ALCOHOL AND TOBACCO COMMISSION

NonRule Policy ATC #22

1. **NOTICE:** Under IC 4-22-7-7, this document is required to be published with the Indiana Register and is effective on its date of publication. It shall remain in effect until the date it is superseded or deleted by the publication of a new document in the Indiana Register. The publication of the document will provide the general public with information about the Alcohol and Tobacco Commission's (ATC) official position concerning a specific issue.

2. **DISCLAIMER:** This nonrule policy is being established by the ATC consistent with the authority under IC 7.1-2-3-7. It is intended solely as guidance and shall be used in conjunction with applicable rules or laws. It does not replace applicable rules and laws, and, if it conflicts with these rules or laws, the rules or laws shall control.

3. **AUTHORIZED:** David E. Cook, Chairman

4. **SUPERCEDES:** New

5. **SUBJECT:** The purpose of this non-rule policy is to clarify and implement the procedure necessary for permitted e-liquid manufacturers to follow in order to comply with IC 7.1-7-5-1.1(j), (k) and (l).

6. **SCOPE:** A permitted e-liquid manufacturer shall annually submit a report to the commission indicating the milligrams per milliliter of nicotine in each product produced as well as the milliliters produced of each e-liquid. In addition, a permitted e-liquid manufacturer must certify, by October 1 of each year, to the commission that each vapor product sold in Indiana has been filed with the federal Food and Drug Administration ("FDA") or tender an annual report to the commission setting forth each new product which is sold in Indiana (including a list of contents and ingredients by volume) and whether the manufacturer has stopped producing products previously produced and sold in Indiana..

7. **POLICY:**

   7.1 Pursuant to IC 7.1-7-5-1.1(k), a permitted e-liquid manufacturer shall annually submit a report to the commission setting forth the milligrams per milliliter of nicotine in each product the manufacturer produces, as well as the milliliters of each product sold in the current year.

   7.2 For the purposes of IC 7.1-7-5-1.1(k), the annual report shall be due on October 1 of each year.

7.3 Pursuant to IC 7.1-7-5-1.1(j), a permitted manufacture is required to submit a report in which the manufacturer listed each new product that the manufacturer is selling in Indiana with a list of contents and ingredients by volume and whether the manufacturer has stopped producing products previously produced and sold in Indiana annually on October 1.

7.4 Pursuant to IC 7.1-7-5-1.1(l), a permitted manufacture is not required to submit the report listed under section 7.3 of this nonrule policy if they certify to the commission by October 1 each year that each of the manufacturer's vapor products sold in Indiana has been filed with the FDA.

7.5 Certification under IC 7.1-7-5-1.1(l) requires submission to the commission of the following:

- 7.5.1 The name of the manufacturer as submitted to the FDA;
- 7.5.2 The address of the manufacturer as submitted to the FDA;
- 7.5.3 The FDA Establishment Identifier Number ("FEI") as assigned by the FDA or an FDA e-mail acknowledgment if the number has not yet been assigned); and
- 7.5.4 The list of products submitted to the FDA, in the format it was submitted (name, SKU, etc.).