e-liquid manufacturer must notify the commission of the completion of the transfer within five (5) days after the completion of the relocation of the samples and equipment.
- (7) The e-liquid manufacturer must maintain a list of employees who had access to the samples during the transfer for a period of three (3) years.

SECTION 8. (a) The manufacturer shall provide a product listing to the commission at the time of the initial application for all e-liquid products manufactured in production batches of more than two (2) liters.

(b) The product listing shall include:

- (1) the product name;**
- (2) for each product, the percentage of nicotine; and**
- (3) the original date of manufacture of each product.**

(c) The manufacturer shall notify the commission within thirty (30) days of the following:

- (1) The manufacture of a new e-liquid product manufactured in production batches of more than two (2) liters and the original date of manufacture.**
- (2) The manufacture of an existing e-liquid product under a new or amended product name and the original date of manufacture under the new or amended product name.**
- (3) The discontinuation and final manufacture date of an e-liquid product.**
- (4) The final date of manufacture of a discontinued product.**

(d) The manufacturer shall maintain a record of each ingredient used in a production batch for three (3) years that includes the following information for each ingredient:

- (1) The ingredient, as listed in [IC 7.1-7-5-1](#);**
- (2) The manufacturer of each ingredient; and**
- (3) The batch from the manufacturer of each ingredient, if applicable.**

The manufacturer shall provide the ingredient information for a production batch to the commission upon request.

SECTION 9. In order to comply with [IC 7.1](#) relating to e-liquid manufacturing, the manufacturing facility must demonstrate compliance with the following:

- (1) An e-liquid container must use a child proof cap that has the child resistance effectiveness set forth in 16 CFR 1700.15(b)(1).**
- (2) An e-liquid container must use a tamper evident package.**
- (3) E-liquid containers must be labeled.**
- (4) Labels on e-liquid containers must identify all active ingredients, including percentage of nicotine.**
- (5) Labels on e-liquid containers must include a batch number.**
- (6) Labels on e-liquid containers must include a means for the commission to obtain the manufacturing date either through a scannable code or printed on the label.**
- (7) The label on an e-liquid container must include a scannable code, including a quick response code, tied to the batch number.**
- (8) An e-liquid container label or tamper resistant packaging may include a "best if used by" date. retailer by the earlier of either the "best if used by" or two (2) years of the date of manufacture. *[sic]***
- (9) The manufacturing facility must conduct all mixing and bottling activities in a clean room as defined in [IC 7.1](#).**
- (10) The manufacturer must take reasonable steps to ensure that an unauthorized ingredient is not included in any e-liquid produced by manufacturer for sale in Indiana.**
- (11) The manufacturer must take reasonable steps to ensure that all ingredients used in the production of e-liquid are stored in a secure area accessible only by authorized personnel.**
- (12) The manufacturer must maintain a remotely monitored security system at the facility in all areas where e-liquid is mixed, bottled, packaged, and stored.**
- (13) The manufacturer shall have an exclusive high security key system that limits access to areas where e-liquid is mixed, bottled, and stored to authorized personnel only.**
- (14) The manufacturer's facility must be subject to twenty-four (24) hour video recording where e-liquids are mixed, bottled, and stored. The video recordings must be retained for at least one hundred eighty (180) days and are subject to commission audit for quality, purity, and compliance reviews.**
- (15) The manufacturer must take reasonable steps to ensure that only authorized personnel have access to secured areas of the facility where e-liquid is mixed, bottled, and packaged.**
- (16) The manufacturer must store and maintain three (3) ten (10) milliliter sample bottles from each production batch of more than two (2) liters for a period of not less than three (3) years in a secure, limited access area with recorded video surveillance.**
- (17) A production log must be maintained listing the following:**
 - (A) Date and time the e-liquid was produced.**
 - (B) The name of the product manufactured.**
 - (C) The amount of the product produced in liters.**

- (D) The code and batch number.
- (E) Any person responsible for the mixing and bottling.

SECTION 10. (a) The commission may require an e-liquid manufacturer to have up to three (3) different products tested annually by one (1) of three (3) independent laboratories approved by the commission for safety, quality, and purity purposes.

(b) The commission will select the three (3) products to be tested pursuant to subsection (a) from the product listing provided to the commission under SECTION 8 of this document.

(c) Failure by the e-liquid manufacturer to submit or pay the costs of a product testing required by subsection (a) will result in disciplinary action by the commission that may include fines, suspension, and revocation of the permit.

(d) The commission may require the laboratory to test for any of the following:

- (1) Nicotine.**
- (2) Ingredients listed on the label.**
- (3) Contaminants.**
- (4) Illegal drugs.**

(e) At the discretion of the commission, products that test positive for ingredients other than those listed on the label or on the ingredient list maintained by the e-liquid manufacturer under SECTION 8 of this document may be subject to retesting at the cost of the e-liquid manufacturer. Section 11. Sections 1 through 10 of this document take effect January 1, 2016 [sic, [IC 4-22-2-37.1](#) establishes the effectiveness of an emergency rule upon filing with the Publisher. This document was filed with the Publisher March 31, 2016].

SECTION 11. Permit violations proceedings for e-liquid manufacturing permits shall be conducted pursuant to [905 IAC 1-37-1](#).

SECTION 12. (a) If an initial or renewal application for an e-liquid manufacturing permit is denied by the commission, the commission shall give written notice of the action to the applicant.

(b) Upon receipt of notice of the commission's action, the applicant shall have 15 days to file:

- (1) a petition for administrative appeal; and**
- (2) a brief objecting to the commission's action.**

(c) The brief shall state any basis on which the applicant believes the application was denied in error.

(d) The commission shall provide for one automatic extension of the 15 day period at the request of the application if made within the original 15 days.

(e) Failure of the applicant to file objections within the 15 day period shall constitute a waiver of any administrative appeal from the commission's action.

(f) At the discretion of the commission, a hearing may be conducted by the full commission, any individual member of the commission, or a duly authorized agent of the commission.

(g) The commission may conduct a prehearing conference. The hearing judge for the prehearing conference shall set the time and place of the conference and give reasonable notice to the applicant.

(h) The hearing officer shall set the time and place of the hearing on the denial and give reasonable notice to the applicant. At the hearing, the applicant may present evidence by presenting testimony, under oath or affirmation, documentary evidence, or written evidence.

(i) If the decision by the commission is ultimately appealed by the applicant, the hearing officer may consider any evidence presented in the original investigation, the commission hearing, or at the appeal hearing.

(j) If the appeal is based on the denial of an application for renewal of an existing license, the applicant may request an extension of the life of the license to allow him to continue operating pending the appeal procedure.

(k) Following the hearing, the hearing officer shall issue proposed findings of fact, conclusions of law, and order to the commission for its final approval.

(l) Such proposed findings of fact, conclusions of law, and order shall be served on the applicant for their written objection which are due to the commission within 15 days of their receipt.

(m) At the conclusion of the time for receipt of written objections, the commission shall approve, deny, or modify the proposed findings of fact, conclusions of law, and order.

(n) In the case of denial of an application, the commission shall inform the applicant that its decision may be subject to judicial review.

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