

105 CMR: DEPARTMENT OF PUBLIC HEALTH

105 CMR 660.000: CIGARETTE AND SMOKELESS TOBACCO PRODUCTS: REPORTS OF ADDED CONSTITUENTS AND NICOTINE RATINGS

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660.001: Purpose

The purpose of 105 CMR 660.000 is to implement M.G.L. c. 94, § 307B, which mandates reporting of certain information relating to tobacco products to the Department of Public Health.

660.002: Authority

105 CMR 660.000 is adopted pursuant to M.G.L. c. 94, § 307B.

660.003: Definitions

As used in 105 CMR 660.000, *et seq.*, the following terms shall have the following meanings, unless the context clearly requires otherwise:

Added Constituent means any ingredient, substance, chemical or compound other than tobacco, water or reconstituted tobacco sheet, which is added by the manufacturer to the tobacco, paper or filter of a cigarette or the tobacco of a smokeless tobacco product during the processing, manufacture, or packing of the cigarette or smokeless tobacco product.

Annual Report means a tobacco manufacturer's annual report to the Department, which provides, for each brand of cigarette and smokeless tobacco product, added constituent information and nicotine yield ratings, as described in 105 CMR 660.100 to 660.103.

Attorney General means the Attorney General of the Commonwealth of Massachusetts.

Cigarette means any product (including components, accessories, or parts) which contains or delivers nicotine, is intended to be burned under ordinary conditions of use, and consists of:

- (1) Any roll of tobacco wrapped in paper or in any substance not containing tobacco; or
- (2) Any roll of tobacco wrapped in any substance containing tobacco which, because of its appearance, the type of tobacco used in the filter, or its packaging and labeling, is likely to be offered to, or purchased by, consumers as a cigarette.

Cigarette Nicotine Yield Rating means a composite of information intended to show the range of nicotine that each cigarette brand can be expected to provide to the average consumer, based on:

- (1) the expected range of nicotine delivery under average smoking conditions based on machine testing parameters that seek to reflect actual smoking behavior; and
- (2) the potential for increased nicotine delivery or increased speed of nicotine delivery based on cigarette design features such as filter vents, pH, and the total nicotine content of the tobacco.

Commissioner means the Commissioner of the Department of Public Health.

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Could Reduce Risks to the Public Health means that knowledge about an added constituent could result in reduced risk of adverse health effects associated with tobacco use, including but not limited to nicotine addiction and adverse health effects associated with exposure to environmental tobacco smoke.

Department means the Department of Public Health.

Federal Trade Commission means the United States Federal Trade Commission.

Manufacturer means any person or entity, including any repacker or relabeler, manufacturing, fabricating, assembling, processing, or labeling a finished cigarette or smokeless tobacco product. The term does not include any person or entity only distributing finished cigarettes or smokeless tobacco products.

Smokeless Tobacco means any cut, ground, powdered, or leaf tobacco that contains or delivers nicotine and that is intended to be placed in the oral cavity without burning.

Smokeless Tobacco Nicotine Yield Rating means a composite of information intended to show the range of nicotine that each smokeless tobacco product can be expected to provide to the average consumer, based upon the amount of nicotine in the tobacco, the pH of the tobacco, and the amount of unionized (free) nicotine in the product.

660.100: General Requirements for Annual Reports by Manufacturers

(A) On December 15, 1997, and on every December 1 thereafter, the manufacturer of any cigarette or smokeless tobacco product sold in the Commonwealth shall report to the Department, in accordance with 105 CMR 660.000, the added constituents and nicotine yield rating of each such cigarette or smokeless tobacco product. To the maximum extent possible, such report shall be submitted electronically to the Department, in accordance with the technical specifications of the Department.

(B) Nothing in 105 CMR 660.100 shall prohibit a manufacturer or distributor of cigarettes or smokeless tobacco products from selling such products to an in-state merchant for sale or distribution outside of the Commonwealth.

660.101: Added Constituent Reporting Requirements

In each annual report, a manufacturer shall provide the following information for each brand, sub-brand and generic unbranded cigarette or smokeless tobacco product sold in the Commonwealth:

(A) the identity of all added constituents in the cigarette or smokeless tobacco product listed in descending order by weight, numerical count or measure; provided, however, that in the manufacturer's discretion, the identity of added constituents which occur at levels below one part per million (0.0001%), by weight of the tobacco and added constituents, may be provided as a separate listing, with the added constituents reported in alphabetical order, rather than in descending order by weight, numerical count or measure. Each added constituent shall be reported by its chemical name and chemical abstract service (CAS) registry number, if available. See 105 CMR 660.400 for the added constituent reporting form;

(B) the name, job title, address, and telephone number of the individual designated by the manufacturer as the Department's contact person concerning 105 CMR 660.000.

660.102: Cigarette Nicotine Yield Rating Reporting Requirements

(A) In each annual report, a manufacturer shall include, as part of the nicotine yield rating for each brand, sub-brand and generic unbranded cigarette, the information specified in 105 CMR 660.102. For purposes of 105 CMR 660.102, the term "brand family" shall mean a number of different, though highly similar cigarette products marketed under one general name; *e.g.* regular, longer-length and menthol cigarettes of the same brand.

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(1) For each brand, sub-brand and generic unbranded cigarette which belongs to a brand family that has a national market share of less than 3%, as reported in the most recent Maxwell Report, Cigarette Brand Sales and Market Share, published by Davenport and Company, Richmond, Virginia, or a comparable report designated by the Department, the annual report shall include the information specified in 105 CMR 660.102(B)(1) and (B)(6). Said report also shall include the information in 105 CMR 660.102(B)(2), (B)(3) and (B)(4) for a limited number of individual sub-brands selected by the Department. The number of sub-brands to be selected by the Department shall be based on the manufacturer's national market share, as reported in the most Maxwell Report. For a manufacturer with greater than 35% of national market share, up to 15 sub-brands shall be selected and tested; for a manufacturer with a national market share of 20% to 35% of national market share, up to nine sub-brands will be selected and tested; and for a manufacturer with a national market share of less than 20%, up to six sub-brands will be selected and tested

(2) For each brand, sub-brand and generic unbranded cigarette which belongs to a brand family that has a national market share of 3% or more, as reported in the most recent Maxwell Report, Cigarette Brand Sales and Market Share, USA, published by Davenport and Company, Richmond, Virginia, or comparable report designated by the Department, the annual report shall include the information specified in 105 CMR 660.102(B)(1) through (5).

(B) As specified in 105 CMR 660.102(A), cigarette manufacturers shall include in their annual report a rating for nicotine yield for each brand, sub-brand and generic unbranded cigarette sold in the Commonwealth, which shall include:

(1) the most recent nicotine level reported for the brand, sub-brand, or generic unbranded cigarette to the Federal Trade Commission, as published in the Federal Trade Commission Report entitled "*Tar, Nicotine, and Carbon Monoxide of the Smoke of Varieties of Domestic Cigarettes*". If no report has been made to the Federal Trade Commission, the manufacturer shall report the nicotine level determined in accordance with the testing methods specified in 105 CMR 660.500(A) and (D)(1).

(2) the total nicotine content of the cigarette, reported in milligrams of nicotine and nicotine content per gram of tobacco, as determined under the testing method set forth in 105 CMR 660.500(B);

(3) percent filter ventilation; that is, the level of air dilution in the whole smoke, as provided by the ventilation holes in the cigarette filter, described in percent, as determined under the method described in 105 CMR 660.500(C);

(4) nicotine delivery under average smoking conditions, reported in milligrams of nicotine per cigarette. Manufacturers shall use the Federal Trade Commission testing method, as described and modified in 105 CMR 660.500(D), with the puff volume adjusted to 45 milliliters, puff interval adjusted to 30 seconds, and puff duration to two seconds. The average number of puffs per cigarette taken in this condition shall be reported. Cigarettes with ventilation holes must have the holes half blocked during testing (see 105 CMR 660.500(D) for hole blocking method). Manufacturers shall classify each brand, sub-brand or generic unbranded cigarette for nicotine yield according to the following standards:

<b>Cigarette Nicotine Delivery</b>	<b>Average Smoking Conditions Nicotine (mg/cigarettes)</b>
High Nicotine	>1.2 mg
Moderate Nicotine	>0.2-1.2
Low Nicotine	.01-0.2
Nicotine Free	<0.01

Testing and measurement for nicotine yield ratings shall comply with the sampling and conditioning standards set forth in 105 CMR 660.500(A). The cigarette nicotine yield ratings shall be reported to the Department on the form attached to 105 CMR 660.600;

(5) for brand families subject to the requirements of 105 CMR 660.102(A)(2), the pH of cigarette smoke, as determined under the method specified in 105 CMR 660.500(E), for three sub-brands selected by the Department from each brand family that has a national market share of 3% or more, as reported in the most recent Maxwell Report;

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(6) For brand families subject to the requirements of 105 CMR 660.102(A)(1), nicotine level reported in 105 CMR 660.102(B)(1) multiplied by a numerical factor approved by the Department which is intended to approximate the ratings for nicotine delivery under average smoking conditions which would have been derived by the tests conducted in the preceding year pursuant to 105 CMR 660.102(B)(1)(4). The cigarette nicotine yield ratings shall be reported to the Department on the form attached to 105 CMR 660.600.

660.103: Smokeless Tobacco Products: Nicotine Yield Reporting Requirements

Smokeless tobacco product manufacturers shall include in their annual report a rating for nicotine yield for each brand, sub-brand or generic unbranded smokeless tobacco product sold in the Commonwealth, which shall include:

- (A) pH of tobacco;
- (B) moisture content as a percent of weight of tobacco;
- (C) nicotine in milligrams per gram of tobacco;
- (D) nicotine as a percent of dry weight of tobacco;
- (E) percent of unionized (free) nicotine; and
- (F) total unionized (free) nicotine in milligrams per gram of tobacco. Smokeless tobacco product manufacturers shall classify each brand, sub-brand and generic unbranded smokeless tobacco product for nicotine delivery, according to the following standard:

<b>Smokeless Tobacco Nicotine Delivery</b>	<b>Total Free Nicotine mg/g</b>
High Nicotine	>2.0
Moderate Nicotine	>0.5-2.0
Low Nicotine	.01-0.5
Nicotine Free	<0.01

The smokeless tobacco nicotine yield rating shall be reported to the Department as specified on the form attached to 105 CMR 660.600.

660.200: Determining Public Availability of Added Constituent Information in Annual Report

- (A) After receipt of an annual report filed pursuant to 105 CMR 660.101, the Department shall make a written preliminary determination as to whether there is a reasonable scientific basis for concluding that the public availability of some or all of the added constituent information contained in the report could reduce risks to public health, which determination shall include the Department’s reason(s) for proposing to make the information available.
- (B) If the Department preliminarily determines that making available the information about some or all of the added constituents is warranted under M.G.L. c. 94, § 307B and 105 CMR 660.000, the Department shall so notify the manufacturer of each added constituent proposed to be made available and shall provide the manufacturer its written preliminary determination. The manufacturer shall have 60 days after its receipt of the written preliminary determination to provide written comment to the Department on the preliminary determination.
- (C) Following expiration of the 60 day response period specified in 105 CMR 660.200(B), the Department shall make a final written determination, including the reasons for so deciding, if it finds that there is a reasonable scientific basis for concluding that making available to the public information about some or all of the added constituents could reduce risks to the public health.

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(D) In the event the Department makes the determination referred to in 105 CMR 660.200(C), it shall request the advice of the Attorney General as to whether making available this information to the public would constitute an unconstitutional taking of property. Information submitted to the Department pursuant to 105 CMR 660.101 and 660.200 (B) shall be regarded by the Department as confidential, and shall not be made available to the public, during the period in which the Department is awaiting advice from Attorney General pursuant to 105 CMR 660.200(D).

(E) In the event that the Attorney General advises the Department that making available to the public information about some or all of the added constituents referred by the Department pursuant to 105 CMR 660.200(D) would not constitute an unconstitutional taking, the Department shall give the manufacturer 60 days written notice of the information to be made available. At the end of the 60 day period, the Department shall make such information available to the public for inspection and copying.

(F) (1) Within 30 days of issuance by the Department of a written notice pursuant to 105 CMR 660.200(E), the manufacturer of any brand, sub-brand or generic unbranded cigarette or smokeless tobacco product containing one or more added constituent(s) identified in said notice (hereafter an "affected product") may notify the Department in writing that it will, within a period of 90 days of receipt of the said notice from the Department, cease sales in Massachusetts of certain affected product(s) or remove certain affected product(s) from the Massachusetts market in order to reformulate the product(s) to remove the added constituent(s) identified in the notice issued pursuant to 105 CMR 660.200(E). For products as to which a manufacturer submits timely written notice to the Department under 105 CMR 660.200(F)(1), the Department shall continue to treat as confidential (and shall not release to the public) for the duration of the 90 day period the added constituent information that had been identified for public release under 105 CMR 660.200(E).

(2) If a manufacturer, within the 90 day period, ceases sales of the affected product(s) or removes the affected product(s) from the Massachusetts market in accordance with its notice to the Department, the Department shall make a determination that there is no reasonable scientific basis for concluding that public availability of the added constituent information contained in the report(s) about the affected product(s) could reduce risks to the public health. The Department shall thereafter treat as confidential (and shall not release to the public) any added constituent information previously submitted by the manufacturer pursuant to 105 CMR 660.101 for such affected product(s). If a manufacturer does not cease sales of the affected product(s) or remove the affected product(s) from the Massachusetts market in accordance with its notice to the Department within the additional 90 day period, the Department shall at the end of the 90 day period make available to the public the information identified in the Department's notice pursuant to 105 CMR 660.200(E).

(3) If a manufacturer intends to resume sales in Massachusetts of an affected product after it has been reformulated, the manufacturer shall file with the Department, prior to resumption of sales, a certification that the reformulated product does not contain any of the added constituent(s) identified in the notice issued pursuant to 105 CMR 660.200(E) that preceded the product reformulation. The manufacturer shall also file all annual reports thereafter required under M.G.L. c. 94, § 307B and 105 CMR 660.000 for such product.

(G) The Department shall treat information submitted pursuant to 105 CMR 660.101 as confidential unless and until:

(1) a manufacturer notifies the Department in writing that it does not consider information it has submitted in its annual report concerning added constituents to be confidential;

(2) a determination to release the information is made in accordance with 105 CMR 660.200(A) through (E), the 60 day period referred to in 105 CMR 660.200(E) has elapsed, and no complaint has been filed in a court of competent jurisdiction challenging disclosure of the information on the grounds that disclosure would make available to the public a trade secret.

(3) disclosure of the information is authorized by judicial decision and the time for appeal in a court of competent jurisdiction has passed; or

(4) disclosure of the information is authorized by agreement of the parties, as specified in 105 CMR 660.200(H).

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If a manufacturer submits in timely fashion to the Department written notice in accordance with 105 CMR 660.200(F)(1), the Department shall treat information submitted by that manufacturer pursuant to 105 CMR 660.101 as confidential as and to the extent provided in 105 CMR 600.200(F).

(H) In the event that a manufacturer files a complaint in a court of competent jurisdiction within the 60 day notice period specified in 105 CMR 660.200(E), challenging a proposed disclosure of information by the Department on the grounds that disclosure would make available to the public a trade secret, the Department shall not disclose any of the information in question unless and until:

- (1) the parties agree in writing to disclosure; or
- (2) the court renders a decision authorizing disclosure; and
- (3) the time has passed for filing an appeal of the decision in a court of competent jurisdiction.

(I) A manufacturer submitting written comments to the Department pursuant to 105 CMR 660.200(B) may request that its submission, and any preliminary or final determinations by the Department pursuant to 105 CMR 660.200, be treated as confidential. The Department will thereafter treat such submission(s) and determinations as confidential to the extent permitted by law; provided, however, that upon making information available to the public pursuant to 105 CMR 660.200(E), the Department shall no longer treat as confidential the preliminary and final determinations it rendered, or any written comments submitted by a manufacturer.

(J) The Commissioner shall establish written procedures to maintain the confidentiality of information treated as confidential pursuant to 105 CMR 660.200(F), (G) and (H). Such procedures shall include the designation of a duly authorized agent to serve as custodian of such information. The agent shall:

- (1) take physical possession of the information and, when not in use by a person authorized by the Commissioner to have access to such information, store it in a locked cabinet or file; and
- (2) maintain a list of persons authorized by the Commissioner to have access to such records and a daily log of each person who inspects the information.

Such procedures shall require that any person permitted access to the information shall be instructed in writing not to make available the information to anyone who is not entitled to have access to the information, and informed of the penalties for failing to comply.

660.300: Severability

If any provisions of 105 CMR 660.000 are held invalid for any reason whatsoever, such declaration shall not effect any other portion of 105 CMR 660.000, which shall remain in full force and effect, and to this end, the provisions of 105 CMR 660.000 *et seq.* are hereby declared severable.

660.400: Added Constituent Reporting Form

**Brand Name** \_\_\_\_\_ **Sub Brand** \_\_\_\_\_

Please list added constituents in descending order according to weight, measure or numerical count.

**Chemical Name**

**C.A.S. Number**

- 1.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.

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- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.
- 15.
- 16.
- 17.
- 18.

660.500: Testing Methods

(A) Sampling and Conditioning. Conditioning for testing of tobacco products shall be done in accordance with the International Organization for Standardization (ISO), 3402, third edition, 1991-07-01 entitled *Tobacco and Tobacco Products -- Atmosphere for Conditioning and Testing*. Cigarettes shall be sampled using international standard ISO §243:98 (E) entitled *Cigarette -- Sampling*. At a minimum, for each brand sampled, 35 packages of cigarettes should be purchased from a Massachusetts wholesaler at a single point in time, which shall be mailed or delivered to the Department of Public Health from the point of purchase. Smokeless tobacco products will follow the sampling protocol outlined in "Protocol for Analysis of Nicotine, Total Moisture, and pH in Smokeless Tobacco Products".

(B) Total Nicotine Content. The protocol for measuring nicotine content in cigarette and smokeless tobacco products and for moisture content and pH in smokeless tobacco products is described in "Protocol for Analysis of Nicotine, Total Moisture, and pH in Smokeless Tobacco Products," (or most recent amended version) announced in the Federal Register of May 2, 1997, volume 62, no. 85, pp. 24115-24116. In measuring nicotine content, the cigarette manufacturer shall use the following sampling method: two cigarettes shall be randomly selected from each pack and conditioned, the tobacco rod split open, and the cigarette tobacco mixed thoroughly before weighing. The minimum sample size shall be 100 grams of tobacco. If the weight of the tobacco is less than 100 grams, additional cigarettes shall be randomly selected from each pack.

(C) Percent Filter Tip Ventilation means the level of air dilution in the whole smoke, as provided by the perforations made in the cigarette filter tip, described in percent. This shall be measured using the Filter Dilution (Ventilation) Testing Instrument (FDT) from Fidus Instrument Corporation, product no. FDT232; or FIAL Tip and Envelope Ventilation/Pressure Drop QTM5U machine; or equal approved by the Department, and shall be used in accordance with manufacturer instructions. Two cigarettes shall be randomly selected from each sampled pack, conditioned, and tested for percent filter ventilation. The average percent filter ventilation shall be computed for the 100 cigarettes tested.

(D) Modified FTC Testing Method.

(1) Nicotine delivery under average smoking conditions shall be evaluated using the Cambridge Method, which has been approved by the Federal Trade Commission (FTC) as the standard for nicotine testing since 1966, and adopted for international purposes by the ISO. See Federal Register, Vol. 32, No. 147, page 11178, dated August 1, 1967, as modified by the FTC in Federal Register, Vol. 45 No. 134, pages 46483-46487, dated July 10, 1980 ISO 10315, 91-08-01 entitled "Cigarette-Determination of Nicotine in Smoke Condensates-Gas Chromatographic Method"; ISO 3308, third edition, 1991-10-15, "Routine Analytical Cigarette-Smoking Machine-Definitions of Standard Conditions"; and ISO 7201, second edition, 1997-01-15, "Routine Analytical Smoking Machine Additional Test Methods." Two cigarettes shall be randomly selected from each pack for a sample of 50 cigarettes

(2) The Department has modified the FTC and ISO conditions to require the following changes to the testing method:

- (a) Puff volume as prescribed in the FTC method and in the ISO 3308:4.3 shall be increased from 35 ml to 45 ml;

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- (b) Puff frequency as prescribed in the FTC method and ISO 3308:4.4 shall be changed from one puff each minute to one puff every 30 seconds;
- (c) Puff duration shall remain at two seconds;
- (d) 50% of the ventilation holes must be blocked by placing a strip of mylar adhesive tape, Scotch Brand product no. 600 Transparent Tape (Acetate) or other method approved by the Department. The tape shall be cut so that it covers 50% of the circumference and is tightly secured from the end of the filter to the tipping overwrap seam;
- (e) Number of cigarettes smoke per port shall be three, provided that the limit of 150 milligrams of tar is not exceeded (see ISO 4387).

(E) pH Testing Method. Testing for pH shall be conducted on a puff by puff basis, in accordance with the testing method described in Sensabough, A.J., Jr. and Candiff, R.H., "A New Technique for Determining the pH of Whole Tobacco Smoke", Tob.Sci., 11:25-30 (1967) and Brunnemann, K.D. and Hoffman, D., "The pH of Tobacco Smoke", Food, Cosmet. Toxicol., 112:115 (1974), or comparable testing method approved by the Department.

660.600: Cigarette Nicotine Yield Rating Form

- (1) Brand \_\_\_\_\_ Sub-Brand \_\_\_\_\_
- (2) Most Recent Nicotine Level Reported to the FTC \_\_\_\_\_
- (3) Total Nicotine Content in Cigarette Tobacco (Milligrams) \_\_\_\_\_
- (4) pH of Smoke \_\_\_\_\_ Percent Filter Ventilation \_\_\_\_\_
- (5) Nicotine Delivery Under Average Smoking Conditions \_\_\_\_\_
- (6) Classification \_\_\_\_\_ Number of Puffs \_\_\_\_\_

(>1/2 milligrams.: high; >0.2-1.2: moderate; .01-0.2: low; <.01: nicotine free)

\_\_\_\_\_  
Smokeless Tobacco Nicotine Yield Rating Form

- (1) Brand \_\_\_\_\_ Sub-Brand \_\_\_\_\_
- (2) Moisture Content in Percent \_\_\_\_\_ Nicotine as a Percent of Dry Weight Tobacco \_\_\_\_\_
- (3) Nicotine in Milligrams per Gram of Tobacco \_\_\_\_\_
- (4) pH \_\_\_\_\_
- (5) Total Unionized (free) Nicotine \_\_\_\_\_
- (6) Classification \_\_\_\_\_

(>2.0 milligrams: high; >0.5-2.: moderate; 0.1-0.5: low; <0.01: nicotine free)

REGULATORY AUTHORITY

105 CMR 660.000: M.G.L. c. 94, § 307B.