

## Chemical Analyses of Blood, Urine, Breath or Saliva for Alcoholic Content

Effective Date: 12/7/11

### Summary of Express Terms

This proposed amendment to Part 59 updates standards, reflects changes in nomenclature and technology, and provides clarification of provisions pertinent to alcohol determinations of breath, blood and other body fluids, and certification of ignition interlock devices used for enforcement of Vehicle and Traffic Law.

The Section 59.1 definition for the term *techniques and methods* is amended to include saliva, which itself is defined in a new subdivision (k). The definition of *testing laboratory* is revised to clarify the Department's requirements. A definition for *calibration* is added. Section 59.2 is modified to introduce current terminology, specifically blood alcohol concentration (BAC). The rule clarifies that urine may be used as a specimen, and its analysis requires controls and blanks similar to those used for analyses of blood. This amendment removes the list of persons authorized to draw blood and eliminates technical specifications not required for analytical accuracy. Section 59.2 is further modified to revise the acceptable range for the alcohol reference standard used for calibration verification of instruments for both breath and blood analysis. This section and others now provide for a 0.08 grams/100 ml (w/v) reference standard. This proposal also requires that units for alcohol determinations of blood and urine be expressed as blood alcohol concentration (BAC), meaning percent weight per volume, rather than the outdated terminology of grams percent.

Section 59.3 is modified in several places to address saliva as a potential specimen. The proficiency testing performance criteria for renewal of a permit for the chemical analysis of

blood, urine and saliva are clarified. “*Competence*” is replaced with “*proficiency*” throughout the section. In Section 59.4, outdated NYS-specific criteria for breath testing instruments are replaced with documentation that the model has been accepted by the U.S. Department of Transportation/National Highway Traffic Safety Administration (NHTSA) as an evidential breath alcohol measurement device. The proposed amendment includes the list of NHTSA-approved breath measurement instruments published in the Federal Register on March 11, 2010 to remove any possible ambiguity about the fact that devices listed therein, including the Alcotest 9510 manufactured by Draeger Safety, Inc., are fully approved by the Department of Health. The training agencies’ responsibilities for instrument maintenance, including the establishment of a calibration cycle, and records retention are clarified.

The Section 59.5 two-hour time frame for specimen collection is eliminated, and the requirement for certain techniques and methods to be a component of each training agency’s curriculum and to be put to use by the analyst is clarified. The requirement for observation of a subject prior to collection of a breath sample has been clarified. Minor technical changes have been made to Section 59.6.

This proposal would reduce the hours spent in initial training for a breath analyst permit as specified in Section 59.7, from 32 hours required to 24 hours, and require training agencies to develop learning objectives. The minimum time for hands-on training with breath analysis instruments is reduced from ten to six hours. Revised Section 59.7 establishes an application window of 120 calendar days preceding the permit’s expiration date. The Section also clarifies that a permit expires and is void when not renewed, but that the Commissioner of Health may extend the permit expiration date for 30 calendar days, during which period the permit remains

valid. The amendment makes clear that failure to renew in accordance with time frames established in the regulation results in the permit becoming void, which then requires the analyst to participate in the 24-hour initial/comprehensive training course. Section 59.7, as revised, requires training agencies to submit information on training sessions and participant lists to the Department of Health in a format designated by the Commissioner.

Section 59.9, as amended, provides for an effective period of four years for technical supervisor certification, an increase of two years. The responsibilities of a technical supervisor have been modified to reflect current practice. Notably, the duty to conduct field inspections has been eliminated, as has the responsibility to provide expert testimony, since the recognition of expertise is a role of the court. Revised Section 59.9 clarifies that a technical supervisor may delegate certain tasks, including instrument maintenance and preparation of chemicals used in testing, to a person not qualified as a supervisor, provided the work product is reviewed and found acceptable. A new sentence at the end of the section codifies long-standing Department policy that suspension or revocation of an operator's permit held by a supervisor triggers suspension or revocation of the person's certification as a technical supervisor.

Existing Sections 59.10 and 59.11 are repealed, and replaced with two new sections that provide criteria, respectively, for certification for ignition interlock devices and for testing of such devices by independent laboratories. The existing reference to a seven-county pilot study of ignition interlock devices is removed, and outdated performance standards for devices are replaced with NHTSA standards. Existing provisions for the application process, manufacturer interaction with testing laboratories, and discontinuance of certification remain in effect. New Section 59.10 requires the manufacturer to provide contact information, including identification

of a person to respond to Department inquiries, and requires the manufacturer to furnish a certificate stating that the company issuing the requisite liability coverage will notify the Department at least 30 days prior to cancellation of the policy before the expiration date. Section 59.10 also makes clear the Department's requirement that the manufacturer must demonstrate, through arrangements with a testing laboratory, that the device meets the NHTSA model specifications when calibrated to a set point of 0.025% BAC; and stipulates that only devices that employ fuel cell technology or another technology with demonstrated comparable accuracy and specificity are eligible for certification.

New Section 59.11 specifies the minimal elements of a testing laboratory report and requires such report to be submitted directly to the Department. In both new sections, a reference to "circumvention" has been added with each occurrence of the word "tampering," to recognize that these are both prohibited in Vehicle and Traffic Law Section 1198.

Existing Section 59.12 is repealed. New Section 59.12 establishes requirements for continued ignition interlock certification. New Section 59.12 requires a manufacturer to notify the Department of any operational modification to a certified device, and to obtain express approval for its continued use, as modified, under the existing certification. The definition of *operational modification* and the process for reporting modifications has been moved from Section 59.10 to Section 59.12. A new requirement is added that the manufacturer notify the Department of each renewal of insurance coverage, each change of issuing company, and each change in liability limits. The section requires manufacturers to supply to installation/service providers a sufficient number of labels with text that conforms to the text mandated by statute. The vast majority of the section's other requirements, including reporting and labeling

requirements and manufacturer-service provider interactions, have been eliminated from Section 59.12; most have been incorporated into a new 9 NYCRR Part 358 being promulgated by the Division of Probation and Correctional Alternatives (DPCA) contemporaneously with this regulation in response to the anticipated August 2010 implementation of the ignition interlock provisions of Leandra's Law (L. 2009, Ch. 496). New Section 59.12 establishes a process for periodic renewal to ensure that information on file with the Department is current. The application form has been removed from the regulation, as it will be available electronically.

Pursuant to the authority vested in the Commissioner of Health by Sections 1194(4)(c) and 1198(6) of the Vehicle and Traffic Law and Section 11-1205(6) of the Environmental Conservation Law, Part 59 of Title 10 of the Official Compilation of Codes, Rules and Regulations is hereby amended, to be effective upon publication of a Notice of Adoption in the New York State Register, as follows:

## PART 59

### CHEMICAL ANALYSES OF BLOOD, URINE, BREATH OR SALIVA FOR ALCOHOLIC CONTENT

(Statutory authority: Environmental Conservation Law, § 11-1205(6); Vehicle and Traffic Law, §§ 1194(4)(c), 1198(6)]; Parks, Recreation and Historic Preservation Law, § 25.24(4))  
Sec.

59.1 Definitions.

59.2 [Methods and procedures] Techniques and methods for determining blood and urine alcohol.

59.3 Blood [and], urine and saliva alcohol analysis; permits.

59.4 Breath analysis instruments.

59.5 Breath analysis; techniques [or] and methods.

59.6 Breath analysis permit program.

59.7 Breath analysis operator permits.

59.8 Revocation or suspension of permits.

59.9 Technical supervisor; qualifications and certification.

59.10 Certification [of devices] criteria for ignition interlock devices.

59.11 Testing [and labelling] of ignition interlock devices.

59.12 [Reporting and additional requirements] Continued ignition interlock device certification.

Subdivisions (a), (b), (c) and (h) of Section 59.1 are amended; existing subdivisions (i), (j) and (k) are repealed; and new subdivisions (i), (j), (k) and (l) are added, to read as follows:

(a) Techniques [or] and methods means the collection, processing and determination of the alcoholic content of body fluids such as human blood, saliva or urine, and of breath or alveolar air by [methods] protocols and/or instruments determined by the commissioner to [meet acceptable scientific standards] be acceptable.

(b) Per centum by weight of alcohol as used in the Vehicle and Traffic Law and the [Parks, Recreation and Historic Preservation] Environmental Conservation Law means percent weight per volume, that is, grams of alcohol per 100 milliliters of whole blood.

(c) Chemical tests/analyses include breath tests conducted on [those instruments found on the Conforming Products List of Evidential Breath Measurement Devices as established by the U.S. Department of Transportation/National Highway Traffic Safety Administration, published in the Federal Register on December 17, 2007. Copies are available for public inspection and copying by appointment at the Department of Health, Records Access Office, Corning Tower, Empire State Plaza, Albany, New York] breath analysis instruments approved by the commissioner in accordance with section 59.4 of this Part.

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(h) Blood alcohol concentration (BAC) means the weight amount of alcohol contained in a unit volume of blood, measured as grams ethanol/100 ml blood and expressed as %, grams %, % [w/v] weight/volume (w/v), and % BAC. Blood alcohol concentration in this Part shall be designated as % BAC.

(i) Testing laboratory means a nationally recognized, independent materials testing laboratory that is not affiliated with, and operates autonomously from, any ignition interlock device manufacturer, is properly equipped and staffed to carry out test procedures required by

this Part, and is independently accredited in accordance with requirements for the competence of testing and calibration laboratories promulgated as a standard by the International Organization for Standardization (ISO), or other commensurate standard acceptable to the department.

(j) Breath analysis instrument means a device that complies with section 59.4 of this Part.

(k) Saliva means oral fluid.

(l) Calibration means the activity of verifying that a value generated by the instrument is in acceptable agreement with the assigned value for a traceable and/or certified reference standard, including any adjustment to the instrument to bring it into acceptable agreement.

The title and subdivisions (a) and (b) of Section 59.2 are amended, and existing subdivision (c) is repealed and new subdivisions (c) through (e) are added, to read as follows:

[Methods and procedures] Techniques and methods for determining blood and urine alcohol.

(a) All blood and urine alcohol determinations shall be made by quantitative methods and [expressed in grams percent or as equivalent to grams of alcohol per 100 milliliters of whole blood] reported as whole blood alcohol concentration (BAC) to the second decimal place as found; for example, 0.137 percent found shall be reported as 0.13 percent weight per volume. If specimens other than whole blood are analyzed, the following conversions shall apply:

(1) [Three] three fourths of the determined concentration of alcohol in the urine shall be equivalent to the corresponding [whole blood alcohol concentration.] BAC; and

(2) [Nine] nine tenths of the determined concentration of alcohol in the serum or plasma shall be equivalent to the corresponding [whole blood alcohol concentration] BAC.

(b) Analytical procedures for blood and urine alcohol analysis shall include the following

controls in conjunction with any sample or series of 10 samples analyzed sequentially or simultaneously:

(1) a blank analysis [where] as appropriate; and

(2) analysis of a suitable reference [or control] sample of known alcoholic content [of ] greater than or equal to 0.08 [grams per 100 milliliters] percent weight per volume, the result of which analysis [must] shall agree with the reference sample value within the limits of plus or minus 0.01 [grams per 100 milliliters] percent weight per volume or such limits as specified by the commissioner.

(c) An analysis of urine shall be made upon two specimens collected at least 30 minutes apart.

(d) If a blood specimen is to be collected for analysis, an aqueous solution of a nonvolatile antiseptic shall be used on the skin. Alcohol or phenol shall not be used as a skin antiseptic.

(e) Specimens shall be clearly identified at the time of collection.

Section 59.3 is amended to read as follows:

Blood [and], urine and saliva alcohol analysis; permits.

(a) Individuals performing chemical analyses for blood [and], urine and saliva alcohol content may apply to the commissioner for a permit.

(b) A permit for the performance of chemical analyses for blood [and], urine and saliva alcohol content shall be issued by the commissioner to an applicant who:

(1) is a high school graduate and has one year of laboratory experience acceptable to the commissioner; or

(2) has satisfactorily completed two years of college study and has six months of laboratory experience acceptable to the commissioner; and

(3) [establishes] demonstrates to the satisfaction of the commissioner [competence to perform] proficiency in the chemical analyses of the alcoholic content of blood and any other sample type that the commissioner requires; and

(4) has access to appropriate laboratory facilities for the performance of such analyses.

(c) The applicant shall demonstrate [competence] proficiency in the [method] techniques and methods of analysis by correctly analyzing and reporting results, within limits of accuracy established by the commissioner, for 75 percent of the [specimens in] samples for each [test submitted] set of proficiency tests issued by the commissioner [for blood alcohol analysis].

(d) A permit shall be issued for a period of one year and may be renewed annually thereafter. A permit shall not be issued or renewed [, or shall be withdrawn, if the results of two consecutive tests of specimens submitted] if, for two consecutive sets of proficiency tests, the applicant or permit holder:

(1) [do] does not meet the [competency] proficiency requirements of this section; or

(2) [are not returned] fails to report proficiency test results; or

(3) [are returned] reports results after three weeks from the date of [submission] distribution of proficiency test [specimens] samples, except that the commissioner, for good cause, may extend such time on request made during such three-week period.

Subdivisions (a) and (b) of Section 59.4 are repealed; and new subdivisions (a) through (d) are added to read as follows:

(a) The commissioner approves, for use in New York State, breath analysis instruments found on the Conforming Products List of Evidential Breath Alcohol Measurement Devices as established by the U.S. Department of Transportation/National Highway Traffic Safety Administration (NHTSA), published in the Federal Register on March 11, 2010 (75 Fed. Reg. 11624-11627, available for public inspection and copying at the Department of Health Records Access Office, Corning Tower, Empire State Plaza, Albany, NY 12237). A facsimile of that list is set forth in subdivision (b) of this section. At the request of a training agency, the commissioner may approve a breath analysis instrument that has been accepted by NHTSA but is not on the Conforming Products List published in the Federal Register on March 11, 2010, if the commissioner determines that approval of such instrument is appropriate.

(b) Conforming Products List of Evidential Breath Measurement Devices

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CONFORMING PRODUCTS LIST OF EVIDENTIAL BREATH MEASUREMENT DEVICES

<b>Manufacturer and model</b>	<b>Mobile</b>	<b>Nonmobile</b>
Alcohol Countermeasure Systems Corp., Mississauga, Ontario, Canada:		
Alert J3AD *	X	X
Alert J4X.ec	X	X
PBA3000C	X	X
BAC Systems, Inc., Ontario, Canada:		
Breath Analysis Computer *	X	X
CAMEC Ltd., North Shields, Tyne and Ware, England:		
IR Breath Analyzer *	X	X
CMI, Inc., Owensboro, Kentucky:		
Intoxilyzer Model:		
200	X	X
200D	X	X
240 (aka: Lion Alcolmeter 400+ outside the U.S.)	X	X
300	X	X
400	X	X
400PA	X	X
1400	X	X
4011 *	X	X

4011A *	X	X
4011AS *	X	X
4011AS-A *	X	X
4011AS-AQ *	X	X
4011 AW *	X	X
4011A27-10100 *	X	X
4011A27-10100 with filter *	X	X
5000	X	X
5000 (w/Cal. Vapor Re-Circ.)	X	X
5000 (w/ <sup>3/8</sup> " ID Hose option)	X	X
5000CD	X	X
5000CD/FG5	X	X
5000EN	X	X
5000 (CAL DOJ)	X	X
5000VA	X	X
8000	X	X
PAC 1200 *	X	X
S-D2	X	X
S-D5 (aka: Lion Alcolmeter SD-5 outside the U.S.)	X	X
Draeger Safety, Inc. (aka: National Draeger) Irving, Texas:		
Alcotest Model:		
6510	X	X
6810	X	X
7010 *	X	X
7110 *	X	X
7110 MKIII	X	X
7110 MKIII-C	X	X
7410	X	X
7410 Plus	X	X
7510	X	X
9510	X	X
Breathalyzer Model:		
900	X	X
900A *	X	X
900BG *	X	X
7410	X	X
7410-II	X	X
EnviteC by Honeywell GmbH, Fond du Lac, Wisconsin:		
AlcoQuant 6020	X	X
Gall's Inc., Lexington, Kentucky:		
Alcohol Detection System-A.D.S. 500	X	X
Guth Laboratories, Inc., Harrisburg, Pennsylvania:		
Alcotector BAC-100	X	X
Alcotector C2H5OH	X	X
Intoximeters, Inc., St. Louis, Missouri:		
Photo Electric Intoximeter *		X

GC Intoximeter MK II *	X	X
GC Intoximeter MK IV *	X	X
Auto Intoximeter *	X	X
Intoximeter Model:		
3000	X	X
3000 (rev B1) *	X	X
3000 (rev B2) *	X	X
3000 (rev B2A) *	X	X
3000 (rev B2A) w/FM option *	X	X
3000 (Fuel Cell) *	X	X
3000 D *	X	X
3000 DFC *	X	X
Alcomonitor		X
Alcomonitor CC	X	X
Alco-Sensor III	X	X
Alco-Sensor III (Enhanced with Serial Numbers above 1,200,000)	X	X
Alco-Sensor IV	X	X
Alco-Sensor IV XL	X	X
Alco-Sensor V	X	X
Alco-Sensor AZ	X	X
Alco-Sensor FST	X	X
Intox EC/IR	X	X
Intox EC/IR II	X	X
Intox EC/IR II (Enhanced with serial number 10,000 or higher)		X
Portable Intox EC/IR	X	X
RBT-AZ	X	X
RBT-III	X	X
RBT III-A	X	X
RBT IV	X	X
RBT IV with CEM (cell enhancement module)	X	X
Komyo Kitagawa, Kogyo, K.K., Japan:		
Alcolyzer DPA-2 *	X	X
Breath Alcohol Meter PAM 101B *	X	X
Lifeloc Technologies, Inc., (formerly Lifeloc, Inc.), Wheat Ridge, Colorado:		
PBA 3000B	X	X
PBA 3000-P *	X	X
PBA 3000C	X	X
Alcohol Data Sensor	X	X
Phoenix	X	X
Phoenix 6.0	X	X
EV 30	X	X
FC 10	X	X
FC 20	X	X
Lion Laboratories, Ltd., Cardiff, Wales, United Kingdom:		
Alcolmeter Model:		
300	X	X

400	X	X
400+ (aka: Intoxilyzer 240 in the U.S.)	X	X
SD-2 *	X	X
SD-5 (aka: S-D5 in the U.S.)	X	X
EBA*	X	X
Intoxilyzer Model:		
200	X	X
200D	X	X
1400	X	X
5000 CD/FG5	X	X
5000 EN	X	X
Luckey Laboratories, San Bernardino, California:		
Alco-Analyzer Model:		
1000 *		X
2000 *		X
Nanopuls AB, Uppsala, Sweden:		
Evidenzer	X	X
National Patent Analytical Systems, Inc., Mansfield, Ohio:		
BAC DataMaster (with or without the Delta-1 accessory):		
BAC Verifier DataMaster (w/or without the Delta-1 accessory)	X	X
DataMaster cdm (w/or without the Delta-1 accessory)	X	X
DataMaster DMT	X	X
Omicron Systems, Palo Alto, California:		
Intoxilyzer Model:		
4011 *	X	X
4011AW *	X	X
PAS International, Fredericksburg, Virginia:		
Mark V Alcovisor	X	X
Plus 4 Engineering, Minturn, Colorado:		
5000 Plus 4 *	X	X
Seres, Paris, France:		
Alco Master	X	X
Alcopro	X	X
Siemans-Allis, Cherry Hill, New Jersey:		
Alcomat *	X	X
Alcomat F *	X	X
Smith and Wesson Electronics, Springfield, Massachusetts:		
Breathalyzer Model:		
900 *	X	X
900A *	X	X
1000 *	X	X
2000 *	X	X
2000 (non-Humidity Sensor) *	X	X
Sound-Off, Inc., Hudsonville, Michigan:		
AlcoData	X	X
Seres Alco Master	X	X

Seres Alcopro Stephenson Corp.:	X	X
Breathalyzer 900 *	X	X
Tokai-Denshi Inc., Tokyo, Japan:		
ALC-PRO II (US)	X	X
U.S. Alcohol Testing, Inc./Protection Devices, Inc., Rancho Cucamonga, California:		
Alco-Analyzer 1000		X
Alco-Analyzer 2000		X
Alco-Analyzer 2100	X	X
Verax Systems, Inc., Fairport, New York:		
BAC Verifier *	X	X
BAC Verifier Datamaster	X	X
BAC Verifier Datamaster II *	X	X

\* Instruments marked with an asterisk (\*) meet the Model Specifications detailed in 49 FR 48854 (December 14, 1984) (i.e., instruments tested at 0.000, 0.050, 0.101, and 0.151 BAC.) Instruments not marked with an asterisk meet the Model Specifications detailed in 58 FR 48705 (September 17, 1993), and were tested at BACs = 0.000, 0.020, 0.040, 0.080, and 0.160. All instruments that meet the Model Specifications currently in effect (dated September 17, 1993) also meet the Model Specifications for Screening Devices to Measure Alcohol in Bodily Fluids.

(c) No law enforcement agency shall use a breath analysis instrument unless the training agency has verified that representative samples of the specific make and model perform properly. Maintenance shall be conducted as specified by the training agency, and shall include, but shall not be limited to, calibration at a frequency as recommended by the device manufacturer or, minimally, annually.

(d) Training agencies shall be responsible for maintaining records pertaining to verification and maintenance (including calibration) of breath analysis instruments and standards; provided, however, that record keeping maintenance may be delegated, in whole or in part, to the law enforcement agency using the breath analysis instrument(s).

Existing subdivision (f) of Section 59.5 is repealed; and the title and introductory statement and subdivisions (a) through (d) of Section 59.5 are amended to read as follows:

Breath analysis; techniques [or] and methods.

[Breath test] The following breath analysis techniques and methods [meeting the following criteria are established] shall be a component of breath analysis instrument operator training provided by [the] training agencies [under the direction of the commissioner.] and shall be used by operators performing breath analysis for evidentiary purposes:

(a) A breath sample shall be collected at the direction and to the satisfaction of a police officer [within two hours of the time of arrest or within two hours of a positive breath alcohol screening test. Such samples] and shall be analyzed with breath analysis instruments meeting the criteria set forth in section 59.4 of this Part.

(b) [Continuous observation of the] The subject shall be [maintained] observed for at least 15 minutes prior to the collection of the breath sample, during which period the subject must not have ingested alcoholic beverages or other fluids, regurgitated, vomited, eaten, or smoked, or [be] have [allowed to place] placed anything in his/her mouth; if the subject should regurgitate, vomit, smoke or place anything in his/her mouth, an additional 15-minute waiting period shall be required.

(c) A system purge [must immediately] shall precede both the testing of each subject and the analysis of the reference standard.

(d) The result of an analysis of a [suitable] reference standard with an alcoholic content greater than or equal to 0.08 percent must agree with the reference standard value within the limits of plus or minus 0.01 percent weight per volume, or such limits as set by the commissioner. [This] An analysis of the reference standard shall [immediately] precede or follow the analysis of the breath of the subject [and] in accordance with the test sequence

established by the training agency. Readings for the reference standard, a blank and the subject's breath, shall be recorded.

The introductory statement, and subdivision (a), (b) and (c) of Section 59.6 are amended to read as follows:

Training agencies shall submit an application for approval of a breath [testing] analysis permit program or a [breath testing] training program for breath analysis to the commissioner. Other agencies seeking approval of such programs shall submit an application to the commissioner through the [Bureau for Municipal Police] Office of Public Safety of the Division of Criminal Justice Services. The application shall include:

- (a) a description of the techniques and methods to be utilized;
- (b) the make and model of the breath analysis instruments used;
- (c) an outline of the material presented in the breath [analyzer] analysis instrument operator and technical supervisor [courses] training program;

Subdivisions (a) and (b) of Section 59.7 are amended, and new subdivisions (c) and (d) are added to Section 59.7 to read as follows:

- (a) A permit valid for two years [will] shall be issued by the commissioner to breath [analyzer] analysis instrument operators who have completed an approved program based upon standards acceptable to the training agency and certified by the commissioner. Such program shall consist of a minimum of [32] 24 hours of instruction and training with identified learning

objectives, supervised by one or more individuals certified as technical supervisors, and shall include:

- (1) three hours of instruction on the effects of alcohol on the human body;
- (2) five hours of instruction on operational principles of the selected [testing method] techniques and methods, including a functional description and a detailed operational description of the [method] breath analysis instrument(s) with a demonstration;
- (3) five hours of instruction on the legal aspects of chemical tests generally, and of the particular [method] techniques and methods to be employed;
- (4) three hours of instruction on supplemental information to include nomenclature appropriate to the field of chemical tests for alcohol;
- (5) [ten] six hours of laboratory participation using approved breath analysis instruments and [equilibrators,] simulators, or other reference standards;
- (6) a passing [grade] score on a one-hour formal examination designed to evaluate whether the operator has met the course learning objectives; and
- (7) a demonstration of analytical proficiency on each breath analysis instrument for which the operator is [being certified] seeking certification.

(b) A permit as a breath [analyzer] analysis instrument operator [will] shall be renewed for a two-year period [if:

- (1) , provided that, within the 120 calendar days preceding the permit's expiration date, the operator; completes a [minimum of three hours of formal instruction] retraining program that minimally includes an instructional course in breath analysis [under the direction and supervision of the] designed to refresh and update the operator's knowledge in areas described in subdivision (a) of this section; satisfactorily meets the course's learning objectives as determined by a

technical supervisor[,]; demonstrates analytical proficiency [with the] on each breath analysis instrument for which the operator is seeking permit renewal; and attains a passing [grade] score on a formal examination; [or

(2) or, in lieu of such formal retraining, with the concurrence of the responsible training agency, provided that the operator and his/her superior officer submits to the training agency, [the operator or his/her supervisor submits] a written declaration that the operator has performed six or more breath [analysis tests] analyses on subjects in accordance with this Part on each breath analysis instrument for which the operator is seeking permit renewal during the [preceding] 24 months [in accordance with this Part and every four years completes the retraining and proficiency requirements of paragraph (1) of this subdivision] preceding permit expiration. Notwithstanding such a submission, every four years all operators shall participate successfully in the retraining course described in this subdivision.

(c)(1) Whenever a breath analysis instrument operator's permit is not renewed prior to the expiration date, the commissioner may extend such expiration date for 30 calendar days, provided that the training agency and operator jointly submit a written request for such extension, describing the reasons for the failure to renew in a timely manner. The operator's permit shall remain valid during the 30-day extension period.

(2) If the operator fails to meet the conditions for permit renewal pursuant to subdivision (b) of this section within the extension period authorized pursuant to paragraph (1) of this subdivision, the permit shall become void and not renewable; an operator whose permit becomes void may apply for a new permit by repeating the requirements of subdivision (a) of this section; and the effective date of any such new permit shall be the date of commissioner approval, without back dating to the date on which the prior permit became void.

(d) A training agency shall submit to the commissioner documentation of breath analysis instrument operator training for initial issuance and renewal of a permit in a format designated by the commissioner.

Subdivisions (a), (b) and (c) of Section 59.8 are amended to read as follows:

(a) The commissioner or the training agencies may at any time and from time to time require breath analysis instrument operators or technical supervisors to demonstrate their ability to operate properly the breath [testing equipment] analysis instrument(s) for which they [have] hold a permit.

(b) The operator's permit may be revoked by the commissioner based on information acquired by the commissioner, or [the] a training agency[(ies)], that the operator does not conduct breath tests in accordance with techniques and methods [established] as instructed by the training agency, that the operator's performance is unreliable, or the operator is incompetent. Upon revocation, the operator shall return any and all permits to the commissioner.

(c) The training agency may suspend the permit of any operator under its supervision when, in its judgment, the operator does not conduct breath tests in accordance with techniques and methods as established by the training agency, the operator's performance is unreliable or the operator is incompetent. The training agency shall immediately notify the commissioner in writing of any such suspension and furnish a copy of such notice to the suspended operator, who shall not be permitted to operate the breath analysis instrument until such time as the suspension is removed.

Subdivisions (a), (c) and (d) of Section 59.9 are amended to read as follows:

(a) The commissioner may authorize certification of an applicant as technical supervisor for a period of [two] four years, provided such applicant submits satisfactory evidence through the training agency that he/she meets the following qualifications:

- (1) thirty semester hours of college credits, including eight semester hours of chemistry;
- (2) certification as an operator of the [chemical] breath analysis [method] instrument(s) to be supervised, or possession of equivalent experience or training to qualify as an operator; and
- (3) satisfactory completion of a technical supervisor's course, the content of which shall include:

- (i) advanced survey of current information concerning alcohol and its effect on the human body (one hour);

- (ii) operational principles and theories applicable to the program (two hours);

- (iii) breath analysis instrument maintenance and calibration (two hours);

- (iv) legal aspects of chemical testing ([t]one hour); and

- (v) principles of instruction (two hours); or

- [(vi)]

- (4) training and experience equivalent to a technical supervisor's course and acceptable to the commissioner.

(c) A technical supervisor shall have responsibility for:

- (1) [supervision of breath analyzer operators, their] breath analysis instrument operator training, competency evaluation, and periodic examination to ensure maintenance of technical knowledge and [competence] proficiency;

- (2) maintenance [and], including calibration of breath [testing] analysis instruments and equipment under his/her supervision[;] and preparation and standardization of chemicals used for

testing and/or evaluation of such chemicals, by direct performance of such tasks or by delegating performance to another person with demonstrated competency, but who need not be qualified as a technical supervisor; provided, however, whenever such tasks are so delegated, the technical supervisor shall review the work product to ensure that the assigned designee's performance meets expectations; and

(3) [field] periodic inspection of breath analysis instrument performance [;

(4) correct preparation and standardization of chemicals used for testing; and/or evaluation of the chemicals for testing; and

(5) provision of expert testimony concerning the breath testing instrument and the testing techniques supervised, as necessary].

(d) A technical supervisor's certificate may be renewed for a period of [two] four years upon submission of a written application and statement that he/she has carried out his/her duties in accordance with this Part. Suspension or revocation pursuant to section 59.8 of this Part of a breath analysis instrument operator's permit held by a technical supervisor shall result in suspension or revocation, respectively, of the individual's certification as a technical supervisor.

Existing section 59.10 is repealed, and a new Section 59.10 is added, to read as follows:

Section 59.10 Certification criteria for ignition interlock devices.

(a) A manufacturer of ignition interlock devices shall apply to the department to certify a device for use in New York State. The application shall be on a form or format specified by the department with documents appended as necessary to provide the requisite information, and shall include, but not be limited to:

(1) name and address of the manufacturer, and contact information, including identification of a person to respond to department inquiries;

(2) name and model of the ignition interlock device;

(3) a detailed description of the ignition interlock device, including: instructions for its installation and operation; technical specifications, including, but not limited to, accuracy; calibration stability; data security; and capability for data collection and recording, tamper detection, and retesting; and unsupervised operation in a range of environmental conditions;

(4) the manufacturer's statement that all ignition interlock devices of the same make and model sold or offered for sale or lease, for which certification is sought, meet the requirements of this Part; and

(5) a certificate or other document from an insurance carrier licensed in New York State demonstrating that the manufacturer holds product liability insurance with minimum liability limits of one million dollars per occurrence and three million dollars aggregate. The documentation shall include the issuing company's statement that at least thirty (30) days notice will be provided to the department whenever the issuing company intends to cancel the insurance before the policy's expiration date. Liability coverage shall include defects in product design and materials, as well as in manufacture, calibration, installation and removal of devices.

(b) The manufacturer shall provide the testing laboratory with:

(1) six representative instruments of each ignition interlock device model for which certification is sought, from which the testing laboratory shall select at least two for testing;

(2) instructions for device installation and operation; and

(3) a description of the device's capabilities, including, but not limited to: security; data collection and recording; tamper detection; circumvention prevention; retesting; and unsupervised operation in a range of environmental conditions.

(c) At the request of a manufacturer of ignition interlock devices, the commissioner shall certify the ignition interlock device for use in New York State, provided the manufacturer:

(1) demonstrates, through arrangements with a testing laboratory, that the model meets or exceeds the model specifications for breath alcohol ignition interlock devices adopted by NHTSA and published in the Federal Register on April 7, 1992 (57 Fed. Reg. 11772 - 11787, available for public inspection and copying at the Department of Health Records Access Office, Corning Tower, Empire State Plaza, Albany, NY 12237);

(2) demonstrates, through arrangements with a testing laboratory, that the device meets the model specifications specified in paragraph (1) of this subdivision when calibrated to a set point of 0.025% BAC;

(3) has requested certification for a device that employs fuel cell technology or another technology with demonstrated comparable accuracy and specificity;

(4) has demonstrated that the certified device can and would be installed to allow normal operation of the vehicle after it is started, except as specifically approved by the department; and

(5) has demonstrated compliance with all the requirements of this Part.

(d) Certification shall be effective as of the date of its issuance.

(e) Certified ignition interlock devices installed in vehicles shall be uniquely serial-numbered.

(f) Each certification shall cover only one model of ignition interlock device. Modifications to a model of a device, without regard to the manufacturer's assigning a new model number,

shall be reported to the department as required in section 59.12 of this Part.

(g) The department may deny, suspend or revoke the certification of an ignition interlock device for reasons including:

(1) the device does not meet the requirements for certification specified in this Part, including but not limited to, the commissioner's determination that the testing laboratory misrepresented a device's meeting such requirements;

(2) the manufacturer has failed to comply with any requirement of this Part or of Part 358 of Title 9 of the Official Compilation of Codes, Rules and Regulations of the State of New York;

(3) substantial evidence exists that devices manufactured, sold, leased, offered for sale or leased, or installed in vehicles do not function in accordance with the specifications in this Part or are easily circumvented or tampered with;

(4) substantial evidence exists that the manufacturer has not made adequate provision for effective and timely maintenance, inspection, calibration and repair of installed devices;

(5) the manufacturer is no longer in the business of manufacturing devices;

(6) the manufacturer fails to retain the required product liability insurance, including through cancellation or non-renewal;

(7) the manufacturer has been convicted of a crime or offense related to fraud; or

(8) the ignition interlock device does not meet federal model specifications for breath alcohol ignition interlock devices adopted by NHTSA after the specifications referred to in paragraph (1) of subdivision (c) of this section are adopted.

(h) Notice of an ignition interlock device's certification, discontinuation, suspension and revocation shall be published in the State Register, and shall be provided promptly to the Division of Probation and Correctional Alternatives. The commissioner shall make available a

list of certified ignition interlock devices upon request.

Existing section 59.11 is repealed, and a new Section 59.11 is added, to be titled and to read as follows:

Testing of ignition interlock devices.

(a) The department may require a testing laboratory, as defined in section 59.1 of this part, to submit its credentials for department review prior to accepting any report submitted by the testing laboratory in support of an ignition interlock device manufacturer's application for certification.

(b) The testing laboratory shall provide, directly to the department, a detailed report of test data and findings of the ignition interlock device's performance on each standard, generated by the testing laboratory, documenting that at least two representative instruments of an ignition interlock device model have successfully met the requirements of subdivision (c) of section 59.10 of this Part.

(c) The testing laboratory's report shall minimally include: a description of tests performed; data and findings for each test conducted, with numerical readouts as appropriate; a description of the effectiveness of the ignition interlock device's security provisions, if any, for detection and recording of attempted tampering and preventing circumvention; the reliability of the device's data recording features; and a description of the effectiveness of the device over a range of environmental conditions. The report shall include a dated and signed attestation by the person supervising such testing that identifies the ignition interlock device model and manufacturer, and states that all tests on the named device model were conducted in accordance with NHTSA specifications.

Existing section 59.12 is repealed, and a new Section 59.12 is added, to be titled and to read as follows:

Continued ignition interlock device certification.

(a) An ignition interlock device certification shall remain in effect until:

(1) the manufacturer files a written request for discontinuance;

(2) the department issues to the manufacturer a written notice of suspension or revocation of approval; or

(3) the manufacturer modifies the device so that it does not meet the federal model specifications for breath alcohol ignition interlock devices in effect when it was certified.

(b) No manufacturer who makes an operational modification to a model of an ignition interlock device that has been certified pursuant to this Part shall release the modified device for use pursuant to Vehicle and Traffic Law Section 1198 without having obtained the express approval of the department. Manufacturers shall submit to the department a description of the intended operational modification(s), and the commissioner shall determine either that the existing certification shall continue in effect for the ignition interlock device as modified or that the manufacturer must apply for separate certification for the modified device. For purposes of this section, “operational modification” means any change to product design or function that would or could affect the device’s anti-circumvention, anti-tampering or analytical features, as determined by the department.

(c) A manufacturer shall ensure that the department is provided with documentation of current insurance by notifying the department in writing of each renewal of coverage, each change of issuing company, and each change in liability limits.

(d) The department may require manufacturers whose devices are certified pursuant to this Part to periodically renew the certifications. Information required for renewal of certification shall minimally include:

(1) verification that information on file with the department, including, but not limited to, manufacturer's address and contact person, is current;

(2) an attestation that the department has been notified of any operational modification made to the certified model, or that no modification was made; and

(3) documentation of current insurance coverage.

(e) Each device shall be provided with a supply of disposable spit-trap mouthpieces, and the manufacturer shall ensure availability of additional mouthpieces.

(f) A manufacturer shall provide to installation/service providers that install its certified device(s) a sufficient number of labels to label each device installed and replace labels as needed.

The label shall contain a notice printed in at least 10-point boldface type, reading as follows:

**“WARNING – ANY PERSON TAMPERING, CIRCUMVENTING OR OTHERWISE MISUSING THE DEVICE IS GUILTY OF A MISDEMEANOR AND MAY BE SUBJECT TO CIVIL LIABILITY.”**

The “New York State Department of Health Wadsworth Center for Laboratories and Research Application for Certification of Ignition Interlock Devices” form at the end of section 59.12 is repealed.

## **REGULATORY IMPACT STATEMENT SUMMARY**

### **Statutory Authority:**

The New York State (NYS) Vehicle and Traffic Law, Section 1194(4)(c), and Department of Environmental Conservation Law, Section 11-1205(6), authorize the Commissioner of Health to adopt regulations concerning methods of testing breath and body fluids for alcohol content. NYS Vehicle and Traffic Law, Section 1198(6) authorizes the Commissioner of Health to promulgate regulations setting standards for use of ignition interlock devices.

### **Legislative Objectives:**

This amendment is consistent with the legislative objective of ensuring effective enforcement of laws against driving while intoxicated (DWI). This proposal is consistent with Chapter 669 of the Laws of 2007, which authorized statewide use of ignition interlock devices, and Chapter 496 of the Laws of 2009 (Leandra's Law), which mandates that every person sentenced for any DWI offense, must have an ignition interlock device installed as a requirement for conditional discharge or probation.

### **Needs and Benefits:**

Part 59 establishes standards for chemical tests on blood, breath, and urine for the presence of alcohol, for purposes of detecting unacceptable levels of alcohol in persons. Courts rely on Part 59 provisions daily in adjudicating alcohol-related offenses; the State's correctional

alternatives program relies on effective operation of ignition interlock devices to prevent repeat offenders from driving while impaired by alcohol. The existing regulation must be updated, as it is inconsistent with existing DWI statutes, as well as current and anticipated usage of ignition interlock devices.

The specificity of Section 59.2 standards for collecting, handling and analyzing a specimen for blood alcohol analysis has prevented convictions even though the defendant was driving while intoxicated. This amendment would delete the list of persons authorized to draw blood, as the listing could present a legal conflict with similar provisions in Vehicle and Traffic Law Section 1194(4)(a) and Public Health Law Section 3703. This amendment would eliminate technical specifications for the collection of blood within a two-hour timeframe, and use of a clean and sterile syringe and anticoagulant, and require that alcohol units be expressed as blood alcohol concentration, rather than the outdated terminology of grams percent. The reference standard for calibration verification of breath and blood analysis instruments has been changed to a standard greater than or equal to 0.08 grams/100 ml, consistent with the Vehicle and Traffic Law provision that sets 0.08% weight per volume (w/v) alcohol in blood as the threshold for certain DWI sanctions. The amendment describes criteria for revocation or nonrenewal of a blood alcohol analysis permit based on unsuccessful proficiency testing (PT) performance or failure to participate in PT challenges.

Section 59.4 affords training agencies the flexibility of establishing retention times for records, as these may vary by record type and potential use in a legal proceeding; delegation of recordkeeping activities is authorized. Section 59.4, as revised, stipulates the commissioner's approval of breath measurement devices for use in NYS provided the device has been accepted by the National Highway Traffic Safety Administration (NHTSA). The revised section includes

the list of NHTSA-approved breath measurement instruments published in the Federal Register on March 11, 2010 to remove any possible ambiguity about the fact that devices listed therein, including the Alcotest 9510 manufactured by Draeger Safety Inc., are fully approved by the Department of Health. The requirement in Section 59.5 for conducting breath analysis within two hours of arrest or a positive breath alcohol screening test has been removed. The requisite for test subject observation prior to testing has been clarified, as the existing provision for *continuous observation* carries the risk of unintended and unnecessarily specific interpretation, thus jeopardizing successful DWI prosecution. The reference to operational checklists, which are no longer used, has been eliminated. The requirement for certain techniques and methods to be a component of each training agency's curriculum and to be put into use by analysts is clarified.

This proposal would reduce from 32 to 24 hours the time trainees must spend in initial training. The reduction from 10 to six hours in hands-on use of instruments is reasonable given the decreasing complexity of instrumentation overall, and the trend towards use of one device model within a jurisdiction. Training agencies would be required to identify learning objectives and design examinations in keeping with objectives. The outdated term *equilibrators* has been deleted, as breath analyzers no longer need to counter a matrix effect from use of simulator solutions. As modified, the rule requires retraining to renew a BTO permit take place via a course designed to refresh applicants' recall of formal training material, such as including mechanisms to assess proficiency and measure retained knowledge. The proposal stipulates that retraining must occur within the 120 days prior to permit expiration, to eliminate overlap within the two-year BTO cycle. This amendment would afford, at the Commissioner's discretion, a 30-day extension in permit expiration date, in an effort to avoid the potential legal dilemma of administrative permit lapses due to paperwork processing delays. Operators whose permits are

voided are required to participate successfully in another initial certification course before a new BTO permit may be issued, to demonstrate that recall and competency have been maintained.

The effective period for a technical supervisor's certification has been increased from two to four years. Supervisor responsibilities have been detailed; and supervisors are permitted to delegate certain tasks, provided they review the work product to ensure the designee's performance meets expectations. A reference to field inspection of instruments by supervisors has been modified to reflect the current practice of remote calibration checks. Provision of expert testimony has also been deleted from the list of supervisor's responsibilities, since the process of qualifying subject matter experts rests with the court.

Existing Section 59.10 is repealed. New Section 59.10 retains many existing ignition interlock certification criteria, rearranged for ease of comprehension. The reference to a seven-county pilot study for ignition interlock devices has been eliminated, as Chapter 669 of the Laws of 2007 amended the Vehicle and Traffic Law to expand the study into a statewide program. New Section 59.10 requires the manufacturer to identify a person to respond to Department inquiries, and requires the manufacturer to furnish a certificate stating that the company issuing the requisite liability coverage will notify the Department at least 30 days prior to cancelling a policy before the expiration date. New Section 59.10 also makes clear that the manufacturer must demonstrate, through arrangements with a testing laboratory, that the device meets the NHTSA model specifications when calibrated to a set point of 0.025% BAC; and stipulates that only devices that employ fuel cell technology or another technology with demonstrated comparable accuracy and specificity are eligible for certification, thus ensuring deployment of state-of-the-art equipment.

Existing Section 59.11 is repealed. New Section 59.11 replaces New York State-specific

criteria for certification of interlock devices with NHTSA standards, as the NYS standards, codified in 1990, are less encompassing than federal standards. Submission of testing agency credentials with each application for device approval is no longer required. New Section 59.11 details requirements for certification of the testing laboratory, the laboratory's responsibilities in the device approval process, and the minimum components of a testing laboratory report. In both new Section 59.10 and 59.11 a reference to "circumvention" has been added with each occurrence of the word "tampering," to recognize that these are distinct Vehicle and Traffic Law violations.

Existing Section 59.12 is repealed. New Section 59.12 establishes requirements for continued ignition interlock certification. New Section 59.12 requires a manufacturer to notify the Department of any operational modification to a certified device, and to obtain approval for continued use, as modified, under the existing certification. The definition of *operational modification* and the process for reporting modifications has been moved to Section 59.12. The amendment codifies a currently implicit requirement that manufacturers notify the Department of changes to insurance coverage. The text required for the warning label is revised to conform to the text mandated by statute. The section requires the manufacturers to supply a sufficient number of labels to installation/service providers. The vast majority of the section's other requirements, including reporting and labeling requirements and manufacturer-service provider interactions, have been eliminated from Section 59.12; most have been incorporated into a new 9 NYCRR Part 358 being promulgated by the Division of Probation and Correctional Alternatives (DPCA) to implement the ignition interlock provisions of Leandra's Law. New Section 59.12 establishes a process for periodic renewal to ensure that information on file with the Department is current. The application form for device certification has been removed from the regulation,

and will be available electronically.

## **COSTS:**

### **Costs to Private Regulated Parties:**

The requirements of this regulation applicable to ignition interlock manufacturers and installation/service providers impose no new costs on these private regulated parties. The newly codified requirement that manufacturers notify the Department of changes to insurance coverage may be accomplished electronically at no cost to the manufacturer. The renewal of certification form/attestation may be electronically submitted.

### **Costs to State Government:**

Affected State agencies other than the Department of Health, i.e., the State Police, the Division of Criminal Justice Services (DCJS), and DPCA, would incur minimal additional costs as a result of adoption of this amendment, as the amendment relaxes, clarifies or codifies practices already implemented. The State Police and DCJS, as training agencies, may realize cost savings from the proposed reduced duration of the breath analyst certification course, from 32 to 24 hours.

### **Costs to Local Government:**

The Nassau County, Suffolk County and New York City Police Departments, which are local-government training agencies, would incur either no to minimal additional costs as a result of this amendment's adoption, as the amendment relaxes, clarifies or codifies processes already in place. These training agencies may realize cost savings from the proposed reduced duration of the breath analyst certification course, from 32 to 24 hours, which represents one full day that officers need not be absent from the work pool.

Prosecutorial units of local government may experience cost savings resulting from this amendment's deletion of specific requirements for specimen collection that, historically, have been challenged successfully by defense attorneys.

**Costs to the Department of Health:**

Adoption of this regulation would impose minimal additional costs on the Department. Implementation of a renewal process for the six manufacturers that currently hold ignition interlock certifications will use existing resources and result in minimal additional work load. Regulated parties will be provided with the text of the final adopted rule by electronic mail.

**Local Government Mandates:**

This regulation does not impose any new mandate on any county, city, town, village, school district, fire district or other special district.

**Paperwork:**

The proposal to extend, from two to four years, the effective period of breath analyzer supervisor permits will reduce paperwork, as will deletion of the requirement for quarterly reporting to multiple agencies of ignition interlock use data. This amendment's emphasis on learning goals rather than course structure would allow for paperwork reduction, as recertification courses would be adaptable to online distance learning modules. Manufacturers are encouraged to utilize electronic means of communication for required notifications and certificate renewals.

**Duplication:**

Part 59 as amended would be consistent with, but not duplicate, federal standards for approval of breath alcohol evidentiary devices as promulgated by the NHTSA.

**Alternative Approaches:**

At the present time, there are no acceptable alternatives to pursuing adoption of the amendment as written. The major stakeholders have reached agreement that inability to move forward with the changes as proposed would likely impede DWI enforcement and prosecutorial activities in NYS. The clarifications and updates in this amendment are required to keep the regulation current with law enforcement practices and changes to laws governing ignition interlock programs and evidence-gathering protocols related to DWI prosecutions, as well as technological advances in the devices themselves.

**Federal Standards:**

The proposed rule does not exceed any minimum standards of the federal government; it references sources for information on federally approved devices, and is consistent with federal standards for ignition interlock and breathalyzer device approval.

**Compliance Schedule:**

Regulated parties should be able to comply with these regulations effective upon publication of a Notice of Adoption in the New York State Register.

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## **REGULATORY IMPACT STATEMENT**

### **Statutory Authority:**

The New York State (NYS) Vehicle and Traffic Law, Section 1194(4)(c), and Department of Environmental Conservation Law, Section 11-1205(6), authorize the Commissioner of Health to adopt regulations concerning methods of testing breath and body fluids for alcohol content. NYS Vehicle and Traffic Law, Section 1198(6) authorizes the Commissioner of Health to promulgate regulations setting standards for use of breath alcohol ignition interlock devices.

### **Legislative Objectives:**

This amendment is consistent with the legislative objective of ensuring effective enforcement of laws against driving while intoxicated (DWI). The revision authorizes law enforcement agencies to use state-of-the-art equipment for breath alcohol testing, as approved by the Commissioner of Health, and removes potential barriers to effective enforcement of DWI laws. This proposal also is consistent with: Chapter 669 of the Laws of 2007, which expanded the use of ignition interlock devices to reduce statewide the tendency of those convicted under DWI laws to relapse into undesirable behaviors, with high risk of harm to oneself and others; and Chapter 496 of the Laws of 2009 (Leandra's Law), which mandates that every person sentenced for any DWI offense must have an ignition interlock device installed as a requirement for conditional discharge or probation.

## **Needs and Benefits:**

Part 59 establishes standards related to the conduct of chemical tests on blood, breath, and urine for the presence of alcohol, for purposes of detecting unacceptable levels of alcohol in operators of motor vehicles (Vehicle and Traffic Law § 1194), boats (Navigation Law § 49-a), snowmobiles (Parks, Recreation and Historic Preservation Law § 25.24), as well as hunters (Environmental Conservation Law § 11-1205). Prosecutors and judges statewide rely on Part 59 provisions daily in adjudicating alcohol-related offenses, and the State's correctional alternatives program and the public rely on effective operation of ignition interlock devices to prevent repeat offenders from driving while impaired by alcohol. The existing regulation must be updated, as it is inconsistent with existing DWI statutes as well as current and anticipated usage of ignition interlock devices. Further, advances in technology – in instrument design and function, as well as electronic communications – have modified the training agencies' approach to educating and evaluating the proficiency of applicants for breath analyzer operator permits. This proposal was drafted with significant input from technical and training experts from the Wadsworth Center's Forensic Toxicology Laboratory and Blood and Breath Alcohol Program, the Division of Criminal Justice Services (DCJS), the State Police, the Division of Probation and Correctional Alternatives (DPCA), the NYS District Attorney's Association, the Governor's Traffic Safety Committee, and county-designated traffic safety prosecutors.

The statutory authority in Part 59 for the Commissioner of Health to approve ignition interlock devices has been clarified. These devices, connected to motor vehicle ignition systems, prevent vehicles from starting unless the operator's breath alcohol level measures within acceptable levels. The qualifications of a *testing laboratory*, formerly termed *testing agency*, have been detailed in an expanded definition. Other modifications to definitions in Section 59.1

recognize emerging technologies for determination of alcoholic content in body fluids using saliva (i.e., oral fluid) as a test specimen, and add a definition for *calibration* to underscore that this activity includes verification of instrument settings and adjustments. The proposal also covers technical corrections for the rule, including substituting *breath analysis* for *breath testing*.

Section 59.2, which sets standards for collecting, handling and analyzing a specimen for analysis of blood alcohol concentration, is unnecessarily specific, preventing some DWI convictions even though the suspect/defendant was, in fact, driving while intoxicated. This proposed amendment would delete the list of persons authorized to draw blood, as such a listing could present a legal conflict with similar provisions in Vehicle and Traffic Law Section 1194(4)(a), which identifies persons authorized to withdraw blood from an intoxicated driver, and the Public Health Law Section 3703, which authorizes physician assistants to supervise and direct the withdrawal of blood for the purpose of determining alcohol or drug content. This proposed amendment to Part 59 would eliminate technical specifications not required for analytical accuracy; specifically, the requirements that collection of blood take place within a two-hour timeframe following the time of arrest, and that a clean and sterile syringe and container with anticoagulant be used in collection. The amendment requires that units for alcohol determinations of blood and urine be expressed as blood alcohol concentration (BAC), meaning percent weight per volume, rather than the outdated terminology of grams percent. The subdivision (b) requirement for use of test controls is extended to urine alcohol analysis. In both Sections 59.2 and 59.5, the stipulated reference standard for calibration verification of breath and blood analysis instruments has been changed to a standard greater than or equal to 0.08 grams/100 ml, consistent with the Vehicle and Traffic Law provision that sets 0.08% weight per

volume (w/v) alcohol in blood as the threshold for certain DWI legal sanctions. Use of a standard at or above threshold level is considered good laboratory practice.

Under this proposal, the applicability of Section 59.3 to saliva (i.e., oral fluid) testing would be highlighted, as use of this noninvasive method of specimen collection is expected to increase. The term for monitoring an analyst's ability to generate accurate results has been updated to reflect a more appropriate emphasis on demonstrating proficiency by successfully analyzing "known" samples and reporting results. The amendment would also describe criteria for revocation or nonrenewal of a blood alcohol analysis permit based on unsuccessful proficiency testing (PT) performance or failure to participate in PT challenges.

Section 59.4 has been revised to include the list of NHTSA-approved breath measurement instruments published in the Federal Register on March 11, 2010 to remove any possible ambiguity about the fact that devices listed therein, including the Alcotest 9510 manufactured by Draeger Safety, Inc., are fully approved by the Department of Health. Section 59.4 also requires records retention, but affords training agencies the flexibility of establishing retention times, as these may vary by record type and potential use in a legal proceeding; delegation of recordkeeping activities is authorized. New subdivision 59.4(c) stipulates that breath analysis instruments not supported by the training agency may not be used by local law enforcement officials. New subdivision 59.4(d) gives the training agency the responsibility for instrument maintenance, including calibration.

The requirement in Section 59.5 for conducting breath analysis within two hours of arrest or obtaining a positive breath alcohol screening test has been removed. Discretion for admissibility of evidence rests with the courts; in fact, the NYS Court of Appeals has found admissible a number of breath and blood alcohol determinations conducted after the two-hour

period, and opined that the “two-hour rule” is not applicable whenever a defendant expressly consents to a chemical (i.e., alcohol or drug) test (See, for example, *People v Atkins*, 85 NY2d 1007). The requisite for test subject observation prior to testing has been clarified, as the current rule’s provision for *continuous observation* carries the risk of unintended and unnecessarily specific interpretation, thus jeopardizing the potential for successful DWI prosecution. The reference to operational checklists, which are no longer used, has been eliminated. The requirement for certain techniques and methods to be a component of each training agency’s curriculum and to be put into use by analysts is clarified.

Proposed changes to Section 59.6 are mostly technical in nature, such as the rule’s identifying the DCJS training agency unit by its current name, the Office of Public Safety.

Section 59.7, which establishes standards for breath test operator (BTO) permits, currently requires 32 hours of initial operator training. Following extensive discussions with DCJS and State Police staff charged with developing and implementing training programs, the Department has determined this number of hours to be excessive given current device technology. This proposal would reduce from 32 to 24 hours the time trainees must spend in an initial training session, including a decrease from 10 to six hours for training in hands-on use of instruments. The reduction in hands-on time is reasonable given the decreasing complexity of instrumentation overall, the trend towards universal use of one device model (eliminating the need to train on several different devices) and a decrease in the number of steps for instrument start-up, as well as the overall complexity of the analytical process. Training agencies would be required to identify learning objectives and design examinations in keeping with those objectives, thus ensuring that training focuses on outcome. The outdated term *equilibrators* has been deleted, as breath analyzers no longer require procedures to counter a matrix effect from use of a

simulator solution. The effective term for a BTO permit would remain at two years. The requisite for formal instruction to renew a BTO permit is modified to allow training agencies to model their retraining programs after current educational techniques and to allow flexibility in curriculum design. As modified, the rule requires retraining via a course of unspecified structure designed to refresh applicants' recall of material covered in formal training, such as including mechanisms to assess proficiency and measure retained knowledge. This approach, which allows online instruction and interactive training modules, has been implemented by one training agency; online retraining was provided to 719 officers from more than 50 departments in 2008, a 75 percent increase from the 2007 participation level. Distance learning lessens the burden of considering wide variances in expiration dates of BTO permits when scheduling training sessions. The proposal stipulates that retraining must occur within the 120 days (i.e., four months) prior to permit expiration, to establish an across-departments period for retraining and reissuance of permits, and eliminate overlap of six months or longer in the two-year BTO cycle. Another anticipated benefit is increased efficiency in this Department's data entry and permit distribution activities. This amendment would afford permit holders the opportunity for a 30-day extension in permit expiration date at the Commissioner's discretion, in an effort to avoid the potential legal dilemma of administrative permit lapses due to paperwork processing delays. The amendment specifies that permits so extended are valid for law enforcement purposes. Operators whose permits are voided are required to participate successfully in another initial certification course before a new BTO permit may be issued. Prosecutors associated with county district attorney offices and the New York Prosecutors Training Institute concur with the Department's position that proficiency wanes during lapses in hands-on use of protocols and instruments, leading to diminished recall and loss of competency. Any burden incurred by a law enforcement

agency's withdrawing an officer from the work pool to attend the three-day course prescribed is far outweighed by the potential that an officer who cannot document recentness in BTO procedures and instrument operation is perceived to be less credible as a witness, and thus jeopardizing a DWI prosecution case. This amendment also provides for submission of BTO permit applicant information in a format specified by the Department, to facilitate data entry and issuance of permits.

The effective period for a technical supervisor's certification in Section 59.9 has been increased from two to four years. Supervisor responsibilities have been detailed; and supervisors are permitted to delegate certain tasks, provided they review the work product to ensure the designee's performance meets expectations. A reference to field inspection of instruments by supervisors has been modified to reflect the current practice of remote calibration checks. Provision of expert testimony has also been deleted from the list of supervisor's responsibilities, since the process of qualifying subject matter experts rests with the court. The proposal specifies that approval to function as a supervisor would be affected by any Department administrative action against the supervisor's breath alcohol analyzer operator permit.

This amendment seeks to consolidate information on ignition interlock devices in more easily referenced sections and to eliminate outdated standards. Existing Section 59.10 is repealed. The reference to a seven-county pilot study on use of ignition interlock devices has been eliminated, as Chapter 669 of the Laws of 2007 amended the Vehicle and Traffic Law to expand the study into a statewide program. As the program is now well-established, also eliminated is a requirement that device manufacturers provide marketing plans or detailed information on device installation and service sites. New Section 59.10 requires the manufacturer to identify a person to respond to Department inquiries, and requires the

manufacturer to furnish a certificate stating that the company issuing the requisite liability coverage will notify the Department at least 30 days prior to cancelling a policy before the expiration date. New Section 59.10 also makes clear that the manufacturer must demonstrate, through arrangements with a testing laboratory, that the device meets the National Highway Traffic Safety Administration (NHTSA) model specifications when calibrated to a set point of 0.025% BAC; and stipulates that only devices that employ fuel cell technology or another technology with demonstrated comparable accuracy and specificity are eligible for certification, thus ensuring deployment of state-of-the-art equipment. Ten devices are currently certified for use in NYS. Of these, one utilizes semiconductor technology, but it is currently not in use in NYS. It is expected the manufacturer will file for discontinuance of certification pending adoption of this amendment.

Existing Section 59.11 is repealed; eliminating the NYS-specific criteria interlock devices must meet in order to gain Department approval, as these criteria are duplicative of NHTSA standards, as well as unnecessary since this Department no longer conducts an independent assessment of each instrument's meeting technical specifications. The NYS standards, codified in 1990, mirror but are less encompassing than federal standards. The federal model specifications for breath alcohol ignition interlock devices were adopted by publication in the Federal Register on April 7, 1992, and are now in place in all states operating ignition interlock device programs. On February 15, 2006, NHTSA published a request for comments about what revisions are needed for the model specifications for breath alcohol ignition interlock devices, and NHTSA may revise the federal model specifications in the future.

Provisions for credentials review of testing laboratories have been moved to a new Section 59.11. Submission to the Department of testing agency credentials with each application

for device approval is no longer required. New Section 59.11 also details requirements for certification of the testing laboratory, the laboratory's responsibilities in the device approval process, and the minimum components of a testing laboratory report. In both new Section 59.10 and 59.11 a reference to "circumvention" has been added with each occurrence of the word "tampering," to recognize these are both prohibited activities and distinct Vehicle and Traffic Law violations.

Existing Section 59.12 is repealed. Requisites for continued certification of interlock devices have been shifted from Section 59.11 to a new Section 59.12. New Section 59.12 establishes requirements for continued ignition interlock certification. New Section 59.12 requires a manufacturer to notify the Department of any operational modification to a certified device, and to obtain approval for continued use, as modified, under the existing certification. The definition of *operational modification* and the process for reporting modifications has been moved to Section 59.12. The amendment codifies a currently implicit requirement that manufacturers notify the Department of changes to insurance coverage. The text required for the warning label is revised to conform to the text mandated by statute. The section requires the manufacturers to supply a sufficient number of labels to installation/service providers. The vast majority of the section's other requirements, including reporting and labeling requirements and manufacturer-service provider interactions, have been eliminated from Section 59.12; most have been incorporated into a new 9 NYCRR Part 358 being promulgated by the Division of Probation and Correctional Alternatives (DPCA) to implement the ignition interlock provisions of Leandra's Law. New Section 59.12 establishes a process for periodic renewal to ensure that information on file with the Department is current. The application form for device certification has been removed from the regulation, as the form will be available on the Department's Web

site in the near future.

## **COSTS:**

### **Costs to Private Regulated Parties:**

The requirements of this regulation applicable to ignition interlock manufacturers and installation/service providers impose no new costs on these private regulated parties. The newly codified requirement that manufacturers notify the Department of changes to insurance coverage may be accomplished electronically at no cost to the manufacturer. The renewal of certification form/attestation may be electronically submitted.

### **Costs to State Government:**

Affected State agencies other than the Department of Health, i.e., the State Police, DCJS, and DPCA, would incur minimal additional costs as a result of adoption of this amendment, as the amendment relaxes, clarifies or codifies practices already implemented. State-operated training agencies may incur minimal expenses for staff time to revise database queries to produce names of officers due for renewal of breath alcohol analyst permits in a format acceptable to the Department; however, such a conversion is ongoing and may be completed prior to adoption of this revised rule. The State Police and DCJS, as training agencies, may realize cost savings from the proposed reduced duration of the breath analyst certification course, from 32 to 24 hours.

### **Costs to Local Government:**

The Nassau County, Suffolk County and New York City Police Departments, which are local-government training agencies for breath alcohol analysts, would incur either no to minimal additional costs as a result of this amendment's adoption, as the amendment relaxes, clarifies or codifies processes already in place. These training agencies may incur minimal expenses for

staff time to revise database queries to produce names of officers due for renewal of breath alcohol analyst permits in a format acceptable to the Department. These training agencies may realize cost savings from the proposed reduced duration of the breath analyst certification course, from 32 to 24 hours, which represents one full day that officers need not be absent from the work pool. Costs associated with training an officer depend on the distance between the trainee's department work place and the training location, rates for lodging and meals, and the overtime pay rate at which the trainee's department compensates a replacement officer. Given the reduction in class time from 32 to 24 hours, overtime costs for a substitute officer's entire eight-hour shift could be eliminated.

Prosecutorial units of local government may experience cost savings resulting from this amendment's deletion of specific requirements for specimen collection that, historically, have been challenged successfully by defense attorneys.

**Costs to the Department of Health:**

Adoption of this regulation would impose minimal additional costs on the Department. The proposed uniform format for submission of BTO permit initial and renewal applications by all training agencies is expected to reduce the time and therefore staffing levels required for data entry. Implementation of a renewal process for the six manufacturers that currently hold a total of ten ignition interlock certifications will use existing resources and result in minimal additional work load. Regulated parties will receive the text of the final adopted rule by electronic mail.

**Local Government Mandates:**

This regulation does not impose any new mandate on any county, city, town, village, school district, fire district or other special district.

**Paperwork:**

This amendment proposes no new reporting requirements; it eliminates the requirement for quarterly reporting to multiple agencies of ignition interlock use data. The proposal to extend, from two to four years, the effective period of breath analyzer supervisor permits will reduce paperwork. This amendment's emphasis on learning goals rather than course structure would allow for paperwork reduction, as recertification courses would be adaptable to online distance learning modules. The hardcopy form for requesting approval of ignition interlock devices has been deleted from the regulation, as the Department expects to post on its Web site a writeable form for electronic submission with electronic attachments, thereby further reducing paperwork. Manufacturers are encouraged to also utilize electronic means of communication for required notifications and certificate renewals.

**Duplication:**

Part 59 as amended would be consistent with, but not duplicate, federal standards for approval of breath alcohol evidentiary devices as promulgated by the NHTSA.

**Alternative Approaches:**

At the present time, there are no acceptable alternatives to pursuing adoption of the amendment as written. The major stakeholders have reached agreement that inability to move forward with the changes as proposed would likely impede DWI enforcement and successful prosecutorial activities in NYS. For example, failure to delete conflicting and superfluous requirements for blood alcohol specimen collection that have resulted in defense challenges to

the admissibility of analysis results would jeopardize law enforcement efforts to combat drunk driving, thereby adversely affecting public safety. The clarifications and updates in this amendment are required to keep the regulation current with law enforcement practices and changes to laws governing ignition interlock programs and evidence-gathering protocols related to DWI prosecutions, as well as technological advances in the devices themselves.

**Federal Standards:**

The proposed rule does not exceed any minimum standards of the federal government; it references sources for information on federally approved devices, and is consistent with federal standards for ignition interlock and breathalyzer device approval.

**Compliance Schedule:**

Regulated parties should be able to comply with these regulations effective upon publication of a Notice of Adoption in the New York State Register.

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**REGULATORY FLEXIBILITY ANALYSIS FINDING  
FOR SMALL BUSINESSES AND LOCAL GOVERNMENTS**

No Regulatory Flexibility Analysis is required pursuant to Section 202-b (3)(b) of the State Administrative Procedure Act. The proposed amendment does not impose any adverse economic impact on small businesses or local governments, and does not impose reporting, recordkeeping or other compliance requirements on small businesses or local governments.

## **RURAL AREA FLEXIBILITY ANALYSIS FINDING**

No Rural Area Flexibility Analysis is required pursuant to Section 202-bb (4)(a) of the State Administrative Procedure Act. The proposed amendment does not impose any adverse impact on facilities in rural areas, and does not impose any reporting, recordkeeping or other compliance requirements on regulated parties in rural areas.

## **JOB IMPACT STATEMENT**

A Job Impact Statement is not required because it is apparent, from the nature and purpose of the proposed rule, that it will not have a substantial adverse impact on jobs and employment opportunities.