

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))

Title: Section 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.

Title: Section 59.10 - Certification criteria for ignition interlock devices

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.

Title: Section 59.11 - Testing of ignition interlock devices

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.

Title: Section 59.12 - Continued ignition interlock device certification

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."