SCC

ACCREDITATION SERVICES

SCC Requirements and Guidance for the Accreditation of Forensic Testing Laboratories

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Introduction

This document is designed to apply to most types of forensic testing and therefore needs to be interpreted with respect to the type of calibration and testing concerned and the techniques involved. It provides an amplification of some requirements in ISO/IEC 17025:2017 that need interpretation when applied in laboratories carrying out forensic analysis and examination. The technical base of this document is drawn from published principles, as well as practices and procedures promoted by national and international organizations.

General and Additional Requirements

A laboratory shall meet all provisions of ISO/IEC 17025:2017 General Requirements for the Accreditation of Calibration and Testing Laboratories, the SCC Accreditation Services Program Overview, this document, and applicable Appendices to this document to qualify for the SCC Program Specialty Area - Forensic Testing (PSA-FT) 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 this document to meet the market needs. Criteria given in a specific discipline may supersede generic criteria where appropriate. This document defines 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 generally refers to the examination of crime scenes, recovery of evidence, laboratory examinations, interpretation of findings and presentation of the conclusions reached for intelligence purposes or for use in court. Forensic science may also refer to other criminal or non-criminal activities, such as (but not limited to): DNA Relationship testing, Drug Testing, or Equine Drug Testing. 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.

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action to suspend or withdraw the laboratory's accreditation, the laboratory's official status becomes "suspended" or "withdrawn" until such time that the suspension is lifted or until any reaccreditation process is complete.

Some examples of the fields of forensic testing can be found below. Please note that this is not an exhaustive list.

Controlled Substances	
• Controlled pharmaceutical and illicit drugs	• Botanical material
• Related chemicals and paraphernalia	
Toxicology	
• Pharmaceutical products	• Alcohol
• Poisons	
Hair, Blood and other Bodily Fluids and Tissues	
• Serology	• DNA profiles
Trace Evidence	
• Fire debris	• Hydrocarbon fuels
• Pyrotechnic devices	• Explosives and explosion debris
• Glass	• Light filaments
• Paint	• Vehicle components
• Metals and alloys	• Firearm discharge residues

• Fibres (natural and man-made)	• 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)	
Equine Drug Testing	
Firearms Examination	
• Legal classification / mechanical assessment	• Firearms, firearms-related items, ammunition
• Firearms identification	• Bullets and cartridge cases
• Serial number restoration	• Impact damage / range determination
• Objects with projectile damage	
Handwriting and Document Examination	
• Handwriting	• Inks and printing materials
• Paper	• Copiers and copied materials
• Rubber stamps	• Indentations
• Security marks	• Typewriters and typewritten material
• Printers and other printed objects	• Embossing and embossed materials
Counterfeits	
• Bank Notes and Negotiable Instruments	• Travel and Identification Documents
• Coins	• Payment Cards
• Computers and IT Equipment	
Fingerprints	
• Fingerprints	• Palmprints
• Footprints	
Marks and Impressions	
• Toolmarks	• Tire prints
• Show 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 spatter pattern interpretation
Forensic pathology, entomology, odontology	

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
• Capillary Electrophoresis	• DNA analysis
• Chromatography	• Mass spectrometry
• Atomic absorption and emission spectrometry	• Nuclear magnetic resonance spectroscopy
• Ultraviolet, infrared and visible spectrophotometry	• Physical measurements e.g. weight, volume, length, density, refractive index
• Optical and electron microscopy	
• Serology	• X-ray analysis
• Metallurgy	• Immunoassay
• Osteology	• Odontology
• Parasitology	• Microbiology
• Chemical pathology	• Haematology
• Visual inspections	• 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: References.

3. Terms and Definitions

For the purposes of the Guide, the relevant terms and definitions given in ISO/IEC Guide 2:2004 apply. The definitions in this section apply as general definitions to the entire document. Subsequent appendices may define the same term as it applies to that section only.

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 **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.

3.3 **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.

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

3.5 **Known (comparison) Sample:** A traceable reference sample.

3.6 **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.

3.7 **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.

3.8 **Precision:** The closeness of agreement between independent test results obtained under prescribed conditions.

3.9 **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.

3.10 **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.

3.11 **Specificity (or Selectivity):** The capability of an analytical procedure to reliably discriminate among chemically or physically related substances.

4. General Requirements

No additional requirements

5. Structural Requirements

No additional requirements

6. Resource Requirements

ISO/IEC 17025:2017	SCC Requirements	SCC Guidance
6.2 Personnel		
6.2.1	In the area of forensic science, emphasis is placed on competence and the training of staff is of prime importance. Where test or technique specific training is given, acceptance criteria shall be assigned in order to determine the competency of an individual e.g. observation of the relevant tests or analyses by experienced personnel, satisfactory performance in the analysis of control samples, correlation of results with those obtained by other trained personnel, use of interlaboratory testing such as proficiency tests. In laboratories that conduct sampling of substances, materials, or products, the laboratory shall have a training program for sampling. Where necessary, training programs shall also include training in the presentation of evidence in court.	

6.3 Facilities and environmental conditions		
6.3.4	The laboratory shall ensure that: a) Access to the operational area of the laboratory shall be controllable and limited. Visitors shall not have unrestricted access to the operational areas of the laboratory. A record shall be retained of all visitors to the operational areas of the laboratory. b) Evidence and file storage areas shall be secure to prevent theft or interference and there shall be limited, controlled access. c) Forensic testing laboratories may be involved in the analysis or determination of trace materials. Special areas shall be designated for this type of work and access to these areas shall be restricted. Appropriate records shall be kept demonstrating careful control of this type of work. These may include, but are not limited to, environmental monitoring (detection of contamination) of equipment, work areas, clothing, and consumables. d) The laboratory shall have and follow a documented process for cleaning and decontaminating facilities and equipment.	
6.4 Equipment		
6.4.1	The quality of standard materials and reagents shall be adequate for the procedure used. Lot/batch numbers of standard materials and critical reagents shall be recorded. All critical reagents shall be tested for their reliability. Standard	

	materials and reagents shall be labeled with: • name; • concentration, where appropriate, • preparation date and/or expiry date; • identity of preparer (if not practical, then traceable to a record); • storage conditions, if relevant; • hazard warning, where necessary.	
6.4.2	As part of a quality system, all laboratories are required to operate a program for the maintenance and calibration of equipment. In a forensic science laboratory, the equipment used is diverse and will range across several different scientific and technical disciplines. The frequency of all maintenance, calibrations and performance checks shall be established by the laboratory based on the criticality of a given equipment within the laboratory process and its impact on the validity of results. Maintenance may include visual examination, safety checks and cleaning as necessary. Some equipment has specific requirements such as: a) General Service equipment not directly used for making measurements e.g. hot plates, stirrers, non-volumetric glassware, cameras, refrigerators, shall be maintained by visual examination, safety checks and cleaning as necessary. Calibrations or performance checks shall 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 shall be cleaned and serviced periodically. Steps shall be taken to ensure microscopes are properly set up for use. Where microscopes are used for measurements the guidance given in paragraph d) applies. c) Volumetric / measuring equipment that require calibration and performance checks may include but is not limited to micropipettes, burettes, flasks, thermometers. d) Analytical equipment that require calibration and performance checks may include but is not limited to; densitometers, chromatographs, spectrometers and spectrophotometers, refractometers, autoanalysers, DNA sequencers. e) 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 shall 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 shall be documented and be satisfactorily completed before the equipment is used or before results are accepted.	
6.4.3		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 and legislation.
6.4.4	Instrument calibration verification shall follow any shut down, service, or other substantial maintenance.	
6.4.7		Calibrations intervals should be related to the level of the criticality of the equipment (risk and impact on the validity of results) and in general, should not be less stringent than manufacturers' recommendations.
6.5 Metrological traceability		
6.5.2	For many types of analysis, calibration may be carried out using a variety of products: certified reference materials, other purchased standards, synthetic standards containing the analytes under test, standards prepared within the laboratory from chemicals of known purity and composition, or use of matrix matched standards. Where possible, laboratories shall obtain certified reference material or standards from suppliers which have implemented an appropriate quality system, e.g. ISO 17034 and provide the information	

	necessary to establish metrological traceability.	
6.5.3	Reference collections of data or items/materials encountered 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) shall be fully documented, uniquely identified and properly controlled.	

7. Process Requirements

ISO/IEC 17025:2017	SCC Requirements	SCC Guidance
7.1 Review of requests, tenders and contracts		
7.1.3	When a customer requests a statement of conformity that may apply, or a statement of conformity as it applies to a legal or regulatory requirement, this statement shall be clearly defined and agreed to, even if inherent in requested specifications or standards.	
7.2 Selection, verification and validation of methods		
7.2.	All methods used by a forensic science laboratory shall be subject to a verification or validation process that addresses risks associated with a selected method in a manner proportional to the potential impact on the validity of laboratory results.	Further information and guidance can be found in *SCC Requirements and Guidance for Method Validation in Testing Laboratories.*
7.2.1.2	All methods shall be fully documented before being used, including procedures for quality control, and, where appropriate, the use of reference materials.	
7.2.1.8	Laboratories shall institute a procedure to identify infrequently performed tests or analyses. For these tests or analyses, there are	

	two means 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.	
7.2.2.1	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). Method validation shall consider quality assurance parameters and interpretation guidelines, including as applicable, guidelines for mixture interpretation. A complete change of detection platform or test kit (or laboratory assembled equivalent) shall require validation.	Validation and or Verification may be appropriate depending on the method, and development performed. See *SCC Requirements and Guidance for Method Validation in Testing Laboratories*.
7.3 Sampling		
7.3.1	Selection, recovery, prioritization and sampling of materials from submitted test items and from scenes of crime are important parts of the forensic process. Where applicable, laboratories shall have a procedure for sampling when carrying out sampling of substances, materials or products for subsequent testing or calibration. The laboratory shall have a sampling plan and method for samples requiring an in-depth examination leading to the creation of sub-samples (i.e. child samples).	

7.4 Handling of test or calibration items		
7.4.2	A 'chain of custody' record shall be maintained from the receipt of items or samples which details each person who takes possession of an item or alternatively the location of that item (e.g. if in storage). There shall be documented procedures which describe the measures taken to secure samples in the process of being examined where samples must be left unattended.	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 unduly compromise the quality of usefulness of the results of the appropriate procedures. If the sample is totally consumed in analysis, a notation to that effect must be present in the work notes (as applicable).
7.7 Ensuring the validity of results		
7.7.1	Validation of confirmation methods shall involve the use of representative reference materials to determine the effectiveness of the method and estimate limits of detection.	Screening methods for drug analyses use 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 other similar technique is recommended. Quantification involves comparison of the response of an authentic reference standard of known purity and 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 analysed to construct a calibration curve covering a range of concentrations bracketing the anticipated analyte concentration in the test sample. The nature of the relationship between the response of the instrument and the concentration of analytes in the procedure, i.e., linear, quadratic, polynomial; should be established by using a minimum of three positive calibration points in the

		case of a linear curve, six or more otherwise. For most chromatographic assays, quantification should typically involve the use of a true internal standard having similar chemical and physical properties to the test analyte. A true internal standard is one that is added to all samples before any manipulation (e.g., extraction, dilution, purification).
7.7.2	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 (PT) programs. Laboratories shall refer to section 4.1 of *SCC Requirements & Guidance – Proficiency Testing for Laboratories (Testing and Medical)* for initial participation. When participating in proficiency testing programs or other interlaboratory comparisons, the laboratory's own documented test procedures shall be used. All methods in the forensic scope shall be tested at least once per year through proficiency testing. All lab personnel involved in testing activities shall be tested at least once per year and shall be tested on applicable parts of all the methods they perform within a 2-year cycle. Performance in PT programs shall be evaluated, and where necessary, corrective action shall be taken. Proficiency testing records shall include: • full details of the analyses/examinations undertaken, the results and conclusions obtained;	

	• conclusions obtained including interpretations, as required; • an indication that system performance has been reviewed; • details of the corrective action undertaken, where necessary.	
7.8 Reporting of results		
7.8.1	Forensic results shall be reviewed by two separate individuals to detect analytical and clerical errors. The nature and extent of such verifications 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 competent forensic analyst. For the final report, which may include both analytical results and interpretation or other comments, it is important that a clerical verification occur, as a minimum.	
7.8.1.2	If preparing court statements, 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-clauses 7.8.2.1 and 7.8.3.1 of ISO/IEC 17025 as the format of these documents is prescribed in legislation or are subject to other legal requirement. Forensic science laboratories shall therefore adopt one or more of the following means of meeting these requirements; a) the preparation of a test report which includes all of the information required by ISO/IEC 17025; b) the preparation of an annex to the Court Statement which includes any additional information required by ISO/IEC 17025;	

	c) ensuring that the case record relating to a specific investigation contains all the relevant information required by ISO/IEC 17025.	
7.8.3	Court (or other official body) statements, reports, or certificates shall clearly differentiate the analytical results obtained from any opinion or interpretation which is offered. While specific details or lists of tests performed may not be required, the court statement, report, or certificate shall not include statements that imply comprehensive testing was performed when only limited testing was performed.	
7.8.6	Statements of conformity are not usually provided in forensic reports. Exceptions are presented within the relevant appendices.	For example, in two areas where a statement of conformity might apply include firearm barrel length (e.g., a measurement that would classify a weapon as legal or illegal), or a blood alcohol concentration (e.g., a measurement of greater than 80 milligrams of alcohol in 100 millilitres of blood is described in the criminal code of Canada; other levels are also described for various conditional driving licences or as a result of prohibition).
7.8.7.3	When applicable, all court testimonies from laboratory members shall be impartial and objective. The laboratory shall follow a documented procedure whereby the court testimony of each member is monitored on a regular basis. The documented procedure will also include remedial action to be taken should any testimony be determined as less than satisfactory. Court testimony evaluation shall include feedback from customers, peers/co-workers, and/or members of the legal community.	
7 .10	The laboratory shall have and follow a policy to document incidents of	

	contamination and its remediation efforts.	

8. Management System Requirements

ISO/IEC 17025:2017	SCC Requirements	SCC Guidance
8.4 Control of Records (Option A)		
8.4.1	The laboratory shall ensure that: a) The forensic science laboratory shall 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 shall 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 shall 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 shall be recorded. c) Where appropriate, observations or test results shall 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) shall be recorded. e) Calculations and data transfers which do not form part of a validated electronic process shall be verified, preferably by a second person. The case record shall include an indication that such verifications have been carried out and by whom. f) Each page of every document in the case record shall be traceable to the analyst/examiner and where appropriate, to a uniquely identified case or sample. It shall 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) The laboratory shall have a mechanism to ensure that the case file is complete and protected. h) The laboratory shall have documented policies and procedures for the review of case records, including test reports. Where independent verifications on critical findings are carried out by other authorized personnel, the records shall indicate that each critical finding has been verified and agreed and by whom the verifications 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.	

ANNEX A: References

ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories.

ISO/IEC Application Document, Supplementary Requirements for Accreditation in the Field of Forensic Science: 2015 version, National Association of Testing Authorities, Australia (NATA).

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ISO 5725-2:1994, *Accuracy (trueness and precision) of measurement methods and results - Part 2. Basic Method for the Determination of Repeatability and Reproducibility of a Standard Measurement Method.*

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.*

ISO 5725-5:1998, *Accuracy (trueness and precision) of measurement methods and results - Part 5. Alternative Methods for determination of the Precision of a Standard Measurement Method.*

ISO 5725-6:1994, *Accuracy (trueness and precision) of measurement methods and results - Part 6. Use in Practice of Accuracy Values.*

ISO/TR 10013:2001, *Guidelines for quality management system documentation.*

ISO/IEC Guide 2:2004, *Standardization and related activities– General Vocabulary*

ISO Guide 30:2015, *Reference materials — Selected terms and definitions.*

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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 shall 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 shall 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 sample 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 shall 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 shall be approved. All approved visitors shall 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, sample 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 sample 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

ANNEX C: DNA Testing for Immigration Purposes

Immigration, Refugees and Citizenship Canada (IRCC) accepts DNA test results for immigration and citizenship applications as proof of relationship between a parent and a child or between brothers and sisters.

IRCC accepts DNA analyses as evidence to establish proof of a genetic parent-child connection for immigration applications and citizenship by descent purposes.

IRCC recognizes DNA results only from laboratories accredited by the Standards Council of Canada (SCC)

What the laboratory will do

Inside Canada

The laboratory chosen by the applicant will arrange a DNA sample collection appointment and shall follow IRCC and SCC's procedures for the collection and submission of DNA samples.

The sample collection site shall be administered by an SCC accredited laboratory.

At the time of the DNA sample collection, applicants shall provide:

- two passport photos, in accordance with IRCC specifications, which shall be included in the documentation shipped with the DNA sample;
- two pieces of identification to establish their identity. One of them shall be a government issued photo ID, such as a provincial/territorial drivers licence, permanent resident card, or Canadian Passport. NOTE: a photocopy of the identification **shall** be included in the documentation shipped with the DNA sample.
- a signed release and consent form provided by the laboratory, authorizing the laboratory to send the DNA test results and the photocopies of the identification documents to IRCC.

Requirements for the collection and shipment of samples

The SCC accredited laboratory shall ensure the integrity of the DNA testing and shipment procedures. At the time of the DNA sample collection, the representative for the laboratory shall ask for the necessary documentation from the applicant, and:

- verifies the identity of the person providing the DNA sample.
- makes a photocopy of the applicant's two pieces of valid photo identification.
- ensures the release and consent form is signed by the applicant.
- ensures the information of the applicant providing the DNA sample matches, as much as possible, the information indicated in the identification provided at the time of the sample collection.
- verifies that the DNA sample kit has not been tampered with.
- collects the DNA sample according to instructions in the DNA sample kit.
- completes the chain of custody document for the DNA sample. The chain of custody record must identify the full name of the employee who collected and packaged the DNA sample as well as the legal name of the sample collection facility.

- packages the DNA sample and documentation according to instructions in the DNA sample kit.
- sends the package directly to the laboratory conducting the DNA test by the fastest, most reliable means possible. Ideally, no more than seven (7) days should elapse between the collection of the DNA sample and receipt of the package by the laboratory.

Outside Canada

What the laboratory will send

The laboratory chosen by the applicant will send a tamper-proof DNA sample kit (including instructions) to the migration office (for an immigration application) or the consular mission (for a citizenship application). The DNA sample kit contains everything necessary to take, package, and ship a DNA sample, including instructions regarding witnessing the sample taking.

Sample collection sites

Sample collection sites are not considered part of the laboratory, but are considered a supplier of service, and must meet the requirements of ISO/IEC 17025:2017 clause 6.6. The laboratory accredited under the DNA relationship testing program shall have legally binding clauses in their contracts with sample collection sites to impose limitations on the advertising of their SCC accredited status or claims of accreditation. The collection sites are required to disclose the name of the affiliated accredited laboratory in all their communications to the donor and IRCC offices. Sample collection sites used by SCC-accredited laboratories under the DNA relationship testing program shall not be permitted to claim accreditation through their laboratory affiliation.

Reporting DNA test results

The laboratory must conduct the DNA test as soon as all samples and necessary documentation have been submitted. The results must be sent directly from the lab that conducted the DNA test to the applicant and the appropriate IRCC office, preferably via mail or courier. Delivering DNA test results by email carries the risk of unauthorized access by third parties. Should a laboratory choose to communicate DNA test results by email, it must ensure the transmission of information is done in a secure manner. IRCC will not accept test results from laboratories that have had their accreditation suspended by SCC. Test results will only be accepted from laboratories that have valid accreditation from SCC.

Parentage test results must have an accuracy of 99.8% or higher. Test results below these levels are not acceptable as proof of relationship.

If a customer does not sign a release and customer consent form, or withdraws consent to release their information, the lab will write to IRCC to say that information cannot be released. In such cases, officers are required to make a decision on the application based on the information on file.

APPENDIX 1 – Toxicology

Introduction

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 shall successfully complete an on-site assessment and participate successfully in one or more recognized proficiency testing programs.

Laboratories accredited under the PSA-FT for toxicology shall use appropriate analytical methodology and document and hold available for possible court testimony all aspects of the testing procedures. All test materials shall 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 ISO/IEC 17025:2017 and the PSA-FT guidelines apply generally to all accredited forensic laboratories. This Appendix is intended only to amplify and interpret the ISO/IEC 17025:2017 requirements specifically for forensic toxicology laboratories.

A1-1. 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.

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 shall 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 shall 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.

A1-2. References

- TECHNICAL REPORT 1993, IUPAC, from Pure and Appl.Chem., vol 65, No. 9, pp. 2123-2124, The International harmonized protocol for the proficiency testing of (chemical) analytical laboratories. Protocol from the IUPAC/ISO/AOAC working party.
- Society of Forensic Toxicologists and American Academy of Forensic Sciences, Toxicology Section, Forensic Laboratory Guidelines, 2006.

A1-3. Terms and Definitions

All definitions in ISO/IEC 17025:2017 e.g. 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.

Other specific definitions that apply are:

3.1 **Alcohol:** ethyl alcohol or ethanol, generally for consumption.

3.2 **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.

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

3.4 **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.

A1-4. General Requirements

No additional requirements

A1-5. Structural Requirements

No additional requirements

A1-6. Resource Requirements

ISO/IEC 17025:2017	SCC Requirements	SCC Guidance
6.2 Personnel		
6.2.1	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 shall 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. For those laboratories engaged in the analysis for ethanol alone or primarily engaged in the analysis for ethanol, the person in charge of the ethanol laboratory shall have analogous education and experience in ethanol testing and	

	interpretation as those described for the qualified forensic toxicologist.	
6.2.3	Where required, Certificates of Analysis (however named) shall be signed by a competent analyst.	
6.3 Facilities and environmental conditions		
6.3.1	The storage and handling of controlled drugs and alcohol must comply with applicable legislation.	
6.5 Metrological traceability		
6.5.1	Where possible, reference drug and drug metabolite materials shall be traceable to S.I. These products shall be purchased from a competent provider and accompanied by certifications that permit metrological traceability. Verification of identity is required prior to placing such products into service. Verification of both identity and purity or concentration are required if the product is being used for quantitative purposes.	
6.5.2	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.	
6.5.3	Solutions of reference materials shall be prepared, labelled and stored in such a way as to maintain their integrity. Documentation shall be complete as to provide a clear audit trail back to the reference material or source.	

A1-7. Process Requirements

ISO/IEC 17025:2017	SCC Requirements	SCC Guidance
7.2 Selection, verification, and validation of methods		
7.2.2.1	If standard methods are not available for a specific forensic toxicology analysis, the laboratory shall develop, validate and document appropriate in-house methods. An analytical result shall be traceable to the analytical method used. a) As part of the validation of in-house screening methods, estimated limits of detection for representative drugs, metabolites, poisons, ethanol, or other volatiles, shall be determined and documented. b) Quantitative analysis shall 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. c) Method validation in quantitative analyses shall include the relationship between the response of the instrument and the concentration of analytes in the procedure, i.e., linear, quadratic, polynomial; and be established by using a minimum of three positive calibration points in the case of a linear curve, a minimum of 6 for quadratic and polynomial curves, specificity, limit of detection, accuracy, and precision. Quantitative results shall be reported using the number of digits that reflect the precision of the assay.	

7.2.3	Confirmation methods for drug analyses usually include an extraction step, possible purification steps and the use of various detection techniques. These methods may be 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. Where appropriate, method validation shall involve the use of representative reference materials to determine the estimated limits of detection.	Wherever possible and practical, the use of mass spectrometry or another specific technique is recommended.
7.7 Ensuring the validity of results		
7.7.1.3	When conducting analyses, laboratories may group specimens into batches. Every analytical batch shall be accompanied by quality control measures that demonstrate the analytical system control status. This shall 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.	
7.7.1.4		Identification of an analyte should not rely solely on analysis of a single aliquot of a sample by a single analytical technique.
7.7.2.1	Prior to becoming accredited, a laboratory shall successfully complete a series of recognized proficiency tests for alcohol and/or drugs as appropriate for the mission of the laboratory.	Laboratories may be accredited for forensic alcohol testing, forensic toxicology testing excluding alcohol, or for forensic alcohol and forensic toxicology testing.

	These tests shall be done within a six-month period prior to accreditation and annually thereafter.	
7.7.2.2		SCC recognized proficiency tests include but are not limited to programs of the College of American Pathologists.
7.7.2.3		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 ±10% of the mean. b) For non-alcohol quantitative analyses, results should fall within ±20% of the target, or ±2 standard deviations of the participant mean. c) For qualitative analysis false positive identifications should not occur. Corrective action must be taken and documented for false negatives and other deficiencies, appropriate for the mission of the laboratory.
7.7.2.4		In assessing the seriousness of reporting so-called false positives, the nature, context and forensic ramifications of the error should be considered. False negatives are usually considered less serious than reporting false positives. However, the difficulty of detection and identification should be considered, taking into account concentration, chemical nature and forensic ramifications of the error.

7.7.2.5		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 retraining 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.

A1-8. Management System Requirements

No additional requirements

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.

The accreditation program is designed to establish minimum quality and reliability standards and to define uniform proficiency testing requirements for laboratories conducting chemistry and trace evidence analysis. Such laboratories must use analytical methodology recognized by scientific consensus as current and appropriate to the task, treat any physical submission 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 for identification and/or comparison purposes all types of trace evidence in the Chemistry and Trace Evidence Analysis discipline. These activities include physical testing related to fire, explosion, and accident investigations in order to aid the reconstruction of events based on physical evidence.

A2-1. Scope

In the discipline of Chemistry and Trace Evidence Analysis, the purpose of the examination 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 probability that the trace evidence has a common origin with samples whose source is known.

Virtually any questioned 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 intermixed with, or be in the presence of, other unknown or known substances. Trace Evidence, as defined herein, does not include characterization or comparison of human or other

animal body fluids or tissue, although some biological materials such as natural fibers fall within the scope of Chemistry and Trace Evidence Analysis.

Comparison normally requires two or more 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 and Trace Evidence Analysis discipline and must continually demonstrate 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, a comprehensive treatment of chemistry analyses cannot be covered here, and the following must be regarded as a representative sample of typical examinations in this discipline. The specific scopes of testing for Chemistry and 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.

1.1.3 To identify unknown substances their composition, and determine their possible source(s)

1.2 Some of the items most commonly submitted for analysis are included in Appendix 2, section 1.4. Some of the techniques employed are listed in Appendix 2, section 1.6. These lists are amplified below for the Chemistry and 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, submission analysis and interpretation. The protocols should include those tests that are generally accepted as necessary for each type of trace evidence and/or additional tests that may be requested by the customer. 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. In general, multi-disciplinary laboratories will have documented methods encompassing them. In alphabetical order, examples are:

- adhesives & glues
- botanical materials
- cosmetics
- dust, sand & other soil samples
- dyes, markers & taggants
- explosives
- fibers & textile materials

- fractured, cut or torn materials
- glass
- hairs
- household products
- ignitable materials
- inks
- metals and items composed of metal
- minerals, including precious stones
- 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) may include, but are not limited to, the following list. In general, multidisciplinary laboratories will have a documented procedure 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 and 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 spectroscopy
- infrared, ultra-violet, and visible spectroscopy,
- X-ray diffraction
- elemental analysis (qualitative and quantitative, by numerous techniques)
- measurement or description of physical properties
- microchemical tests

A2-2. References

- SWGMAT Fiber Examination Guidelines, Forensic Science Communications, 2005
- 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

- ASTM D 93-20, Standard Test Methods for Flash Point by Pensky-Martens Closed Cup Tester
- ASTM D 3278-20, Standard Test Methods for Flash Point of Liquids by Small Scale Closed-Cup Apparatus
- ASTM D 3828-16a, Standard Test Methods for Flash Point by Small Scale Closed-Cup Tester
- ASTM E 1386-15, Standard Practice for Separation of Ignitable Liquid Residues from Fire Debris Samples by Solvent Extraction
- ASTM E 1388-17, Standard Practice Static Headspace Sampling of Vapors from Fire Debris Samples
- ASTM E 1412-19, Standard Practice for Separation of Ignitable Liquid Residues from Fire Debris Samples by Passive Headspace Concentration With Activated Charcoal
- ASTM E 1413-13, Standard Practice for Separation of Ignitable Liquid Residues from Fire Debris Samples by Dynamic Headspace Concentration onto an Adsorbent Tube
- ASTM E 1459-13(2018), Standard Guide for Physical Evidence Labeling and Related Documentation
- ASTM E 1492-11(2017), Standard Practice for Receiving, Documenting, Storing, and Retrieving Evidence in a Forensic Science Laboratory
- ASTM E 1588-20, Standard Practice for Gunshot Residue Analysis by Scanning Electron Microscopy/Energy Dispersive X-Ray Spectrometry
- ASTM E 1610-18, Standard Guide for Forensic Paint Analysis and Comparison
- ASTM E 1618-19, Standard Test Method for Ignitable Liquid Residues in Extracts from Fire Debris Samples by Gas Chromatography-Mass Spectrometry

A2-3. Terms and Definitions

All definitions in this document, ISO/IEC 17025:2017 and those applicable from ISO 8402 apply, as well as the following items specific to this document:

3.1 **Questioned Sample**: A sample whose original source is not known.

3.2 **Sub-sample**: Any material, e.g., fibers, removed from an item, e.g., clothing, for subsequent analysis, comparison and/or retention.

3.3 **Significant difference**: A difference between two samples that establishes that the two samples are chemically or physically distinct from one another.

3.4 **Common Origin**: A single source from which two or more samples, questioned or known, have originated.

A2-4. General Requirements

No additional requirements

A2-5. Structural Requirements

No additional requirements

A2-6. Resource Requirements

ISO/IEC 17025:2017	SCC Requirements	SCC Guidance
6.3 Facilities and Environment Conditions		
6.3.1	Trace evidence includes many commonly encountered materials that have been 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, cross contamination, or inadvertent contamination has occurred within the laboratory system. In particular, the work environment must physically and/or temporally separate examination areas appropriate to the trace evidence being handled. (Example: fibre examinations require separate work areas for known and questioned samples). All procedures, controls and facilities must be signed-off as acceptable for their stated purpose by at least one scientist who will be directly involved with performing the covered examination type. The laboratory must have restricted access, adequate workspace to accommodate large items, secure storage space and tools including lifting equipment appropriate to each sample type. Cleaning procedures must be designed and routinely tracked/documented to minimize	

	contamination from the working environment.	

A2-7. Process Requirements

ISO/IEC 17025:2017	SCC Requirements	SCC Guidance
7.2 Selection, verification and validation of methods		
7.2.1		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 prior to destructive alternatives. Destructive tests should be considered in light of available sample, the need for future analysis or other limitations.
7.2.2		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 interferences from containers or sampling techniques may need to be considered. The analysis of several representative known samples may be necessary to document that the procedure used does allow the detection of significant differences.
7.2.5	Some of the types of trace evidence, as defined in Appendix 2, 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 within the current marketplace. Information from the industry involved in the production or distribution of the material may be sought. The documentation shall include references to any standard methods, method guides, or published literature that is used as the basis for the development of the test applied.	
7.2.6	For all techniques, such as those described in Appendix 2, 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.	
7.3 Sampling		
7.3.1	The Chemistry and 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 shall 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.
7.4 Handling of Test and Calibration Items		
7.4.1	In the Chemistry and Trace Evidence Analysis discipline, samples may be removed from the submitted item for analysis and comparison. Each sample shall be uniquely identified	

	and subject to the same control as the item itself. The laboratory shall have a documented policy regarding the consumption of samples in analysis, and procedures for return, retention or destruction for each type of sample and any sub-sample material.	
7.4.2		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 unduly compromise the quality of usefulness of the results of the test procedures. If the sample is totally consumed in analysis, a notation to that effect should be present in the work notes.

A2-8. Management System Requirements

No additional requirements

APPENDIX 3 - Biology

Introduction

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

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

The technical base of this appendix 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 "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 Appendix is harmonized with the ISO/IEC 17025:2017 document "General Requirements for the Competence of Testing and Calibration Laboratories", this document, and the International harmonized protocol for the proficiency testing of (chemical) analytical laboratories (Protocol from the IUPAC/ISO/AOAC working party).

A3-1. 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 (subcontractors). 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.

A3-2. References

- 42 Code of Federal Regulations, Chapter IV, (10-1-11 Edition), Health Care Financing Administration, Health and Human Services.
- American Society of Crime Laboratory Directors-Laboratory Accreditation Board (ASCLDLAB), International Program Overview 2015 Edition
- DNA Advisory Board, "Quality Assurance Standards for Forensic DNA Testing Laboratories", Federal Bureau of Investigation, July 1, 2020.

- 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.

A3-3. Terms and Definitions

As used in this appendix, the following terms shall have the meanings specified:

3.1 **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.

3.2 **DNA analyst** (sometimes called **Reporting Scientist**, 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 conduct and/or directs the analysis of forensic samples, interprets data and reaches conclusions.

3.3 **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.

3.4 **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.

3.5 **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).

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

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

3.8 **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.

3.9 **Forensic Serologist** (or equivalent role, position or title as designated by the Laboratory Director) is an employee that performs analytical techniques dealing with the

identification and characterization of biological evidentiary samples such as blood, saliva, sweat, or other bodily fluids, and is generally not associated with DNA work.

3.10 **Forensic Serology Technician** (or equivalent role, position or title as designated by the Laboratory Director) is an employee that performs analytical techniques dealing with the identification and characterization of biological evidentiary samples such as blood, saliva, sweat, or other bodily fluids, and is generally not associated with DNA work, They work under the supervision of a qualified Serologist, and do not interpret data, reach conclusions, or prepare final reports.

3.11 **Inconclusive** is a determination that no inclusion or exclusion can be drawn from the comparison of a casework reference sample to a forensic sample. This could result from statistical analyses that fail to provide sufficient support for an inclusion or exclusion. An inconclusive conclusion could be due to uninterpretable data or data determined by the laboratory as not suitable for comparisons.

3.12 **Interpretation Software** is a tool to assist the analyst in assessing the analyzed data by applying quality assurance rules, performing mixture deconvolution, and/or evaluating comparisons. Interpretation software may include probabilistic genotyping software or expert systems.

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

3.14 **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.

3.15 **Negative sequencing control** is an analytical control that is used to detect DNA contamination of the sequencing reagents. This analytical control consists of only sequencing reagents without the intentional addition of template DNA. The negative amplification control can be used as the negative sequencing control.

3.16 **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 subcontract laboratory for the purposes of forensic testing (i.e. a subcontract laboratory prepares an extract that will be analyzed by the originating laboratory);
(2) the originating laboratory will interpret the data generated by the subcontract 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 subcontract laboratory.

3.17 **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.

3.18 **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.

3.19 **Positive sequencing control** is an analytical control that is used to determine if the sequencing performed properly. This control consists of the sequencing reagents and a known DNA sample. The positive amplification control can be used as the positive sequencing control.

3.20 **Rapid DNA analysis** is the fully automated (hands-free) process of developing a STR profile from a casework reference sample. The "swab in – profile out" process consists of automated extraction, amplification, separation, detection and allele calling without human intervention.

3.21 **Rapid DNA cartridge** is a preassembled set of reagents and other analytical components (such as typing test kit) designed for use in a Rapid DNA instrument/System for the extraction, amplification and/or separation of DNA samples.

3.22 **Rapid DNA System** is the collection of components that together performs a Rapid DNA analysis consisting of a Rapid DNA instrument, the PCR STR typing test kit. Rapid DNA cartridge and an integrated Expert System used to develop a STR profile from a casework reference sample.

3.23 **Stochastic threshold** is the peak height value, determined through validation testing, below which it is reasonable to assume that, given locus, allelic dropout of a sister allele in a heterozygous pair may have occurred.

3.24 **Uninterpretable** is a determination that DNA data cannot be interpreted (e.g., due to poor or limited data quality, data that fail to meet laboratory quality requirements). Uninterpretable data may result in an inconclusive conclusion.

A3-4. General Requirements

No additional requirements

A3-5. Structural Requirements

ISO/IEC 17025:2017	SCC Requirements	SCC Guidance
5. Structural requirements		
5.5.1	The laboratory shall have a technical leader (however named) who is accountable for the technical operations. Multi-laboratory systems shall have at least one technical leader.	

5.5.2	The laboratory shall have at least two full time employees who are qualified DNA analysts.	

A3-6. Resource Requirements

ISO/IEC 17025:2017	SCC Requirements	SCC Guidance
6.2 Personnel		
6.2.2.1	**The DNA technical leader (however named) 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 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 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.	

6.2.2.2	**Minimum experience requirements:** A DNA technical leader (however named) 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.	
6.2.2.3	**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 (however named) 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.
	Degree requirements for technical leader (however named) of a laboratory conducting forensic serology and/or hair identification and comparison examinations:
	The technical leader must have at a minimum a bachelor's degree in biology, chemistry, or forensic science-related area.	

6.2.2.4	**Accessibility:** The technical leader (however named) 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 annually. The technical leader shall be a full-time employee of the laboratory or multi-laboratory system.	
6.2.2.5	The DNA analyst shall be an employee of the laboratory and meet the following qualifications: Minimum educational requirements: The DNA analyst shall have completed post-secondary education in a biology-, chemistry-, or forensic science- related area and shall have successfully completed post-secondary course work 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. Applicable personnel 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 (however named) shall document approval of compliance with this standard.	
6.2.2.6	**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 DNA Analyst shall complete the analysis of a range of samples routinely encountered in forensic casework prior to independent work using DNA technology. The DNA Analyst shall successfully complete a competency test before beginning independent DNA analysis.	
6.2.2.7	The Forensic Serologist (however named) or forensic analyst who conducts hair identification and comparison examinations shall meet the following qualifications: • Minimal education requirements: a post-secondary 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. They shall successfully complete a qualifying test before beginning independent casework responsibilities.	
6.2.2.8	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.	
6.2.2.9	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.	
6.2.5.1	The laboratory shall have a documented program to ensure technical qualifications are maintained through participation in continuing education. Continuing education: The technical leader (however named) and reporting scientist(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.	

6.3 Facilities and environmental conditions		
6.3.4.1	Except for cases covered by Appendix 3, section 6.3.4.3, 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.	
6.3.4.2	Except for cases covered by Appendix 3, section 6.3.4.3, 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.	
6.3.4.3	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 7.2. If the robot performs analysis through amplification, the robot shall be housed in a separate room from that used for initial evidence examinations.	
6.3.4.4	The laboratory shall have secure, controlled access areas for evidence storage and work product in progress.	
6.4 Equipment		
6.4.6	At a minimum, the following critical instruments or equipment shall require performance checks and/or calibration where applicable. • Thermal cycler temperature verification system • Thermal cycler including quantitative-PCR	

	• Electrophoresis detection systems/Genetic Analyzers • Robotic systems • Pipettes used in any stage of the typing process These checks shall be performed to an established schedule based on the risk involved.	
6.6 Externally provided products and services		
6.6.2.1	A laboratory that outsources DNA sample(s) to a subcontracted laboratory to generate DNA data that will be entered into CODIS shall require the subcontract laboratory to provide documentation of accreditation and compliance with these standards. The laboratory shall maintain such documentation.	
6.6.2.2	A laboratory shall not upload or accept DNA data for upload to CODIS from any subcontracted 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 (however named).	
6.6.2.3	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 subcontracted laboratory.	
6.6.2.4	A laboratory outsourcing DNA sample(s) to a subcontracted laboratory or accepting ownership of DNA data from a subcontracted laboratory shall have and follow a procedure to perform a site visit of the subcontracted laboratory. This procedure shall include, at a minimum, the following elements:	

	a) A documented initial site visit prior to the subcontracted laboratory's beginning of casework analysis for the laboratory b) The site visit shall be performed by the technical leader (however named) 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. c) If the outsourcing agreement extends beyond one year, an annual site visit shall be required. Each annual visit shall occur every calendar year and shall be at least 6 months and no more than 18 months apart	

A3-7. Process Requirements

ISO/IEC 17025:2017	SCC Requirements	SCC Guidance
7.2 Selection, verification and validation of methods		
7.2.2.1.1	Method validation shall include, where applicable; characterization of the genetic marker, species specificity, sensitivity studies, stability studies, reproducibility, case-type samples, population studies, mixture studies, and PCR-based studies. PCR-based studies include reaction conditions, assessment of differential and preferential amplification, and effects of multiplexing. Internal validation studies conducted 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 (however named) shall approve the internal validation studies	
7.2.2.1.2	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.	
7.2.2.1.3	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, e.g., upgrade of instrument model.	
7.2.2.1.4	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 (however named) and documented, select a methodology that has been validated and published by a recognized technical organization or in relevant peer-reviewed scientific journals, or by supplier, and has been tested with known samples in the laboratory.	
7.4 Handling of test or calibration items		
7.4.1	Where possible, the laboratory shall retain or return a portion of the evidence sample and/or extract.	
7.7 Ensuring the validity of results		
7.7.1.1	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: a) Test kits or systems for performing quantitative PCR and genetic typing b) Thermostable DNA polymerase, primer sets and allelic ladders used for genetic analysis that are not tested as test kit components	
7.7.1.2	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.	
7.7.1.3	The laboratory shall monitor the analytical procedures using the following controls and standards: a) Where quantitation is used, quantitation standards shall be used. b) Positive and negative amplification or sequencing 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. c) Internal Standard Control. d) Reagent Blank Control. e) Appropriate allelic ladders and internal size markers for the specific PCR-based system used.	

7.7.1.4	Reagent blank controls associated with samples being analyzed shall be: a) Extracted concurrently with the forensic sample(s) and amplified with the most sensitive typing system; b) Analyzed utilizing the same instrument model and volume conditions consistent with the forensic sample(s); c) Amplified utilizing the same primer, instrument model and concentration conditions as required by the forensic sample(s) containing the least amount of DNA; d) Allelic ladders and internal size makers for variable number tandem repeat sequence PCR based systems.	
7.7.1.5	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.	
7.7.1.6	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 SWDGAM.	
7.7.1.7	Laboratories analyzing forensic samples shall have and follow a documented procedure for mixture interpretation that addresses major and minor contributors, inclusions	

	and exclusions, and guidelines for the reporting of results and statistics.	
7.7.2.1	Laboratories that use a team approach to casework examination may do so on proficiency tests. However, all Reporting Scientists, technicians, and technical reviewers shall be proficiency tested at least once in a two-year cycle in their respective tasks, including test kits for DNA typing, and each platform in which they perform forensic DNA analysis.	
7.7.2.2	The laboratory shall include, at a minimum, the following criteria for evaluating proficiency test results: a. 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. b. All results reported as inconclusive or not interpretable are consistent with written laboratory guidelines.	
7.7.2.3	The DNA technical leader (however named) 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.	
7.8 Reporting of results		
7.8.2	Casework reports shall include the following elements: • Case identifier; • A unique report identifier; • Description of evidence examined, and identification of	

	samples tested; Description of the methodology; if relevant • Locus or amplification system; if relevant • Results and/or conclusions for each sample tested; • A quantitative or qualitative interpretative statement to support all conclusions; if relevant • 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.	

A3-8. Management System Requirements

No additional requirements

APPENDIX 4 – Equine Drug Testing

Introduction

This program is intended for laboratories that conduct forensic drug residue analysis in equine body fluids or other tissues (such as hair). 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 two rounds of proficiency testing and an on-site assessment held in coincidence with the testing of a third round of PT samples.

Accreditation under this 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.

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 cooperative agreement between SCC and CPMA upon which this program is founded.

Reliable discrimination between the presence and absence of prohibited 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 sample as evidence, and document and hold available for possible testimony at hearings 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 sample chain of custody, security, proper documentation, retention, and storage of records, and positive samples, presentation of evidence at hearings, and expert witness testimony.

The requirements of ISO/IEC 17025 and this document 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.

A4-1. 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 regulatory requirements and demand. These scopes may be modified, depending on 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. Reference to prohibited drugs can be found in Section 1 of the Schedule of Drugs to the Pari-Mutuel Betting Supervision Regulations.

Laboratory Capabilities for Equine Body Fluids

An accredited laboratory must be capable of testing for a variety of drugs and metabolites in equine urine, blood, and if applicable, hair samples, using a multi-step strategy of screening methods, target tests, and confirmatory analysis.

For any designated drug or metabolite in Section 2 & 3 of the Schedule of Drugs of the Pari-Mutuel Betting Supervision Regulations, laboratories must demonstrate their capability to perform quantitative analysis in blood or urine, or both. Accredited laboratories will be expected to broaden their testing capabilities accordingly.

A4-2. References

In addition to the references cited in this document:

- ILAC G7:02/2016 Accreditation Requirements and Operating Criteria for Horseracing Laboratories
- Canadian Pari-Mutuel Agency (CPMA), Guidance for Official Laboratories, current issue.
- Pari-Mutuel Betting Supervision Regulations.

A4-3. Terms and Definitions

The definitions contained below apply to this Appendix but may also apply to other appendices as appropriate.

3.1 **Confirmatory Analysis:** Analytical procedures applied to a sample to identify the presence of a specific drug, metabolite, volatile or other substance that is independent of the initial testing and that may use different analytical techniques.

3.2 **Drug Administration:** The application of a drug (dosing) to a horse by various routes for the purpose of collecting biological samples for analysis.

3.3 **Drug Elimination**: Biological process of the removal of drugs or metabolites from the body.

3.4 **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 equine body fluids, interpretation of testing results, and presentation of expert testimony. The person should also be eligible for professional membership in the Association of Official Racing Chemists (AORC).

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

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

3.7 **Spiked Sample:** A test sample or material consisting of a representative matrix to which a known amount of analyte has been added.

3.8 **Target Test:** A screening method applied to a sample or series of samples to detect the presence of a drug or a chemically related group of substances.

A4-4. General Requirements

No additional requirements

A4-5. Structural Requirements

No additional requirements

A4-6. Resource Requirements

ISO/IEC 17025:2017	SCC Requirements	SCC Guidance
6.2 Personnel		
6.2.1	The person in charge of a forensic equine drug testing laboratory shall be a forensic equine toxicologist with a minimum of a bachelor's degree in a biological or chemical discipline	

	and five years experience. The forensic equine toxicologist shall have documented training and experience in the forensic application of analytical toxicology such as testimony at hearings, participation in continuing education programs and knowledge of evidentiary procedures.	
6.2.3	Certificate of Positive Analysis shall be signed by an approved signatory, such as an official chemist according to the Pari-Mutuel Supervision Regulations. 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.	
6.5 Measurement Traceability		
6.5.2	Reference drug and drug metabolite materials, traceable to a national standard or certified by a body of recognized status, are to be used when commercially available. Verification is required prior to placing such materials into service.	
6.5.3	Where a reference material is not certified, the laboratory shall verify its identity by comparison with published data or by instrumental verification before implemented in the testing of samples.	
6.5.4		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.

A4-7. Process Requirements

ISO/IEC 17025:2017	SCC Requirements	SCC Guidance
7.2 Selection, verification and validation of methods		
7.2.2	For each screening test, the laboratory shall document how they decide which samples proceed to confirmatory testing.	
7.2.4	The laboratory shall document and verify 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.	Confirmation methods usually include an extraction method, possible purification step and the use of various detection techniques. These methods may be generic in nature and therefore applicable numerous drugs or a family of drugs. In some cases, they may be very specific and can only be applied to one chemical.
7.7 Ensuring the validity of results		
7.7.1.1	The laboratory must implement quality control schemes which monitor all the steps and phases of the laboratory's analytical operation. This includes screening methods, confirmatory analysis, and quantitative analysis related to the CPMA Special Programs, along with other programs to be implemented in the future. Every analytical batch shall be accompanied by quality control measures that demonstrate the analytical system control status. This shall 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.	
7.7.1.4	The laboratory must verify positive analytical findings by the re-testing of a second portion of the customer samples using the same or different analytical techniques, or both.	
7.7.1.5	Where appropriate, the laboratory's internal quality control system shall 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.	
7.7.2.1	The CPMA operates a QA program for laboratories conducting analysis on samples obtained from horses participating in racing in Canada. Participation in this program is accepted by SCC as evidence of laboratory participation in an inter-laboratory QA scheme. The Association of Official Racing Chemists PT program may also be used as evidence of laboratory proficiency.	
7.7.2.2	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 customer samples.	
7.8 Reporting of results		
7.8.1	Certificates of Positive Analysis must be signed by an approved signatory, such as an official chemist according to the Pari-Mutuel Betting Supervision Regulations.	

A4-8. Management System Requirements

ISO/IEC 17025:2017	SCC Requirements	SCC Guidance
8.4 Control of Records (Option A)		
8.4.1	All records, including those for negative results, must be reviewed by an approved signatory of the laboratory.	
8.4.2	The laboratory is required to maintain records in secure storage pertaining to a positive case until all legal challenges are resolved. i.e. test results and associated physical evidence, where applicable.	Document retention periods should ensure that the statute of limitations is met.

APPENDIX 5 - DNA Databasing Laboratory

Introduction

These standards are applicable to a data basing laboratory performing DNA analyses on biological samples obtained from known individuals for the purpose of entering the resulting DNA profiles or DNA records into a DNA database.

If the data basing laboratory is performing DNA analyses on known or casework reference samples considered evidence by that laboratory or biological samples submitted as part of a missing persons or human remains investigation, the data basing laboratory shall follow the appropriate standards as outlined in Appendix 3 – Biology.

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.

This Appendix is intended only to amplify and interpret ISO/IEC 17025:2017 and the requirements specifically for a DNA data basing laboratory processing biological samples obtained from known individuals, such as convicted offenders.

A5-1. Scope

These 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 known identified individuals for inclusion in a DNA database, such as convicted offender samples. 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 forensic DNA analysis.

A5-2. References

- Federal Bureau of Investigation, “Quality Assurance Standards for DNA Databasing Laboratories”, last modified September 1, 2011
- Federal Bureau of Investigation, “Quality Assurance Standards for Forensic DNA Testing Laboratories”, last modified September 1, 2011.

A5-3. Terms and Definitions

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

3.1 **CODIS** is the Combined DNA Index System And is used by databasing and forensic DNA laboratories to store and compare DNA profiles derived from biological samples derived from convicted offenders, victims of crime, voluntary donors, relatives of missing persons, missing persons, unidentified human remains and from crime scene samples.

3.2 **Convicted offender** is an individual who is required by statute to submit a biological sample for DNA data basing.

3.3 **Convicted offender sample** is biological material collected from an individual for DNA typing analysis and inclusion of the resulting DNA profile into CODIS.

3.4 **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 contained in other DNA indices as permitted by the *DNA Identification Act*.

3.5 **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 conduct and/or directs the analysis of data base samples, interprets data and reaches conclusions.

3.6 **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.

3.7 **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.

A5-4. General Requirements

No additional requirements

A5-5. Structural Requirements

ISO/IEC 17025:2017	SCC REQUIREMENTS	SCC Guidance
5. Structural requirements		
5.1.2	The laboratory shall have a technical leader (however named) who is	

	accountable for the technical operations of the data basing laboratory.	
5.5.1	A subcontract laboratory performing data basing analysis shall be accredited and comply with these standards.	
5.5.1.1	A laboratory that outsources DNA sample(s) to a subcontract laboratory to generate DNA data that will be entered into CODIS shall require the subcontract laboratory to provide documentation of accreditation and compliance with these standards. The laboratory shall maintain such documentation.	
5.5.2	A laboratory shall not upload or accept DNA data for upload to CODIS from any subcontract 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 (however named).	
5.5.3	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 subcontracted laboratory.	
5.5.4	A laboratory outsourcing DNA sample(s) to a subcontract laboratory or accepting ownership of DNA data from a subcontracted laboratory shall have and follow a procedure to perform a site visit(s) of the subcontracted laboratory. This procedure shall include, at a minimum, the following elements:	
5.5.4.1	A documented initial site visit prior to the subcontract laboratory's beginning of casework analysis for the laboratory.	

5.5.4.1.1	The site visit shall be performed by the technical leader (however named) 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.	
5.5.4.2	If the outsourcing agreement extends beyond one year, an annual site visit shall be required. Each annual site visit shall occur every calendar year and shall be at least 6 months and no more than 18 months apart.	

A5-6. Resource Requirements

ISO/IEC 17025:2017	SCC REQUIREMENTS	SCC Guidance
6.2 Personnel		
6.2.1	Laboratory personnel shall have the education, training and experience commensurate with the examination and analysis provided. The laboratory shall: a) have a written job description for personnel which includes responsibilities, duties and skills. b) have a documented training program for qualifying the DNA Analysts. c) maintain records on the relevant qualifications, training, skills and experience of the technical personnel.	
6.2.2	**Continuing Education** The Technical Leader, the CODIS Administrator 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. The laboratory shall: 1. Document the continuing education hours 2. Have and follow a program for the annual review of scientific literature	
6.2.3	Degree requirements for the technical leader (however named) of a DNA typing analysis laboratory: The Technical Leader 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 and 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 course work in statistics and/or populations genetics as it applies to forensic DNA analysis. Individuals who have completed course work with title other than those listed above 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.	
6.2.4	**Minimum experience requirements:** The Technical Leader of a data basing laboratory must have a minimum of three years of human forensic DNA typing analysis laboratory experience as a qualified DNA Analyst processing data base samples or a Reporting Scientist processing forensic samples	

	The technical leader (however named) shall have previously completed or will successfully complete auditor training within one year of appointment	
6.2.5	**Duty requirements:** The technical leader (however named) is responsible for: a) evaluating all methods used by the laboratory and for proposing new or modified analytical procedures to be used by laboratory personnel. b) solving technical problems of analytical methods and for the supervision of training, quality assurance and proficiency testing in the laboratory. **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 studies and methodologies currently used by the laboratory.
	  ○ Educational qualifications and training records of currently qualified analysts.	

6.2.6	The technical leader (however named) shall be accessible to the laboratory to provide on site, telephone or electronic consultation as needed.	
6.2.7	**Requirements for a DNA Analyst** 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.	
6.2.8	A DNA Analyst must have a minimum of three months of human DNA laboratory experience in a forensic or database DNA laboratory, including the successful analysis of a range of	

	samples typically encountered by the laboratory. If prior (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.	
6.2.9	A DNA Analyst must successfully complete a qualifying test before assuming DNA typing responsibilities for data basing samples.	
6.2.10	**Requirements for the CODIS Manager** The CODIS Manager must have at a minimum a 4-year bachelor's degree in biology, biochemistry, chemistry, or applicable forensic science-related area. The CODIS Manager must have successfully completed undergraduate or graduate courses in biochemistry, genetics, molecular biology (molecular genetics, recombinant DNA technology and course work in statistics and population genetics as it applies to forensic or data basing DNA analysis. If the completed course work has titles other than those listed above then compliance with this standard shall be demonstrated through a combination of pertinent materials, such as transcripts, syllabus, letter from an instructor, or other documents that support the course content. The technical leader (however named) shall document approval of compliance with this Standard. The CODIS Manager must have successfully completed a Reporting Scientist training program with documented training in mixture interpretation.	

6.2.11	The CODIS Manager must have a working knowledge of computers, computer networks and computer database management.	
6.2.12	The CODIS Manager is the system administrator of the CODIS network and is responsible for: a) ensuring the security of DNA profile data stored in CODIS. b) overseeing CODIS computer training and quality assurance of data.	
6.2.13	The CODIS Manager has the authority to terminate a laboratory's participation in CODIS in the event of a problem until the reliability of the computer data can be assured.	
6.2.14	**Requirements for Laboratory Support Personnel** Education, experience and training for Laboratory Support Personnel are commensurate with their responsibilities as outlined in their job description. Laboratory support personnel shall have documented training specific to their job function(s).	
6.3 Facilities and Environmental Conditions		
6.3.1	The laboratory shall have a facility that is designed to provide adequate security and minimize contamination. The laboratory shall ensure that: a) access to the laboratory is controlled and limited. b) prior to PCR amplification, initial processing of the biological sample, DNA purification (if required) and PCR set-up are conducted at separate times or in separate spaces. c) amplified DNA product is generated, processed and maintained in a room(s) separate	

	from the initial processing of the biological sample, DNA purification (if required) and PCR set-up areas. d) the laboratory follows written procedures for monitoring, cleaning and decontaminating facilities and equipment.	
6.3.2	The laboratory shall have and follow a documented sample inventory control system. This system shall ensure that: a) data basing samples are marked for identification. b) documentation of sample identity, collection, receipt, storage and disposition is maintained. c) if the data basing laboratory is processing reference samples as evidence, a chain of custody shall be documented and maintained in hard or electronic format. d) the laboratory follows documented procedures that minimize sample loss, contamination, and/or deleterious change. e) the data base samples shall be safely and securely stored consistent with the nature of the sample.	
6.4 Equipment		
6.4.1	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/Genetic Analyzers • Robotic systems • Pipettes used in any stage of the typing process The laboratory shall have and follow written procedures for conducting performance checks and evaluating results of critical equipment or instruments.	
6.6 Externally provided products and services		
6.6.1	A subcontract laboratory performing data basing analysis shall be accredited and comply with these standards.	
6.6.1.1	A laboratory that outsources DNA sample(s) to a subcontract laboratory to generate DNA data shall require the subcontract laboratory to provide documentation of accreditation and compliance with these standards. The laboratory shall maintain such documentation.	
6.6.2	A laboratory shall not accept DNA data from any subcontract 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 (however named).	
6.6.3	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 subcontract laboratory.	
6.6.4	A laboratory outsourcing DNA sample(s) to a subcontract laboratory or accepting ownership of DNA data from a subcontract laboratory shall have and follow a procedure to perform a site visit(s) of the subcontract laboratory. This	

	procedure shall include, at a minimum, the following elements: a) A documented initial site visit prior to the subcontract laboratory's beginning of casework analysis for the laboratory. b) The site visit shall be performed by the technical leader (however named) 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. c) If the outsourcing agreement extends beyond one year, an annual site visit shall be required. Each annual visit shall occur every calendar year and shall be at least 6 months and no more than 18 months apart.	

A5-7. Process Requirements

ISO/IEC 17025:2017	SCC REQUIREMENTS	SCC Guidance
7.2 Selection, verification and validation of methods		
7.2.5	Internal validation shall be performed and documented by the laboratory.	
7.2.6	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). A complete change of detection platform or test kit (or laboratory assembled equivalent) shall require internal validation studies. The performance of a modified procedure shall be evaluated by comparison with the original procedure using similar DNA samples.	

	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, e.g., upgrade of instrument model. 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.	
7.2.7	The laboratory shall verify 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.	
7.2.8	Before the introduction of a significant change or novel procedure into database sample analysis, the DNA Analyst shall successfully complete a qualifying test.	
7.4 Handling of Test or Calibration Items		
7.4.1	The laboratory shall follow documented procedures designed to minimize loss, contamination and/or deleterious change of evidence and work product in progress.	
7.4.2	Where possible, the laboratory shall retain or return a portion of the data base sample	
7.4.3	The laboratory shall have and follow a documented policy for the disposition of data base sample that includes a policy on sample consumption	
7.7 Ensuring the validity of results		
7.7.1.1	The laboratory shall have and follow	

	written analytical procedures that have been validated and approved by the technical leader (however named). The standard operating procedures are to be reviewed annually by the technical leader and this review shall be documented.	
7.7.1.2	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 equipment, and controls which are standard for DNA analysis and data interpretation.	
7.7.1.3	The following controls shall be used for PCR analysis of DNA database samples: a) Internal Standard Control. b) Reagent Blank Control. c) Positive Amplification Control. d) Negative Amplification Control. e) Appropriate allelic ladders and internal size markers for the specific PCR- based system used.	
7.7.1.4	The laboratory shall use reagents that are suitable for the methods employed.	
7.7.1.5	The laboratory shall have and follow written procedures for documenting commercial supplies and for the formulation of reagents.	
7.7.1.6	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.	
7.7.1.7	The laboratory shall identify critical reagents and evaluate them prior to use.	
7.7.1.8	The laboratory shall have and follow written general guidelines for the	

	interpretation of data.	
7.7.1.9	The laboratory shall verify that all control results are within established guidelines. A written procedure must be in place to address control results that are outside guidelines	
7.7.1.10	The laboratory shall have and follow written procedures for reviewing DNA database sample information, results and matches.	
7.7.1.11	The laboratory shall have a mechanism in place to address unresolved discrepant conclusions between the initial analyst and the second analyst.	
7.7.1.12	The laboratory shall have and follow a policy to document incidents of contamination and its remediation efforts.	
7.7.2.1	The data basing laboratory will participate in both an external and an internal proficiency testing program. all personnel shall participate in the external or the internal proficiency testing program semi-annually. All personnel qualified in more than one technology or more than one typing test kit shall be proficiency tested in each technology or typing test kit at least once per calendar year. Personnel that perform analytical procedures on database, known, or casework reference samples shall perform a proficiency test at least one method in each methodology at least once per calendar year, with all methods being tested over a 2-year cycle.	
7.7.2.4	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.	
7.8 Reporting of Results		
7.8.1	The laboratory shall have and follow written procedures for generating and maintaining documentation for DNA database samples.	
7.8.2	The laboratory shall have written procedures for the release of DNA database sample information.	

A5-8. Management System Requirements

No additional requirements

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 this document 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 this document 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 customers; business transactions between an accredited testing laboratory and its customers are legal matters between the two parties.

The requirements of ISO/IEC 17025:2017 and this document apply generally to all accredited forensic laboratories. This Appendix is intended only to amplify and interpret the ISO/IEC 17025:2017 requirements specifically for forensic drug chemistry laboratories.

A6-1. Scope

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.

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.

Should a laboratory be required to collect samples, recommendations are provided in Appendix 6, section 9.

A6-2. References

In addition to the references cited in ANNEX A: References:

- ISO/IEC 17043:2010 Conformity assessment -- General requirements for proficiency testing
- SCC Accreditation Services Program Overview

A6-3. Terms and Definitions

3.1 **Uncontrolled Substance**: Substances which are not listed in the schedules of the Controlled Drugs and Substances Act.

3.2 **Controlled Substance**: A substance included in Schedule I, II, III, VI, or V of the Controlled Drugs and Substances Act.

A6-4. General Requirements

No additional requirements

A6-5. Structural Requirements

No additional requirements

A6-6. Resource Requirements

ISO/IEC 17025:2017	SCC REQUIREMENTS	SCC Guidance
6.2 Personnel		
6.2.1	The manager of a drug chemistry laboratory must be a qualified forensic analyst with a minimum of a bachelor's degree (or equivalent) in a chemical discipline and significant, recent and relevant experience.	
6.2.2	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.	
6.2.3	Certificate or report of analyst must be signed by an analyst.	
6.3 Facilities and Environmental Conditions		
6.3.1	The storage and handling of controlled drugs and substances must comply with applicable legislation.	
6.3.3		It is recommended that the laboratory make use of an intrusion alarm to help prevent unauthorized access.
6.5 Metrological Traceability		
6.5.1	Where possible, reference drugs and related substances shall be traceable to a recognized standard or certified by a body of recognized status. Checks for identity are required prior to placing such materials into service.	
6.5.2	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.	
6.5.3	Solutions of reference materials shall be prepared, labelled and stored in such a way as to maintain their	

	integrity. Documentation must be complete as to provide a clear audit trail back to the reference material or source.	

A6-7. Process Requirements

ISO/IEC 17025:2017	SCC REQUIREMENTS	SCC Guidance
7.2 Selection, verification and validation of methods		
7.2.2	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.	
7.2.3	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 variety 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 shall involve the use of representative reference materials to determine the estimated limits of detection.	
7.2.4	Quantitative analysis shall utilize an appropriate method which has been documented and validated by the laboratory. It shall be established that other substances known to be present in the matrix do not interfere with the quantification of the target analyte.	
7.2.5	Method validation for quantitative methods shall include determination of linearity, specificity, range, accuracy,	

	precision, and robustness. Method validation for quantitative methods for unique samples need not include robustness testing.	
7.2.6	Quantitative results shall be reported using a number of significant figures not greater than that which reflects the precision of the analysis.	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.
7.2.7	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.	
7.7 Ensuring the validity of results		
7.7.1.1	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.	
7.7.1.2	Whenever appropriate in the quality control system, statistical techniques such as control charts shall be used.	
7.7.1.3	When conducting analyses, laboratories may group samples into batches. Every analytical batch shall be accompanied by quality control measures that demonstrate the analytical system control status. This shall 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.	
7.7.1.4	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.	
7.7.2.1	**General Conditions** Prior to becoming accredited, a laboratory shall 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.	
7.7.2.2	**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 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.	
7.7.2.3	**False Positives/False Negatives** In assessing the seriousness of reporting so-called false positives, the nature, context and forensic ramifications of the error shall be considered.	

7.7.2.4	False negatives are usually considered less serious than reporting false positives. However, the difficulty of the analysis shall be considered, taking into account the concentration, chemical nature and forensic ramifications of the error.	
7.7.2.5	**Corrective Action** It is imperative that where an error occurs, regardless of its seriousness, prompt and appropriate corrective action shall be taken, and that it be documented.	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.
7.8 Reporting of Results		
7.8.1	Certificate or report of analyst are legal documents.	

A6-8. Management System Requirements

ISO/IEC 17025:2017	SCC REQUIREMENTS	SCC Guidance
8.4 Control of Records (Option A)		
8.4.1	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 customers.	
8.4.2	Calculations and data transfers which do not form part of a validated electronic process shall be verified by the person in charge of the case being investigated. Where an independent verification has been carried out by other authorized personnel, the records shall indicate	

	that such verifications have been carried out and by whom.	

A6-9. 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 customers.
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 customer.

- End of Document -