

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))

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59.1 Definitions

(a) Techniques 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 protocols and/or instruments determined by the commissioner to be acceptable.

(b) Per centum by weight of alcohol as used in the Vehicle and Traffic Law and the 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 breath analysis instruments approved by the commissioner in accordance with section 59.4 of this Part.

(d) Training agency or agencies means the Office of Public Safety of the Division of Criminal Justice Services, the Division of State Police, the Nassau County Police Department, the Suffolk County Police Department, and/or the New York City Police Department.

(e) Commissioner means the New York State Commissioner of Health.

(f) Department means the New York State Department of Health.

(g) Ignition interlock device means any blood alcohol concentration equivalence measuring device which connects to a motor vehicle ignition system and prevents a motor vehicle from being started without first determining through a deep lung breath sample that the operator's equivalent blood alcohol level does not exceed the calibrated setting on the device as required by standards in this Part.

(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 %, % 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.

59.2 Techniques and methods for determining blood and urine alcohol.

(a) All blood and urine alcohol determinations shall be made by quantitative methods and 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 fourths of the determined concentration of alcohol in the urine shall be equivalent to the corresponding BAC; and

(2) nine tenths of the determined concentration of alcohol in the serum or plasma shall be equivalent to the corresponding 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 as appropriate; and

(2) analysis of a suitable reference sample of known alcoholic content greater than or equal to 0.08 percent weight per volume, the result of which analysis shall agree with the reference sample value within the limits of plus or minus 0.01 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.

59.3 Blood, urine and saliva alcohol analysis; permits.

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

(b) A permit for the performance of chemical analyses for blood, 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) demonstrates to the satisfaction of the commissioner 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 proficiency in the techniques and methods of analysis by correctly analyzing and reporting results, within limits of accuracy established by the commissioner, for 75 percent of the samples for each set of proficiency tests issued by the commissioner.

(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 if, for two consecutive sets of proficiency tests, the applicant or permit holder:

(1) does not meet the proficiency requirements of this section; or

(2) fails to report proficiency test results; or

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

59.4 Breath analysis instruments.

(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
Federal Register / Vol. 75, No. 47 / Thursday, March 11, 2010 / Notices

CONFORMING PRODUCTS LIST OF EVIDENTIAL BREATH MEASUREMENT DEVICES

Nonmobile	Manufacturer and model	Mobile
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/ ^{3/8} " 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
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Gall's Inc., Lexington, Kentucky:

Alcohol Detection System-A.D.S. 500	X	X
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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
Siemens-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	X	X
Stephenson Corp.:		
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).

59.5 Breath analysis; techniques and methods.

The following breath analysis techniques and methods shall be a component of breath analysis instrument operator training provided by training agencies 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 and shall be analyzed with breath analysis instruments meeting the criteria set forth in section 59.4 of this Part.

(b) The subject shall be 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 have 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 shall precede both the testing of each subject and the analysis of the reference standard.

(d) The result of an analysis of a 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. An analysis of the reference standard shall precede or follow the analysis of the breath of the subject 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.

(e) Results of an analysis of breath for alcohol shall be expressed in terms of percent weight per volume, to the second decimal place as found; for example, 0.237 percent found shall be reported as 0.23 percent.

59.6 Breath analysis permit program.

Training agencies shall submit an application for approval of a breath analysis permit program or a training program for breath analysis to the commissioner. Other agencies seeking approval of such programs shall submit an application to

the commissioner through the 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 analysis instrument operator and technical supervisor training program;
- (d) the name of the individual primarily responsible for each training program and for the breath analysis program;
- (e) the name and qualifications of one or more individuals meeting the requirements for technical supervisor under section 59.9 of this Part; and
- (f) such other information as the commissioner shall require.

59.7 Breath analysis operator permits.

(a) A permit valid for two years shall be issued by the commissioner to breath 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 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 techniques and methods, including a functional description and a detailed operational description of the breath analysis instrument(s) with a demonstration;
- (3) five hours of instruction on the legal aspects of chemical tests generally, and of the particular 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) six hours of laboratory participation using approved breath analysis instruments and simulators, or other reference standards;
- (6) a passing 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 seeking certification.

(b) A permit as a breath analysis instrument operator shall be renewed for a two-year period, provided that, within the 120 calendar days preceding the permit's expiration date, the operator: completes a retraining program that minimally includes an instructional course in breath analysis 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 on each breath analysis instrument for which the operator is seeking permit renewal; and attains a passing score on a formal examination; 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, a written declaration

that the operator has performed six or more breath analyses on subjects in accordance with this Part on each breath analysis instrument for which the operator is seeking permit renewal during the 24 months 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.

59.8 Revocation or suspension of permits.

(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 analysis instrument(s) for which they hold a permit.

(b) The operator's permit may be revoked by the commissioner based on information acquired by the commissioner, or a training agency, that the operator does not conduct breath tests in accordance with techniques and methods 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.

(d) An operator whose permit has been suspended by the training agency may appeal to the commissioner who shall decide whether suspension shall be

affirmed or set aside. The commissioner may reinstate the permit of the operator making such appeal under such conditions as the commissioner deems necessary.

(e) An operator whose permit has been revoked shall not be eligible for a new permit within 12 months from the date of revocation or at such other time as may be determined by the commissioner.

59.9 Technical supervisor; qualifications and certification.

(a) The commissioner may authorize certification of an applicant as technical supervisor for a period of 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 breath analysis 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 (one hour); and

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

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

(b) A technical supervisor's certificate may be terminated by the commissioner based on documented evidence that the technical supervisor's performance is not in keeping with the best interests of the breath alcohol testing program.

(c) A technical supervisor shall have responsibility for:

(1) breath analysis instrument operator training, competency evaluation, and periodic examination to ensure maintenance of technical knowledge and proficiency;

(2) maintenance, including calibration of breath 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) periodic inspection of breath analysis instrument performance

(d) A technical supervisor's certificate may be renewed for a period of 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.

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.

59.11 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.

59.12 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."