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RECOMMENDED STANDARDS AND PROCEDURES OF THE CANADIAN SOCIETY OF FORENSIC SCIENCE ALCOHOL TEST COMMITTEE

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 (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. Previous publications [2-7], track the updated versions of the *Standards and Procedures* over a period spanning 40 years.

As in the past, this publication focuses on the two major roles of the Alcohol Test Committee. The first concerns standards that new instruments, screening devices or containers must meet. As well these standards provide recommended evaluation procedures and guidelines by which evaluations will be performed. This ensures that any new equipment which requires approval within the Criminal Code, not only meet rigid specifications, but that the manner in which evaluation occurs is consistent.

The second major role is to provide standards and procedures for the implementation and use of approved instruments and screening devices. This encompasses comprehensive recommendations in training, maintenance and operation, as well as providing recommendations on the roles and qualifications of key personnel involved in the administration of a breath test program.

1. The unmodified word alcohol refers to ethyl alcohol.

In the development of standards and procedures for a breath-testing program, and to facilitate interpretation, it must be recognized that units of breath testing equipment are scientific instruments used for scientific measurements. The only difference is that breath test instruments are operated in a setting different from the traditional laboratory conditions. Nevertheless, the primary goal of these standards and procedures is to provide a quality system which considers the interests of the criminal justice system. Where necessary and appropriate, limitations of operating in a non-laboratory environment are considered.

These standards are consistent with established quality assurance principles used in other scientific measurements. It must be recognized, however, that consistent with other quality assurance practices, all standards do not necessarily have a direct bearing on the result, only on the overall quality system that is in place. As such, the standards and procedures contained herein are intended as recommendations to encourage the development of a quality system or best practices within a breath test program. They are not to be considered as required elements of proof additional to those already provided in the Criminal Code.

This version of the *Recommended Standards and Procedures* is in keeping with new developments in science, technology and the law. The ATC will continue to anticipate changes, monitor developments and act accordingly.

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TABLE OF CONTENTS

STANDARDS

I EQUIPMENT

The *Criminal Code of Canada* defines four types of equipment for tests for alcohol, "Approved Instrument", "Approved Screening Device", "Approved Container" (breath samples) and "Approved Container" (blood samples).

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].

l. Instruments shall comply with generally recognized safety requirements in Canada.

2. 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).

3. 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.

4. 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%.

5. 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.

2. Sections and Subsections refer to the *Criminal Code of Canada* as of July 2, 2008.

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 may indicate numerical results at or below the lower specified BAC.
4. Screening Devices shall be capable of having the greater specified BAC set at 50 mg/100 mL, 120 mg/100 mL or a value intermediate between these two.
5. Battery operated Screening Devices shall be equipped with a low battery indicator.
6. Screening Devices shall indicate when an unsuitable 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 Devices with an Alcohol Standard.
9. Screening Devices shall maintain calibration for at least two weeks when not in use.
10. Screening Devices shall not be adversely affected by cold temperature conditions normally encountered during Screening Device operation in Canada.
11. Screening Devices shall not be adversely affected by radio frequency interference (RFI).
12. A test of alcohol-free breath shall not yield an incorrect result. If numerical results are provided below the lower specified BAC, it shall not contribute to an apparent BAC by more than 10 mg/100 mL.
13. When vapours of known alcohol concentration corresponding to 10 mg/100 mL greater than, and 10 mg/100 mL less than, the specified BAC are analyzed, Screening Devices shall indicate correct results in at least 95% of a minimum of thirty trials at each concentration.
14. 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.

C. Approved Containers

The *Criminal Code* describes two types of "Approved Container", one for breath samples and one for blood samples.

"Approved Container" means:

(a) in respect of breath samples, a container of a kind that is designed to receive a sample of the breath of a person for analysis and is approved as suitable for the purposes of Section 258 by order of the Attorney General of Canada; and

(b) in respect of blood samples, 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)].

a. Breath Samples

l. Containers shall be capable of receiving, preserving and presenting for analysis, the alcohol from a specimen of deep lung breath in such a way that the result of the analysis shall not be significantly different from that obtained with an Approved Instrument.

2. Containers shall present the alcohol for analysis by a procedure or procedures generally available and accepted by the forensic science community in Canada. Where a specific analytical procedure is required, details of the procedure shall be supplied with the other documentation required of the manufacturer.

3. Where ancillary collection or delivery devices are integral parts of the Container system, they shall comply with generally recognized safety requirements.

4. Analysis of the content of Containers which have received breath specimens from alcohol-free subjects shall not yield results greater than 10 mg/100 mL of alcohol either immediately following collection or after storage.

5. Analysis of the content of Containers which have received vapours of known alcohol concentration shall yield results that are not significantly different from those obtained with an Approved Instrument.

6. Containers shall meet the requirements of standard l after being subjected to transport by postal and courier services in Canada.

b. Blood Samples

l. 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 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 as a preservative sodium fluoride in sufficient quantity to produce a final concentration of 1.00 (± 0.15) %w/v when filled. They shall also contain an anticoagulant potassium or sodium oxalate or citrate in an amount sufficient to produce a final concentration of 0.20 plus or minus 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. Acceptance of a lot or batch of a "material" shall not necessarily require or imply that each of the specifications has been confirmed.

A. Alcohol Standards

1. An aqueous solution which contains ethyl alcohol in such a concentration that, at a specified temperature, the vapour in equilibrium with the solution will produce a specified result with a properly calibrated Approved Instrument. Solutions of different concentrations from those outlined below may be used provided that the concentration is within ± 3 milligrams of ethyl alcohol per 100 millilitres of the required concentration unless otherwise specified.

   a. For use with an "equilibrator"*:*

      A solution to produce a result of 150 mg/100 mL at 25.0°C shall be prepared to contain 338 ± 7 milligrams of ethyl alcohol per 100 millilitres of solution.

   b. For use with a "simulator"*:*

      A solution to produce a result of 100 mg/100 mL at 34.0°C shall be prepared to 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 that will produce a specified result with a properly calibrated Approved Instrument with an accuracy of ± 2% of the Alcohol Standard's stated value in parts per million or milligrams per 100 millilitres of solution**.** A chart showing correction factors for altitude, or a device that corrects the specified result for altitude, shall be provided.

B. Breathalyzer® Ampoules

l. Ampoules

a) Shall be made of clear, colourless, chemically inert glass of a quality suitable for injectables.

b. Shall have an outside diameter of not less than 16.00 mm and not more than 16.50 mm.

c. Shall have a wall thickness of not less than 0.60 mm and not more than 0.70 mm.

2. Ampoule Contents (Potassium Dichromate Breath Test Solution)

a. The solution shall be void of precipitate or other particulate matter.

b. The volume shall be not less than 3.00 mL and not more than 3.07 mL.

c. The solution shall be prepared to contain 0.024 – 0.027%w/v potassium dichromate and 0.024 – 0.027%w/v silver nitrate in an aqueous sulphuric acid solution.

d. The solution shall have a specific gravity within ±0.005 of a specified specific gravity within the range of 1.510 to 1.540 as specified by the purchaser.

III GENERAL ADMINISTRATIVE CONSIDERATIONS

The administration of a breath test program requires close co-operation of key personnel. This includes the Program Director, Training Course Director, and Field Co-ordinators. Together it is their responsibility to ensure that the major aspects of quality breath operation are followed. Significant aspects are training for the use and/or calibration of Approved Instruments and Approved Screening Devices, compliance with recommended operational procedures as set out in the ATC Standards and Procedures and maintenance requirements of breath test equipment.

A. Program Director

The breath test program director shall be a person who, if not the Training Course Director, works in cooperation with the Training Course Director. The Program Director shall have extensive knowledge and experience in breath alcohol testing, including all scientific and technical aspects, and should be employed by a forensic laboratory.

The duties of the Program Director should include the following:

a. coordinates and monitors all activities as described in these Standards and Procedures, for all breath test programs in the province or territory;

b. implements and/or recommends breath test policies and procedures for the province or territory;

c. monitors changes and events in breath alcohol testing and takes appropriate action when warranted;

d. if not the Training Course Director, liaises with the Training Course Director on all aspects related to training;

e. liaises with field co-ordinators who control or co-ordinate activities in their respective regions.

f. ensures that ‘on-site’ examinations of authorized service centres are conducted, either personally or through a delegate.

B. Training Course Director

The Training Course Director may be the Program Director. He or she has the overall responsibility for directing all breath alcohol test courses and shall have the responsibility for recommending candidates suitable for designation as Qualified Technicians to the Attorney General of the province or territory; shall be employed in a forensic laboratory; and shall possess the following qualifications:

a. a recognized Honours degree in science or appropriate equivalent;

b. knowledge of, and experience with, the analysis for alcohol in biological specimens and the interpretation of the results;

c. knowledge of the principles of current breath test methods;

d. experience as an expert witness in this subject matter.

The Training Course Director is involved in the selection of training course resource personnel. Normally this includes suitably qualified persons from a forensic laboratory and experienced qualified technicians.

C. Field Co-ordinator

A Field Co-ordinator shall be an experienced Qualified Technician who has been approved by the Program Director:

The duties of the field co-ordinator should include the following:

a. inspect and review breath test activities in their designated region;

b. advise Qualified Technicians and others whose duties impact on breath test programs;

c. assist in the selection of trainees;

d. maintain continuous liaison with the Program Director or forensic science laboratory providing support services;

e. assist as required during training courses.

IV TRAINING AND DESIGNATIONS

Training should be provided under the direction of a forensic science laboratory in Canada.

A. Approved Instruments

1. Qualified Technicians

The *Criminal Code* requires that breath samples taken pursuant to a demand under paragraph 254(3)(a) be such that in the opinion of a qualified technician a proper analysis can be made. "Qualified Technician" in respect of breath samples means a person designated by the Attorney General as being qualified to operate an Approved Instrument [Subsection 254(1)]. The formal designation of Qualified Technicians as being qualified to operate an Approved Instrument should specify the specific model(s) of Approved Instrument(s) to which the designation applies.

Note: Section 2 of the *Criminal Code* defines "Attorney General" as "the Attorney General or Solicitor General of a province and includes his lawful

deputy". For the Northwest Territories, the Yukon Territory, and Nunavut, "Attorney General" means the Attorney General of Canada and includes his lawful deputy.

a) *Initial Qualifications of Candidates* – selection of candidates for training should be from peace officers who have:

   i) regular involvement in the enforcement of impaired driving offenses;
   ii) an interest in and an aptitude for technical aspects of law enforcement;
   iii) an ability to be an effective witness.

b. *Training Course* – Minimum Standards

   i) Appropriate theory including:
      - general scientific background information;
      - principles of breath tests for alcohol;
      - principles of the Instrument technology;
      - design and theory of operation of the Instrument, including potential interfering substances and, where applicable, status codes and error messages;
      - operational procedures for the Instrument;
      - Instrument maintenance and service (if applicable);
      - quality assurance procedures;
      - appropriate aspects of chemistry, physics, physiology and pharmacology;
      - appropriate information on alcohol, drugs and traffic safety;
      - appropriate aspects of law, evidence and testimony.

   ii Practical training including:
      - testing standard alcohol solutions and other volatile substances;
      - quality assurance and maintenance procedures;
      - screen and error messages;
      - performing at least thirty breath tests on a minimum of ten drinking subjects;
      - procedures for the processing of drinking drivers;
      - evidence presentation.

   iii. Written and practical examinations.

2. Conversion Training

Before Technicians who are qualified to operate a specific model(s) of Approved Instrument(s) are designated as qualified to operate a different model of Approved Instrument, the Program Director or Training Course Director must determine that they are so qualified. In making this determination, the Program Director may decide that the difference between the models is not sufficient to require a formal training course. If the Program Director determines that a conversion training course is required, the course shall be under the supervision of the Training Course Director and shall contain the following elements:

a) *Training Course* – Minimum Standards

   i. Appropriate Theory including:
      - review of the principles of breath tests for alcohol;

- appropriate aspects of chemistry and physics;
- principles of the Instrument technology;
- design and theory of operation of the Instrument, including potential interfering substances and, where applicable, status codes and error messages;
- operational procedures for the Instrument;
- Instrument maintenance and service;
- quality assurance procedures;
- appropriate aspects of law, evidence and testimony.

ii Practical training including:

- testing standard alcohol solutions and other volatile substances;
- quality assurance and maintenance procedures;
- performing 15 breath tests on a minimum of three drinking subjects;
- screen and error messages;
- evidence presentation.

iii. Written and practical examinations

3. Proficiency Testing of Qualified Technicians

Each breath test program shall have a process to determine the proficiency of all qualified technicians on an annual basis. If proficiency is not demonstrated, a Technician must successfully complete refresher training before resuming activity as a Qualified Technician.

4. Refresher Training

Qualified Technicians who have not been actively engaged in testing for more than twelve months, or who have failed to demonstrate competence during their annual proficiency review, shall undergo refresher training. The duration of this training and its supervision shall be at the discretion of the Training Course Director. The course shall include a review of all appropriate elements of the initial training course, including demonstration of independent operational competence of the candidates.

5. Authority to Revoke Designation

The Program Director should have the authority to recommend that a Qualified Technician's designation be revoked.

B. Approved Screening Devices

The *Criminal Code* does not specify any particular designation or qualifications for users of Approved Screening Devices other than that they be peace officers [Subsection 254(2)]. Nevertheless, some training is essential and standards are recommended herein for two types of personnel:

1. Screening Device Calibration Technicians
2. Screening Device Users

l. Screening Device Calibration Technicians

a. *Initial Qualifications* – shall be a screening device user, and a Qualified Technician or possess equivalent relevant training.

b. *Training* – shall be under the control of the Training Course Director.

c. *Training Course Instructors* – shall be persons who have appropriate scientific knowledge and experience in breath alcohol testing and are authorized for this purpose by the Training Course Director.

d. *Training Course* – Minimum Standards.

i. Appropriate Theory including:
- principles of calibration;
- review of the principles of breath tests for alcohol;
- blood alcohol absorption and elimination curves;
- principles of mouth alcohol absorption;
- interfering substances and false positive readings;
- design and theory of operation of the appropriate Screening Device(s);
- appropriate aspects of law and evidence.

ii. Practical training including:
- basic operation procedure(s);
- use of accessories;
- calibration procedure with appropriate Alcohol Standards;
- performing five calibration procedures;

iii. Instruction on the field use of the Screening Device(s) including:
- storing, handling and transporting;
- frequency of calibration;
- battery recharging and/or replacement procedure;
- maintenance and repair;
- operational trouble-shooting;
- use of data forms and calibration logs;
- department policy.

iv Written and/or practical examinations

2. Screening Device Users

a. *Initial Qualifications* – shall be peace officers engaged in general law enforcement and/or traffic law enforcement.

b. *Training* – shall be provided by persons who are authorized for this purpose by the Training Course Director.

c. *Training Course Instructors* – shall be Qualified Technicians and Screening Device Calibration Technician.

d. *Training Course* – Minimum Standards.

i. Appropriate Theory including:
- principles of breath tests for alcohol;
- principles of mouth alcohol absorption;
- interfering substances and false positive readings;
- significance of Screening Device readings as compared with Approved Instrument results;
- appropriate aspects of law and presentation of evidence;

- department policy including frequency of battery recharging and/or replacement, frequency of calibration, and use of data forms and logs.

ii. Practical training including:
- basic operation procedure(s);
- use of accessories;
- sampling techniques;
- performing breath tests on human subjects to develop the proper technique for collection of breath samples;
- storing, handling and transporting.

iii. Written and/or practical examinations.

V MAINTENANCE AND MODIFICATIONS

Proper calibration and/or calibration check procedures are the primary means of assuring accuracy of the Approved Instrument, Approved Screening Device and accessory equipment at the time of use. Calibration of Approved Instruments shall be done with a wet-bath simulator. In addition to these calibrations and/or calibration checks, formal maintenance procedures are essential to the integrity of the breath test program.

A. Inspections

All Approved Instruments, Approved Screening Devices and accessory equipment intended for active use in the program shall be individually inspected before being placed into service, and periodically thereafter, to ensure that they initially meet, and continue to meet, the manufacturer's specifications. The recommended interval between inspections is one year. All inspections shall be performed by persons deemed by the Program Director to meet the qualifications described in paragraph V.C. below. Accessory equipment includes simulators, equilibrators or other equipment required for the use or calibration of Approved Instruments and Approved Screening Devices.

The Program Director shall be responsible for ensuring that an on-site audit of the facility and competencies of staff have been completed before authorizing a service centre to perform maintenance.

B. Field Maintenance

In addition to periodic inspections some Instruments and Devices may require additional preventative maintenance, which may be performed at the field level by suitably trained individuals. If applicable, the Program Director shall develop a protocol for such maintenance, appropriate to the Approved Instrument, Approved Screening Device or accessory equipment.

C. Qualifications of Authorized Service Personnel

The Program Director shall ensure that persons performing preventative maintenance and/or periodic inspections on Approved Instruments, Approved Screening Devices and accessory equipment have:

a. Appropriate training in the maintenance of all components of the respective Approved Instruments, Approved Screening Devices and accessory equipment.

b. Detailed manuals for the procedures necessary to determine that the Approved Instruments, Approved Screening Devices and accessory equipment are in proper working order and continue to meet the manufacturer's specifications.

D. Modifications

Any modification to Approved Instruments or Approved Screening Devices must be approved by the Alcohol Test Committee. Installation of approved modifications shall be performed only by persons authorized by the Program Director. Following any modification, the equipment shall not be returned to active use in the program until it has successfully passed the equivalent of an initial inspection.

E. Maintenance Logs

A maintenance log shall be kept for each Approved Instrument, Approved Screening Device and accessory equipment in active use in the program. Logs should include the results of all inspections, documentation of the maintenance history including records of parts replaced and approved modifications to hardware or software.

PROCEDURES

I OPERATIONAL PROCEDURES

A. Approved Instruments

Before an Approved Instrument is placed into service at a location, a Qualified Technician must ensure that the location is adequate for effective secure operation and has adequate ventilation. There must be sufficient space for the Approved Instrument, the simulator/equilibrator/dry gas Alcohol Standard cylinder, the Qualified Technician, the test subject and, if required, one observer. The Qualified Technician must also ensure that the power supply is adequate for the proper operation of the Approved Instrument, and that the Instrument is surge-protected.

l. The subject shall not have consumed or placed alcohol (or any other substance that may interfere with the test) in the mouth for at least fifteen minutes prior to the collection of a breath sample.

2. A system blank test shall be conducted and shall give a reading not greater than 10 mg/100 mL.

3. A system calibration check shall be conducted within the range of 50 to 200 mg% and shall give a reading within ±10 mg/100 mL of the expected reading with an Alcohol Standard.

   a. Where an equilibrator is used for the calibration check, it shall be protected from drafts and the temperature of the Alcohol Standard shall be such that it results in a target concentration that is within the range of 50 to 200 mg/100 mL. The standard solution shall furthermore be within +/-2°C of the ambient temperature. The use of a portion of a batch/lot of Alcohol Standard in an equilibrator shall not exceed seven days or sixteen calibration checks, whichever occurs first.

   b. Where a simulator is used for the calibration check, the temperature of the Alcohol Standard shall be within the range of 33.8 to 34.2 degrees C. The

use of a portion of a batch/lot of Alcohol Standard in a simulator with a non-recirculating system shall not exceed seven days or sixteen calibration checks, whichever occurs first. For a simulator with a recirculating system, use shall not exceed fifteen days or 50 calibration checks, whichever occurs first.

c. Where a dry gas ethyl alcohol standard is used for a calibration check, the cylinder shall be kept at a stable ambient room temperature and used only within the acceptable temperature range specified by the manufacturer. The dry gas ethyl alcohol standard shall not be used at a cylinder regulator gauge pressure below a pressure specified by the manufacturer.

d. Any alcohol standard, aqueous or gaseous, used for a calibration check or for comparison purposes, shall not be used past its expiry date.

4. Readings for the blank and calibration checks shall be recorded to the nearest milligram and shall not be truncated.

5. Two samples of deep lung breath collected at least fifteen minutes apart shall be tested.

   a. Readings of breath tests shall be truncated before being reported.

   b. If the reported results of two tests differ by more than 20 mg/100 mL, a third sample should be collected and tested.

   c. If more than two samples of breath are necessary for a "proper analysis" as specified in the *Criminal Code*, a certificate of a Qualified Technician should not be tendered into evidence; the Qualified Technician should present *viva voce* testimony.

6. During performance of breath tests, no radio transmissions shall be made from the room in which the Approved Instrument is being operated.

Addendum - Mobile or Remote Location Use

Some Approved Instruments have designs which permit their use in mobile operations (e.g. in vans or vessels), or in isolated locations not served by a conventional public power supply. Before any Approved Instrument is used in such a location, the Program Director must obtain written confirmation from the manufacturer that the Instrument design permits such operation. In addition, information about any special requirements for mobile or remote use shall be obtained. Any agency proposing to institute such a program must develop data which satisfies the Program Director that the Instrument will meet the standards for an Approved Instrument under the specific conditions and environment expected.

The following additional procedures apply to mobile and, as appropriate, remote use of Approved Instruments:

7. In mobile operations, the Instrument shall, if required by its design, be securely fitted to an appropriate bench or counter.

8. If necessary, an auxiliary power supply may be used to operate the Instrument. A voltage monitor may be desirable, depending on the design of the Approved Instrument.

9. A wet bath simulator or dry gas alcohol standard shall be used in mobile operations.

10. Before operation is commenced at a location, the instrument's operating conditions shall be stabilized. Acceptable blank and system calibration checks must be obtained.

B. Approved Screening Devices

l. The calibration of the Approved Screening Device shall be checked by a Screening Device Calibration Technician with an Alcohol Standard at least every 31 days.

   a. Where a simulator is used for the calibration check, the temperature of the Alcohol Standard shall be within the range of 33.8 to 34.2 degrees C. The use of a portion of a batch/lot of Alcohol Standard in a simulator shall not exceed seven days or sixteen calibration checks, whichever occurs first.

   b. Where a dry gas ethyl alcohol standard is used for a calibration check, the cylinder shall be kept at a stable ambient room temperature and used only within the acceptable temperature range specified by the manufacturer. The dry gas ethyl alcohol standard shall not be used at a cylinder regulator gauge pressure below a pressure specified by the manufacturer.

   c. Any alcohol standard, aqueous or gaseous, used for a calibration check or for comparison purposes, shall not be used past its expiry date.

   d. During the calibration check, the result shall give a reading within ± 5 mg/100 mL of the expected reading with an Alcohol Standard. If the result falls outside of this range, the Approved Screening Device must be re-calibrated.

2. Appropriate steps shall be taken to restrict access to the calibration adjustment by anyone other than a Screening Device Calibration Technician.

3. The results of the calibration check shall be recorded in an appropriate log which shall be available to users of the Screening Device.

4. Units with rechargeable batteries shall be charged according to the manufacturer's recommendations.

5. If the Screening Device is battery operated, a battery check shall be part of the test procedure.

6. A check to determine that the Screening Device is ready to receive a sample shall be conducted before the subject is tested.

7. A test on a subject shall not be conducted until at least fifteen minutes after the time the subject states alcohol has last been consumed.

8. The Screening Device shall be operated according to the manufacturer's recommendations.

C. Approved Containers (Breath Samples)

This section is reserved for a procedure to be recommended at such time as a Container for breath samples may be approved.

D. Approved Containers (Blood Samples)

l. Approved Containers shall be stored in a sealed package until presented for use.

2. Samples shall be venous blood and shall be taken from the subject only by a Qualified Medical Practitioner or a Qualified Technician (in respect of blood samples), in accordance with recognized medical procedures.

   Note: "Qualified Medical Practitioner" means a person duly qualified by provincial law to practice medicine. "Qualified Technician" (in respect of blood samples) means any person or class of persons designated by the Attorney General as being qualified to take samples of blood for the purposes of Sections 254, 256 and 258 [Subsection 254(1)].

3. If a swab is used to clean the puncture site, it shall not contain ethyl alcohol.

4. Blood samples should be stored under refrigeration (approximately 4°C) at all times that it is practicable to do so. Access shall be limited to authorized persons only. The expiry refers to the date beyond which the required vacuum is no longer warranted by the manufacturer.

II 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. data confirming that the equipment complies with generally recognized safety requirements in Canada**;**

   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 provided by the manufacturer that are capable of using a dry gas alcohol standard must be accompanied by any required plumbing or adaptors necessary for its use with the instrument, and dry gas alcohol standards as required.

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 (as per Standards, II Materials, A. Alcohol Standards). Sufficient Alcohol Standard of the same batch of each Alcohol Standard used shall be available to complete the testing. All other reagents and solutions shall meet the requirements specified by the manufacturer of the equipment.

5. Any Approved Instrument used for comparison purposes shall be shown to meet the requirements of Approved Instrument Standard 4 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 inferences 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 Instrument

1. Instruments shall comply with generally recognized safety requirements in Canada

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 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.)

3. 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 twenty 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 ± 0.2 degrees 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 4. 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 be not sensitive to acetone may be tested with the 50 mg% acetone vapour first, and if there is no resultant effect, no further testing at the lower concentrations is required.

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 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.

4. 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.

If the Instrument is also capable of using a dry gas ethyl alcohol standard to check its calibration, the instrument shall be capable of producing the proper expected result, and the mean result of 30 consecutive analyses shall be within +/- 5% of the target value, and the precision shall be as stated in 4a. or 4b. above.

5. 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 - 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 at least five replicate results per subject. All tests shall be recorded to the nearest 1 mg/100 mL (by estimation if necessary). 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 4 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 with software/hardware to measure sampling parameters, detect RFI and/or mouth alcohol, or actuate any other automated error check(s), the function of these checks shall be investigated and tested by the Evaluator(s) to see whether the appropriate response is produced.

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 metre 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 ticket or recording what was displayed. These results shall be subject to interpretation by the Committee.

Addendum

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

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 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 4.
    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 $\overline{y}_n$ = mean of the differences for each subject, e.g. for subject 1, $\overline{y}_1 = \Sigma Y_{A–B}/r_1$ and for subject 2, $\overline{y}_2 = \Sigma Y_{A–B}/r_2$, where r_1, r_2, r_n = the number of replicates per subject.
7. Calculate the following:
   a. $\overline{d}$ = mean of the Y_n differences

      $$= \frac{\Sigma Y_n}{n}$$

      where n = number of subjects

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

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

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

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

      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

l. Screening Devices shall comply with generally recognized safety requirements in Canada.

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 13 and 14. 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 may indicate numerical results at or below the lower specified BAC.**

   This standard shall be confirmed by visual inspection.

4. **Screening Devices shall be capable of having the greater specified BAC set at 50 mg/100 mL, 120 mg/100 mL or a value intermediate between these two.**

   This standard is met if it can be shown that the Screening Device is capable of calibration at 50, 100 and 120 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 breath sample is unsuitable.**

   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 14 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 after 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 (e.g. 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 13 will reflect this capability).

9. **Screening Devices shall maintain calibration for at least two weeks from the last calibration when not in use.**

   This standard shall be evaluated by calibrating the Screening Device, waiting two weeks, and then checking the calibration.

10. **Screening Devices shall not be adversely affected by cold temperature conditions normally encountered during Screening Device operation in Canada.**

    The Screening Device shall be calibrated at room temperature. The following evaluation procedure shall be conducted with the Screening Device being operated according to the manufacturer's operating instructions and maintained between tests as it would in normal police practice in Canada.

    Twenty tests shall be conducted at an ambient temperature of approximately 5ºC, with Alcohol Standards corresponding to 15 mg/100 mL above and 15 mg/100 mL below the upper specified BAC. Ten tests shall be conducted at each level. There shall be an interval of approximately five minutes between tests. This standard tests whether the device can be used in a low temperature environment and can be evaluated by testing the device in a walk-in refrigerator.

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

11. **Screening Devices shall not be adversely affected by 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.

12. **A test of alcohol-free breath shall not yield an incorrect result. If numerical results are provided below the lower specified BAC, it shall not contribute 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. For Screening Devices with a digital readout capability below the lower specified BAC, a proper result for this standard is no more than 10 mg/100 mL.

13. **When vapours of known alcohol concentration corresponding to 10 mg/100 mL greater than, and 10 mg/100 mL less than, the specified BACs are analyzed, 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.

14. **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 sample 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 Screening Device and the Approved Instrument.

C. Approved Containers

a. Breath Samples

If the Container uses an independent collection system, any type of Approved Instrument may be used in the evaluation. If the Container uses an Approved Instrument as all or part of the collection system, the same Approved Instrument shall be used as the Approved Instrument required in the evaluation.

During the analysis of the contents of the Containers, appropriate Alcohol Standards shall be run regularly. Unless otherwise specified, storage of Containers shall be at room temperature.

l. Containers shall be capable of receiving, preserving and presenting for analysis, the alcohol from a specimen of deep lung breath, in such a way that the result of the analysis shall not be significantly different from that obtained with an Approved Instrument.

Tests shall be made with no fewer than ten human subjects in the post-absorptive phase who have BACs distributed across the range of 50 to 150 mg/100 mL. A total of at least fifty tests shall be performed with at least five tests on each subject. Each test sequence shall consist of an analysis with the Approved Instrument followed by the collection of a sample in each of four Containers followed by another analysis with the Approved Instrument. The samples constituting a test shall be collected within as short a period as practicable but with an interval of at least sixty seconds between each expiration. For each subject there shall be an interval of at least five minutes between each test sequence. The time of each sample collection shall be reported.

All results shall be recorded to the nearest l mg/100 mL (by estimation if necessary). The calibration of the Approved Instrument shall be checked after not more than five tests and, if it is not within ±5 mg/100 mL of the target value, all tests since the last satisfactory calibration check shall be rejected.

One Container from each test shall be analyzed as soon as possible and within twenty-four hours of collection. A second container shall be analyzed after not less than sixty days nor more than seventy days. The other two Containers from each test sequence shall be used for the evaluation of Standard 6. The Container for each analysis shall rotate between the first, second, third and fourth collected.

The data developed in these tests shall be analyzed as outlined in the

Addendum to the Procedure for Evaluation of Approved Instruments, using the average of the two Approved Instrument results for each test sequence.

2. **Containers shall present the alcohol for analysis by a procedure or procedures generally available and accepted by the forensic science community in Canada. Where a specific analytical procedure is required, details of the procedure shall be supplied with the other documentation required of the manufacturer.**

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

3. **Where ancillary collection or delivery devices are integral parts of the Container system, they shall comply with generally recognized safety requirements.**

   Containers and ancillary equipment that have been approved by an electrical safety certification body recognized in Canada shall be considered as meeting the requirement of Standard 3. Containers that have not been so approved shall be reasonably inspected for potential safety hazards. If there is no apparent safety hazard, the Container shall be considered to meet this standard.

4. **Analysis of the content of Containers which have received breath specimens from alcohol-free subjects shall not yield results greater than 10 mg/100 mL of alcohol either immediately following collection or after storage.**

   Breath samples from at least twenty alcohol-free subjects shall be collected in each of two Containers. One Container of each pair shall be analyzed within twenty-four hours of collection and the other shall be analyzed not less than sixty days nor more than seventy days following collection. No test result shall exceed 10 mg/100 mL.

5. **Analysis of the content of Containers which have received vapours of known alcohol concentration shall yield results that are not significantly different from those obtained with an Approved Instrument.**

   Containers shall be tested using Alcohol Standards with target values at or near alcohol concentrations corresponding to BACs of 50, 100 and 150 mg/100 mL. Target values shall be determined with an Approved Instrument.

   At each concentration, at least thirty tests shall be made. Each test shall consist of the collection of a sample in each of two Containers. One Container from each test shall be analyzed as soon as possible and within twenty-four hours of collection. A second Container shall be analyzed not less than sixty days nor more than seventy days following collection. The Container shall meet the requirements of this standard at all three concentrations. The data developed in these tests shall be analyzed as outlined in the Addendum to the Procedure for Evaluation of Approved Instruments.

6. **Containers shall meet the requirements of Standard 1 after being subjected to transport by postal and courier services in Canada.**

One of the Containers from each test sequence shall be individually packaged for shipping and sent by regular mail to other members of the ATC at five different locations across Canada. On receipt, these members shall collect the packages into one group and return them to the originator by commercial courier service. These Containers shall then be analyzed not less than sixty days nor more than seventy days following collection. The evaluator shall comment on the type of packaging used in shipping the Containers.

The data developed in these analyses shall be analyzed together with the data for Standard l.

To assess the effects of exposure to temperature extremes, fifteen Containers collected for the evaluation of standard 1 shall be stored in a freezer at -15º to -20ºC and another fifteen in an oven at 30º to 40ºC for seventy-two hours. They shall be allowed to return to ambient temperature before analysis. The results shall be evaluated by the Committee.

b. Blood Samples

l. 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 a preservative sodium fluoride in sufficient quantity to produce a final concentration of 1.00 (± 0.15)%^{w}/v when filled. They shall also contain an anticoagulant potassium or sodium oxalate or citrate in an amount suf-

ficient 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.