CANADIAN SOCIETY OF FORENSIC SCIENCE
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Alcohol Test Committee - Comité des analyses d'alcool

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

Effective: 2015 September 30

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 this 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 (1-9), track updated versions of standards and procedures over a period spanning more than 40 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

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

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 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:

T. C. Cherlet, Edmonton, AB (Chair)
D. J. Mayers, Toronto, ON (Vice Chair)
K. L. Blake, Edmonton, AB
A. Dion, Montreal, QC
P. M. Harding, Madison, WI
R. M. Langille, Toronto, ON
T. L. Martin, Toronto, ON
V. M. Mendes, Vancouver, BC
B. K. Wong, Ottawa, ON

Department of Justice Liaison: H. Pruden, Ottawa, ON
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Past members of the Committee are:
K. Ackland
A.K. Bergh
W.D. Bowthorpe
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F.J.E. Comeau
L. Dehaut
S.M. Elves
E.J. Fennell
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B.T. Hodgson
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R.A. Pon
R.T. Prokopanko
J.P. Robitaille
L.C. Van Berkom
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.

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7. Recommended Standards and Procedures of the Canadian Society of Forensic Science Alcohol Test Committee. Can. Soc. Forensic Sci. J. 2003; 36(3): 101-127.

8. Recommended Standards and Procedures of the Canadian Society of Forensic Science Alcohol Test Committee. Can. Soc. Forensic Sci. J. 2009; 42(3): 1-61.

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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 full evaluation of instruments, screening devices and blood alcohol containers as well as specific requirements for all alcohol standards used for breath testing equipment.

I EQUIPMENT

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 shall provide a precise set of specifications including schematic drawings for the equipment being evaluated and any associated systems. Actual performance data purporting to satisfy the following standards shall be provided by the manufacturer. Detailed operating instructions shall be supplied with each piece of equipment.

A. Approved Instruments

"Approved Instrument" means an instrument of a kind that is designed to receive and make an analysis of a sample of the breath of a person in order to measure the concentration of alcohol in the blood of that person and is approved as suitable for the purposes of Section 258 by order of the Attorney General of Canada [Subsection 254 (l)].[2]

1. Instruments shall comply with generally recognized safety requirements.

2. Instruments shall be capable of having their calibration checked with both an aqueous and gaseous alcohol standard. Instruments shall be capable of determining the target value of the gaseous alcohol standard.

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).

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

[2]Sections and Subsections refer to the Criminal Code as of 2014.

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 ±5% 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%.

6. The results of a minimum total of fifty analyses using no fewer than ten human subjects with BACs in the approximate range of 50 to 150 mg/100 mL shall be at least as accurate and precise as the results of near-simultaneous similar tests with an Approved Instrument.

B. Approved Screening Devices

"Approved Screening Device" means a device of a kind that is designed to ascertain the presence of alcohol in the blood of a person and that is approved for the purposes of this section by order of the Attorney General of Canada [Subsection 254(l)].

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

2. Screening devices shall be capable of indicating, within approximately one minute, whether a person's BAC is less than a specified BAC, more than a second greater specified BAC, or intermediate between the two specified BACs.

3. Screening devices shall not indicate numerical results above the lower specified BAC referred to in standard 2. They shall indicate numerical results at or below the lower specified BAC.

4. Screening devices shall have a greater specified BAC set at 100 mg/100 mL.

5. Battery operated screening devices shall be equipped with a low battery indicator.

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

7. Screening devices shall be capable of proper operation within approximately five minutes of completion of the previous test.

8. It shall be possible to monitor the calibration of the screening device with an alcohol standard.

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

10. Screening devices shall be capable of having their calibration checked with both an aqueous and gaseous alcohol standard.

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

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

13. A test of alcohol free breath shall not yield an incorrect result. Tests of alcohol free breath shall not contribute to an apparent BAC by more than 10 mg/100 mL.

14. When vapours of known alcohol concentration are analyzed, corresponding to 10 mg/100 mL greater than and 10 mg/100 mL less than the specified BAC, screening devices shall indicate correct results in at least 95% of a minimum of thirty trials at each concentration.

15. The results of a minimum total of thirty analyses using no fewer than five human subjects with BACs across the approximate range of the lower to the upper specified BACs shall produce correct results in at least 95% of the trials when compared with near simultaneous breath samples on an Approved Instrument.

16. When vapours of known alcohol concentrations are analyzed, at least fourteen out of fifteen analyses shall be within ±5% of the target value during a calibration check.

C. Approved Containers (Blood Samples)

The Criminal Code describes an "Approved Container" for blood samples. "Approved Container" means a container of a kind that is designed to receive a sample of the blood of a person for analysis and is approved as suitable for the purposes of Section 258 by order of the Attorney General of Canada [Subsection 254(1)].

1. Containers shall be capable of receiving and preserving a sample of blood for an analysis for alcohol.

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

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

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

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.

6. Containers shall contain sodium fluoride as a preservative in sufficient quantity to produce a final concentration of l.00 (±0.15) %w/v when filled. They shall also contain potassium or sodium oxalate or citrate as an anticoagulant in an amount sufficient to produce a final concentration of 0.20 (±0.03) %w/v when filled.

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

II MATERIALS

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

A. Alcohol Standards

l. An aqueous solution shall contain 121 ± 3 milligrams of ethyl alcohol per 100 millilitres of solution.

2. A gaseous solution of anhydrous ethyl alcohol vapour in an inert gas in a pressurized container shall produce a result of ±5% of the target value in parts per million. The target value is the manufacturer's stated 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 EQUIPMENT EVALUATION PROCEDURES

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. They are intended only as guidelines for the members of the ATC and may not necessarily be followed in every evaluation. Modifications may be necessary depending on the specific instrument, device, or container.

General Guidelines

l. 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:

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 where applicable;

c. sufficient details to allow proper use of the equipment, including any specific analytical procedures required and any precautions that should be observed in the use of the equipment;

d. performance data relating to the appropriate ATC standards;

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

f. all details pertaining to the theory and operation of the equipment other than those the manufacturer can justify as being proprietary. These details shall be sufficient to allow evaluators to identify potential malfunctions which could adversely affect the results. (If any proprietary information is provided it will be held confidential by the Committee);

g. confirmation that the units provided for evaluation are commercially available production units;

h. instruments and screening devices provided by the manufacturer must be capable of using a dry gas alcohol standard and must be accompanied by any required plumbing or adaptors necessary for its use with the instrument/device, and dry gas alcohol standards as required.

i. adequate number of mouthpieces to complete the evaluation.

2. Each evaluator shall comment on each standard and each standard shall be considered separately.

3. All test results shall be reported. Results which the Committee considers to be inappropriate may be rejected; the reason for doing so shall be included in the final report. If, in a series of five or more measurements, a single measurement differs from the mean of the others by more than four times their average deviation, it may be rejected as discordant data.

4. Any alcohol standard used in the evaluation shall meet the ATC recommended specifications (II Materials, A. Alcohol Standards). Sufficient alcohol standard of the same batch of each alcohol standard used shall be available to complete the testing.

5. Any Approved Instrument used for comparison purposes shall be shown to meet the requirements of Approved Instrument standard 5 at 100 mg/100 mL. Using these data, the mean and the percentage by which the mean deviates from the target value must be calculated and included in the report.

6. Where a non-recirculating simulator is used to provide vapours of known concentration, its contents shall be changed after not more than sixteen deliveries. Where a recirculating simulator is used, its contents shall be changed after not more than fifty deliveries.

7. 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 evaluators and clearly identified in any recommendation for approval.

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

9. 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.

Individual Standards

A. Approved Instruments

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. Instruments which have not been so approved shall be reasonably inspected for potential safety hazards. If there is no apparent safety hazard, the instrument shall be deemed to meet this standard.

2. Instruments shall be capable of having their calibration checked with both an aqueous and gaseous alcohol standard. Instruments shall be capable of determining the target value of the gaseous alcohol standard.

Standard 5 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 evaluators 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.**

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

   In addition, the following solutions shall be tested using a simulator maintained at $34.0 \pm 0.2^{o}C$:

   a. aqueous acetone solutions of 5, 10 and 50 mg/100 mL acetone;

   b. aqueous solutions containing alcohol (to give an apparent BAC of approximately 100 mg/100 mL) which also contain the acetone concentrations listed in (a).

   In a series of fifteen tests on each of the solutions containing 5 and 10 mg/100 mL acetone, instruments shall yield results in which the acetone does not contribute to the apparent BAC. A purge, or an alcohol standard and a purge, shall be run between each test to simulate field operation. Test results on solutions containing alcohol shall be interpreted by allowing for variations permitted under standard 5. Instruments sensitive to acetone but designed to detect interference by acetone shall indicate interference in all tests on solutions containing 50 mg/100 mL acetone. Instruments which are purported to not be sensitive to acetone may be tested with the 50 mg/100 mL acetone vapour first, and if there is no resultant effect, no further testing at the lower concentrations is required.

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 ± 5% 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 instrument shall be set up and calibrated (or checked for calibration) according to the manufacturer's operating instructions. If a calibration solution is required and the alcohol concentration is not specified by the manufacturer, an alcohol standard corresponding to a BAC of 100 mg/100 mL shall be used. If the calibration tolerance is not specified by the manufacturer, the calibration shall be adjusted so that results with the calibration solution are approximately evenly distributed around the target value (a minimum of five tests shall have a mean that is not more than ±2.5% from the target value).

Testing shall be conducted on alcohol standards with target values at or near alcohol concentrations corresponding to BACs of 50, 100, 150, 250 and 350 mg/100 mL. The instrument shall not be recalibrated between tests in a series at any given concentration. Discordant data may be rejected as outlined in the General Guidelines. 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.

If the instrument has an internal system for the input of the alcohol standard, which follows a different path from that followed by a breath sample, the evaluator shall conduct tests to determine if there is a significant difference. A minimum of thirty comparisons shall be made with a 100 mg/100 mL alcohol standard using the normal breath pathway and the internal alcohol standard pathway.

Tandem simulators shall be used to deliver the appropriate samples through the breath pathway (ABA testing) in order to increase the saturation of the vapour.

The instrument shall be capable of producing the proper expected result with a gaseous alcohol standard, and the mean result of thirty consecutive analyses shall be within ±5% of the target value, and the precision shall be as stated in 5a or 5b above. The dry gas alcohol standard shall be kept at ambient room temperature and used within the temperature range specified by the manufacturer.

6. The results of a minimum total of fifty analyses using no fewer than ten human subjects with BACs in the approximate range of 50 to 150 mg/100 mL shall be at least as accurate and precise as the results of near-simultaneous similar tests with an Approved Instrument.

The subjects shall be in the post-absorptive phase and shall have BACs distributed across the approximate range of 50 to 150 mg/100 mL. Breath samples shall be collected on each instrument near-simultaneously (approximately 1 minute apart)

with the first of each pair alternating between instruments. 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 at least as frequently as required by the manufacturer's specifications or 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.

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 evaluators 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 that was displayed. These results shall be subject to interpretation by the Committee.

The descriptive information provided by the manufacturer shall be reviewed. If specific mention is made of particular sensitivity to compounds including volatile substances other than ethyl alcohol, these shall be tested at concentrations that might reasonably be encountered in a breath sample. If the theory of operation of the instrument suggests potential problems with this standard, the evaluators shall seek comments from other members of the Committee with respect to appropriate tests. Tests shall then be designed by the evaluators to determine if the potential problem substances may contribute to a BAC reading.

Addendum

Procedure for Statistical Analysis of Results Obtained for Standard 5 for Approved Instruments

l. Approved Instrument

a. Using the data reported as required under General Guideline 5, calculate the mean result. Calculate the percentage by which the mean deviates from the target value.

b. Correct the data obtained with the Approved Instrument for standard 5 by the percentage calculated in 1.a.

2. Test Instrument

a. Calculate a percentage deviation 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 percentage calculated in 2.a.

3. If either instrument is recalibrated before or during the tests, calculate the new percentage deviation 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)

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

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 $\alpha = .005$. 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

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. Screening devices which have not been so approved shall be reasonably inspected for potential safety hazards. If there is no apparent safety hazard, the device shall be deemed to meet this standard.

2. Screening devices shall be capable of indicating, within approximately one minute, whether a person's BAC is less than a specified BAC, more than a second greater specified BAC, or intermediate between the two specified BACs.

The basic requirement of this standard is that the screening device has the necessary means for indicating the range of BACs. The standard shall be evaluated by visual inspection and by reviewing the results for standards 14 and 15. It is not necessary to evaluate the accuracy of the BAC reporting mechanism for this standard.

3. Screening devices shall not indicate numerical results above the lower specified BAC referred to in standard 2. They shall indicate numerical results at or below the lower specified BAC.

This standard shall be confirmed by visual inspection.

4. Screening devices shall have a greater specified BAC set at 100 mg/100 mL.

This standard is met if it can be shown that the screening device is capable of calibration at 100 mg/100 mL. It is not necessary to check the calibration performance in this standard.

5. Battery operated screening devices shall be equipped with a low battery indicator.

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

6. **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. Confirmation that a mechanism exists for indicating a suitable sample and that it appears to accomplish the purpose shall be achieved with actual breath samples. It is not necessary to check the accuracy of this mechanism for this standard. (Standard 15 will reflect whether the mechanism for indicating a suitable sample is accurate.)

7. **Screening devices shall be capable of proper operation within approximately five minutes of completion of the previous test.**

   This standard requires that, as a minimum, the screening device is capable of proper operation each time two tests are conducted approximately five minutes apart. The evaluation shall be performed by conducting ten successive tests not more than five minutes apart.

   These tests shall be done with alternating alcohol standards 10 mg/100 mL above and 10 mg/100 mL below the upper specified BAC (i.e. 90, 110, 90, 110 mg/100 mL).

8. **It shall be possible to monitor the calibration of the screening device with an alcohol standard.**

   This standard is met if the screening device is capable of being checked with an alcohol standard. (Standard 16 will reflect this capability).

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

   This standard shall be evaluated by calibrating the screening device, waiting 31 days, and then checking the calibration on that date. The device shall not be used in this 31 day period.

10. **Screening devices shall be capable of having their calibration checked with both an aqueous and gaseous alcohol standard.**

    Standard 16 will reflect this capability.

11. **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. This standard shall be evaluated by testing the device in a refrigerator.

Twenty tests shall be conducted to evaluate this standard. Alcohol standards corresponding to 15 mg/100 mL above and 15 mg/100 mL below the upper specified BAC shall be used. Ten tests shall be conducted at each level. There shall be an interval of approximately five minutes between tests.

The screening device shall be kept at approximately 5^{o}C for a minimum of one hour prior to testing and throughout the testing procedure. The simulator shall be kept at room temperature. Once the screening device is ready for sampling, the device shall be briefly removed from the refrigerator. A sample is provided from the simulator at room temperature. Once a sample has been accepted by the device, the screening device shall be returned to the refrigerator.

This standard is met if the percentage of correct results is 90% or greater.

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

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 metre from the device while taking a reading.

13. A test of alcohol free breath shall not yield an incorrect result. Tests of alcohol free breath shall not contribute to an apparent BAC by more than 10 mg/100 mL.

Ten subjects with alcohol-free breath shall be tested. To meet this standard, all breath samples shall provide a proper result on the screening device. A proper result for this standard is no more than 10 mg/100 mL.

14. When vapours of known alcohol concentration are analyzed, corresponding to 10 mg/100 mL greater than and 10 mg/100 mL less than the specified BAC, screening devices shall indicate correct results in at least 95% of a minimum of thirty trials at each concentration.

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

15. **The results of a minimum total of thirty analyses using no fewer than five human subjects with BACs across the approximate range of the lower to the upper specified BAC shall produce correct results in at least 95% of the trials when compared with near simultaneous breath samples on an Approved Instrument.**

    The subjects shall be in the post-absorptive phase and should have a BAC in the approximate range of 30 to 120 mg/100 mL. A near-simultaneous 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.

    This standard is met if the percentage of correct results is 95% or greater. Correct results are defined as results that correspond within the tolerances of the Approved Screening Device and the Approved Instrument.

16. **When vapours of known alcohol concentrations are analyzed, at least fourteen out of fifteen analyses shall be within +/- 5% of the target value during a calibration check.**

    This standard ensures that a screening device produces accurate results during a calibration check using both an aqueous and gaseous alcohol standard.

    The calibration of the screening device shall be verified prior to any testing and adjusted, if necessary.

    An aqueous alcohol standard corresponding to a BAC of 100 mg/100 mL shall be used.

    A gaseous alcohol standard supplied by the manufacturer with a target value of 100 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 with an appropriate accessory device (e.g. TrueCal) capable of determining the target value from the stated value in mg/100 mL.

    This standard is met if at least fourteen out of fifteen consecutive analyses are within +/- 5% of the target value.

C. Approved Containers (Blood Samples)

1. **Containers shall be capable of receiving and preserving a sample of blood for an analysis for alcohol.**

    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 such as**

manufacturer and unique code.

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

3. **Containers shall be made of glass or plastic 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 or citrate 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 or citrate 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.