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

Effective: 2018 December 18

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]The unmodified word alcohol refers to ethyl alcohol.

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 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:

D. J. Mayers, Toronto, ON (Chair)
V. M. Mendes, Vancouver, BC (Vice Chair)
T. C. Cherlet, Edmonton, AB
P. M. Harding, Madison, WI
G. Huppé, Montreal, QC
T. L. Martin, Toronto, ON
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J. Tremblay, Montreal, QC
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Department of Justice Liaison: H. Pruden, Ottawa, ON
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Past members of the Committee are:

K. Ackland
A.K. Bergh
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R.T. Prokopanko
J.P. Robitaille
L.C. Van Berkom
A.E. Wells
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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.

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.

9. Recommended Standards and Procedures of the Canadian Society of Forensic Science Alcohol Test Committee. Can. Soc. Forensic Sci. J. 2013; 46(1): 1-50.

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 www.csfs.ca.

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.

General Guidelines

1. 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 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). Training by the manufacturer may be requested;

d. documentation pertaining to any RFI/EMI (radio frequency/electro-magnetic interference) testing 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 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;

h. adequate 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.

4. Aqueous alcohol standards used in the evaluation shall be verified by headspace gas chromatography prior to use.

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 (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.

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. 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.

8. 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.

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

10. 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.

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).[2]

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 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 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.)

[2]Sections and Subsections refer to the Criminal Code as of December 18, 2018.

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 aqueous solutions shall be tested using a simulator maintained at 34.0 ± 0.2°C:
   - 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 gaseous alcohol standard with nominal value of 100 mg/100 mL is analyzed by the instrument, the mean result of thirty consecutive analyses shall be within ± 5 mg/100 mL of the target value and the standard deviation shall not exceed 3 mg/100 mL.

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.

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 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
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 for standard 5 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)

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

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

"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).

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 being operated in a fully digital mode and 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.

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 an aqueous and gaseous 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 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.

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 5ºC 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 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. 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 95% or greater. For this standard, good agreement is defined as a screening device result that is within 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 gaseous alcohol standard with a nominal value of 100 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 standard deviation shall not exceed 3 mg/100 mL.

A gaseous alcohol standard supplied by the manufacturer with a nominal 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.

B. 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).

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.

2. A gaseous solution of anhydrous ethyl alcohol in an inert gas in a pressurized container, 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.