Canadian Society of Forensic Science
La Société canadienne des sciences judiciaires

Canadian Society of Forensic Science Alcohol Test Committee Equipment Standards and Evaluation Procedures

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Introduction

The Canadian Society of Forensic Science (CSFS) established a "Special Committee on Breath Testing" in 1967 to study scientific, technical and law enforcement aspects of breath tests for alcohol[1]. The Society believed it was important to emphasize that the determination of blood alcohol concentrations (BACs) by means of breath tests is a scientific process and, for that reason, must be performed according to proper scientific practices and standards established by scientists with specific knowledge of the subject. With this focus, the CSFS Committee developed recommended procedures for the performance of breath tests as well as minimum standards for training police officers in the use of the equipment, for the administration of a breath test program and for the materials to be used with the equipment. These standards were published in the CSFS Journal in December 1969, coincident with the introduction of the so-called "Breathalyzer" laws in Canada (1).

Because of these initial contributions to the development of a high standard of practice, the widely recognized expertise of the Society and the members of the Committee, the Department of Justice invited the CSFS Committee (which became known as the Breath Test Committee) to be its principal scientific advisor on matters related to breath testing, a function that has continued to the present. Over many years, the Breath Test Committee kept abreast of advancements in breath test technology, changes in *Criminal Code* legislation and various issues surrounding breath testing. Some highlights include the introduction of road-side screening devices, the advent of automated breath test equipment, mobile breath testing and provisions to demand blood samples. The latter demonstrated the broadening interests of the Committee, and its name was changed to Alcohol Test Committee (ATC) in 1985.

In the past, the Recommended Standards and Procedures of the Canadian Society of Forensic Science Alcohol Test Committee were published as a single document. Previous publications (1-14), track updated versions of standards and procedures over a period spanning more than 50 years. To provide better clarity the recommendations of the Committee have been separated into 3 documents:

1. Canadian Society of Forensic Science Alcohol Test Committee Recommended Operational Procedures. This document addresses recommended procedures for the operational use of Approved Instruments, Approved Screening Devices and Approved Containers.

2. Canadian Society of Forensic Science Alcohol Test Committee Recommended Best Practices for a Breath Alcohol Testing Program. This document addresses recommendations on the roles and qualifications of key personnel involved in the administration of a breath test program as well as

[1] The unmodified word alcohol refers to ethyl alcohol.

recommendations regarding training, inspections, maintenance, modifications and physical factors.

3. Canadian Society of Forensic Science Alcohol Test Committee Equipment Standards and Evaluation Procedures. This document addresses equipment, materials and equipment evaluation procedures.

Current members of the ATC are:

M. Rosland, Surrey, BC (Chair)
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G. Huppé, Montreal, QC (Secretary)
C. Frenette, Ottawa, ON
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M. Brisson, Ottawa, ON
J. Motard, Montreal, QC

Department of Justice Liaison:

M. Boyle, Ottawa, ON

ATC Archivist:

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Past members of the Committee are:

K. Ackland
A.K. Bergh
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J.P. Robitaille
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A.E. Wells
W. Westenbrink
J.G. Wigmore
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2. The Breath Test Committee of the Canadian Society of Forensic Science. Can. Soc. Forensic Sci. J. 1977; 10: 135-138.

3. Breath Testing Standards. Can. Soc. Forensic Sci. J. 1980; 13: 38-41.

4. Recommended Standards and Procedures of the Canadian Society of Forensic Science Alcohol Test Committee. Can. Soc. Forensic Sci. J. 1986; 19(3): 164-222.

5. Recommended Standards and Procedures of the Canadian Society of Forensic Science Alcohol Test Committee. Can. Soc. Forensic Sci. J. 1995; 28(1): 1-25.

6. Recommended Standards and Procedures of the Canadian Society of Forensic Science Alcohol Test Committee. Can. Soc. Forensic Sci. J. 1998; 31(4): 205-231.

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8. Recommended Standards and Procedures of the Canadian Society of Forensic Science Alcohol Test Committee. Can. Soc. Forensic Sci. J. 2009; 42(1): 1-29.

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10. Canadian Society of Forensic Science Alcohol Test Committee Equipment Standards and Evaluation Procedures, Can. Soc. Forensic Sci. J. 2014; 47(4): 200-213.

11. Canadian Society of Forensic Science Alcohol Test Committee Equipment Standards and Evaluation Procedures. Effective date: 2015 September 30. Published on-line at https://www.csfs.ca/.

12. Canadian Society of Forensic Science Alcohol Test Committee Equipment Standards and Evaluation Procedures. Effective date: 2018 December 18. Published on-line at https://www.csfs.ca/.

13. Canadian Society of Forensic Science Alcohol Test Committee Equipment Standards and Evaluation Procedures. Effective date: 2021 September 27. Published on-line at https://www.csfs.ca/.

14. Canadian Society of Forensic Science Alcohol Test Committee Equipment Standards and Evaluation Procedures. Effective date: 2023 April 20. Published on-line at https://www.csfs.ca/.

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OVERVIEW

A key component to any quality assurance program is confidence in the equipment used to conduct or facilitate an analysis. The Alcohol Test Committee establishes standards and procedures that ensure reliability and reproducibility in breath test equipment as well as containers used for blood alcohol analysis. These standards and procedures are in keeping with new developments in science, technology and the law. This document contains the requirements for the ATC to evaluate instruments, screening devices and blood alcohol containers. Requirements for all alcohol standards used for breath testing equipment are also specified.

I. EQUIPMENT STANDARDS AND EVALUATION PROCEDURES

The *Criminal Code* defines three types of equipment for alcohol testing: "Approved Instrument", "Approved Screening Device" and "Approved Container".

All equipment presented for evaluation shall be commercially available production units. Where the manufacturer produces equipment variations, through significant modifications of integral components and functions, the equipment presented for evaluation shall be clearly identified by a model designation. Manufacturers should provide a precise set of specifications including schematic drawings for the equipment being evaluated and any associated systems. Detailed operating instructions shall be supplied with each piece of equipment.

These procedures are recommended for determining the capability of instruments, devices and containers to meet the appropriate Alcohol Test Committee standards. Not all requirements are applicable to every evaluation; however, each applicable requirement shall be addressed by either the manufacturer or evaluator, where appropriate, and commented on in the evaluation.

The ATC reserves the right to publish or otherwise make public the data resulting from a successful evaluation of equipment that leads to the approval by the Attorney General of Canada. The ATC will submit any such manuscript or release to the manufacturer for comment prior to publication or release to ensure that no proprietary information is included.

General Guidelines

1. Manufacturers must indicate their intention to submit equipment for evaluation by December 31st of any given calendar year for consideration in the following calendar year. The ATC reserves the right to consider submissions at additional times.

2. Before an evaluation for approval is commenced, the manufacturer shall provide to the Chair of the ATC (or persons designated by the Chair) the following, where applicable:

   a) two identical units with the same specific software/firmware version that will be retained by the ATC; the instruments and devices so submitted must be calibrated according to a blood:breath ratio of 2100:1;

   b) documentation confirming that the equipment complies with generally recognized safety requirements (e.g. Canadian Standards Association (CSA), Conformité Européenne (CE), Underwriter Laboratories (UL), etc);

   c) sufficient details pertaining to the theory and operation of the equipment to allow proper evaluation, e.g., operator's manual, administrator/supervisor's manual, calibration procedures, and any precautions that should be observed in the use of the equipment (if any proprietary information is provided it will be held confidential by the Committee). Technical support and training by the manufacturer may be requested;

   d) documentation confirming that RFI/EMI (radio frequency/electro-magnetic interference) testing was conducted on the submitted equipment;

   e) sufficient identification of the equipment to distinguish it by name from other equipment;

   f) confirmation that the units provided for evaluation are commercially available production units;

   g) instruments and screening devices provided by the manufacturer must be capable of using both wet bath and dry gas alcohol standards. The manufacturer must supply:

      i) all the accessory equipment required for their proper use (e.g. True-Cal device, barometer, gas tank regulator, grommet, tubing, water-trap, etc)
      ii) at least two dry gas alcohol standards (with Certificate of Analysis (CoA))
      iii) device or procedure necessary to determine the target value of the dry gas alcohol standard.

   h) adequate mouthpieces to complete the evaluation.

3. Both submitted instruments or screening devices will be assessed against each standard individually.

4. The Committee will review all assessments and test results and issue a final report.

5. Wet bath alcohol standards used in the evaluation shall be verified by headspace gas chromatography prior to use, unless accompanied by a Certificate of an Analyst from a Canadian Forensic Laboratory.

6. Any Approved Instrument used for comparison purposes shall be shown to meet the requirements of Approved Instrument standard 5 at 100 mg/100 mL[2] (Section I.A(5)). Using these data, the mean and the percentage by which the mean differs from the target value must be calculated and included in the report.

7. Where a single non-recirculating simulator is used to provide vapours of known concentration, its contents shall be changed after a maximum of sixteen deliveries or 7 days, whichever occurs first. Where a recirculating simulator or a tandem non-recirculating simulator is used, its contents shall be changed after a maximum of fifty deliveries or 15 days, whichever occurs first.

8. The calibration of instruments and screening devices shall be checked prior to, and at the conclusion of, the evaluation of each standard where analytical data are generated.

9. Where more than one procedure or mode of operation is possible, the evaluator shall use the procedure or mode that would normally be employed in breath testing operations in Canada. The mode used in the evaluation will be subject to comment by the Committee and clearly identified in any recommendation for approval.

10. Where the experimental results for one standard satisfy the requirements of another standard, duplication of testing is not required.

11. Where numerical results are not required to evaluate a standard, reasonable inference may be drawn from the manufacturer's literature or other available information and the standard need only be confirmed to the extent possible by general observation or examination.

12. Instruments shall have the capability of producing a permanent record and electronically storing that record to allow for later retrieval.

13. Instruments and devices shall be designed with security features to protect the integrity of the data and to restrict access to certain functions.

14. Instruments shall be capable of performing an automated testing sequence.

[2] mg/100 mL = milligrams of alcohol per 100 millilitres of blood

A. Approved Instruments

"Approved Instrument" means an instrument that is designed to receive and make an analysis of a sample of a person's breath to determine their blood alcohol concentration and that is approved by the Attorney General of Canada under paragraph 320.39(c) of the *Criminal Code*.

1. **Instruments shall comply with generally recognized safety requirements.**

   Instruments that have been approved by an electrical safety certification body recognized in Canada shall be deemed to meet the requirements for this standard.

2. **Instruments shall be capable of having their calibration checked with both a wet bath and dry gas alcohol standard. Instruments shall be capable of determining the target value of the dry gas alcohol standard utilizing barometric pressure.**

   Standards 5 and 6 will reflect this capability.

3. **Instruments shall be capable of performing a system blank test (i.e. a test of the instrument's breath sampling and detection systems, and of the ambient air). In this test, instruments shall indicate interference when contaminants contribute to an apparent blood alcohol concentration (BAC) by more than 10 milligrams in 100 millilitres of blood (mg/100 mL).**

   This standard shall be evaluated by purging the instrument with vapours containing the equivalent of an apparent BAC of 0, 10 and 20 mg/100 mL. The vapours shall be introduced by a simulator with the instrument in the blank analysis mode. A series of fifteen tests shall be conducted at each concentration, with each simulator sample preceded by a normal purge. The instrument calibration shall be checked (results within 5 mg/100 mL of the target value) before and after each series of tests.

   The instrument shall indicate interference in each test at the 20 mg/100 mL apparent BAC. The results at the 0 and 10 mg/100 mL apparent BAC shall be subject to interpretation by the Committee. The Committee shall comment on the results of the tests in conjunction with the theory of the blank analysis mode. (Note: If the instrument provides numerical values for a blank analysis and gives proper readings with the 0 and 10 mg/100 mL vapours, it is not necessary to purge with a 20 mg/100 mL vapour. If no response is given at vapours up to 10 mg/100 mL, then testing at 20 mg/100 mL is required.)

4. **Substances which are produced endogenously and are present in the breath shall not contribute to the apparent BAC by more than 10 mg/100 mL.**

   a) Tests on ten alcohol-free human subjects shall not yield a result greater than 10 mg/100 mL.

   b) In addition, the following solutions shall be tested using a simulator maintained at 34.0 ± 0.2ºC:

- acetone 5 mg/100 mL
- acetone 20 mg/100 mL
- methanol 5 mg/100 mL
- isopropanol 10 mg/100 mL
- acetone 5 mg/100 mL in combination with ethanol 121 mg/100 mL
- acetone 20 mg/100 mL in combination with ethanol 121 mg/100 mL
- methanol 5 mg/100 mL in combination with ethanol 121 mg/100 mL
- isopropanol 10 mg/100 mL in combination with ethanol 121 mg/100 mL

In a series of ten tests on each of the solutions, instruments shall yield results in which any contribution to the apparent BAC is no more than 10 mg/100 mL. Tandem simulators shall be used to deliver the appropriate samples through the breath pathway. A purge shall be run between each test. A calibration check shall be conducted before each series of ten tests.

5. **When vapours of known alcohol concentration in the range corresponding to BACs from 50 to 350 mg/100 mL are analyzed, the mean result of thirty consecutive analyses at each concentration in the range shall be within the greater of 5% or 5 mg/100 mL of the target value and the precision shall be:**

   a) at concentrations of 100 mg/100 mL or less, the standard deviation shall not exceed 3 mg/100 mL, and

   b) at concentrations greater than 100 mg/100 mL, the coefficient of variation shall not exceed 2.5%.

   Testing shall be conducted using the alcohol standard pathway on aqueous alcohol standards with target values at or near alcohol concentrations corresponding to BACs of 50, 100, 150, 250 and 350 mg/100 mL. If the instrument does not allow for the simulator to be connected in a recirculation pathway, tandem simulators shall be used. The instrument calibration shall be checked (results within 5 mg/100 mL of the target value) before and after each series of tests at a given concentration. The instrument shall not be recalibrated while evaluating this standard.

   Since this standard tests for linearity of response as well as accuracy and precision, test results at all five concentrations shall meet the requirements of this standard.

6. **When a dry gas alcohol standard with a nominal value between 70 and 120 mg/100 mL is analyzed by the instrument, the mean result of thirty consecutive analyses shall be within the greater of 5% or 5 mg/100 mL of the target value and the precision shall be:**

   a) at concentrations of 100 mg/100 mL or less, the standard deviation shall not exceed 3 mg/100 mL, and

b) at concentrations greater than 100 mg/100 mL, the coefficient of variation shall not exceed 2.5%.

The dry gas alcohol standard shall be kept at ambient room temperature and used within the temperature range specified by the manufacturer.

7. The results of a minimum total of fifty analyses using no fewer than ten human subjects with BACs in the approximate range of 30 to 150 mg/100 mL shall be at least as accurate and precise as the results of near-simultaneous tests with an Approved Instrument.

A 30-minute wait period should be observed after the end of the last drink, assuring subjects are in a post-absorptive phase. The subjects shall have BACs distributed across the approximate range of 30 to 150 mg/100 mL. Breath samples shall be collected on each instrument near-simultaneously (approximately 1 minute apart). There shall be five replicate results per subject. All tests shall be recorded to the nearest 1 mg/100 mL. There shall be at least 5 minutes between each pair of tests and the time of each sample collection shall be reported.

Calibration of each instrument shall be checked after not more than five pairs of results. If a calibration check on either instrument is not within 5 mg/100 mL of the target value, all tests since the last satisfactory calibration check shall be rejected. If either instrument is recalibrated during the testing of this standard, calculate the new percent difference of the mean by conducting a minimum of five alcohol standard tests (performed at the time of calibration).

The data developed in these tests shall be analyzed and reported as outlined in the Addendum to this procedure. Where this statistical analysis indicates a difference between the results with the test instrument and those with the Approved Instrument, the results obtained in tests for standard 5 may be considered and the Committee may express an opinion as to which instrument showed greater accuracy and precision.

Additional Testing:

If an instrument is equipped to measure sampling parameters, detect mouth alcohol, RFI and/or other disturbances, or actuate any other automated error check(s), the function of these checks shall be investigated. Where third party testing has been performed according to recognized testing standards (e.g. OIML R 126) the results of such testing shall be brought to the attention of the Committee who shall review these results and determine whether further testing is required.

If additional testing is required, the evaluator shall provide breath samples to trigger various error messages (e.g. shallow blows, intermittent samples, mouth alcohol, etc.) as deemed necessary to evaluate the sampling parameters. To evaluate instrument response to RFI, this test shall be conducted by transmitting from a portable radio, of the type, power, and frequency used in police operations, approximately one meter from the device while taking a subject test.

To account for differences in instrument design, the evaluator will document the testing procedure and subsequent responses either by keeping a copy of the printout or recording results displayed. These results shall be subject to interpretation by the Committee.

The Committee reserves the right to perform additional testing as required.

Addendum
Statistical Analysis of Results Obtained for Instrument Evaluation Standard 7

1. Approved Instrument
   a) Using the data reported as required under General Guideline 5, calculate the mean result. Calculate the percentage by which the mean differs from the target value.
   b) Correct the data obtained with the Approved Instrument by the percentage calculated in 1a.

2. Test Instrument
   a) Calculate the percent difference of the mean from the target value using the 100 mg/100 mL data from standard 5.
   b) Correct the data obtained with the test instrument by the percent calculated in 2a.

3. If either instrument is recalibrated before or during the tests, calculate the new percent difference of the mean from the results of at least five Alcohol Standard tests (performed at the time of calibration).

4. Report both corrected and uncorrected values.

5. Group the corrected data in tabular format under the following headings: "Subject Number", "Time of Sampling - A" (Approved Instrument = A), "Results - A", "Time of Sampling - B" (Test instrument = B), and "Results - B".

6. Group subject data individually in a second table. Every subject must have the same number of replicate results. For each subject list data under the headings: "Results - A", "Results - B", and "Difference A-B= Y_{A-B}". Calculate $\bar{y}_n$ = mean of the differences for each subject, e.g. for subject 1, $\bar{y}_1 = \Sigma Y_{A-B} / r_1$ and for subject 2, $\bar{y}_2 = \Sigma Y_{A-B} / r_2$, where r_1 ,r_2 , r_n = the number of replicates per subject.

7. Calculate the following:
   a) $\bar{d}$ = mean of the Y_n differences
      $= \frac{\Sigma Y_n}{n}$
      where n = number of subjects

   b) s = standard deviation of n observations (subjects)

$$= \sqrt{\frac{\sum(Y_n - \bar{d})^2}{n-1}}$$

c) C.I. = the confidence interval at the 99% level

$$= \bar{d} \pm t_{n-1,.005} \ \frac{s}{\sqrt{n}}$$

where $t_{n-1,.005}$ is the Student's one-sided table value t with n-1 degrees of freedom and level α = .005. If the calculated C.I. is entirely contained within the interval -10 mg/100 mL to +10 mg/100 mL, then one may have confidence at the 99% level that the interval covers the true mean difference between the two Instruments and that this true mean difference is less than 10 mg/100 mL in magnitude.

B. Approved Screening Devices

"Approved Screening Device" means a device that is designed to ascertain the presence of alcohol in a person's blood and that is approved by the Attorney General of Canada under paragraph 320.39(a) of the *Criminal Code*.

1. **Screening devices shall comply with generally recognized safety requirements.**

   Screening devices which have been approved by an electrical safety certification body recognized in Canada shall be considered as meeting this standard.

2. **Screening devices shall be capable of displaying results in two modes, either separately or combined on the screen:**
   a. **a fully digital mode, and**
   b. **a mode which is capable of indicating whether a person's BAC is less than a specified BAC, between the specified BAC and 100 mg/100 mL or more than 100 mg/100 mL (e.g., digital, warn, fail).**

   The standard shall be evaluated by visual inspection and by reviewing the results of Standards 11 and 13.

3. **Screening devices shall be battery operated and equipped with a low battery indicator.**

   This standard shall be confirmed by visual inspection and/or review of the information provided by the manufacturer.

4. **Screening devices shall indicate when a suitable breath sample has been provided.**

This standard shall be evaluated by referring to the description provided by the manufacturer. Observations made with actual breath samples shall be made to verify the information provided by the manufacturer.

5. **Screening devices shall be capable of indicating a result within approximately one minute and shall be capable of proper operation within approximately five minutes of completion of the previous test.**

   This standard will be evaluated by referring to the results of Standard 11.

6. **Screening devices shall be capable of having their calibration checked with both a wet bath and dry gas alcohol standard.**

   Standards 13 and 14 will reflect this capability.

7. **Screening devices shall maintain calibration for at least 31 days from the last calibration.**

   This standard shall be evaluated by calibrating the screening device, verifying the calibration, and subsequently checking the calibration at least 31 days later (e.g., a device calibrated on December 1st would be checked on January 1st). The device shall not be used during this period. This standard is met if the result of the calibration check is within the greater of 5% or 5 mg/100 mL of the target value.

8. **Screening devices shall not be adversely affected by cold temperature conditions normally encountered during screening device operation in Canada.**

   This standard tests whether the device can be used in a low temperature environment. The following evaluation procedure shall be conducted with the screening device being operated according to the manufacturer's operating instructions. The calibration of the screening device shall be verified at room temperature prior to testing. The final calibration check will be performed after the device has been kept at room temperature for at least 30 minutes.

   Ten tests shall be conducted at 100 mg/100 mL with the screening device in digital mode. There shall be an interval of approximately five minutes between tests.

   The screening device shall be kept at approximately 5°C for a minimum of one hour prior to testing and throughout the testing procedure. The simulator will be used in normal operating conditions and not placed in the refrigerator. Once the screening device is ready for sampling, the device shall be briefly removed from the refrigerator and a simulator sample provided. Once result has been obtained, the screening device shall be returned to the refrigerator.

   This standard is met if the mean result is within 5% of the target value and the standard deviation

shall not exceed 3 mg/100 mL.

9. **Screening devices shall not be adversely affected by radio frequency interference (RFI).**

   This test shall be conducted by transmitting from a portable radio, of the type, power, and frequency used in police operations, approximately one metre from the device while performing a breath test on an alcohol free subject and separately with a 100 mg/100 mL standard.

10. **A test of alcohol-free breath shall not produce an apparent BAC of more than 10 mg/100 mL.**

    Ten subjects with alcohol-free breath shall be tested. To meet this standard, all breath samples shall produce a result of 10 mg/100 mL or less.

11. **When vapours of known alcohol concentration are analyzed, corresponding to 10 mg/100 mL greater than and 10 mg/100 mL less than each specified BAC, screening devices shall indicate correct results in at least 90% of a minimum of ten tests at each concentration.**

    This standard shall be tested with the screening device in a mode which is capable of indicating whether a person's BAC is less than a specified BAC, more than 100 mg/100 mL, or between the specified BAC and 100 mg/100 mL (e.g., digital, warn, fail).

    The screening device shall be tested with alcohol standards 10 mg/100 mL above and 10 mg/100 mL below each of the specified BACs. The alcohol standards shall be run alternately (e.g., 40, 60, 40, 60 and 90, 110, 90, 110), not more than 5 minutes apart. Calibration shall be checked and, if necessary, adjusted after every 20 tests.

12. **The results of a minimum total of thirty analyses using no fewer than five human subjects with BACs in the approximate range of 30 to 120 mg/100 mL shall be in good agreement with the results of near-simultaneous tests with an Approved Instrument.**

    This standard shall be evaluated with the screening device in fully digital mode. A 30-minute wait period should be observed after the end of the last drink, assuring subjects are in a post-absorptive phase. Subjects should have a BAC in the approximate range of 30 to 120 mg/100 mL. A breath sample on an Approved Instrument shall be collected within approximately one minute of the test with the screening device. The time of each sample collection shall be reported.

    Calibration shall be checked after not more than five pairs of results. If a calibration check on either instrument/device is not within 5 mg/100 mL of the target value, all tests since the last satisfactory calibration check shall be rejected.

    This standard is met if the percentage of results in good agreement is 90% or greater. For this

standard, good agreement is defined as a screening device result that is **within the greater of 10 % or 10 mg/100 mL** of the result obtained using the Approved Instrument.

13. **When vapours of known alcohol concentration corresponding to BACs of 40, 100, and 150 mg/100 mL are analyzed, the mean result of 15 consecutive analyses at each concentration shall be within the greater of 5 % or 5 mg/100 mL of the target value and the precision shall be:**
    a. **at concentrations of 100 mg/100 mL or less, the standard deviation shall not exceed 3 mg/100 mL, and**
    b. **at concentrations greater than 100 mg/100 mL, the coefficient of variation shall not exceed 2.5%**

    This standard shall be evaluated with the screening device in fully digital mode. Aqueous alcohol standards corresponding to BACs of approximately 40, 100, and 150 mg/100 mL shall be used. Consecutive tests shall be conducted not more than five minutes apart at each concentration tested.

    The calibration of the screening device shall be verified prior to, and after each set of concentrations tested.

14. **The screening device shall be capable of analyzing a dry gas alcohol standard with a nominal value between 70 and 120 mg/100 mL. The mean result of 15 consecutive analyses shall be within the greater of 5% or 5 mg/100 mL of the target value and the precision shall be:**

    a. **at concentrations of 100 mg/100 mL or less, the standard deviation shall not exceed 3 mg/100 mL, and**

    b. **at concentrations greater than 100 mg/100 mL, the coefficient of variation shall not exceed 2.5%.**

    A dry gas alcohol standard supplied by the manufacturer with a nominal value between 70 and 120 mg/100 mL at sea level shall be used. The dry gas alcohol standard shall be kept at ambient room temperature and used within the temperature range specified by the manufacturer. The target concentration of the dry gas alcohol standard shall be determined as per the manufacturer's instructions.

C. Approved Containers (Blood Samples)

The *Criminal Code* describes an "Approved Container" for blood samples. "Approved Container" means a container that is designed to receive a sample of a person's blood for analysis and that is approved by the Attorney General of Canada under paragraph 320.39(d) of the *Criminal Code*.

1. **Containers shall be capable of receiving and preserving a sample of blood.**

   This standard shall be evaluated by general examination of the container and the documentation provided by the manufacturer.

2. **Containers shall be identified by type with a conspicuous marking including manufacturer and unique code.**

   This standard shall be evaluated by general examination of the container.

3. **Containers shall be made of glass with an inert stopper and shall have a capacity of not less than 7 mL.**

   This standard shall be evaluated by general examination of the container and the documentation provided by the manufacturer.

4. **Containers shall be capable of being sealed with a tamper-resistant seal.**

   This standard shall be evaluated by general examination of the container and the documentation provided by the manufacturer.

5. **Evacuated containers shall be sterile in accordance with the appropriate regulations of the Medical Devices Regulations of the Food and Drugs Act and shall be labeled with an expiry date beyond which the required vacuum is no longer warranted by the manufacturer.**

   This standard shall be evaluated by general examination of the container and the documentation provided by the manufacturer.

6. **Containers shall contain sodium fluoride as a preservative in sufficient quantity to produce a final concentration of 1.00 (± 0.15) %w/v when filled. They shall also contain potassium or sodium oxalate as an anticoagulant in an amount sufficient to produce a final concentration of 0.20 (± 0.03) %w/v when filled.**

   Ten containers shall be filled with water and the contents dissolved. The fluoride and oxalate concentrations shall be determined by an appropriate procedure approved by the Committee. The results shall be expressed as percentages w/v. Each tube shall meet the standard.

7. **Containers shall be capable of being packaged to withstand the rigors of transport by postal and courier services in Canada.**

   This standard shall be evaluated by general examination of the container and the documentation provided by the manufacturer.

II. MATERIALS

These specifications are intended for the assistance of manufacturers and purchasers.

A. Alcohol Standards

1. An aqueous solution shall contain 121 ± 3 milligrams of ethyl alcohol per 100 millilitres of solution (wet bath).

2. A gaseous solution of anhydrous ethyl alcohol in an inert gas in a pressurized container (dry gas), when analyzed, shall produce a result of ± 5% of the target value in parts per million. The target value is the manufacturer's nominal value in parts per million adjusted for barometric pressure.

3. The manufacturers of alcohol standards, accredited to the international standard for calibration and testing laboratories (ISO 17025), shall make an analysis of the alcohol standard. Alternatively, the manufacturer may have an independent laboratory which is accredited to ISO 17025 make an analysis of the alcohol standard.

III. Modification of Approved Instruments or Screening Devices

Following the initial designation of Approved Instruments or Approved Screening Devices, manufacturers may make improvements or modifications to the approved equipment for various purposes such as software updates, replacement of a part that is out of production, improvement of technology etc. The procedures to verify that a modified instrument or device continues to meet the testing requirements of the ATC standards were previously described (15) and are detailed below.

General Guidelines

1. If manufacturers decide to upgrade or modify their equipment, they shall notify the Chair of the ATC of the proposed changes to the equipment.

2. The manufacturers shall submit a formal request for consideration of the proposed modification(s) to the ATC, including information on the purpose of the modification(s) and technical specifications such that the impact of the proposed changes can be assessed. The Chair of the ATC, through consultation with the other members of the ATC, will classify the proposed modification(s) as Category 1, 2, or 3.

3. The Chair of the ATC will notify the Department of Justice (DOJ) of a Category 1 or 2 modification.

4. Changes to an Approved Instrument or Approved Screening Device that were not considered by the ATC will jeopardize the approval status of the equipment. The designation of an equipment with unapproved modifications may be revoked leading to the removal of the equipment from the list of the Approved Instruments/Screening Devices Order. Once the approved status of the equipment is revoked, it is recommended that the equipment not be used by police agencies in Canada.

Verification of modified Approved Instrument or Approved Screening Device

1. Modifications are classified into 3 categories, Category 1, 2, or 3.

a. Category 1:
Category 1 modifications apply to major changes to the Approved Instrument or Approved Screening Device where the sampling protocol, measurement protocol, calibration etc. may be affected by the modification. For example, replacement of a detector or an alteration on components that may affect the analytical performance of the equipment would be deemed a Category 1 modification. A full evaluation of the modified equipment is required for Category 1 modifications to ensure the equipment continues to meet the standards as set out in Part I Equipment Standards and Evaluation Procedures following the modification. The manufacturer shall provide two new identical units with the same specific software/firmware version that will be retained by the ATC for a full re-evaluation. The changes are documented by the ATC.

b. Category 2:
Category 2 modifications apply to changes to components that are material to the sampling pathway, measurement system, or any other operationally significant part of the equipment. These may include:

2.1 Hardware e.g. breath tube, sampling valves.
2.2 Software/firmware changes that modify calibration, sampling results, etc.
2.3 Other changes that may affect the performance of the equipment.

A partial evaluation of the modified equipment is required for Category 2 modifications. The evaluation may involve testing a specific standard(s) as set out in Part I Equipment Standards and Evaluation Procedures or testing as required by the ATC. The Committee will decide which appropriate tests or standards need to be evaluated. The manufacturer shall provide one new unit with the same specific software/firmware version that will be retained by the ATC for a partial re-evaluation. The changes are documented by the ATC.

c. Category 3:
Category 3 modifications apply to minor changes manufacturers make to update and improve the usability of their equipment. These may include:

3.1 Hardware: internal or external components not expected to impact calibration/results e.g.

power supply to the instrument, Wi-Fi, Bluetooth, GPS, modems, printer drivers, etc.

3.2 Software/firmware changes not expected to impact calibration/results e.g. customized software for specific data capture such as driver's license information.

3.3 Other changes that are not expected to impact calibration/results.

As Category 3 modifications do not affect the analytical performance of the equipment, no re-evaluation is required, and the changes are documented by the ATC.

2. Modifications to external components that are not fundamental to the actual breath analysis of the approved equipment do not require review by the ATC. Examples of such external components may include breath simulators, mouthpieces, external printers, external computers, carrying cases, power cords, etc.

3. The ATC may upgrade the modification to a higher category should further testing be required based on the initial re-evaluation.

4. Once the ATC has completed the re-evaluation on Category 1 or 2 modifications and determined the modification(s) has not changed the original performance, the Chair of the ATC will advise the DOJ and the manufacturer of the results. If the analytical performance of the equipment is unaffected by the modification(s), the equipment remains as an Approved Instrument or Approved Screening Device. For Category 3 modifications, as no re-evaluation is required, the Chair of the ATC will advise the manufacturer that the modified equipment remains as an Approved Instrument or Approved Screening Device.

5. In the event where the modified equipment fails the re-evaluation, the Chair will advise the DOJ and the manufacturer of the findings. The manufacturer may 1) change the modification and re-submit the equipment for consideration or 2) forsake any change to the original approved equipment in order to maintain its original designation.