




Standards Council of Canada
Conseil canadien des normes



Guidelines for the Accreditation of Forensic Testing Laboratories

CAN-P-1578
May 2009

Program Speciality Area – Forensic Testing Laboratories (PSA-FT)

GUIDELINES FOR THE ACCREDITATION OF FORENSIC TESTING LABORATORIES

Program Specialty Area - Forensic Testing Laboratories [PSA-FT]

LIGNES DIRECTRICES RÉGISSANT L'ACCREDITATION DES LABORATOIRES JUDICIAIRES

Domaine De Spécialité De Programme – Laboratoires Judiciaires [DSP-LJ]

**CAN-P-1578
May 2009**

This document supersedes CAN-P-1578 Guidelines for the Accreditation of Forensic Testing Laboratories – May 2005

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PREFACE

Forensic Science is the application of science to the law, without distinction between civil and criminal proceedings. The Canadian Society of Forensic Science (CSFS) is incorporated to promote the study, raise the standards, and to enhance the status of forensic science as a distinct discipline. In pursuit of these goals, in March, 1994, the CSFS approved the formation of a committee to study accreditation processes available to Canadian forensic laboratories and identify the best means for them to become accredited. The SCC's primary interest is to accredit laboratories that provide analytical results of documented quality to the Canadian Courts of Law in both criminal and civil proceedings. The assurance that a laboratory adheres to recognized practices and standards can be achieved through accreditation in the Program Specialty Area - Forensic Testing (PSA-FT) using the Guidelines for the Accreditation of Forensic Testing Laboratories (CAN-P-1578), which can be applied to all types of testing performed in Canadian forensic science laboratories. The ultimate goal of an accreditation program is to enhance the reliability and the comparability of test data generated from individual laboratories. The members of this committee (see Annex A) worked with the Standards Council of Canada (SCC) to develop the following document as a framework for accreditation of forensic laboratories within Canada under the auspices of the Standards Council of Canada.

In September of 1994, the Canadian Department of Justice released a consultation paper entitled "Obtaining and Banking DNA Forensic Evidence". This document, which mentioned that the Canadian government was investigating various aspects of forensic deoxyribonucleic acid (DNA) analysis with a view to developing legislation, asked the question "should forensic laboratories conducting DNA analysis be accredited?" Despite its high profile, forensic DNA analysis constitutes only one part of the broad field of forensic science; most Canadian forensic laboratories are multidisciplinary in nature. The CSFS accreditation committee strove to ensure that the guidelines in the following document embraced the entire Canadian forensic science community and that they were in place prior to passage of legislation demanding accreditation. To ensure that they were complementary with the legislation under consideration, the CSFS Accreditation Committee augmented its membership with representatives from the CSFS DNA Advisory Committee and the Department of Justice Working Group on DNA Legislation.

The services of forensic testing laboratories in Canada are generally organized into the following divisions or sections: toxicology (drugs, alcohol and poisons), firearms and tool mark identification, questioned documents and counterfeit examinations, biology (serology and DNA), and chemistry/trace evidence analysis. These divisions of work are often referred to as forensic science "specialty areas" or "disciplines." Within a forensic testing laboratory, they may be organized as sections. The activities of forensic testing laboratories generally take place within the laboratory itself. There are, however, occasions when attendance at a (crime) scene is necessary in order to best provide the services required. In most instances, scene attendance and any evidence recognition and collection are carried out by specially trained personnel who also deal with other forms of evidence such as fingerprints, footprints, and tire prints. These evidence types may not be directly included in a Forensic Testing Laboratory.

This document was designed to meet International Organization for Standardization (ISO/IEC 17025 requirements. Rather than serving as a "stand alone" document, it was designed to harmonize with and complement the SCC document CAN-P-4E, "General Requirements for the Accreditation of Calibration and Testing Laboratories", which is ISO/IEC 17025. In development of this document, the committee relied on the International Laboratory Accreditation Co-operation (ILAC) Forensic Working Group document.

Accreditation requires on-site assessment of the laboratory and continued participation in proficiency testing programs, where available. The accreditation program is operated and managed by the SCC through its Program for Accreditation of Laboratories - Canada (PALCAN). PALCAN is operating in accordance with ISO/IEC Guide 58 Calibration and Testing Laboratory Accreditation Systems - General Requirements for Operation and Recognition.

Accreditation under the PSA-FT program is the formal recognition by the Standards Council of Canada of the competence of a forensic testing laboratory to manage and perform this type of activity. It is not a guarantee that test results will conform to standards or agreements between a testing laboratory and its clients; business transactions between an accredited testing laboratory and its clients are legal matters between the two parties.

These guidelines will be evaluated periodically and revised as necessary to respond to client and laboratory needs or to reflect improvements in the available science and technology.

INTRODUCTION

These Guidelines are designed to apply to all types of forensic objective testing and therefore need to be interpreted in respect of the type of calibration and testing concerned and the techniques involved. It provides an amplification of those requirements in CAN-P-4E that need interpretation when applied in laboratories carrying out forensic analysis and examination. The technical base of these guidelines is drawn from published principles, as well as practices and procedures promoted by national and international organizations.

The Standards Council of Canada accredits laboratories for carrying out forensic objective tests and does not accredit subjective tests, opinions and field sampling.

Objective tests will be controlled by:

- Documentation of the test
- Validation of the test
- Training and authorization of staff
- Maintenance of equipment

and where appropriate by:

- Calibration of equipment
- Use of appropriate reference materials
- Provision of guidance for interpretation
- Checking of results
- Testing of staff proficiency
- Recording of equipment and test performance

GENERAL AND ADDITIONAL REQUIREMENTS

A laboratory must meet all provisions of CAN-P-4E *General Requirements for the Accreditation of Calibration and Testing Laboratories*, the PALCAN Handbook – *Program Requirements for Applicants and Accredited Laboratories*, these Guidelines, and applicable Appendices to these Guidelines to qualify for the SCC Program Specialty Area - Forensic Testing Laboratory accreditation. This document provides generic information for forensic testing laboratories, independent of discipline. Specific detailed requirements for each discipline, as identified in the preface, will be provided as Appendices to these Guidelines to meet the market needs. Criteria given in a specific discipline may supersede generic criteria, where appropriate. In particular, each discipline will define the performance criteria required to maintain standing in proficiency testing or quality assurance programs, where these exist and are part of accreditation requirements.

1. SCOPE

Forensic science refers to the examination of scenes of crime, recovery of evidence, laboratory examinations, interpretation of findings and presentation of the conclusions reached for intelligence purposes or for use in court. The activities range from instrumental analysis with unequivocal results, such as blood alcohol determination and glass refractive index measurement, to the investigation of suspicious fires and vehicle accidents, to comparison work such as handwriting and toolmark examination, which is largely subjective in nature but which, with training, can produce consistent outcomes between different forensic scientists.

- 1.1 Forensic science work involves the examination of a wide range of items and substances. The following list describes the activities that may be encountered in a forensic laboratory. This does not, however, preclude other activities being undertaken in a forensic laboratory.

Controlled Substances	
<ul style="list-style-type: none"> Controlled pharmaceutical and illicit drugs 	<ul style="list-style-type: none"> Botanical material
<ul style="list-style-type: none"> Related chemicals and paraphernalia 	
Toxicology	
<ul style="list-style-type: none"> Pharmaceutical products 	<ul style="list-style-type: none"> Alcohol
<ul style="list-style-type: none"> Poisons 	
Hairs, Blood, Body Fluids and Tissues	
<ul style="list-style-type: none"> Serology 	<ul style="list-style-type: none"> DNA profiling
Trace Evidence	
<ul style="list-style-type: none"> Fire debris 	<ul style="list-style-type: none"> Hydrocarbon fuels
<ul style="list-style-type: none"> Pyrotechnic devices 	<ul style="list-style-type: none"> Explosives and explosion debris
<ul style="list-style-type: none"> Glass 	<ul style="list-style-type: none"> Light filaments
<ul style="list-style-type: none"> Paint 	<ul style="list-style-type: none"> Vehicle components
<ul style="list-style-type: none"> Metals and alloys 	<ul style="list-style-type: none"> Firearm discharge residues
<ul style="list-style-type: none"> Fibres and hairs 	<ul style="list-style-type: none"> Clothing/garments

• Adhesives	• Dyes and pigments
• Oils and greases	• Cosmetics
• Lachrymatory chemicals	• Soils
• Fertilisers	• Corrosives
• Acids	• Alkalis
• Food	• Lubricants and spermicidal agents
• Feeding stuffs and ancillary items	• Electrical devices and components
• Components of technical or household appliances	• Manufacturers marks (incl serial number restoration)
• Botanical material (excluding controlled substances)	
Firearms and ballistics	
• Firearms	• Bullets and cartridges
	•
Handwriting and Document Examination	
• Handwriting	• Inks and printing materials
• Paper	• Copiers and copied material
• Rubber stamps	• Indentations
• Security marks	• Typewriters and typewritten material
• Printers and other printed objects	• Embossing and embossed materials
Fingerprints	
• Fingerprints	• Palmprints
• Footprints	
Marks and Impressions	
• Toolmarks	• Tyre prints
• Shoe prints	• Fabric prints

• Glove marks	• Non-friction ridge body prints
• Toolmarks and impressions	

Audio, Video and Computer Analysis	
• Audiotape recordings	• Speech samples
• Language samples	• Computers (hardware and software)
• Image enhancement	• Videogrammetry
• Facial mapping	• Recovery of information
Accident Investigation	
• Tachograph charts	• Trace evidence
• Component failures	• Unsafe loads
• Speed calculations	• Electrical failures
• Car immobiliser systems	
Scene Investigation	
• Crime scene investigation	• Evidence recovery
• Computer simulations	• Photography
• Fire investigation	• Blood splash pattern interpretation
Forensic pathology, Entomology, Odontology	

1.2 The techniques adopted in the analysis and examination of forensic material cover a broad range from visual examination to sophisticated instrumental procedures. Techniques which are employed include but are not limited to:

• Chemical colour tests	• Autoradiography
• Chemiluminescence	• DNA analysis
• Chromatography	• Mass spectrometry
• Atomic absorption and emission spectrometry	• Nuclear magnetic resonance spectroscopy
• Ultraviolet, infrared and visible spectrophotometry	• Physical measurements eg weight, volume, length, density, refractive index
• Optical and electron microscopy	• X-ray analysis
• Serology	• Immunoassay
• Electrophoresis	• Visual inspections
• Metallurgy	• Odontology
• Osteology	• Microbiology
• Parasitology	• Haematology
• Chemical pathology	• Computer simulations

It is anticipated that the majority of the work carried out in forensic science laboratories will be capable of satisfying the definition of an objective test, although in some instances a different emphasis may be placed on the particular aspect of 'control' required. The level of training and experience for staff involved in the work will be dependent on the nature of the examination or test.

2. REFERENCES: Refer to ANNEX A

3. TERMS AND DEFINITIONS

For the purposes of the Guide, the relevant terms and definitions given in ISO/IEC Guide 2: 2004 apply.

Objective Test

A test which having been documented and validated is under control so that it can be demonstrated that all appropriately trained staff will obtain the same results within defined limits. These defined limits relate to expressions of degrees of probability as well as numerical values.

Objective tests will be controlled by:

- documentation of the test
- validation of the test
- training and authorization of staff
- maintenance of equipment
-
- and where appropriate by;

- calibration of equipment
- use of appropriate reference materials
- provision of guidance for interpretation
- checking of results
- testing of staff proficiency
- recording of equipment/test performance
-

Visual inspection, qualitative examinations and computer simulations are included in the definition of objective test.

Reference Collection

A collection of stable materials, substances, objects or artifacts of known properties or origin, that may be used in the determination of the properties or origins of unknown items.

Court Statement

A written report of the results and interpretations of forensic tests/examinations submitted to court. Such reports may be in a format prescribed in legislation.

4. MANAGEMENT REQUIREMENTS (ADDITIONAL TO CAN-P-4E)

4.12 Control of records

- 4.12.2.1
- a) The forensic science laboratory should have documented procedures to ensure that it maintains a coordinated record relating to each case under investigation. The information that is to be included in case records should be documented and may include records of telephone conversations, evidence receipts, descriptions of evidence packaging and seals, subpoenas, records of observations and test/examination results, reference to procedures used, diagrams, print-outs, autoradiographs, photographs, etc. In general, the records required to support conclusions should be such that in the absence of the analyst/examiner, another competent analyst/examiner could evaluate what had been performed and interpret the data.
 - b) Where instrumental analyses are conducted, operating parameters should be recorded.
 - c) Where appropriate, observations or test results should be preserved by photography or electronic scanning (e.g. electrophoretic runs, physical matches). Photocopies, tracings or hand-drawn facsimiles may also be suitable (e.g. thin-layer chromatography results, questioned documents).
 - d) When a test result or observation is rejected, the reason(s) should be recorded.
 - e) Calculations and data transfers which do not form part of a validated electronic process should be checked, preferably by a second person. The case record should include an indication that such checks have been carried out and by whom.
 - f) Each page of every document in the case record should be traceable to the analyst/examiner and where appropriate, to a uniquely identified case or exhibit. It should be clear from the case record who has performed all stages of the analysis/examination and when each stage of the analysis/examination was performed (e.g. relevant date(s)).
 - g) Laboratory generated examination records should be paginated using a page numbering system which indicates the total number of pages.
 - h) The laboratory should have documented policies and procedures for the review of case records, including test reports.

Where independent checks on critical findings are carried out by other authorized personnel, the records should indicate that each critical finding has been checked and agreed and by whom the checks were performed. This may be indicated in a number of ways including entries against each finding, entry on a summary of findings or a statement to this effect in the records.

5. TECHNICAL REQUIREMENTS (ADDITIONAL TO CAN-P-4E)

5.2 Personnel

5.2.1 The laboratory should have a defined policy that ensures that all staff working in the laboratory are competent to perform the work required. The term 'competent' implies possessing the requisite knowledge, skills and abilities to perform the job. The laboratory's policy should also include procedures for retraining and maintenance of skills and expertise.

Where test or technique specific training is given, acceptance criteria should be assigned e.g. observation of the relevant tests or analyses by an experienced officer, satisfactory performance in the analysis of quality control/quality assurance samples, correlation of results with those obtained by other trained staff. Where necessary, training programs should also include training in the presentation of evidence in court.

5.2.5 A laboratory should have clear statements of the competencies required for all jobs and records should be maintained to demonstrate that all staff are competent for the jobs they are asked to carry out.

Each laboratory or section should maintain an up-to-date record of the training that each member of staff has received. These records should include academic and professional qualifications, external or internal courses attended and relevant training (and retraining, where necessary) received whilst working in the laboratory.

Records should be sufficiently detailed to provide evidence that staff performing particular tasks have been properly trained and that their subsequent ability to perform these tests has been formally assessed.

5.3 Accommodation and environmental conditions

5.3.3 Special care is needed in forensic testing laboratories involved in the analysis or determination of trace levels of materials, including DNA. Physical separation of high-level and low-level work is required. Where special areas are set aside for this type of work, access to these areas should be restricted and the work undertaken carefully controlled. Appropriate records should be kept to demonstrate this control. It may also be necessary to carry out 'environmental monitoring' of equipment, work areas, clothing and consumables.

5.3.4 a) Access to the operational area of the laboratory should be controllable and limited. Visitors should not have unrestricted access to the operational areas of the laboratory. A record should be retained of all visitors to the operational areas of the laboratory.

b) Evidence storage areas should be secure to prevent theft or interference and there should be limited, controlled access. The storage conditions should be such as to prevent loss, deterioration and contamination and to maintain the integrity and identity of the evidence; this applies both before and after examinations have been performed.

5.4 Test and calibration methods and method validation

5.4.1 All methods should be fully documented including procedures for quality control, and, where appropriate, the use of reference materials.

- 5.4.2 a) All technical procedures used by a forensic science laboratory should be fully validated before being used on casework.
- b) Where a laboratory introduces a new (validated) method, it should first demonstrate the reliability of the procedure in-house against any documented performance characteristics of that procedure.

Records of performance verification should be maintained for future reference.

- c) Laboratories should institute a procedure to identify infrequently performed tests or analyses. For these tests or analyses, there are two methods of demonstrating competence, either of which would be equally valid. These are:
- i. regular analysis of control samples and use of control charts even when 'real' samples are not being analyzed; or
 - ii. re-verification before the test or analysis in question is performed on a real sample involving at least the use of an appropriate reference material, followed by replicate testing or analysis of the real sample.
- d) The quality of standard materials and reagents should be adequate for the procedure used. Lot/batch numbers of standard materials and critical reagents should be recorded. All critical reagents should be tested for their reliability. Standard materials and reagents should be labeled with:
- name;
 - concentration, where appropriate,
 - preparation date and or expiry date;
 - identity of preparer;
 - storage conditions, if relevant;
 - hazard warning, where necessary.

5.4.5.1 All technical procedures used by a forensic science laboratory must be fully validated before being used on casework.

Methods may be validated by comparison with other established methods using certified reference materials (where available) or materials of known characteristics. In validating test methods, the following issues (among others) may need to be determined, as appropriate:

- matrix effects
- sample homogeneity
- specificity
- interference's
- concentration ranges
- stability of measured compounds

- linearity range
- precision
- population distribution
- measurement uncertainty

Validation studies can be conducted by the scientific community (as in the case of standard or published methods) or by the forensic science laboratory itself (as in the case of methods developed in-house or where significant modifications are made to previously validated methods).

5.5 Equipment

5.5.2 As part of a quality system, all laboratories are required to operate a program for the maintenance and calibration of equipment used in the laboratory. The equipment used in a forensic science laboratory is diverse and will range across a number of different scientific and technical disciplines.

l a) General Service equipment not directly used for making measurements e.g. hot plates, stirrers, non-volumetric glassware, cameras, refrigerators, thermal cyclers. Such equipment will typically be maintained by visual examination, safety checks and cleaning as necessary. Calibrations or performance checks will only be necessary where the equipment setting can significantly affect the test or analytical result (e.g. temperature of a muffle furnace or constant temperature bath).

b) Microscopes including attachments
Microscopes should be cleaned and serviced periodically. Steps should be taken to ensure that microscopes are properly set up for use and are used only by competent staff. Where microscopes are used for measurement the guidance given in paragraph d) applies.

c) Volumetric equipment

d) Volumetric equipment will typically be maintained by visual examination and cleaning but calibration and performance checks will need to be carried out before initial use and at intervals depending on the type and frequency of use.

Measuring instruments - thermometers, balances, densitometers, chromatographs, spectrometers and spectrophotometers, refractometers, autoanalysers, DNA sequencers

Correct use combined with periodic servicing, cleaning and calibration will not necessarily ensure that a measuring instrument or detection system is performing adequately. Therefore, where appropriate, periodic performance checks shall be carried out and predetermined limits of acceptability shall be assigned. The frequency of such performance checks should be determined by need, type and previous performance of the equipment.

It is often possible to build performance checks or system suitability checks into test methods (e.g. chromatographic systems, measurement of glass refractive index). These checks should be documented and should be satisfactorily completed before the equipment is used or before results are accepted.

e) Computers and data processors

5.6 Measurement traceability

- 5.6.1 Individual calibration programs should be established depending on the specific requirements of the testing or analytical work being carried out. It will normally be necessary to check instrument calibration after any shut down, deliberate or otherwise, and following service or other substantial maintenance. In general, calibration intervals should not be less stringent than manufacturers' recommendations.
- 5.6.2.2.2 For many types of analysis, 'calibration' may be carried out using synthetic standards containing the analytes under test, prepared within the laboratory from chemicals of known purity and composition, or matrix matched standards. Alternatively, 'standard' solutions may be purchased. Many chemicals can be purchased with manufacturer's statements or certificates. Wherever possible, laboratories should obtain supplies of chemical standards from suppliers which have implemented quality systems e.g. as required by ISO 9000.
- 5.6.3.2 Reference collections of data or items/materials encountered in casework which are maintained for identification, comparison or interpretation purposes (e.g. mass spectra, motor vehicle paints or headlamp lenses, drug samples, typewriter print-styles, wood fragments, bullets, cartridges, DNA profiles, frequency databases) should be fully documented, uniquely identified and properly controlled.

5.7 Sampling

- 5.7.1 Selection, recovery, prioritization and sampling of materials from submitted test items and from scenes of crime are important parts of the forensic process. In the area of forensic science emphasis is placed on the competence of the scientist and the training of staff in these activities is therefore of prime importance. Laboratories should ensure that there are documented procedures and training programs to cover this aspect of their work and that detailed competency/training records are kept for all staff involved.

5.8 Handling of test and calibration items

- 5.8.1 For legal purposes, forensic science laboratories should be able to demonstrate that the items/samples examined and reported on were those submitted to the laboratory. A 'chain of custody' record should be maintained from the receipt of items/samples which details each person who takes possession of an item or alternatively the location of that item (e.g. if in storage).
- 5.8.4 There should be documented procedures which describe the measures taken to secure exhibits in the process of being examined which must be left unattended.

5.9 Assuring the quality of test and calibration results

- 5.9.1 a) Analytical performance should be monitored by operating quality control schemes which are appropriate to the type and frequency of testing undertaken by a laboratory. The range of quality control activities available to laboratories includes the use of:
- reference collections;

- certified reference materials and internally generated reference materials;
- statistical tables;
- positive and negative controls;
- control charts;
- replicate testing;
- alternative methods;
- repeat testing;
- spiked samples, standard additions and internal standards;
- independent checks (verification) by other authorized personnel.

Depending on the particular test being performed, the laboratory may make use of one or several of these examples to demonstrate that the test or examination is 'under control'.

The quality control procedures necessary in any particular area of work should be determined by the laboratory responsible for the work, based on best professional practice. The procedures should be documented and records should be retained to show that all appropriate QC measures have been taken, that all QC results are acceptable or, if not, that remedial action has been taken.

- b) An effective means for a forensic science laboratory to monitor its performance, both against its own requirements and against the performance of peer laboratories, is to take part in proficiency testing programs. When participating in proficiency testing programs, the laboratory's own documented test procedures should be used. Performance in the programs should be reviewed regularly and where necessary, corrective action should be taken.

Proficiency testing records should include:

- full details of the analyses/examinations undertaken and the results and conclusions obtained;
- an indication that performance has been reviewed;
- details of the corrective action undertaken, where necessary.

- c) The laboratory should have and follow a documented procedure whereby the testimony of each examiner is monitored on a regular basis. The evaluation should include appearance, performance and effectiveness of presentation. The monitoring procedure should also prescribe the remedial action that is to be taken should the evaluation be less than satisfactory.

5.10 Reporting the results

- 5.10.2 It is accepted that forensic science laboratories may not be able to include all of the items in 'Court Statements' that are detailed in sub-clause 5.10 of ISO/IEC 17025 as

the format of these documents is prescribed in legislation. Forensic science laboratories may therefore elect to adopt one or more of the following means of meeting these requirements;

- the preparation of a test report which includes all of the information required by ISO/IEC 17025;
- the preparation of an annex to the Court Statement which includes any additional information required by ISO/IEC 17025;
- ensuring that the case record relating to a specific investigation contains all the relevant information required by ISO/IEC 17025.

ANNEX A: REFERENCES

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Specific Criteria for Forensic Analysis, Raad voor Accreditatie (RVA), October 1993.

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ISO 5725-3: 1994, *Accuracy (trueness and precision) of measurement methods and results - Part 3 Intermediate measures of the Precision of a Standard Measurement Method*.

ISO 5725-4: 1994, *Accuracy (trueness and precision) of measurement methods and results - Part 4. Basic Method for the Determination of the Trueness of a Standard Measurement Method*.

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ANNEX B: GUIDELINES FOR THE ASSESSMENT OF SECURITY IN FORENSIC LABORATORIES

PURPOSE:

To ensure uniform evaluation of the basic security criteria are present in the accommodation and operations of a forensic laboratory.

POLICY:

By the nature of its role, the Forensic Laboratory should have a policy for the security features of its establishment, which may include a threat and risk assessment..

MINIMAL OPERATIONAL ELEMENTS:

SECURITY OFFICER:

A staff member should be assigned as the security officer who has overall knowledge and control of the security system. (This can be a receptionist, clerk, secretary, manager, or technical staff)

KEY SYSTEM:

1. The person designated as the security officer should have necessary control and be able to account for all the appropriate keys, and copies, used in the laboratory. Similarly if combination locks are used, is the cipher protected.
2. Duplicate copies of keys should be held by the security officer in sealed or secure containers, consistent with practices of continuity of possession.
3. There should be a policy plan for the disbursement of keys for use in common building areas and lockers for exhibit materials, in terms of individual or section access. The policy should include the procedure when a locker has to be opened in cases of emergency or similar situation.
4. When a staff member leaves employment, all security items should be returned and recorded.

ALARMS:

The policy should include procedures for testing the operational status of alarms and sensors.

Considerations for Levels of Security:

There can be four levels of security considered in the assessment of a forensic laboratory. These should be identified in the quality manual or the threat assessment plan.

1. Reception Zone.

Initial point of control; it is from this point that further access to the laboratory is controlled, or from which information is provided. It can be staffed by a receptionist, or be a telephone to call staff inside the laboratory. Persons who proceed beyond this point must be approved. All approved visitors must wear a visible badge, or be otherwise identified.

2. Common Operational Zones.

These areas have general circulation of staff and approved visitors, and are commonly accessible only through the reception zone. (Such zones are office areas, exhibit reception rooms, washrooms, general utility, receiving and shipping areas, hallways, lunchroom, etc.)

3. Controlled Zones.

The laboratories and rooms in which casework is conducted should be restricted to only the staff that normally works in that area. Access to the area should be recorded and monitored at all times in the quiet hours by an appropriate technical means. (Such zones are the general examination areas and laboratories, instrument rooms, and rooms containing the individual exhibit storage lockers.)

4. High Security Control Zones

The room/ laboratory in which examinations or testing is occurring, which is susceptible to contamination for such things as: - trace evidence, DNA, gunshot residue etc. should be under the direct control of the analyst conducting the test/ examination. There should be strict control of section staff entering this area while the examination/ testing of casework is in progress.

Approach for a Threat and Risk Assessment:

1. Determine what is at risk
2. Environmental threat – (fire, flood, contamination)
3. Persons threat - intrusion from outside; - inside personnel
4. Physical security features of building
 - Exterior zones, -interior zones, -secure rooms
5. Circulation of personnel and visitors
6. Communications
7. I.T. security

APPENDIX 1 – TOXICOLOGY

INTRODUCTION

These specific requirements were established by an Ad Hoc Technical Working Group on Toxicology (see Annex A).

This voluntary program is intended for laboratories that conduct forensic toxicology analysis. In this context, forensic toxicology is that branch of forensic science involved in the detection, identification and quantification of alcohol, other drugs and poisons in human biofluids and tissues. The program is designed to establish minimum quality and reliability standards and to define uniform proficiency requirements for these laboratories. To obtain initial accreditation by SCC, a laboratory must successfully complete an on-site assessment and participate successfully in one or more recognized external proficiency testing programs.

Laboratories accredited under the PSA-FT for toxicology must use appropriate analytical methodology and document and hold available for possible court testimony all aspects of the testing procedures. All test materials must be treated as evidence with appropriate security, proper documentation, retention and storage of records and items. Accredited laboratories engaged in forensic toxicology require the services and advice of at least one qualified forensic toxicologist.

The requirements of CAN-P-4E and the PSA-FT guidelines apply generally to all accredited forensic laboratories. This Appendix is intended only to amplify and interpret the CAN-P-4E requirements specifically for forensic toxicology laboratories.

1. SCOPE

Given the wide variety of analytical demands, this program cannot cover all aspects of forensic toxicology testing and must be regarded as being representative of this area of activity.

Individual Forensic Toxicology Laboratories may engage in the analysis of alcohol only, toxicology analysis excluding alcohol, or both.

The scope of testing described below is generic, because of the extensive range of different substances which must be covered by the analytical process. The ability to detect new drugs or substances is a routine requirement for forensic toxicology testing laboratories. Standard methods may not be available for this type of testing.

1.1 Qualitative Tests

An accredited laboratory must be capable of testing for all or at least one of the following; a broad range of drugs, metabolites, poisons, alcohol, or other volatiles in blood, urine and other samples, using a multi-step strategy of screening methods and

confirmatory analysis.

1.2 Quantitative Tests

An accredited laboratory must be capable of performing quantitative analysis in blood, urine and other samples for all or at least one of the following; a broad range of drugs, metabolites, poisons, alcohol or other volatiles.

2. REFERENCES

- ISO/IEC Guide 17025 - 1999, General requirements for the competence of calibration and testing laboratories.
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- ISO 8402:1994 Quality Management and Quality Assurance- Vocabulary
- Society of Forensic Toxicologists and American Academy of Forensic Sciences, Toxicology Section, Forensic Laboratory Guidelines, 1991.
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- CAN-P-1572, Guidelines for the Accreditation of Pesticide Residue Testing Laboratories, SCC, 1995.
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3. TERMS AND DEFINITIONS

All definitions in CAN-P-4E [i.e. laboratory, testing laboratory, calibration laboratory, calibration, test, calibration method, test method, verification, quality system, quality manual, reference standard, reference material, certified reference material (CRM), traceability, proficiency testing, (accreditation) requirements] and those applicable from ISO 8402 [e.g., quality assurance, quality control] apply, as well as the following items specific to this document.

3.2 Other specific definitions that apply are:

3.2.1 **Accuracy:** the closeness of agreement between a test result and the accepted reference value. The test result may be a mean of several values.

3.2.2 **Alcohol:** Ethyl alcohol or ethanol.

3.2.3 **Confirmatory Analysis:** analytical procedures applied to a sample to identify the presence of a specific drug, metabolite, poison, alcohol or other volatile that are independent of the initial test and that should use different analytical techniques.

3.2.4 **False Negative:** failing to report a substance as being present in a sample, when in fact it was present and would ordinarily be reported if found.

3.2.5 **False Positive:** reporting a substance detected which is not actually present in the sample analyzed.

3.2.6 **Limit of Detection:** an estimate of the lowest concentration of analyte in a real sample matrix that can be detected using a specific test method, as compared with known matrix spikes and blanks carried through the complete method.

3.2.7 **Metabolite:** a product formed by in vivo conversion of a drug to a different chemical form.

3.2.8 **Precision:** the closeness of agreement between independent test results obtained under prescribed conditions.

3.2.9 **Quantitative Analysis:** the accurate measurement of the amount of a specific drug, metabolite, poison, alcohol or other volatile contained in a human biofluid, tissue or other sample.

3.2.10 **Screening Method:** an initial analytical procedure applied to a sample, or series of samples, designed to provide preliminary evidence of possible drug, metabolite, poison, alcohol or other volatile presence which may require confirmatory follow up.

3.2.11 **Specificity:** the capability of an analytical procedure to reliably discriminate among chemically or physically related substances.

4. MANAGEMENT REQUIREMENTS

No additional interpretation of this clause is required for Toxicology

5. TECHNICAL REQUIREMENTS

5.1 General

No additional interpretation of this clause is required for Toxicology

5.2 Personnel

5.2.1 The person in charge of a toxicology laboratory must be a qualified forensic toxicologist. For purposes of this document the term qualified forensic toxicologist refers to a person who meets certain criteria of education and experience. Recommended requirements include a doctoral degree in a biological or chemical discipline and three years of full-time laboratory experience in forensic toxicology; or a Master's degree in a chemical or biological discipline and five years of experience in forensic toxicology; or a Bachelor's degree in a biological or chemical discipline and seven years of experience in forensic toxicology. The qualified forensic toxicologist should have documented training and experience in the forensic application of analytical toxicology such as court testimony, research, participation in continuing education programs and knowledge of evidentiary procedures.

5.2.2 For those laboratories engaged primarily in the analysis of alcohol, the person in charge of the alcohol laboratory must have analogous education and experience in alcohol testing and interpretation as those described for the qualified forensic toxicologist.

5.2.3 Certificate of Analysis: where required, Certificates of Analysis must be signed by a designated analyst.

5.3 Accommodation and Environment Conditions

5.3.1 The storage and handling of controlled drugs and alcohol must comply with applicable legislation.

5.3.2 All substances in the laboratory which present potential risks to health and safety, including drug reference standard materials, should be labeled and handled according to appropriate documented procedures and in accordance to occupational health and safety requirements/legislation.

5.4 Test and Calibration Methods and Method Validation

5.4.1 If standard methods are not available for a specific forensic toxicology analysis, the laboratory should develop, validate and document appropriate in-house methods. An analytical result should be traceable to the analytical method used.

5.4.2 As part of the validation of in-house screening methods, estimated limits of detection for representative drugs, metabolites, poisons, alcohol or other volatiles should be determined and documented.

5.4.3 Confirmation methods for drug analyses usually include an extraction step, possible purification steps and the use of various detection techniques. These methods may be fairly generic in nature and therefore applicable to a large number of drugs or a family of drugs. In some cases they may be very specific and can only be applied to one chemical. Wherever possible and practical, the use of mass spectrometry or another specific technique is recommended. The laboratory shall document and validate their confirmation methods. Where appropriate method validation should involve the use of representative reference materials to determine the estimated limits of detection.

5.4.4 Quantitative analysis should utilize an appropriate method that has been documented and validated by the laboratory. It must be established that other substances known to be present in the matrix do not interfere with the quantification of the target analyte.

5.4.5 Quantification will normally involve comparison of the response of an authentic reference standard of known purity to that of the target analyte in the test sample. Dilutions of a reference standard solution of accurately known composition should be used to spike a series of appropriate matrix blanks and analyzed to construct a calibration graph covering a range of concentrations bracketing the anticipated analyte concentration in the test sample. Linearity of the procedure should be established by using at least three positive calibration points. For most chromatographic assays, quantification should typically involve the use of an internal standard having similar chemical and physical properties to the test analyte.

5.4.6 Method validation should include determination of linearity, specificity and, where appropriate for frequently run assays, limit of detection, accuracy and precision. Quantitative results should be reported using the number of digits that reflect the precision of the analysis.

5.5 Equipment

No additional interpretation of this clause is required for Toxicology

5.6 Measurement Traceability

5.6.1 Where possible reference drug and drug metabolite materials should be traceable to a recognized standard or certified by a body of recognized status, such as USP, BP, or WHO. Checks for identity are required prior to placing such materials into service.

5.6.2 Where a reference material is not certified or traceable to a recognized standard, the laboratory should make reasonable efforts to verify its identity and purity by comparison with published data or by chemical characterization.

5.6.3 Solutions of reference materials should be prepared, labelled and stored in such a way as to maintain their integrity. Documentation should be complete so as to provide a clear audit trail back to the reference material or source.

5.7 Sampling

5.7.1 Forensic toxicology includes a wide variety of case types. Recommendations for sample type and amount follow. This list is not to be considered exhaustive.

A) Post-Mortem - for toxicology plus alcohol

- (i) Blood - two grey-stoppered* tubes from a peripheral source
- (ii) Blood - about 30 mL other blood, e.g., cardiac
- (iii) Liver - about 50 - 200 g
- (iv) Stomach contents - about 100 mL (state total volume)
- (v) Vitreous humour - contents of one eyeball in a grey-stoppered* tube
- (vi) Urine - about 30 mL (include one grey-stoppered* tube for alcohol)

B) Post-Mortem - for alcohol only

- (i) Blood - one grey-stoppered* tube from a peripheral source
- (ii) Urine - one grey-stoppered* tube

- (iii) Vitreous humour - contents of one eyeball in a grey-stoppered* tube

C) Impaired Operation of Motor Vehicle - alcohol and/or drugs

- (i) Blood - two grey-stoppered* tubes (two sealed approved containers as identified in the Criminal Code of Canada)
- (ii) Urine - one grey-stoppered* tube if possible

D) Sexual Assault - alcohol and/or drugs

- (i) Blood - one grey-stoppered* tube
- (ii) Urine - about 30 mL (include one grey-stoppered* tube for alcohol)

E) Miscellaneous - unusual circumstances may dictate unique sample collections.

* grey stoppered tubes commonly refer to glass blood collection tubes containing 1 % sodium fluoride and 0.1 % potassium oxalate when filled.

5.8 Handling of Test and Calibration Items

No additional interpretation of this clause is required for Toxicology

5.9 Assuring the Quality of Test and Calibration Results

5.9.1 The laboratory must implement internal quality control schemes which monitor all the steps and phases of the laboratory's analytical operation. This includes screening methods, confirmatory analysis and quantitative assays.

5.9.2 Whenever appropriate for the volume of testing, statistical techniques such as control charts may be used.

5.9.3 When conducting analyses, laboratories may group specimens into batches. Every analytical batch must be accompanied by quality control measures that demonstrate the analytical system control status. This should include, but not necessarily be limited to, results from a representative blank, calibration of instrument performance parameters by suitably selected chemical standards, and control samples spiked in a representative matrix. Records of instrument calibration and performance parameters shall be maintained.

5.9.4 Identification of an analyte should not rely solely on analysis of a single aliquot of a sample by a single analytical technique.

5.9.5 Proficiency testing programs and criteria

5.9.5.1 Description of the Program

5.9.5.1.1 Accreditation: Laboratories may be accredited for forensic alcohol testing, forensic toxicology testing excluding alcohol, or for forensic alcohol and forensic toxicology testing. Prior to becoming accredited, a laboratory must successfully complete a series of recognized external proficiency tests for alcohol and/or drugs as appropriate for the mission of the laboratory. These tests should be done within a twelve month period prior to accreditation and annually thereafter.

5.9.5.1.2 SCC recognized proficiency tests include but are not limited to programs of the College of American Pathologists.

5.9.5.2 Evaluation of Laboratory Proficiency

5.9.5.2.1 To become accredited and subsequently to maintain accreditation, the

proficiency test results should meet the following standards:

- A) For alcohol, where the target value is 100 mg/dL or less, the quantitative results should fall within ± 10 mg/dL of the mean; where the target value is greater than 100 mg/dL, the quantitative results should fall within $\pm 10\%$ of the mean.
- B) For non-alcohol quantitative analyses, results should fall within $\pm 20\%$ of the target, or ± 2 standard deviations of the participant mean.
- C) For qualitative analysis false positive identifications should not occur.
- D) Corrective action must be taken and documented for false negatives and other deficiencies, appropriate for the mission of the laboratory.

5.9.5.3 False Positives/False Negatives

5.9.5.3.1 In assessing the seriousness of reporting so-called false positives, the nature, context and forensic ramifications of the error should be considered.

5.9.5.3.2 False negatives are usually considered less serious than reporting false positives. However, the difficulty of detection and identification should be considered, taking into account the concentration, chemical nature and forensic ramifications of the error.

5.9.5.4 Corrective Action

It is recognized that even in a well run laboratory errors in detecting, identifying, quantifying and reporting alcohol, drugs and other poisons, may occur. Corrective action may be as simple as a brief review to establish that the quality assurance procedures in place are reasonable, that they were followed, and that the error was truly random. In other circumstances, corrective action may require re-development of a method, or re-training of an analyst, or determining the source of a systematic bias. It is imperative that where an error occurs, regardless of its seriousness, that prompt and appropriate corrective action be taken, and that it be documented.

5.9.5.5 Procedures for Unsatisfactory Performance

5.9.5.5.1 Failure of a laboratory to comply with any aspect of these Guidelines may lead to suspension or withdrawal of accreditation in accordance with the withdrawal procedure documented in section 4 of CAN-P-1515.

5.9.5.5.2 In the context of the proficiency testing programs, the SCC will consider several factors in determining whether disqualification of an applicant laboratory or withdrawal of accreditation of an accredited laboratory is necessary. These may include:

- A) Unsatisfactory participation or failure to participate in a recognized external

proficiency test, or

B) Failure to take appropriate action on unsatisfactory performance.

The action required following initial unsatisfactory performance will be assessed on an individual basis but could include a thorough investigation of potential problems for any occurrence of an unacceptable result. The frequency of errors will be considered.

5.9.5.5.3 Should the SCC initiate action to suspend or withdraw the laboratory's accreditation, the laboratory's official status will become "suspended" or "withdrawn" until such time that the suspension is lifted or until any re-accreditation process is complete.

5.10 Peer Review and Reporting

5.10.1 In forensic analytical toxicology results should be reviewed by two separate individuals to detect analytical and clerical errors. The nature and extent of such checks will depend on the size of the laboratory and type of reports issued. The initial analytical review should normally be conducted by the analyst with the final review being by a forensic toxicologist. For the final report, which may include both analytical results and interpretation or other comments, it is important that a clerical check occur, as a minimum.

5.10.2 Analogous reviews should occur in forensic alcohol analysis.

5.10.3 The report should clearly differentiate the analytical results obtained from any opinion or interpretation which is offered. While specific details or lists of tests performed are not required, the report should not include statements which imply comprehensive testing was performed when only limited testing was performed.

APPENDIX 2 - CHEMISTRY AND TRACE EVIDENCE ANALYSIS

INTRODUCTION

There is a strong demand for the identification and comparison of a wide range of non-biological materials that may be associated with a crime or accident. Such materials are collectively termed "trace evidence" and this area of forensic analysis has traditionally been called "chemistry" in Canada. To fully represent the scope of activities, this Appendix is entitled Chemistry and Trace Evidence Analysis. It outlines the wide range of sample types and addresses issues of quality assurance and sample management in the laboratory that are specific to the field of chemistry and trace evidence analysis. The technical base was drawn from published principles, as well as practices and procedures promoted by national and international organizations.

This Appendix was developed by an Ad Hoc Technical Working Group (see Annex A) of the Forensic Working Group (FWG). It is intended only to amplify and interpret the CAN-P-4E requirements specifically for Chemistry/Trace Evidence Analysis.

The accreditation program is designed to establish minimum quality and reliability standards and to define uniform proficiency testing requirements for laboratories conducting chemistry/trace evidence analysis. Such laboratories must use appropriate analytical methodology, treat the item as evidence and document all aspects of the testing procedures in order to provide court testimony as an expert witness.

This voluntary program is intended for use in single or multi-disciplinary forensic laboratories conducting analysis to identify and compare all types of trace evidence in the Chemistry/Trace Evidence Analysis discipline. The activities include both analytical testing and physical testing related to fire, explosion and accident investigations in order to aid the reconstruction of events based on physical evidence.

1. SCOPE

In the discipline of Chemistry/Trace Evidence Analysis, the purpose of the examinations is to characterize materials or to establish associations between persons, places and things. Based on the tests performed, different types of trace evidence can be individualized to different degrees. Depending on the degree to which these different types of trace evidence can be individualized, expert opinions are given on the likelihood that the trace evidence has a common origin with samples whose source is known.

Virtually any unknown material may be submitted for identification, or for comparison to a known source. The items for comparison are most often common, manufactured materials that may be contaminated with other unknown or known substances. The trace evidence does not include human or other animal body fluids or tissue, although it does include some biological material such as natural fibers.

The comparison may require a number of different tests to establish that there are no forensically significant differences. The interpretation of the results from those tests requires that the forensic scientist have the qualifications (education, training and experience) necessary for the Chemistry /Trace Evidence Analysis discipline and must have the demonstrated competence (knowledge, skills and abilities) to do the tests.

- 1.1 Given the extensive range of trace evidence types that may be submitted for analysis, all aspects of chemistry analyses cannot be covered and the following must be regarded as being representative of this discipline. The specific scopes of testing for Chemistry/Trace Evidence Analysis are:
 - 1.1.1 To search for, recover and identify material in questioned samples and to compare it to known samples in order to determine the likelihood of their common origin.
 - 1.1.2. To recognize, detect and identify trace evidence such that the information can be used to aid in the investigation or reconstruction of events at a crime or accident scene.
- 1.2 Some of the items most commonly submitted for analysis are included in the list in these Guidelines Section 1.1. Some of the techniques employed are listed in these Guidelines Section 1.2. These lists are amplified below for the Chemistry/Trace Evidence Analysis discipline.
- 1.3 A generic approach to the analysis of all types of trace evidence can be implemented and documented. A laboratory must be capable of conducting a multi-step strategy of method validation, analysis and interpretation. The protocols should include those tests that are generally accepted as necessary for each type of trace evidence and/or those tests that are requested by the client. All tests performed by a laboratory will be clearly documented. The ability to identify and compare trace evidence not discussed in this annex is a fundamental component of the forensic scientist's task.
- 1.4 The various types of trace evidence (generally non-biological) encountered may include, but are not limited to, the following list. They are examples of materials referred to in 1.1.1. In general, multi-disciplinary laboratories will have a documented method to deal with them. In alphabetical order, examples are:
 - adhesives & glues
 - botanical materials
 - cosmetics
 - dust, sand & other soil samples
 - dyes, markers & taggants
 - explosives

- fibers & textile materials
- fire accelerants
- fractured, cut or torn materials
- glass
- hairs
- household products
- inks
- metal articles & components
- paint & other surface coatings
- petroleum products & other ignitable gases, liquids or solids
- plastics, rubbers & other polymers
- safe insulation & other building products
- sexual lubricants

1.5 The various types of trace evidence (generally non-biological) referred to in 1.1.2 may include, but are not limited to, the following list. Again, in general, multi-disciplinary laboratories will have a documented method to deal with them. In alphabetical order, examples are:

- explosives, explosives residues & accessories with respect to investigations of explosions
- fire debris & incendiary devices with respect to fire investigation
- gunshot residue with respect to investigations related to firearms
- lamps & lamp filaments with respect to accident investigations

1.6 The techniques adopted in the analysis and examination of samples in the Chemistry/ Trace Evidence Analysis discipline cover a broad range from visual examination to sophisticated instrumental procedures, involving both screening methods and confirmatory analysis. The techniques used include, but are not limited to, the following:

- microscopy
- chromatography

- mass spectrometry
- infrared and ultra-violet/visible spectrometry
- X-ray diffraction
- elemental analysis (qualitative and quantitative)
- measurement of physical properties
- microchemical tests

2. REFERENCES

- SWGMAT Fiber Examination Guidelines, Forensic Science Communications, v.1 April 1999
- SWGMAT Forensic Paint Analysis and Comparison Guidelines, Forensic Science Communications, v.1 July 1999
- SWGMAT Guidelines for a Quality Assurance Program in Trace Material Analysis, Forensic Science Communications, v.2 January 2000
- SWGMAT Trace Evidence Recovery Guidelines, Forensic Science Communications, v.1 October 1999

[NOTE: All SWGMAT documents are published in Forensic Science Communications, available at www.for-swg.org/swgmatin.htm]

- ASTM D 93-85, Standard Test Method for Flash Point by Pensky-Martens Closed Tester
- ASTM D 3278-89, Standard Test Methods for Flash Point of liquids by Setaflash Closed Tester
- ASTM D 3828-87, Standard Test Methods for Flash Point by Setaflash Closed Tester
- ASTM E 1385-95, Practice for Separation and Concentration of Flammable or Combustible Liquid Residues from Fire Debris Samples by Steam Distillation
- ASTM E 1386-95, Practice for Separation and Concentration of Flammable or Combustible Liquid Residues from Fire Debris Samples by Solvent Extraction
- ASTM E 1387-95, Standard Test Method for Flammable or Combustible Liquid Residues in Extracts from Samples of Fire Debris by Gas Chromatography.
- ASTM E 1388-95, Standard Practice for Sampling of Headspace Vapours from Fire Debris Samples.
- ASTM E 1412-95, Practice for Separation and Concentration of Flammable or Combustible Liquid Residues from Fire Debris Samples by Passive Headspace Concentration
- ASTM E 1413-95, Practice for Separation and Concentration of Flammable or Combustible Liquid Residues from Fire Debris Samples by Dynamic Headspace Concentration
- ASTM E 1459-92 (1998), Physical Evidence Labelling and Related Documentation

- ASTM E 1492-92 (1999), Practice for Receiving, Documenting, Storing and Retrieving Evidence in a Forensic Science laboratory
- ASTM E 1588-95, Guide for Gunshot Residue Analysis by Scanning Electron Microscopy / Energy Dispersive Spectroscopy
- ASTM E 1610-95, Standard Guide for Forensic Paint Analyses and Comparison
- ASTM E 1618-97, Standard Guide for Ignitable Liquid Residues in Extracts from Fire Debris Samples by Gas Chromatography - Mass Spectrometry.

3. TERMS AND DEFINITIONS

All definitions in these Guidelines, CAN-P-4E and those applicable from ISO 8402 apply, as well as the following items specific to this document:

- 3.1 **Known (comparison) Sample:** A sample of established origin.
- 3.2 **Questioned Sample:** A sample whose original source is not known.
- 3.3 **Sub-sample:** Any material, e.g., fibers, removed from an item, e.g., clothing, for subsequent analysis, comparison and/or retention.
- 3.4 **Significant difference:** A difference between two samples that established that the two samples are distinct from one another.
- 3.5 **Common Origin:** A single source from which two or more samples, questioned or known, have originated.

4. MANAGEMENT REQUIREMENTS

No additional interpretation of this section for Chemistry/Trace Evidence is required.

5. TECHNICAL REQUIREMENTS

5.1 General

No additional interpretation of this clause for Chemistry/Trace Evidence is required.

5.2 Personnel

No additional interpretation of this clause for Chemistry/Trace Evidence is required.

5.3 Accommodation and Environmental Conditions

By definition, trace evidence includes many commonly encountered materials that have been accidentally transferred from one object to another. The integrity and significance of trace evidence as associative evidence relies on proper handling and preservation. The laboratory quality assurance policy must define the necessary and proper practices for each type of trace evidence such that it can be demonstrated that no extraneous or cross contamination has occurred within the laboratory system. In particular, the work environment must have physically separate examination areas appropriate to the trace evidence being handled. (Example: fibre examinations require separate rooms for known and questioned exhibits). The laboratory must have restricted access, adequate workspace to accommodate large items, secure storage space and tools and lifting materials appropriate to each sample type. The cleaning procedures must be designed to eliminate contamination from the working environment.

5.4 Test and Calibration methods and method validation

5.4.1 The analysis of unknown trace evidence can be accomplished by a variety of tests. These tests should be appropriate to the samples and to the questions asked or requested by the person authorizing the analysis. Non-destructive tests should be performed first. Destructive tests should be considered in light of available sample, the need for future analysis or other limitations.

5.4.2 In the validation of procedures used to identify trace materials and to compare questioned samples to those of known origin, the effects of different substrates, the relative sample size and shape, and the possibility of contamination from containers or sampling techniques may need to be considered. The analysis of a number of representative known samples may be necessary to document that the procedure used does allow the detection of significant differences.

5.4.3 No additional interpretation of this clause for Chemistry/Trace Evidence is required.

- 5.4.4 No additional interpretation of this clause for Chemistry/Trace Evidence is required.
- 5.4.5 Some of the types of trace evidence, as defined in Section 1.4, may be infrequently encountered. In that case procedures are required for the collection and the analysis of comparable samples to determine the variability inherent in the sample type. This allows the forensic scientist to evaluate the degree to which the material can be individualized. Information from the industry involved may be sought. The documentation must include references to any standard methods, method guides, or published literature (as described in Section 10.3 of CAN-P-4D) that is used as the basis in the development of the test applied.
- 5.4.6 For all techniques, such as those described in Section 1.6, regardless of whether they are used frequently or infrequently, it must be demonstrated through documentation that the test is applied correctly and that any equipment used is functioning correctly. The documentation becomes part of the work notes for the file.

5.5 Equipment

No additional interpretation of this clause for Chemistry/Trace Evidence is required.

5.6 Measurement Traceability

No additional interpretation of this clause for Chemistry/Trace Evidence is required.

5.7 Sampling

- 5.7.1 The Chemistry/Trace Evidence Analysis accreditation program does not attempt to address or test the documentation required or procedures related to sampling at the event site or crime scene. It must be recognized that laboratory results and their interpretation are directly affected by the quality of the sampling procedures. The testing laboratory is required to have available for investigators or other personnel responsible for the detection and collection of trace evidence written procedures that address the collection of appropriate samples, using techniques for the avoidance of contamination or the deterioration of samples. This document should include instructions regarding sample containers and packaging for the different types of trace evidence, procedures for shipping of samples, preservation, chain-of-custody and any other laboratory submission concerns.
- 5.7.2 The laboratory may, or may not, have a mandate to be an active participant in the training of all personnel responsible for the collection of trace evidence. If the laboratory is not involved in such training, then it should, as a minimum, be prepared to advise or provide some references on sample collection to these personnel when requested.

5.8 Handling of Test and Calibration Items

- 5.8.1 In the Chemistry/Trace Evidence Analysis discipline, sub-samples may be

removed from the submitted item for analysis and comparison. Each sub-sample must be uniquely identified and subject to the same control as the item itself. The laboratory must have documented policy regarding the consumption of samples in analysis, and procedures for return, retention or destruction for each type of exhibit and any sub-sample material.

- 5.8.2 If destructive tests are used, each sample should be divided to preserve a portion in its original state. A division of the sample is not required when, in the judgment of the scientist, it will prevent the application of the appropriate procedures. If the sample is totally consumed in analysis, a notation to that effect must be present in the work notes.

5.9 Assuring the Quality of Test and Calibration Results

5.9.1 Proficiency Testing

5.9.1.1 Proficiency testing measures both the capabilities of the scientists and the reliability of the analytical results produced. To become accredited in the Chemistry/Trace Evidence Analysis discipline a laboratory must have a documented proficiency testing policy in place. The program will include administrative and documentation procedures, monitoring of results and a protocol for corrective action and follow-up.

5.9.1.2 The laboratory must be able to demonstrate successful participation in SCC recognized proficiency testing programs. Every chemistry/trace evidence analysis scientist and technical support person must participate annually in at least one proficiency test. It is strongly recommended that each scientist participates in proficiency testing for each of the types of trace evidence that person examines. In the absence of these programs, participation in other inter-laboratory proficiency tests or other types of inter-laboratory sample exchange programs is acceptable. For trace evidence types where sample exchange is not feasible or timely, participation in an intra-laboratory testing program, as developed by the laboratory's Quality Assurance administrator, is also acceptable.

5.9.1.3 Failure of the accredited laboratory to participate in SCC-recognized proficiency tests or to take corrective action after unsatisfactory performance in such a program may result in the suspension and subsequent withdrawal of accreditation in the relevant area(s) of that scope of testing in accordance with the procedures documented in Section 4 of the SCC document CAN-P-1515.

5.9.1.4 Since accreditation in the Chemistry/Trace Evidence Analysis discipline does not encompass sampling procedures, proficiency testing programs, or other inter-laboratory exchange programs do not attempt to address or test the documentation required or procedures related to the field or site-sampling event.

5.9.2 Evaluation of Laboratory Proficiency and Procedures for Unsatisfactory Performance

- 5.9.2.1 A full documented review of the proficiency test, all the results and the necessary documentation is required to substantiate that an administrative error, a systematic error or an analytical/interpretative error resulting in a mistaken conclusion has, in fact, occurred.
- 5.9.2.2 The variety of problems that could result in errors precludes a complete listing of corrective measures. The laboratory policy must include appropriate action(s) to be taken, a set time frame for implementation, and documentation for every such incident. For the three error types listed above, corrective measures may include the following:
- 5.9.2.3 Any performance standard not met due to an administrative error (e.g., clerical, sample confusion, improper storage, documentation) may be corrected according to the laboratory's established policy.
- 5.9.2.4 Any performance standard not met as the result of a systematic error, such as a problem with equipment or standards, may require a complete review of all casework that utilized such equipment or standards, since it was last used in the successful completion of a proficiency test or from the identification of the inception of the problem. All scientists in relevant areas must be made aware of the problem, once identified, and of the appropriate corrective action required to prevent a recurrence.
- 5.9.2.5 Any performance standard not met as the result of an analytical/interpretative error requires immediate action. The cause of the error and its scope must be identified. Such errors can be at the individual level, unit level or system-wide. Further, such errors can be limited to the proficiency test at hand or have occurred in casework over an extended period of time. Once the nature of the problem has been identified, corrective action at the appropriate level must be taken as soon as possible.

5.10 Reporting the Results

No additional interpretation of this clause for Chemistry/Trace Evidence is required.

APPENDIX 3- BIOLOGY

INTRODUCTION

The increasing demand for forensic DNA analysis as well as the attention and scrutiny which this new technology has generated, has led to calls for regulation and monitoring by governments in Canada and many other countries.

To ensure the most efficient and effective use of resources in this field of testing, it is important that data generated from a group of individual laboratories be reliable and comparable. This can be achieved through the use of a laboratory accreditation scheme.

Therefore an *ad hoc* Technical Group in Biology was established to develop this Appendix. The technical base of this appendix is drawn from published principles, as well as practices and procedures promoted by national and international organizations. In particular, this document is primarily based on the document "Quality Assurance Standards for DNA Testing Laboratories" produced by the DNA Advisory Board in the USA. Appropriate modifications have been made to fit the Canadian situation. This revision has been approved by forensic DNA laboratories accredited by Standards Council of Canada.

This Appendix is harmonized with the SCC CAN-P-4E document "General Requirements for the Competence of Testing and Calibration Laboratories", these Guidelines, and the *International harmonized protocol for the proficiency testing of (chemical) analytical laboratories* (Protocol from the IUPAC/ISO/AOAC working party).

This document consists of definitions and standards. The standards are quality assurance measures that place specific requirements on the laboratory and are mandatory. Equivalent measures not outlined in this document may also meet the standard.

All requirements of CAN-P-4E and the CAN-P-1578 guidelines apply generally to all accredited forensic laboratories in Canada and are not repeated in this document. These guidelines are intended only to amplify and interpret the CAN-P-1578 requirements specifically for forensic biology.

1. SCOPE

This document describes the quality assurance requirements that laboratories performing forensic DNA testing shall follow to ensure the quality and integrity of the data generated by the laboratory. This Appendix also applies to vendor laboratories that perform forensic DNA testing in accordance with 4.5. This Appendix does not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated.

2. REFERENCES

- 42 Code of Federal Regulations, Chapter IV, (10-1-95 Edition), Health Care Financing Administration, Health and Human Services.
- American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLD-LAB), ASCLD-LAB Accreditation Manual, June 2005
- DNA Advisory Board, "Quality Assurance Standards for Forensic DNA Testing Laboratories", Forensic Science Communications, July 2000, Volume 2, Number 3.
- Technical Working Group on DNA Analysis Methods, "Guidelines for a Quality Assurance Program for DNA Analysis", Crime Laboratory Digest, April 1995, Volume 22, Number 2, pp. 21-43.

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3. DEFINITIONS

As used in these standards, the following terms shall have the meanings specified:

- 3.1 Accuracy** is the degree of conformity of a measured quantity to its actual (true) value.
- 3.2 Administrative review** is an evaluation of the report and supporting documentation for consistency with laboratory policies and for editorial correctness.
- 3.4 Analytical documentation** is the documentation of procedures, standards, controls and instruments used, observations made, results of tests performed, charts, graphs, photos and other documentation generated which are used to support the analyst's conclusions. This may either be in hardcopy or electronic format.
- 3.5 Analytical procedure** is an orderly step-by-step process designed to ensure operational uniformity and to minimize analytical drift.
- 3.6 Audit** is an inspection used to evaluate, confirm, or verify activity related to quality.
- 3.7 Biochemistry** is the study of the nature of biologically important molecules in living systems, DNA replication and protein synthesis, and the quantitative and qualitative aspects of cellular metabolism.
- 3.8 Calibration** is the set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material, and the corresponding known values of a measurement.
- 3.9 CODIS** is the Combined DNA Index System administered by the Royal Canadian Mounted Police (RCMP). CODIS links DNA evidence obtained from crime scenes, thereby identifying serial criminals. CODIS also compares crime scene evidence to DNA profiles from offenders, thereby providing investigators with the identity of the putative perpetrator.
- 3.10 Competency test(s)** is a written, oral and/or practical test or series of tests, designed to establish that an individual has demonstrated achievement of skills and met minimum standards of knowledge necessary to perform forensic DNA analysis. Competency shall mean the demonstration of skills and knowledge necessary to perform forensic DNA analysis successfully.
- 3.11 Contamination** is the unintentional introduction of exogenous DNA into a DNA sample or PCR reaction.
- 3.12 Continuing education** is an educational activity (such as a class, lecture series, conference, seminar, or short course) that is offered by a recognized organization or individual that brings participants up to date in their relevant area of knowledge.
- 3.13 Coursework** is an academic class officially recognized and taught through a college or university program in which the participating student successfully completed and received one or more credit hours for the class.

3.14 Critical equipment or instruments are those requiring calibration or a performance check prior to use and periodically thereafter.

3.15 Critical reagents are determined by empirical studies or routine practice to require testing on established samples before use on forensic casework samples.

3.16 Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on forensic samples.

3.17 DNA analyst (or equivalent role, position, or title as designated by the Laboratory Director) is an employee that has successfully completed the laboratory's training requirements for casework sample analysis, passed a competency test, and has entered into a proficiency testing program. This individual conducts and/or directs the analysis of forensic samples, interprets data and reaches conclusions.

3.18 DNA record is a database record that includes the DNA profile as well as data required to manage and operate CODIS, i.e. the Originating Agency Identifier which serves to identify the submitting agency; the Specimen Identification Number; names of the participating laboratories; and DNA personnel associated with the DNA profile analyses.

3.19 DNA technician (or equivalent role, position, or title as designated by the laboratory director) is an employee who performs analytical techniques on forensic samples under the supervision of a qualified analyst. DNA technicians do not interpret data, reach conclusions on typing results, or prepare final reports.

3.20 DNA type (also known as a DNA profile) is the genetic constitution of an individual at defined locations (also known as loci) in the DNA. A DNA type derived from nuclear DNA typically consists of one or two alleles at several loci (e.g., short tandem repeat loci). The DNA type derived from mitochondrial DNA is described in relation to the revised Cambridge Reference Sequence (Nature Genetics 1999, 23, 147).

3.21 Employee is a person: (1) in the service of the applicable federal or provincial government, subject to the terms, conditions and rules of federal/provincial employment and eligible for the federal/provincial benefits of service; or (2) formerly in the service of a federal, provincial or territorial government who returns to service in the agency on a part time or temporary basis; or (3) in the service of a vendor laboratory and subject to the applicable terms, conditions and rules of employment of the vendor laboratory.

3.22 Forensic DNA analysis is the process of identification and evaluation of biological evidence in criminal matters using DNA technologies.

3.23 Forensic hair identification is the process of identifying whether a hair is of human or animal origin.

3.24 Forensic hair comparison is the comparison of questioned hairs to samples of known origin. This may include macroscopic and microscopic comparisons or, if appropriate, DNA testing of the questioned and known hair samples.

3.25 Forensic sample is a biological sample originating from and associated with a crime scene. A sample associated with a crime scene may include a sample that has been carried

away from the crime scene.

3.26 Forensic serology is the examination and characterization of forensic biological evidence (e.g. body fluids and tissues).

3.27 Forensic serology technician (or equivalent role, position, or title as designated by the laboratory director) is an employee who performs serological techniques on forensic samples under the supervision of a qualified forensic serology analyst. Serology technicians do not prepare final reports.

3.28 Genetics is the study of inherited traits, genotype/phenotype relationships, and population/species differences in allele and genotype frequencies.

3.29 Guidelines are a set of general principles used to provide direction and parameters for decision making.

3.30 Integral component is that portion of an academic course that is so significant and necessary to the understanding of the subject matter as a whole, that the course would be considered incomplete without it.

3.31 Internal validation is the accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

3.32 Known samples are biological material whose identity or type is established.

3.33 Laboratory is a facility: (1) employing at least two full time employees who are qualified DNA analysts; and (2) having and maintaining the capability to perform the DNA analysis of forensic casework samples at that facility.

3.34 Laboratory support personnel (or equivalent role, position, or title as designated by the laboratory director) are employee(s) who perform laboratory duties exclusive of analytical techniques on forensic or database samples.

3.35 Methodology is used to describe the analytical processes and procedures used to support a DNA typing technology: for example, extraction methods (manual vs. automated), quantitation methods (slot blot, fluorometry, real time PCR), typing test kit (e.g. Powerplex, Identifiler) and platform (capillary electrophoresis, real-time gel and end-point gel systems).

3.36 Molecular biology is the study of the theories, methods, and techniques used in the study and analysis of gene structure, organization, and function.

3.37 Multi-laboratory system is used to describe an organization that has more than one laboratory performing forensic DNA analysis.

3.38 Multiplex system is a test providing for simultaneous amplification of multiple loci that is either prepared commercially or by a laboratory.

3.39 Negative amplification control is used to detect DNA contamination of the amplification reagents. This control consists of only amplification reagents without the addition of template DNA.

3.40 NIST is the National Institute of Standards and Technology.

3.41 On-site visit is a scheduled or unscheduled visit by one or more representatives of the outsourcing laboratory to the vendor laboratory work site performed to verify compliance with contract specifications.

3.42 Outsourcing is the utilization of a vendor laboratory to provide DNA services in which the CODIS participating laboratory takes or retains ownership of the DNA data for entry into CODIS.

3.43 Ownership occurs when there is an existing outsourcing contract and any of the following criteria are applicable:

- (1) the originating laboratory will use any samples, extracts or any materials from the vendor laboratory for the purposes of forensic testing (i.e. a vendor laboratory prepares an extract that will be analyzed by the originating laboratory);
- (2) the originating laboratory will interpret the data generated by the vendor laboratory;
- (3) the originating laboratory will issue a report on the results of the analysis; or
- (4) the originating laboratory will enter or search a DNA profile in CODIS from data generated by the vendor laboratory.

3.44 Performance check is a quality assurance measure to assess the functionality of laboratory instruments and equipment that affect the accuracy and/or validity of forensic sample analysis.

3.45 Platform is the type of analytical system utilized to generate DNA profiles such as capillary electrophoresis, real-time gel, and end-point gel instruments or systems.

3.46 Polymerase Chain Reaction (PCR) is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles which consist of the following:

- (1) denaturation of the template;
- (2) annealing of primers to complementary sequences at an empirically determined temperature; and
- (3) extension of the bound primers by a DNA polymerase.

3.47 Positive amplification control is an analytical control sample that is used to determine if the PCR performed properly. This control consists of the amplification reagents and a known DNA sample.

3.48 Precision characterizes the degree of mutual agreement among a series of individual measurements, values, and/or results.

3.49 Procedure (protocol, SOP or other equivalent) is an established practice to be followed in performing a specified task or under specific circumstances.

3.50 Proficiency testing is a quality assurance measure used to monitor performance and

identify areas in which improvement may be needed. Proficiency tests may be classified as:

- (1) An internal proficiency test, which is produced by the agency undergoing the test.
- (2) An external proficiency test, which may be open or blind, is a test obtained from an approved proficiency test provider.

3.51 Qualified auditor is a current or previously qualified DNA analyst who has successfully completed the appropriate SCC approved auditor training course.

3.52 Quality system is the organizational structure, responsibilities, procedures, processes and resources for implementing quality management.

3.53 Quantitative PCR is a method of determining the concentration of DNA in a sample by use of the polymerase chain reaction.

3.54 Reagent blank control is an analytical control sample that contains no template DNA and is used to monitor contamination from extraction to final fragment or sequence analysis. This control is treated the same as, and parallel to, the forensic casework samples being analyzed. If a representative amount of the reagent blank control is found by Quantitative PCR not to contain any DNA, the that blank need not be processed further.

3.55 Reference material (certified or standard) is a material for which values are certified by a technically valid procedure and accompanied by, or traceable to, a certificate or other documentation which is issued by a certifying body.

3.56 Reproducibility is the ability to obtain the same result when the test or experiment is repeated.

3.57 Review is an evaluation of documentation to check for consistency, accuracy, and completeness.

3.58 Second agency is an entity or organization external to and independent of the laboratory.

3.59 Semi-annual is used to describe an event that takes place two times during one calendar year, with the first event taking place in the first six months of that year and the second event taking place in the second six months of that year and where the interval between the two events is at least four months and not more than eight months.

3.60 Service is the performance of those adjustments or procedures specified which are to be performed by the user, manufacturer or other service personnel in order to ensure the intended performance of instruments and equipment.

3.61 Technical Leader (or equivalent role, position, or title as designated by the laboratory director) is an employee who is accountable for the technical operations of the laboratory and who is authorized to stop or suspend DNA laboratory operations.

3.62 Technical review is an evaluation of reports, notes, data, and other documents to ensure there is an appropriate and sufficient basis for the scientific conclusions.

3.63 Technical reviewer is an employee who is a current or previously qualified analyst in the methodology being reviewed that performs a technical review of, and is not an author of, the applicable report or its contents.

3.64 Technology is used to describe the type of forensic DNA analysis performed in the laboratory, such as RFLP, STR, mini-STR, YSTR, or mitochondrial DNA.

3.65 Test kit is a pre-assembled set of reagents that allows the user to conduct a specific DNA extraction, quantitation or amplification.

3.66 Traceability is the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.

3.67 Underlying scientific principle is a rule concerning a natural phenomenon or function that is a part of the basis used to proceed to more detailed scientific functions.

3.68 Validation is a process by which a procedure is evaluated to determine its efficacy and reliability for forensic casework analysis and includes the following:

- (1) Developmental validation is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on forensic samples.
- (2) Internal validation is an accumulation of test data within the laboratory to demonstrate that established methods and procedures perform as expected in the laboratory.

3.69 Vendor laboratory is a governmental or private laboratory that provides DNA analysis services to another laboratory or agency

3.70 Work product is the material that is generated as a function of analysis, which may include extracts, amplified product and amplification tubes or plates as defined by the laboratory.

4. MANAGEMENT REQUIREMENTS

4.1 The laboratory shall:

4.1.2 Have a technical leader who is accountable for the technical operations. Multi-laboratory systems shall have at least one technical leader.

4.1.3 Have at least two full time employees who are qualified DNA analysts.

4.2, 4.3, 4.4 Reserved

4.5. Outsourcing

4.5.1 A vendor laboratory performing forensic DNA analysis shall be accredited and comply with these standards.

4.5.1.1 A laboratory that outsources DNA sample(s) to a vendor laboratory to generate DNA data that will be entered into CODIS shall require the vendor laboratory to provide documentation of accreditation and compliance with these standards. The laboratory shall maintain such documentation.

4.5.2 A laboratory shall not upload or accept DNA data for upload to CODIS from any vendor laboratory or agency without the documented prior approval of the technical specifications of the outsourcing agreement and/or documented approval of acceptance of ownership of the DNA data by the laboratory technical leader.

4.5.3 A laboratory shall have and follow a procedure to verify the integrity of the DNA data received through the performance of the technical review of DNA data from a vendor laboratory.

4.5.4 A laboratory outsourcing DNA sample(s) to a vendor laboratory or accepting ownership of DNA data from a vendor laboratory shall have and follow a procedure to perform an on-site visit(s) of the vendor laboratory. This procedure shall include, at a minimum, the following elements:

4.5.4.1 A documented initial on-site visit prior to the vendor laboratory's beginning of casework analysis for the laboratory.

4.5.4.1.1 The on-site visit shall be performed by the technical leader or designated employee of the laboratory who is a qualified or previously qualified DNA analyst in the technology, platform and typing amplification test kit, used to generate the DNA data.

4.5.4.2 If the outsourcing agreement extends beyond one year, an annual on-site visit shall be required. Each annual on-site visit shall occur every calendar year and shall be at least 6 months and no more than 18 months apart.

5. TECHNICAL REQUIREMENTS

5.1 General

No additional interpretation of this section for Biology is required.

5.2 Personnel

5.2.1.1 The DNA technical leader shall meet the following qualifications:

Minimum educational requirements: The DNA technical leader of a laboratory shall have, at a minimum, a Master's degree in a biology-, chemistry- or forensic science- related area and successfully completed 12 semester or equivalent credit hours from a combination of undergraduate and graduate course work covering the following subject areas: biochemistry, genetics, molecular biology, and either statistics or population genetics.

The 12 semester or equivalent credit hours shall include at least one graduate level class registering three (3) or more semester or equivalent credit hours.

The specific subject areas listed in 5.2.1.1 shall constitute an integral component of any class or coursework used to demonstrate compliance with this standard.

Individuals who have completed course work with titles other than those listed in 5.2.1.1 shall demonstrate compliance with this standard through a combination of pertinent materials such as a transcript, syllabus, and letter from the instructor or other document that supports the course content.

5.2.1.2 Minimum experience requirements:

A DNA technical leader of a laboratory shall have three years of forensic DNA laboratory experience obtained at a laboratory where forensic DNA testing was conducted for the identification and evaluation of biological evidence in criminal matters. As of the effective date of this revision, any newly appointed technical leader shall have a minimum of three years of human DNA (current or previous) experience as a qualified analyst on forensic samples. The technical leader shall have previously completed or will successfully complete auditor training within one year of appointment.

5.2.1.3 General duties and authority:

Oversee the technical operations of the laboratory.

Authority to initiate, suspend and resume DNA analytical operations for the laboratory or an individual.

The minimum specific responsibilities to be performed by the technical leader include the following:

To evaluate and document approval of all validations and methods used by the laboratory and to propose new or modified analytical procedures to be used by analysts.

In the event a new technical leader is appointed, the new technical leader shall document his/her review of all validations and methods currently used by the laboratory.

To review the academic transcripts and training records for newly qualified analysts and approve their qualifications prior to independent casework analysis and document such review.

To approve the technical specifications for outsourcing agreements.

To review internal and external DNA Audit documents and, if applicable, approve corrective action(s), and document such review.

To review, on an annual basis, the standard operating procedures of the laboratory and document such review.

To review and approve the training, quality assurance and proficiency testing programs in the laboratory.

Newly appointed technical leaders shall be responsible for the documented review of the following:

Validation and methodologies currently used by the laboratory, and;

Educational qualifications and training records of currently qualified analysts.

5.2.1.4 Degree requirements for technical leader of a laboratory conducting forensic serology and/or hair identification and comparison examinations:

The technical leader must have at a minimum a four (4) year bachelor's degree in a biology-, or chemistry-, or forensic science-related area.

5.2.1.5 Accessibility:

The technical leader shall be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. A multi-laboratory system may have one technical leader over a system of separate laboratory facilities. For multi-laboratory systems the technical leader shall conduct a site visit to each laboratory at least semi-annually.

The technical leader shall be a full time employee of the laboratory or multi-laboratory system.

5.2.1.6 The DNA analyst shall be an employee of the laboratory and meet the following qualifications:

Minimum educational requirements: The DNA analyst shall have a four (4) year bachelor's degree or an advanced degree in a biology-, chemistry-, or forensic science- related area and shall have successfully completed university course work (graduate or undergraduate level) covering the following subject areas: biochemistry, genetics, molecular biology; and course work and/or training in statistics and/or population genetics as it applies to forensic DNA analysis.

The specific subject areas listed above shall be an integral component of any class or coursework for compliance with this standard.

Analysts hired after the effective date of these revisions whose educational qualifications have not been reviewed and documented through two external audits shall have a minimum of nine cumulative semester hours or equivalent that cover the required subject areas.

Analysts who have completed course work with titles other than those listed above shall demonstrate compliance with this requirement through a combination of pertinent materials, such as a transcript, syllabus, letter from the instructor, or other document that supports the course content. The technical leader shall document approval of compliance with this standard.

5.2.1.7 Minimum experience requirements:

The DNA analyst shall have six (6) months of forensic human DNA laboratory experience prior to independent casework responsibilities. If prior forensic human DNA laboratory experience is accepted by a laboratory, the prior experience shall be documented and augmented by additional training, as needed, in the analytical methodologies, platforms and interpretations of human DNA results used by the laboratory.

The analyst shall complete the analysis of a range of samples routinely encountered in forensic casework prior to independent work using DNA technology.

The analyst shall successfully complete a competency test before beginning independent DNA analysis.

5.2.1.8 The forensic serology analyst or forensic analyst who conducts hair identification and comparison examinations shall meet the following qualifications:

Minimal education requirements: a four (4) year bachelor's degree in a biology-, or chemistry-, or forensic science-related area.

Minimum experience requirements: four (4) months of forensic serology laboratory training, including the successful analysis of a range of samples typically encountered in forensic casework prior to independent casework responsibilities.

The forensic serology analyst shall successfully complete a qualifying test before beginning independent casework responsibilities.

5.2.1.9 The DNA technician shall meet the following qualifications:

Minimum educational requirements: a 2 year college diploma in a biology- or forensic science-related area.

Minimum experience requirement: six (6) months of forensic human DNA laboratory experience prior to independent casework responsibilities.

Documented training specific to their job function(s).

Successful completion of a qualifying test, prior to participating in DNA analysis on evidence.

5.2.1.10 The forensic serology technician shall meet the following qualifications:

Minimum educational requirements: a 2 year college diploma in a biology- or forensic science-related area.

Minimum experience requirement: four (4) months of forensic serology laboratory experience prior to independent casework responsibilities.

Documented training specific to their job function(s).

Successful completion of a qualifying test, prior to performing DNA analysis on evidence.

5.2.1.11 Laboratory support personnel shall have documented training specific to their job function(s).

5.2.2 The laboratory shall have a documented program to ensure technical qualifications are maintained through participation in continuing education.

Continuing education: The technical leader and analyst(s) shall stay abreast of developments within the field of DNA typing by attending seminars, courses, professional meetings or documented training sessions/classes in relevant subject areas at least once each calendar year. A minimum of eight cumulative hours of continuing education are required annually and shall be documented.

If continuing education is conducted internally, the title of the program, a record of the presentation, date of the training, attendance list, and the curriculum vitae of the presenter(s) shall be documented and retained by the laboratory.

If the continuing education is conducted externally, the laboratory shall maintain documentation of attendance through a mechanism such as certificates, program agenda/syllabus, or travel documentation. Attendance at a regional, national or international conference shall be deemed to provide a minimum of 8 hours of continuing education.

Programs based on multimedia or internet delivery shall be subject to the approval of the technical leader. Participation in such programs shall be formally recorded and after its completion shall be submitted to the technical leader for review and approval. The documentation shall include the time required to complete the program.

The laboratory shall have a program for the annual review of scientific literature approved by the technical leader that documents the analysts' ongoing reading of scientific literature. The laboratory shall maintain or have physical or electronic access to a collection of current books, reviewed journals, or other literature applicable to DNA analysis.

The laboratory shall maintain records on the relevant qualifications, training, skills and experience of the technical personnel.

5.3. Accommodation and Environmental Conditions

- 5.3.3.1 Except as provided in 5.3.3.3, techniques performed prior to PCR amplification such as evidence examinations, DNA extractions, and PCR setup shall be conducted at separate times or in separate spaces from each other. Standard 5.3.3.3 is applicable if robotic workstations are used by the laboratory.
- 5.3.3.2 Except as provided in 5.3.3.3, amplified DNA product, including real time PCR, shall be generated, processed and maintained in a room(s) separate from the evidence examination, DNA extractions and PCR setup areas. The doors between rooms containing amplified DNA and other areas shall remain closed except when used for passage into and out of the room.
- 5.3.3.3 A robotic workstation may be used to carry out DNA extraction, quantitation, PCR setup, and/or amplification in a single room, provided that the analytical process has been validated in accordance with 5.4. If the robot performs analysis through amplification, the robot shall be housed in a separate room from that used for initial evidence examinations.
- 5.3.3.4 The laboratory shall have and follow written procedures for cleaning and decontaminating facilities and equipment.
- 5.3.3.5 The laboratory shall have secure, controlled access areas for evidence storage and work product in progress.

5.4. Test and Calibration Methods and Method Validation

- 5.4.5.1 The laboratory shall use validated methodologies for DNA analyses. There are two types of validations: developmental and internal.
- 5.4.5.2 Developmental validation shall precede the use of a novel methodology for forensic DNA analysis.
- 5.4.5.3 Developmental validation studies shall include, where applicable, characterization of the genetic marker, species specificity, sensitivity studies, stability studies, reproducibility, case-type samples, population studies, mixture studies, precision and accuracy studies, and PCR-based studies. PCR-based studies include reaction conditions, assessment of differential and preferential amplification, effects of multiplexing, assessment of appropriate controls, and product detection studies. All validation studies shall be documented.
- 5.4.5.4 Peer-reviewed publication of the underlying scientific principle(s) of a technology shall be required.
- 5.4.5.5 Except as provided in 5.4.5.7, internal validation of all manual and robotic methods shall be conducted by each laboratory and reviewed and approved by the laboratory's technical leader prior to using a procedure for forensic applications.

- 5.4.5.6 Internal validation studies conducted after the date of this revision shall include as applicable: known and non-probative evidence samples or mock evidence samples, reproducibility and precision, sensitivity and stochastic studies, mixture studies, and contamination assessment. Internal validation studies shall be documented and summarized. The technical leader shall approve the internal validation studies
- 5.4.5.7 Internal validation data may be shared by all locations in a multi-laboratory system. Each laboratory in a multi-laboratory system shall complete a performance check of the equipment and/or test kit, and document and maintain, as applicable, precision and sensitivity studies. The summary of the validation data shall be available at each site.
- 5.4.5.8 Internal validation shall be the basis of defining quality assurance parameters and interpretation guidelines, including as applicable, guidelines for mixture interpretation.
- 5.4.5.9 A complete change of detection platform or test kit (or laboratory assembled equivalent) shall require internal validation studies.
- 5.4.5.10 Before the introduction of a methodology into the laboratory, the analyst or examination team shall successfully complete a competency test to the extent of his/her/their participation in casework analyses.
- 5.4.5.11 The performance of a modified procedure shall be evaluated by comparison with the original procedure using similar DNA samples.
- 5.4.5.12 Each additional critical instrument shall require a performance check. Modifications to an instrument, such as a detection platform, that do not affect the analytical portion of the instrument shall require a performance check, i.e., upgrade of instrument model.
- 5.4.5.13 When case or sample-specific circumstances necessitate the use of a methodology that is not part of the laboratory's validated procedures, the laboratory shall, if approved by the technical leader and documented, select a methodology that has been validated and published by a recognized technical organization or in relevant peer-reviewed scientific journals, and has been tested with known samples in the laboratory.
- 5.4.7 Modifications to software, such as an upgrade, shall require a performance check prior to implementation. New software or significant software changes that may impact interpretation or the analytical process shall require a validation prior to implementation.

5.5 Equipment

- 5.5.1 At a minimum, the following critical instruments or equipment shall require annual performance checks and/or calibration where applicable:

Thermometer that is used for conducting performance checks must be traceable to national or international standard(s).

Balance/scale

Thermal cycler temperature verification system

Thermal cycler including quantitative-PCR

Electrophoresis detection systems

Robotic systems

Genetic Analyzers

Pipettes used in any stage of the typing process.

5.6 Measurement Traceability

No additional interpretation of this section for Biology is required.

5.7 Sampling

No additional interpretation of this section for Biology is required.

5.8 Handling of Test and Calibration Items

5.8.1.1 The laboratory shall follow documented procedures designed to minimize loss, contamination, and/or deleterious change of evidence and work product in progress.

5.8.1.2 Where possible, the laboratory shall retain or return a portion of the evidence sample and/or extract.

5.8.1.3 The laboratory shall have and follow a documented policy for the disposition of evidence that includes a policy on sample consumption.

No additional interpretation of this section for Biology is required.

5.9 Assuring the Quality of Test and Calibration Results

The laboratory shall have and follow written analytical procedures approved by the technical leader. The standard operating procedures are to be reviewed annually by the technical leader and this review shall be documented.

5.9.1.1 The laboratory shall have and follow a standard operating procedure for each analytical method used by the laboratory. The procedures shall specify reagents, sample preparation, extraction methods (to include differential extraction of nuclear DNA samples with adequate amount of sperm), equipment, and controls which are standard for DNA analysis and data interpretation.

- 5.9.1.2 The laboratory shall identify critical reagents and evaluate them prior to use in casework. These critical reagents shall include but are not limited to the following:
- 5.9.1.2.1 Test kits or systems for performing quantitative PCR and genetic typing
 - 5.9.1.2.2 Thermostable DNA polymerase, primer sets and allelic ladders used for genetic analysis that are not tested as test kit components under
- 5.9.1.3 The laboratory shall quantify the amount of human DNA in forensic samples prior to nuclear DNA amplification. Quantitation of human DNA is not required for known samples if the laboratory has a validated system that has been demonstrated to reproducibly and reliably yield successful DNA amplification and typing without prior quantitation.
- 5.9.1.4 The laboratory shall monitor the analytical procedures using the following controls and standards.
- 5.9.1.4.1 Where quantitation is used, quantitation standards shall be used.
 - 5.9.1.4.2 Positive and negative amplification controls associated with samples being analyzed shall be amplified concurrently with the samples at all loci and with the same primers as the forensic samples. All samples typed shall also have the corresponding amplification controls typed.
 - 5.9.1.4.3 Reagent blank controls associated with samples being analyzed shall be:
 - 5.9.1.4.3.1 Extracted concurrently with the forensic sample(s) and amplified with the most sensitive typing system;
 - 5.9.1.4.3.2 Analyzed utilizing the same instrument model and volume conditions consistent with the forensic sample(s);
 - 5.9.1.4.3.3 Amplified utilizing the same primer, instrument model and concentration conditions as required by the forensic sample(s) containing the least amount of DNA;
 - 5.9.1.4.4 Allelic ladders and internal size makers for variable number tandem repeat sequence PCR based systems.
 - 5.9.1.4.5 The laboratory shall check its DNA procedures annually or whenever substantial changes are made to the protocol(s) against an appropriate and available NIST standard reference material or standard traceable to a NIST standard.
- 5.9.1.5 The laboratory shall have and follow written guidelines for the interpretation of data.
- 5.9.1.5.1 The laboratory shall verify that all control results meet the laboratory's interpretation guidelines for all reported results.

- 5.9.1.5.2 For a given population(s), the statistical interpretation of autosomal loci shall be made following the recommendations 4.1, 4.2 or 4.3 as deemed applicable of the National Research Council report entitled "The Evaluation of Forensic DNA Evidence" (1996). These calculations shall be derived from a documented population database appropriate for the calculation.
- 5.9.5.1.3 For a given population(s), the statistical interpretation of YSTR or mitochondrial DNA typing shall be made following the recommendations contained in the interpretation guidelines issued by either the Canadian Scientific Working Group on DNA Analysis Methods or by SWGDAM, if available.
- 5.9.5.1.4 Laboratories analyzing forensic samples shall have and follow a documented procedure for mixture interpretation that addresses major and minor contributors, inclusions and exclusions, and policies for the reporting of results and statistics.
- 5.9.1.6 The laboratory shall have and follow a policy to document incidents of contamination and its remediation efforts.

5.9.1.7 Proficiency testing

DNA analysts, technical reviewers, technicians, and other personnel designated by the technical leader, shall undergo semi-annual internal and/or external proficiency testing in each technology performed to the full extent in which they participate in casework. Such internal or external proficiency testing shall be an open proficiency testing program and shall be submitted to the proficiency testing provider in order to be included in the provider's published summary report.

The laboratory shall use an external proficiency test provider that is in compliance with the current proficiency testing manufacturing guidelines established by the American Society of Crime Laboratory Directors/ Laboratory Accreditation Board or be in compliance with the current approved proficiency test provider standards.

- 5.9.1.7.1 Individuals routinely utilizing both manual and automated methods shall be proficiency tested in each at least once per year to the full extent in which they participate in casework.
- 5.9.1.7.2 Newly qualified individuals shall enter an internal or external proficiency testing program within six months of the date of their qualification.
- 5.9.1.7.3 For purposes of tracking compliance with the semi-annual proficiency testing requirement, the laboratory shall define, document and consistently use the date that the proficiency test is performed as the received date, submitted date, or the due date.
- 5.9.1.7.4 Except as provided in 5.9.1.7.4.1, each DNA analyst shall be assigned and complete his/her own internal and/or external proficiency test.
- 5.9.1.7.4.1 Laboratories that use a team approach to casework examination may do so on proficiency tests. However, all DNA analysts, technicians, and technical reviewers shall be proficiency tested at least once per year in each of the DNA

technologies, including test kits for DNA typing, and each platform in which they perform forensic DNA analysis.

5.9.1.7.5 The laboratory shall maintain the following records for proficiency tests:

The test set identifier, Identity of the analyst, and other participants, if applicable, Date of analysis and completion, Copies of all data and notes supporting the conclusions, The proficiency test results, Any discrepancies noted, and Corrective actions taken.

5.9.1.7.6 The laboratory shall include, at a minimum, the following criteria for evaluating proficiency test results:

5.9.1.7.6.1 Inclusions and exclusions as well as all reported genotypes and/or phenotypes are correct or incorrect according to consensus results or are within the laboratory's interpretation guidelines.

5.9.1.7.6.2 All results reported as inconclusive or not interpretable are consistent with written laboratory guidelines.

5.9.1.7.6.2.1 The technical leader shall review any inconclusive result for compliance with laboratory guidelines.

5.9.1.7.6.3 All discrepancies/errors and subsequent corrective actions shall be documented.

5.9.1.7.6.4 All final reports are graded as satisfactory or unsatisfactory.

5.9.1.7.6.4.1 A satisfactory grade is attained when there are no analytical errors for the DNA profile typing data.

5.9.1.7.6.4.1.1 Administrative errors and corrective actions, as applicable, shall be documented.

5.9.1.7.7 All proficiency test participants shall be informed of his/her final test results and this notification shall be documented.

5.9.1.7.8 The DNA technical leader shall be informed of the results of all participants and this notification shall be documented. The technical leader shall inform the casework CODIS administrator of all non-administrative discrepancies that affect the typing results and/or conclusions at the time of discovery.

Administrative and Technical Reviews

5.9.1.8 The laboratory shall conduct and document administrative and technical reviews of all case files and reports to ensure conclusions and supporting data are reasonable and within the constraints of scientific knowledge. The review of data generated external to the laboratory is governed by 4.5.

5.9.1.8.1 An individual conducting technical reviews shall be or have been an analyst qualified in the methodology being reviewed.

- 5.9.1.9. Completion of the technical review shall be documented and the technical review of forensic casework shall include the following elements:
- 5.9.1.9.1 A review of all case notes, all worksheets, and the electronic data (or printed electropherograms or images) supporting the conclusions.
 - 5.9.1.9.2 A review of all DNA types to verify that they are supported by the raw or analyzed data (electropherograms or images).
 - 5.9.1.9.3 A review of all profiles to verify correct inclusions and exclusions (if applicable) as well as a review of any inconclusive result for compliance with laboratory guidelines.
 - 5.9.1.9.4 A review of all controls, internal lane standards and allelic ladders to verify that the expected results were obtained.
 - 5.9.1.9.5 A review of statistical analysis, if applicable.
 - 5.9.1.9.6 A review of the final report's content to verify that the results/conclusions are supported by the data. The report shall address each tested item or its probative fraction.
 - 5.9.1.9.7 For entry into a searchable category at CODIS, verification of the following criteria for DNA profiles by two concordant assessments by a qualified analyst and technical reviewer or Expert System: eligibility for CODIS; correct DNA types; and appropriate specimen category.
 - 5.9.1.10 The administrative review shall include the following elements, any or all of which may be included within the technical review:
 - 5.9.1.10.1 A review of the case file and final report for clerical errors and that information specified in 5.10.2.1 is present and accurate.
 - 5.9.1.10.2 A review of chain of custody and disposition of evidence.
 - 5.9.1.10.3 A procedure to document the completion of the administrative review.
 - 5.9.1.11 The laboratory shall document the elements of a technical and administrative review. Case files shall be reviewed and documented according to the laboratory's procedure.
 - 5.9.1.12 The laboratory shall have and follow a documented procedure to address unresolved discrepant conclusions between analysts and reviewer(s).
 - 5.9.1.13 The laboratory shall have and follow a documented procedure for the verification and resolution of database matches.
 - 5.9.1.14 The laboratory shall have and follow a program that documents the annual monitoring of the testimony of each analyst.

5.10 Reporting the Results

The laboratory shall have and follow written procedures for taking and maintaining casework notes to support the conclusions drawn in laboratory reports. The laboratory shall maintain all analytical documentation generated by analysts related to case analyses. The laboratory shall retain, in hard or electronic format, sufficient documentation for each technical analysis to support the report conclusions such that another qualified individual could evaluate and interpret the data.

5.10.2.1 Casework reports shall include the following elements:

Case identifier;

A unique report identifier;

Description of evidence examined;

A description of the methodology;

Locus or amplification system;

Results and/or conclusions;

A quantitative or qualitative interpretative statement;

Date issued;

Disposition of evidence, when appropriate; and

a signature and title, or equivalent identification, of the person accepting responsibility for the content of the report.

5.10.2.2 Except as otherwise provided by federal/provincial/territorial law, reports, case files, DNA records and databases shall be confidential.

5.10.2.2.1 The laboratory shall have and follow written procedures to ensure the privacy of the reports, case files, DNA records and databases.

5.10.2.2.2 The laboratory shall have and follow written procedures for the release of reports, case files, DNA records and databases in accordance with applicable federal/provincial/territorial law.

5.10.2.2.3 Personally identifiable information shall only be released in accordance with applicable federal/provincial/territorial).

APPENDIX 4 - EQUINE DRUG TESTING

INTRODUCTION

This voluntary program is intended for laboratories that conduct forensic drug residue analysis in equine body fluids and tissues. The program is designed to establish minimum quality and reliability standards and to define uniform proficiency requirements for these laboratories. To obtain initial accreditation by SCC, a laboratory must successfully complete both a proficiency testing regimen and an on-site assessment held coincident with the testing of the third cycle of proficiency samples.

Accreditation under the PSA-FED program is the formal recognition by the Standards Council of Canada of the competence of a forensic equine drug testing laboratory to manage and perform this type of activity. It is not a guarantee that test results will conform with standards or agreements between a testing laboratory and its clients; business transactions between an accredited testing laboratory and its clients are legal matters between the two parties.

Notwithstanding the generality of the above, there are regulatory and policy criteria established by the Canadian Pari-Mutuel Agency (CPMA) for equine drug testing according to the Pari-Mutuel Betting Supervision Regulations made pursuant to s.204 of the Criminal Code of Canada. The regulatory framework forms the basis of the co-operative agreement between SCC and CPMA upon which PSA-FED is founded.

Reliable discrimination between the presence and absence of specific drugs or their metabolites in equine samples is critical. The possible impact of a positive test result on an individual's livelihood, particularly for trainers of horses that participate in pari-mutuel racing, together with the possibility of a legal challenge of the result, sets this type of test apart from general laboratory testing.

Forensic equine drug testing is a special application of forensic toxicology. The accredited laboratory must use appropriate analytical methodology, treat the specimen as evidence, and document and hold available for possible court testimony all aspects of the testing procedures. Accredited laboratories engaged in forensic equine drug testing require the services and advice of forensic equine toxicologists to address the specific needs of the testing program. These include the demands of specimen chain of custody, security, proper documentation, retention and storage of records and positive specimens, presentation of evidence in court, and expert witness testimony.

The requirements of CAN-P-4E and CAN-P-1578 guidelines apply generally to all accredited forensic laboratories. This Appendix is intended only to amplify and interpret these requirements specifically for forensic equine drug testing laboratories.

1. SCOPE

Given the wide variety of analytical demands, this program cannot cover all aspects of

forensic equine drug testing and must be regarded as being representative of this area of activity. The specific scopes of testing described below were selected because of market demand. These scopes may be modified, depending on market and regulatory requirements.

The scope of testing described below is generic, because of the extensive range of different substances which must be covered by the analytical process. A current list of drugs taken from the Pari-Mutuel Betting Supervision Regulations is available from the Canadian Pari-Mutuel Agency.

1.1 Lab Capabilities for Equine Body Fluids

- 1.1.1 An accredited laboratory must be capable of testing for a large number of drugs and metabolites in equine urine and blood samples, using a multi-step strategy of screening methods and confirmatory analysis. Screening methods should include a combination of multi-residue and target tests.
- 1.1.2 For any designated drug or metabolite, laboratories must demonstrate their capability to perform quantitative analysis in blood or urine, or both. Accredited laboratories will be provided with an updated list of quantitative analyses criteria as required, and will be expected to broaden their testing capabilities accordingly.

2. REFERENCES

In addition to the references cited in CAN-P-1578:

- Accreditation Requirements and Operating Criteria for Horseracing Laboratories, ILAC G-7, 1996.
- Canadian Pari-Mutuel Agency (CPMA), Guidance for Official Laboratories, current issue.
- Pari-Mutuel Betting Supervision Regulations [Definitions, Part V, Schedule SOR/2000/, April, 2000, as amended from time to time].

3. TERMS AND DEFINITIONS

- 3.1 Specific agreed definitions that apply, in addition to or in substitution for those cited in CAN-P-1578 are:
- 3.1.1 **Accuracy:** the closeness of agreement between a test result and the accepted reference value. The test result may be a mean of several values, (Harmonized Guidelines For Internal Quality Control In Analytical Chemistry Laboratories, Draft 2.1, 1994, protocol by the IUPAC/ISO/AOAC working party)
 - 3.1.2 **Chain of custody:** a series of documented procedures to account for the integrity of each sample by tracking its handling and storage from the point of sample collection to final disposition. Note: In Canadian usage, also known as Continuity of Possession.
 - 3.1.3 **Confirmatory analysis:** analytical procedures applied to a sample to identify the presence of a specific drug or its metabolites, that are independent of the initial test and that may use different analytical techniques.
 - 3.1.4 **Drug administration:** the application of a drug (dosing) to a horse by various routes for the purpose of collecting biological samples for analysis.
 - 3.1.5 **Drug elimination:** biological process of removal of drugs or drug metabolites from the body.
 - 3.1.6 **Limit of detection:** an estimate of the lowest concentration of analyte in a real sample matrix that can be detected using a specific test method, as compared with known matrix spikes and blanks carried through the complete method.
 - 3.1.7 **Metabolite:** a product formed by in vivo conversion of a drug to a different chemical form.
 - 3.1.8 **Forensic equine toxicologist:** a person who, using the appropriate combination of knowledge, skill, experience and integrity, undertakes one or more of the following tasks in the discipline of equine drug testing: analysis of evidentiary materials, interpretation of evidence, and presentation of expert testimony. The person should also be eligible for professional membership in the Association of Official Racing Chemists (AORC).
 - 3.1.9 **Precision:** the closeness of agreement between independent test results obtained under prescribed conditions. (Harmonized Guidelines For Internal Quality Control In Analytical Chemistry Laboratories, Draft 2.1, 1994, protocol by the IUPAC/ISO/AOAC working party)

NOTES: - Precision depends only on the distribution of random errors and does not relate to the accepted reference value

The measure of precision is usually expressed in terms of imprecision and computed as a standard deviation of the test results. Higher imprecision is reflected by a larger standard deviation.

"Independent test results" means results obtained in a manner not influenced by any previous result on the same or similar material.

- 3.1.10 **Quantitative Analysis:** the accurate measurement of the amount of a specific drug, metabolite, volatile or other substance contained in a body fluid, tissue or other sample.
- 3.1.11 **Screening method:** an initial analytical procedure applied to a sample, or series of samples, designed to provide preliminary evidence of possible drug or metabolite presence which may require confirmatory follow-up.
- 3.1.12 **Specificity:** the capability of an analytical procedure to reliably discriminate among chemically or physically related substances.
- 3.1.13 **Spiked sample:** a test material consisting of a representative matrix to which a known amount of analyte has been added.
- 3.1.14 **Target test:** a screening method applied to a sample or a series of samples to detect the presence of a specific drug or of a chemically related group of substances.

4. MANAGEMENT REQUIREMENTS

- 4.1 **Organization and Management** - no additional requirements
- 4.2 **Quality System** – no additional requirements
- 4.3 **Document Control** - no additional requirements
- 4.4 **Review of Requests, Tenders and Contracts** - no additional requirements
- 4.5 **Subcontracting of Tests and Calibrations** - no additional requirements
- 4.6 **Purchasing Services and Supplies** - no additional requirements
- 4.7 **Service to the Client** - no additional requirements
- 4.8 **Complaints** - no additional requirements
- 4.9 **Control of Non-Conforming Testing and/or Calibration Work** - no additional requirements
- 4.10 **Improvement**
- 4.11 **Corrective Action** - no additional requirements
- 4.12 **Preventive Action** - no additional requirements
- 4.13 **Control of Records**
 - 4.12.1 All records, including those for negative results, must be reviewed by an approved signatory of the laboratory.
 - 4.12.2 The laboratory is required to maintain for an indefinite period of time all original documents, i.e. test records and associated physical exhibits, for any sample under legal challenge.
- 4.14 **Internal Audits** - no additional requirements
- 4.15 **Management Reviews** - no additional requirements

5. TECHNICAL REQUIREMENTS

5.1 General - no additional requirements

5.2 Personnel

5.2.1 The person in charge of a forensic equine drug testing laboratory must be a qualified forensic equine toxicologist with a minimum of a Bachelor's degree in a biological or chemical discipline and five years experience. The qualified forensic equine toxicologist should have documented training and experience in the forensic application of analytical toxicology such as court testimony, research, participation in continuing education programs and knowledge of evidentiary procedures.

5.2.2 Where required, certificates of analysis must be signed by an approved signatory, such as an official chemist according to the Pari-Mutuel Betting Supervision Regulations, or other designated analyst.

5.2.3 In addition to the above criterion, it is a legislative requirement in some provinces that a signatory be a member of the professional association of chemists.

5.3 Accommodation and Environmental Conditions

5.3.1 The storage and handling of controlled drugs must comply with applicable legislation.

5.3.2 All substances in the laboratory which present potential risks to health and safety, including drug reference standard materials, shall be labelled and handled according to appropriate documented procedures.

5.4 Test and Calibration Methods and Method Validation

5.4.1 Standard methods are generally not available for forensic equine drug analysis. Therefore the laboratory shall develop, validate and document representative in-house methods. The use of these methods shall be subject to agreement with the client and shall be available to the client and other recipients of the relevant reports.

5.4.2 Initial screening methods must specify the minimum schedule of tests for samples to be recorded as negative. The laboratory must document for each screening test how they decide which samples proceed to confirmatory testing.

5.4.3 As part of the validation of in-house screening methods, estimated limits of detection for representative drugs must be determined and documented.

5.4.4 Confirmation methods usually include an extraction method, possible purification

step and the use of various detection techniques. These methods may be fairly generic in nature and therefore applicable to a large number of drugs or a family of drugs. In some cases they may be very specific and can only be applied to one chemical. The laboratory shall document and validate their confirmation methods. Method validation shall involve the use of appropriate representative reference materials to determine the estimated limits of detection. There must be written laboratory criteria for what constitutes a "match" between a reference material and a sample component.

5.4.5 Where quantitative analysis is required, those methods shall be documented and validated by the laboratory. Method validation shall include determination of linearity, specificity, limit of detection, accuracy and precision.

5.4.6 Where a method is varied for valid technical reasons, the changes shall be authorized and documented to the extent necessary to enable the test or analysis to be repeated under identical conditions at a later date.

5.5 Equipment - no additional requirements

5.6 Measurement Traceability

5.6.1 Few of the available reference drug and drug metabolite materials are traceable to national or international standards.

5.6.2 Reference drug and drug metabolite materials, traceable to a national standard or certified by a body of recognized status, such as USP, BP, WHO, are to be used when commercially available. Simple checks for identity are required prior to placing such materials into service.

5.6.3 Where a reference material is not certified, the laboratory shall verify its identity and purity by comparison with published data or by exhaustive chemical characterization.

5.6.4 A reference material may also be an isolate from a biological matrix following an authentic and verifiable administration, providing that the analytical data are sufficient to fully justify its identity as a metabolite of the substance administered.

5.6.5 Solutions of reference materials shall be prepared in such a way as to maintain their integrity. Documentation shall be complete so as to provide a clear audit trail back to the reference material or source.

5.7 Sampling

5.7.1 The laboratory should comply with the following:

a) Prepare and follow documented procedures for the actions of obtaining, handling, labeling, packaging and shipping of the sample to the laboratory. These

procedures shall meet the needs of individual clients.

- b) Ensure that sampling personnel are qualified and that their training is maintained current.
- c) Carry out on-site inspections or audits of the various sampling action details and different facilities, as needed.
- d) Follow documented procedures which ensure the integrity of the sample at all times during collection and transportation.
- e) Implement documented procedures for tracing late or lost samples, and for reporting any such incidents to the client.

5.8 Handling of Test and Calibration Items- no additional requirements

5.9 Assuring the Quality of Test and Calibration Results

- 5.9.1 The laboratory must implement internal quality control schemes which monitor all the steps and phases of the laboratory's analytical operation. This includes screening methods, confirmatory analysis, quantitative limit and other programs in place or to be implemented in the future.
- 5.9.2 Whenever appropriate in the quality control system, statistical techniques such as control charts should be used.
- 5.9.3 Every analytical batch must be accompanied by quality control measures that demonstrate the analytical system control status. This should include, but not necessarily be limited to, results from a representative matrix blank, calibration of instrument performance parameters by suitably selected chemical standards, and control samples spiked in a representative matrix. In instances where a large number of samples are analyzed, of which most are negative, the samples themselves may serve as the system blank. Records of instrument calibration and performance parameters shall be maintained.
- 5.9.4 The laboratory must verify positive analytical findings by the re-testing of a second portion of the client samples using the same or different analytical techniques, or both.
- 5.9.5 The laboratory's internal quality control system should include the following:
 - a) the blind submission of known blank samples into the analytical system.
 - b) the blind submission of spiked samples or known positive samples into the analytical system.

5.9.6 Evaluation of Laboratory Performance

5.9.6.1 General Conditions

- 5.9.6.1.1 Results of the CPMA PT Program will be used to support initial accreditation and maintenance of standing for this program. The CPMA will appoint a coordinator for the PT Program. Any appeal by a participating laboratory regarding the assessment of reported results will be administered by SCC through its Forensic Working Group (FWG), as explained in CAN-P-15, sections 4.2 and 4.3.
- 5.9.6.1.2 Current drug lists for PT are available from CPMA. All procedures associated with the handling and testing of PT samples by the laboratory shall be carried out to the greatest extent possible in a manner identical to that applied to routine client samples. Methods for screening and confirmatory analysis must be validated. Changes to the test lists may be made by consensus of the SCC PSA-FED WG.
- 5.9.6.1.3 PT sample results are due three (3) weeks after receipt of PT samples by the laboratory. Results will be issued to participants by the PT program coordinator within 2 weeks of receipt of all laboratory reports, giving the result of qualitative assessment, and including the name of the drug or metabolite spiked, the target concentration where applicable, any significant participating laboratory group results and any other pertinent information related to the preparation of each sample.
- 5.9.6.1.4 Incorrect identifications on any client samples or PT samples are unacceptable for any substance for which an accredited laboratory offers service and will result in initiation of action according to section 4.4. Incorrect negative identifications are usually considered less serious than incorrect positive identifications.
- 5.9.6.1.5 The CPMA operates a QA program for laboratories conducting analysis on samples obtained from horses participating in pari-mutuel racing in Canada. Participation in this program is accepted by SCC as evidence of laboratory participation in an inter-laboratory QA scheme.

5.9.6.2 Proficiency Testing (PT) and its Requirements

- 5.9.6.2.1 A PT cycle consists of the following:
- a) A set of 10 samples for qualitative analysis, which are either:
 - i) Blanks or spiked samples prepared in equine body fluids according to specified minimum concentrations for each drug or metabolite obtained from the test list provided by CPMA, or
 - ii) Samples obtained from horses before or after administration of one or more of the drugs listed in the lists provided by CPMA, for which

the content and concentration of the drug or metabolite, or both, has been verified to equal or exceed the minimum specifications in that list; and

b) A set of 2 samples for quantitative analysis, which are either spiked samples prepared in equine body fluids according to protocols available from CPMA or are verified post-administration samples of equine body fluids.

5.9.6.2.2 Prior to becoming accredited, a laboratory must successfully complete three (3) PT cycles. Analysis must be completed and results reported within three weeks of receipt of each PT cycle of samples. The third cycle of PT samples will be timed to coincide with an on-site assessment to confirm that procedures and practices conform to accreditation requirements. A laboratory that fails the first cycle may be provided with another initial cycle, if requested, after corrective action has been taken. If the second such cycle is not analyzed satisfactorily, further corrective action must be taken and the laboratory must submit a new application before another initial cycle may be requested.

5.9.6.2.3 In order to remain accredited, the laboratory shall complete, as provided, two (2) annual cycles of PT samples.

5.9.6.2.4 To pass a set of qualitative PT samples, the laboratory must correctly identify 100% of the samples within the time permitted.

5.9.6.2.5 To pass a set of quantitative PT samples, the laboratory must correctly report the drug or metabolite concentration within a specified range of the target concentration as follows: $\pm 20\%$ for drugs reported in the $\mu\text{g/mL}$ range or $\pm 40\%$ for drugs reported in the ng/mL range; or ± 2 s.d. (s.d. = Standard deviation) of group mean as applicable, based on consensus among the group of accredited laboratories.

5.9.6.3 Procedures for Unsatisfactory Laboratory Performance

5.9.6.3.1 Failure of a laboratory to comply with any aspect of these Guidelines may lead to suspension or withdrawal of accreditation in accordance with the withdrawal procedure documented in sub-section 4.2 and 4.3 of CAN-P-15. In addition, the laboratory will be subject to the suspension and withdrawal procedures below, when its testing performance does not meet the specified performance criteria.

5.9.6.3.2 SCC will consider the following factors in determining whether disqualification of an applicant laboratory or suspension or withdrawal of accreditation of an accredited laboratory is necessary:

- a) unsatisfactory participation or failure to participate in the PT Program;
- b) failure to take corrective action on incorrect identifications.

- 5.9.6.3.3 Incorrect positive identifications on any client samples or PT samples are unacceptable for any substance for which an accredited laboratory offers service. The actions requested will be an audit of the process conducted on the sample and a comprehensive written response indicating the outcome of the corrective action(s) implemented to be sent to the PT program coordinator, with a copy to SCC, within ten (10) working days from the receipt of notification of the unsatisfactory results by the laboratory. The written response should also include any action to prevent reoccurrence and any remedial action taken.
- 5.9.6.3.4 Failure to provide the written response required by section 4.4.3 following an incorrect positive result will result in suspension or withdrawal of accreditation. Generating evidence that the problem has been identified and corrected may require the laboratory's analysis of additional PT samples, or the initiation of an on-site visit by the SCC, or both. Where there is a second occurrence of an incorrect positive result, SCC may suspend the laboratory, after investigation of the circumstances. Following three (3) occurrences of an incorrect positive result, SCC will obtain the approval from the TASC Chairperson to suspend the laboratory accreditation immediately and initiate withdrawal according to the procedure in CAN-P-15, clause 4.2.2 and 4.3 respectively.
- 5.9.6.3.5 Following an incorrect negative identification or incorrect quantification in the PT program (as specified in clause 4.2.5), the action required will be assessed on an individual basis. The required actions could include such elements as passing an additional set of PT samples, an audit of the process conducted on the sample and a comprehensive written response, indicating the outcome of the corrective action(s) implemented, or a combination of several elements. Written responses, where required, shall be sent to the PT program coordinator, copy to SCC, within ten (10) working days from the receipt of notification of the unsatisfactory results by the laboratory.
- 5.9.6.3.6 Following a second incorrect negative identification or incorrect quantification within three (3) cycles of PT, the outcome may be suspension, depending on the seriousness of the errors and whether there is evidence that the problem has been identified and corrected. Generating evidence that the problem has been identified and corrected may require the laboratory's analysis of additional PT or QA samples, or the initiation of an on-site visit by the SCC, or both.
- 5.9.6.3.7 If the laboratory fails to participate in any required element of this document, SCC will immediately suspend the laboratory and notify the laboratory of its intention to initiate its accreditation withdrawal procedure in CAN-P-15, clause 4.3.
- 5.9.6.3.8 Should the SCC initiate action to suspend or withdraw the laboratory's

accreditation, the laboratory's official status will become "suspended" or "withdrawn" until such time that the suspension is lifted or until any re-accreditation process is complete.

5.10 Reporting the Results

5.10.1 Certificates of Analysis are legal instruments. As such, information contained in these reports is directed by the appropriate laws of the land.

5.10.2 Drug testing programs performed under this accreditation program generally involve a large number of samples, many thousands of possible analytes and very few positive findings. Different clients have different reporting requirements. Where clients do not require individual reports on negative samples, such reports are not routinely issued.

APPENDIX 5 - NATIONAL DNA DATA BANK OF CANADA

INTRODUCTION

The National DNA Data Bank of Canada is conducted in accordance with RCMP Forensic Laboratory Services Directorate Policy. The National DNA Data Bank performs forensic DNA identification analysis of biological samples from convicted offenders.

To ensure the most efficient use of resources in this field of testing, it is important that data generated by the National DNA Data Bank of Canada be reliable and comparable with data generated by individual forensic casework laboratories. This can be achieved by the use of the laboratory accreditation scheme.

These specific requirements were established by an Ad Hoc Technical Working Group on the National DNA Data Bank of Canada. The technical base is drawn from published principles, as well as practices and procedures promoted by national and international organizations. This document is primarily based on the document A Quality Assurance Standards for Convicted Offender DNA Data Basing Laboratories[®] produced by the DNA Advisory Board in the USA. Appropriate modifications have been made to adapt to the Canadian situation.

This document consists of definitions and standards. The standards are quality assurance measures that place specific requirements on the laboratory. Equivalent measures not outlined in this document may also meet the standard.

All requirements of the CAN-P-4 and the PSA-FT guidelines apply generally to all accredited forensic laboratories in Canada and are not repeated in this document. This Appendix is intended only to amplify and interpret the CAN-P-4 and the PSA-FT requirements specifically for a DNA Data Basing laboratory processing biological samples from convicted offenders.

1. SCOPE

The standards describe the quality assurance requirements necessary to ensure the quality and integrity of the data and competency of a laboratory regularly performing DNA typing analysis on biological samples from convicted offenders. These standards do not preclude the participation of a laboratory, by itself or in collaboration with others, in research and development, on procedures that have not yet been validated for use in casework.

2. REFERENCES

- DNA Advisory Board, A Quality Assurance Standards for Convicted Offender DNA Data Basing Laboratories@, Forensic Science Communications, July 2000, Volume 2, Number 3.
- DNA Advisory Board Quality Assurance Standards for Forensic DNA Testing Laboratories, last modified August 10, 1999. Retrieved November 17, 2000 from the World Wide Web: <http://www.cstl.nist.gov/biotech/strbase/dabqas.htm>
- Technical Working Group on DNA Analysis Methods, A Guidelines for a Quality Assurance Program for DNA Analysis@, Crime Laboratory Digest, April 1995, Volume 22, Number 2, pp.21- 43.

3. TERMS AND DEFINITIONS

As used in these standards, the following terms shall have the meanings specified:

- 3.1 Analytical procedure** is an orderly step by step procedure designed to ensure operational uniformity and to minimize analytical drift.
- 3.2 Blood Internal Standard Control** is an internal quality control measure designed to monitor the entire DNA typing protocol and serve as a control for gender determination.
- 3.3 CODIS** is the Combined DNA Index System administered by the National DNA Data Bank of Canada. It houses DNA profiles from convicted offenders and from forensic specimens.
- 3.4 Commercial test kit** is a pre-assembled kit that allows the user to conduct a specific forensic DNA test.
- 3.5 Convicted offender** is an individual who is required by statute to submit a biological sample for DNA data basing.
- 3.6 CODIS Coordinator** is the individual responsible for the administration and security of the laboratory's CODIS.
- 3.7 Convicted offender sample** is biological material collected from an individual for DNA typing analysis and inclusion of the resulting DNA profile into CODIS.

- 3.8 Critical reagents** are determined by empirical studies or routine practice to require testing on established samples before use on evidentiary samples in order to prevent unnecessary loss of sample.
- 3.9 Database sample** is a known biological sample (blood, buccal or hair) obtained from an individual whose DNA profile is to be included in a computerized database and searched against other profiles.
- 3.10 DNA Analyst** is an individual who conducts and/or directs the analysis of database samples, interprets data and reaches conclusions.
- 3.11 Known samples** are biological material whose identity or DNA type is established.
- 3.12 Laboratory** is a facility in which DNA testing of biological samples from convicted offenders is performed.
- 3.13 Laboratory support personnel** are individuals who perform laboratory duties but do not analyze samples.
- 3.14 Negative Amplification Control** consists of only amplification reagents without the addition of sample DNA. This control is used to detect DNA contamination of the amplification reagents.
- 3.15 Polymerase chain reaction (PCR)** is an enzymatic process by which a specific region of DNA is replicated during repetitive cycles which consist of (1) denaturation of the template; (2) annealing of primers to complementary sequences at an empirically determined temperature; and (3) extension of the bound primers by a DNA polymerase.
- 3.16 Positive Amplification Control** is a quality control measure designed to monitor the amplification process and serve as a control for gender determination.
- 3.17 Proficiency test sample** is biological material whose DNA profile has been previously determined and which is used to monitor the quality performance of a laboratory or an individual.
- 3.18 Proficiency testing** is a quality assurance measure used to monitor performance and identify areas where improvement may be needed. Proficiency tests may be classified as:
- (1) internal proficiency tests, which may be open or blind, are prepared and administered by the laboratory.
 - (2) external proficiency tests, which may be open or blind, are obtained from an outside agency.
- 3.19 Qualifying test** is a measure of proficiency in both technical skills and knowledge, which must be successfully completed prior to undertaking sample analysis.
- 3.20 Reagent Blank Control** consists of all reagents and substrates (without the addition of a DNA sample) that are used in the test process. It is used to detect DNA contamination of any of the analytical reagents.

- 3.21 Reference material** (certified or standard) is a material for which values are certified by a technically valid procedure and accompanied by, or traceable to, a certificate or other documentation which is issued by the certifying body.
- 3.22 Sample Receptionist** is the individual responsible for the reception and the initial processing of the convicted offender sample collection kit.
- 3.23 Secure area** is a locked space (for example, cabinet, vault or room) with access restricted to authorized personnel.
- 3.24 Technical Manager** is the individual accountable for the technical operations of the laboratory.
- 3.25 Technical review** is an evaluation of notes, data, and other documents to ensure that there is an appropriate and sufficient basis for scientific conclusions. This review is conducted by a second qualified individual.
- 3.26 Traceability** is the property of a result of a measurement whereby it can be related to appropriate standards, generally international or national standards, through an unbroken chain of comparisons.
- 3.27 Validation** is a process by which a procedure is evaluated to determine its efficacy and reliability for DNA typing analysis and includes:
- (1) A developmental validation which is the acquisition of test data and determination of conditions and limitations of a new or novel DNA methodology for use on samples.
 - (2) An internal validation which is an accumulation of test data within the laboratory to demonstrate that established procedures perform as expected in the laboratory.

4. MANAGEMENT REQUIREMENTS

No additional interpretation of this section for the National DNA Data Bank is required.

5. TECHNICAL REQUIREMENTS

5.1 General

No additional interpretation of this section for the National DNA Data Bank is required.

5.2 Personnel

5.2.1 Laboratory personnel shall have the education, training and experience commensurate with the examination and analysis provided. The laboratory shall:

- 1) have a written job description for personnel which includes responsibilities, duties and skills.
- 2) have a documented training program for qualifying the DNA Analysts.
- 3) maintain records on the relevant qualifications, training, skills and experience of the technical personnel.

5.2.2 Continuing Education

The Technical Manager, the CODIS Coordinator and the DNA Analysts must stay abreast of developments within the field of DNA typing analysis by reading current scientific literature and by attending seminars, courses, professional meetings or documented training sessions/classes in relevant subject areas whenever possible.

5.2.3 Requirements for Technical Manager

5.2.3.1 Degree requirements for Technical Manager of a DNA typing analysis laboratory:

The Technical Manager must have at a minimum a M.Sc. degree in biology or chemistry or forensic science-related area and successfully completed a minimum of 12 semesters or equivalent credit hours of a combination of under-graduate course work covering the subject areas of biochemistry, genetics, and molecular biology (molecular genetics, recombinant DNA technology) or other subjects which provide a basic understanding of the foundation of forensic analysis as well as statistics and/or populations genetics as it applies to forensic DNA analysis.

5.2.3.2 Experience requirements:

A Technical Manager of a laboratory must have a minimum of three years of DNA typing analysis laboratory experience.

5.2.3.3 Duty requirements:

The Technical Manager is responsible for:

- (a) evaluating all methods used by the laboratory and for proposing new or modified analytical procedures to be used by lab personnel.
- (b) solving technical problems of analytical methods and for the supervision of training, quality assurance and proficiency testing in the laboratory.

5.2.3.4 The technical Manager shall be accessible to the laboratory to provide on site, telephone or electronic consultation as needed.

5.2.4 Requirements for DNA Analyst

5.2.4.1 The DNA Analyst must have at a minimum a three-year diploma in a program such as Biotechnology, Biochemical Technology, Biology, Chemistry, Molecular biology or Life Sciences from a recognized college.

5.2.4.2 A DNA Analyst must have a minimum of three months of DNA laboratory experience and training at the National DNA Data Bank, including the successful analysis of a range of samples typically encountered in the DNA typing analysis of samples from convicted offenders.

5.2.4.3 A DNA Analyst must successfully complete a qualifying test before assuming DNA typing responsibilities for samples from convicted offenders.

5.2.5 Requirements for CODIS Coordinator

5.2.5.1 The CODIS Coordinator must have at a minimum a Bachelor degree in a biological science or computer science from a recognized University.

5.2.5.2 The CODIS Coordinator must have a working knowledge of computers, computer networks and computer database management as well as an understanding of DNA profile interpretation.

5.2.5.3 The CODIS Coordinator is the system administrator of the laboratory's CODIS network and is responsible for:

- (a) ensuring the security of DNA profile data stored in CODIS.
- (b) overseeing and participating in CODIS computer training and quality assurance of data.

5.2.5.4 The CODIS Coordinator has the authority to terminate the laboratory's participation in CODIS in the event of a problem until the reliability of the computer data can be assured.

5.2.6 Requirements for Laboratory Support Personnel

Education, experience and training for Laboratory Support Personnel are commensurate with their responsibilities as outlined in their job description.

5.3 Accommodation and Environmental Conditions

- 5.3.1 The laboratory shall have a facility that is designed to provide adequate security and minimize contamination. The laboratory shall ensure that:
- (1) access to the laboratory is controlled and limited.
 - (2) prior to PCR amplification, initial processing of the biological sample, DNA purification and PCR set-up are conducted at separate times or in separate spaces.
 - (3) amplified DNA product is generated, processed and maintained in a room(s) separate from the initial processing of the biological sample, DNA purification and PCR set-up areas.
 - (4) the laboratory follows written procedures for monitoring, cleaning and decontaminating facilities and equipment.
- 5.3.2 the laboratory shall have and follow a documented sample inventory control system. This system shall ensure that:
- (1) convicted offender samples are marked for identification.
 - (2) documentation of sample identity, collection, receipt, storage and disposition is maintained.
 - (3) the laboratory follows documented procedures that minimize sample loss, contamination, and/or deleterious change.
 - (4) the convicted offender samples shall be safely and securely stored.

5.4 Test and Calibration Methods and Method Calibration

- 5.4.1 The laboratory shall use validated methods and procedures for DNA analysis.
- 5.4.2 Developmental validation that is conducted shall be appropriately documented.
- 5.4.3 Novel DNA database methodologies shall undergo developmental validation to ensure the accuracy, precision and reproducibility of the procedure.
- 5.4.4 Documentation shall be available which defines and characterizes all loci.
- 5.4.5 Internal validation shall be performed and documented by the laboratory.
- 5.4.5.1 The procedure shall be tested using known samples. The laboratory shall monitor and document the reproducibility and precision of the procedure using human DNA control(s).
- 5.4.5.2 Before the introduction of a significant change or novel procedure into database sample analysis, the DNA Analyst shall successfully complete a qualifying test.
- 5.4.6 The laboratory shall have written analytical procedures which have been approved by the laboratory management.
- 5.4.6.1 The laboratory shall have a step by step procedure for each analytical procedure

used.

5.4.6.2 The procedures shall include reagents, sample preparation, DNA purification, equipment, controls and standards used for DNA typing analysis and data interpretation.

5.4.7 The laboratory shall use reagents that are suitable for the methods employed.

5.4.7.1 The laboratory shall have written procedures for documenting commercial supplies and for the formulation of reagents.

5.4.7.2 Reagents shall be labeled with the identity of the reagent, the date of preparation and expiration and the identity of the individual who prepared the reagent.

5.4.7.3 The laboratory shall identify critical reagents and evaluate them prior to use.

5.5 Equipment

No additional interpretation of this section for the National DNA Data Bank is required.

5.6 Measurement Traceability

No additional interpretation of this section for the National DNA Data Bank is required.

5.7 Sampling

No additional interpretation of this section for the National DNA Data Bank is required.

5.8 Handling of Test and Calibration Items

No additional interpretation of this section for the National DNA Data Bank is required.

5.9 Assuring the Quality of test and Calibration Results

5.9.1 The laboratory shall monitor the analytical procedures using appropriate controls and standards.

5.9.2 The following controls shall be used for PCR analysis of DNA database samples:

- (1) Blood Internal Standard Control.
- (2) Reagent Blank Control.
- (3) Positive Amplification Control.
- (4) Negative Amplification Control.
- (5) Appropriate allelic ladders and internal size markers for the specific PCR-based system used.

5.9.3 The laboratory shall check its DNA typing analysis procedures annually or whenever substantial changes are made to the protocol(s) against an appropriate and available NIST standard material or a standard traceable to a NIST standard.

5.9.4 The laboratory shall have and follow written general guidelines for the interpretation of data.

5.9.5 The laboratory should verify that all control results are within established guidelines. A written procedure should be in place to address control results that are outside guidelines

5.9.6 The laboratory shall have and follow written procedures for reviewing DNA database sample information, results and matches.

5.9.7 The laboratory shall have a mechanism in place to address unresolved discrepant conclusions between the initial analyst and the second analyst.

5.9.8 The National DNA Data Bank laboratory will participate in both an external and an internal proficiency testing program. DNA Analysts shall participate in the external or the internal proficiency testing program semi-annually. If an analyst conducts more than one type of DNA typing analysis, then that individual must be tested in each type.

5.9.9 Sample Receptionists shall participate in a semi-annual internal proficiency testing program related to the type of examination they perform.

5.9.10 The laboratory shall maintain the following records for proficiency tests:

- (1) the test set identifier
- (2) identity of the DNA Analyst or Sample Receptionist
- (3) date of analysis and completion
- (4) copies of all data and notes supporting the conclusions
- (5) the proficiency test results
- (6) any discrepancies noted
- (7) corrective action taken

5.9.11 The laboratory shall establish at a minimum the following criteria for evaluation of proficiency tests:

- (1) All reported genotypes are correct or incorrect.
- (2) All results reported as inconclusive or uninterpretable are consistent with written laboratory guidelines. The basis for inconclusive interpretation in proficiency tests must be documented.
- (3) All discrepancies/errors and subsequent corrective actions must be documented.
- (4) All final reports are graded satisfactory or unsatisfactory. Absence of analytical errors is necessary but not sufficient to obtain a satisfactory grade. Administrative errors shall be documented and corrective actions taken to minimize the possibility of recurrence of the error in the future.

5.9.12 All proficiency test participant shall be informed of the final test results.

5.9.13 The laboratory shall establish and follow procedures for corrective action whenever proficiency testing discrepancies or analytical errors are detected.

5.9.14 The laboratory shall maintain documentation for the corrective action.

5.10 Reporting the results

5.10.1 The laboratory shall have and follow written procedures for generating and maintaining documentation for DNA database samples.

5.10.2 The laboratory shall have written procedures for the release of DNA database sample information.

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APPENDIX 6 - DRUG CHEMISTRY

INTRODUCTION

This voluntary program is intended for laboratories that conduct forensic drug chemistry analysis. In this context, forensic drug chemistry is that branch of forensic science involved in the detection, identification and quantification of drugs of abuse and related substances in matrices other than human biofluids and tissues. The program is designed to establish minimum quality and reliability standards and to define uniform proficiency requirements for these laboratories. To obtain initial accreditation by the Standards Council of Canada (SCC), a laboratory must successfully complete an on-site assessment and participate successfully in one or more recognized external proficiency testing programs.

Laboratories accredited under the Program Speciality Area - Forensic Testing (PSA-FT) for drug chemistry must use appropriate analytical methodology and document and hold available for possible court testimony all aspects of the testing procedures. All test materials must be treated as evidence with appropriate security, proper documentation, retention and storage of records and items. Accredited laboratories engaged in forensic drug chemistry require the services and advice of at least one qualified forensic chemist.

Accreditation under the PSA-FT for drug chemistry program is the formal recognition by the Standards Council of Canada of the competence of a forensic drug chemistry testing laboratory to manage and perform this type of activity. It is not a guarantee that test results will conform with standards or agreements between a testing laboratory and its clients; business transactions between an accredited testing laboratory and its clients are legal matters between the two parties.

The requirements of CAN-P-4 and CAN-P-1578 guidelines apply generally to all accredited forensic laboratories. This Appendix is intended only to amplify and interpret the CAN-P-4 requirements specifically for forensic drug chemistry laboratories.

1. SCOPE

- 1.1 Given the wide variety of analytical demands, this program cannot cover all aspects of forensic drug chemistry testing and must be regarded as being representative of this area of activity.
- 1.2 The scope of testing described below is generic, because of the extensive range of different substances which must be covered by the analytical process. The ability to detect new drugs or substances is a routine requirement for forensic drug chemistry laboratories. Standard methods may not be available for this type of testing.
- 1.3 Should a laboratory be required to collect samples, recommendations are

provided in Annex 6A.

1.4 Qualitative Tests

An accredited laboratory must be capable of testing for a wide variety of controlled and non-controlled drugs and related substances, using a multi-step strategy of non-confirmatory and confirmatory analyses.

1.5 Quantitative Tests

An accredited laboratory must be capable of performing quantitative analyses of controlled and non-controlled drugs and related substances.

2.0 REFERENCES

In addition to the references cited in section 1 of CAN-P-1578:

- ISO/IEC Guide 43-1, 1997, Proficiency Testing by Interlaboratory Comparisons -Part 1: Development And Operation Of Laboratory Proficiency Testing Schemes.
- ISO/IEC Guide 43-2, 1997, Proficiency Testing by Interlaboratory Comparisons -Part 2: Selection and Use of Proficiency Testing Schemes by Laboratory Accreditation Bodies.
- ISO 8402:1994 Quality Management and Quality Assurance- Vocabulary
- CAN-P-15, Accreditation Programs: Requirements and Procedures for Suspension and Withdrawal, Complaints, Appeals and Hearings, SCC, 2000.

3.0 TERMS AND DEFINITIONS

All definitions in CAN-P-4E and CAN-P-1578 and those applicable from ISO 8402 apply, as well as the following items specific to this document:

- 3.1 **Accuracy:** the closeness of agreement between a test result and the accepted reference value. The test result may be a mean of several values.
- 3.2 **Analyst:** a person designated under section 44 of the Controlled Drugs and Substances Act.
- 3.3 **Continuity of Possession:** a series of documented procedures to account for the integrity of each sample by tracking its handling and storage from the point of sample collection to final disposition. Also referred to as Chain of Custody.
- 3.4 **Confirmatory Analysis:** analytical procedures applied to a sample to identify the presence of a scheduled or non-scheduled drug or related substance that has the capability of identifying the drug or substance that has been presumptively identified by another technique, thus eliminating all other substances from consideration.
- 3.5 **False Negative:** failing to report a substance as being present in a sample, when in fact it was present and would ordinarily be reported if found.
- 3.6 **False Positive:** reporting a substance detected which is not actually present in the sample analysed.
- 3.7 **Limit of Detection:** an estimate of the minimum amount or concentration of an analyte which provides sufficient response to make a positive identification (but not necessarily reliable quantification).
- 3.8 **Non-confirmatory Analysis:** an initial analytical procedure applied to a sample, or series of samples, designed to provide evidence of scheduled or non-scheduled drugs or related substances which requires confirmatory follow up.
- 3.9 **Non-scheduled Drugs:** Drugs which are not listed in the schedules of the Controlled Drugs and Substances Act or Schedule F of the Regulations to the Food and Drugs Act.
- 3.10 **Precision:** the closeness of agreement between independent test results obtained under prescribed conditions.
- 3.11 **Quantitative Analysis:** the accurate measurement of the amount of a specific drug, contained in a sample.

- 3.12 **Related Substances:** Chemical substances which may be identified but which are not regulated by Canadian law relating to the control of drugs.
- 3.13 **Scheduled Drugs:** Controlled drugs or substances that appear in Schedule I to VI of the Controlled Drugs and Substances Act or Schedule F of the Regulations to the Food and Drugs Act.
- 3.14 **Specificity:** the capability of an analytical procedure to reliably discriminate among chemically or physically related substances.

4. MANAGEMENT REQUIREMENTS

- 4.1 **Organization and management**- no additional requirements.
- 4.2 **Quality system** - no additional requirements.
- 4.3 **Document control** -no additional requirements.
- 4.4 **Review of requests, tenders and contracts** - no additional requirements.
- 4.5 **Subcontracting of tests and calibrations** - no additional requirements.
- 4.6 **Purchasing of services and supplies** - no additional requirements.
- 4.7 **Service to the client** - no additional requirements.
- 4.8 **Complaints** - no additional requirements.
- 4.9 **Control of non-conforming testing and/or calibration work** - no additional requirements.
- 4.10 **Improvement**:- no additional requirements.
- 4.11 **Corrective action** - no additional requirements.
- 4.12 **Preventive action** - no additional requirements.
- 4.13 **Control of records**
 - 4.12.1 The laboratory is required to maintain for a period of at least 15 years all original documents, i.e. test records, calibration records and reports, unless otherwise negotiated with the client.
 - 4.12.2 Calculations and data transfers which do not form part of a validated electronic process shall be checked by the person in charge of the case being investigated. Where an independent check has been carried out by other authorized personnel, the records shall indicate that such checks have been carried out and by whom.
- 4.14 **Internal audits** - no additional requirements.
- 4.15 **Management reviews** - no additional requirements.

5. TECHNICAL REQUIREMENTS

5.1 General - no additional requirements.

5.2 Personnel

5.2.1 The manager of a drug chemistry laboratory must be a qualified forensic analyst with a minimum of a Bachelor's degree in a chemical discipline and significant, recent and relevant experience.

5.2.2 The qualified forensic analyst shall have a minimum of a Bachelor's degree in a chemical discipline or at least five years practical experience in the field of forensic drug chemistry examination and have demonstrated competency following the completion of a formal, documented training program and post training competency assessment. In addition, a qualified forensic analyst will have documented training and/or experience in the forensic application of analytical chemistry such as court testimony, participation in continuing education programs and knowledge of evidentiary procedures.

5.2.3 Certificates of Analyst must be signed by an analyst.

5.3 Accommodation and environmental conditions

5.3.1 The storage and handling of controlled drugs and substances must comply with applicable legislation.

5.3.2 All substances in the laboratory which present potential risks to health and safety, including drug reference standard materials, should be labelled and handled according to appropriate documented procedures and in accordance to occupational health and safety requirements/legislation.

5.3.3 Access to the operational areas of the laboratory must be controlled. In addition, the exterior of the laboratory area must inhibit unauthorised access, either through the use of intrusion alarms or wall and ceiling construction which doesn't allow undetected entry to the laboratory.

5.4 Test and calibration methods and method validation

5.4.1 If standard methods are not available for a specific forensic drug

chemistry analysis, the laboratory shall develop, validate and document appropriate in-house methods. An analytical result should be traceable to the analytical method used.

- 5.4.2 As part of the validation of in-house screening methods, estimated limits of detection for representative drugs or other related substances shall be determined and documented.
- 5.4.3 Confirmation methods for drug analyses may include an extraction step, possible purification steps and the use of various detection techniques. These methods may be generic in nature and therefore applicable to a large number of drugs or a family of drugs. In some cases they may be very specific and can only be applied to one chemical. The use of a confirmatory technique, such as mass spectroscopy or infra-red spectrometry, is required for a positive identification. The laboratory shall document and validate their confirmation methods. Where appropriate, method validation should involve the use of representative reference materials to determine the estimated limits of detection.
- 5.4.4 Quantitative analysis shall utilize an appropriate method which has been documented and validated by the laboratory. It must be established that other substances known to be present in the matrix do not interfere with the quantification of the target analyte.
- 5.4.5 Method validation for quantitative methods shall include determination of linearity, specificity, range, accuracy, precision, ruggedness and robustness. Method validation for quantitative methods for unique samples need not include ruggedness or robustness testing.
- 5.4.6 Quantification will normally involve comparison of the response of a verified reference standard of known purity to that of the analyte in the test sample. For most chromatographic assays, quantification should typically involve the use of an internal standard having similar chemical and physical properties to the test analyte. Quantitative results shall be reported using a number of significant figures not greater than that which reflects the precision of the analysis.
- 5.4.7 Where a method is varied for valid technical reasons, the changes shall be authorized and documented to the extent necessary to enable the test or analysis to be repeated under identical conditions at a later date.

5.5 Equipment - no additional requirements.

5.6 Measurement traceability

- 5.6.1 Where possible, reference drugs and related substances shall be

traceable to a recognized standard or certified by a body of recognized status, such as the United States Pharmacopeia (USP), British Pharmacopoeia (BP), or the World Health Organization (WHO). Checks for identity are required prior to placing such materials into service.

5.6.2 Where a reference material is not certified or traceable to a recognized standard, the laboratory shall make reasonable efforts to verify its identity and purity by comparison with published data or by chemical characterization.

5.6.3 Solutions of reference materials shall be prepared, labelled and stored in such a way as to maintain their integrity. Documentation must be complete so as to provide a clear audit trail back to the reference material or source.

5.7 Sampling - no additional requirements.

5.8 Handling of test and calibration items - no additional requirements.

5.9 Assuring the quality of test and calibration results

5.9.1 The laboratory must implement internal quality control schemes which monitor all the steps and phases of the laboratory's analytical operation. This includes screening methods, confirmatory analysis, quantitative assays and other programs in place or to be implemented in the future.

5.9.2 Whenever appropriate in the quality control system, statistical techniques such as control charts should be used.

5.9.3 When conducting analyses, laboratories may group samples into batches. Every analytical batch must be accompanied by quality control measures that demonstrate the analytical system control status. This should include, but not necessarily be limited to, results from a representative blank and calibration of instrument performance parameters by suitably selected chemical standards. In instances where a large number of samples are analyzed, of which most are negative, the samples themselves may serve as the system blank. Records of instrument calibration and performance parameters shall be maintained.

5.9.4 Positive analytical findings are based upon a minimum of two tests and, when sample size allows, the second test is applied on a separate sampling, for quality assurance reasons.

5.9.5 Proficiency Testing Programs and Criteria

5.9.5.1 General Conditions

Prior to becoming accredited, a laboratory must successfully complete at least one recognized external proficiency test for drugs as appropriate for the mission of the laboratory. The test shall be done within a twelve month period prior to accreditation and at least annually thereafter.

5.9.5.2 Evaluation.

To become accredited and subsequently to maintain accreditation, the proficiency test results must meet the following standards:

- a) For qualitative analysis, the laboratory must correctly identify 100% of the samples within the time permitted.
- b) For quantitative analyses, results must fall within $\pm 20\%$ of the target, or 2 standard deviations of the participant mean, whichever is less.
- c) Corrective action must be taken and documented for false negatives and other deficiencies, appropriate for the mission of the laboratory.

5.9.5.3 False Positives/False Negatives.

5.9.5.3.1 In assessing the seriousness of reporting so-called false positives, the nature, context and forensic ramifications of the error should be considered.

5.9.5.3.2 False negatives are usually considered less serious than reporting false positives. However, the difficulty of the analysis should be considered, taking into account the concentration, chemical nature and forensic ramifications of the error.

5.9.5.4 Corrective Action.

It is recognized that even in a well run laboratory errors in detecting, identifying, quantifying and reporting drugs and other substances may occur. Corrective action may be as simple as a brief review to establish that the quality assurance procedures in place are reasonable, that they were followed, and that the error was truly random. In other circumstances, corrective action may require re-development of a method, or re-training of an analyst, or determining the source of a systematic bias. It is imperative that where an error occurs, regardless of its seriousness, prompt and appropriate corrective action be taken, and that it be documented.

5.9.5.5 Procedures for Unsatisfactory Performance

5.9.5.5.1 Failure of a laboratory to comply with any aspect of these Guidelines may lead to suspension or withdrawal of accreditation in accordance with the withdrawal procedure documented in CAN-P-15.

5.9.5.5.2 In the context of the proficiency testing programs, the SCC will consider several factors in determining whether disqualification of an applicant laboratory or withdrawal of accreditation of an accredited laboratory is necessary. These may include:

- a) Unsatisfactory participation or failure to participate in a recognized external proficiency test, or
- b) Failure to take appropriate action on unsatisfactory performance.

The action required following initial unsatisfactory performance (as specified in clause 5.9.5) will be assessed on an individual basis. The required actions could include such elements as passing an additional set of proficiency testing samples, a thorough investigation of potential problems for any occurrence of an unacceptable result including a comprehensive written response indicating the corrective action(s) implemented, or a combination of several elements. The frequency of errors will also be considered.

5.9.5.5.3 Should the SCC initiate action to suspend or withdraw the laboratory's accreditation, the laboratory's official status will become "suspended" or "withdrawn" until such time that the suspension is lifted or until any re-accreditation process is complete.

5.10 Reporting the results

5.10.1 Certificates of Analyst are legal documents. As such, information contained in these reports is directed by the appropriate laws of the land.

5.10.2 Where feasible, court testimony of Analysts shall be monitored on an annual basis.

ANNEX 6A

SAMPLE COLLECTION

The laboratory must comply with the following:

1. Prepare and follow documented procedures for obtaining, handling, labeling, packaging and shipping samples to the laboratory. These procedures shall meet the needs of individual clients.
2. Ensure that sampling personnel are qualified and that required training is current.
3. Carry out on-site inspections or audits of the sampling procedures and facilities, as needed.
4. Follow documented procedures to ensure the integrity of samples at all times during collection and transportation.
5. Implement documented procedures for tracing late or lost samples, and for reporting such incidents to the client.