UNIFORM DRUG TESTING LAB STANDARDS

Adopted by RCI Board on July 24, 2010

3.0 Application of ISO/IEC 17025:2005 to the Analysis of Urine and Blood Drug and Medication Control Samples

3.1 Introduction and Scope

This section of the document is intended as an application as described in ISO/IEC 17025:2005 for the field of Drug and Medication Control. Any aspect of testing or management not specifically discussed in this document shall be governed by ISO/IEC 17025:2005. The application focuses on the specific parts of the processes that are critical with regard to the quality of the laboratory's performance as a Drug and Medication Control Laboratory and are therefore determined to be significant in the evaluation and accreditation process.

This section introduces the specific performance standards for a Drug and Medication Control Laboratory. The conduct of testing is considered a process within the definitions of ISO 17000:2004. Performance standards are defined according to a process model where the Drug and Medication Control Laboratory practice is structured into three main categories of processes:

Please note the numbering has not been adjusted from the original RMTC proposal, although modifications have been made and adopted by RCI. Renumbering will be subsequently addressed.

- Analytical and technical processes;
- Management processes;
- Support processes.

Wherever possible, the application will follow the format of the ISO/IEC 17025:2005 document. The concepts of the quality management system, continuous improvement, and customer satisfaction have been included.

3.2 Analytical and Technical Processes

3.2.1 Receipt of Samples

3.2.1.1 Samples (Blood or Urine) may be received by any method acceptable within the concepts of the International Standard for Testing.

3.2.1.2 The transport container shall first be inspected and any irregularities recorded.

3.2.1.3 The transfer of the Samples from the courier or other person delivering the Samples shall be documented including, at a minimum, the date, the time of receipt, and the name and signature of the Laboratory representative receiving the Samples. This information shall be included in the Laboratory Internal Chain of Custody record.

3.2.2 Handling and Retention of Samples

3.2.2.1 The Laboratory shall have a system to uniquely identify the Samples and associate each Sample with the collection document or other external chain of custody.

3.2.2.2 The Laboratory shall have Laboratory Internal Chain of Custody procedures to maintain control of and accountability for Samples from receipt through final disposition of the Samples.

3.2.2.3 The Laboratory shall observe and document conditions that exist at the time of receipt that may adversely impact on the integrity of a Sample. For example, irregularities noted by the Laboratory should include, but are not limited to:

- Sample tampering is evident;
- Sample is not sealed with tamper-resistant device or not sealed upon receipt;
- Sample is without a collection form (including Sample identification code) or a blank form is received with the Sample;
- Sample identification is unacceptable. For example, the number on the container does not match the Sample identification number on the form;
- Sample volume is inadequate to perform the requested testing menu;
- Sample transport conditions are not consistent with preserving the integrity of the

Sample for analysis.

3.2.2.4 The Laboratory shall notify and seek instructions from the State Horse Racing Authority regarding rejection or testing of Samples for which irregularities are noted. If applicable, any agreement between a State Horse Racing Authority and Laboratory that establishes Sample rejection criteria shall be documented.

3.2.2.5 The Laboratory shall retain the "A" Sample(s) without an Adverse Analytical Finding or Atypical Finding for a minimum of one (1) month after the final analytical ("A" Sample) report is transmitted to the State Horse Racing Authority. The Sample shall be stored frozen during the long term storage.

Samples with irregularities shall be stored frozen for a minimum of three (3) months following the report to the State Horse Racing Authority.

After the applicable storage period the Laboratory shall either make the Samples anonymous for research purposes or dispose of the Samples. Samples used for research purposes shall have any means of identification removed or be transferred into an anonymous container such that they cannot be traced back to a particular Horse. Disposal of Samples shall be conducted and recorded under the Laboratory Internal Chain of Custody.

3.2.2.6 The Laboratory shall retain frozen the "A" Sample with an Adverse Analytical Finding for as long as necessary pending the conclusion of a regulatory and legal action.

3.2.2.7 If the Laboratory has been informed by the State Horse Racing Authority that the analysis of a Sample is challenged, disputed or under investigation, the Sample shall be stored frozen and all the records pertaining to the Testing of that Sample shall be stored until completion of any regulatory and legal challenges.

3.2.2.8 The Laboratory shall maintain a policy pertaining to retention, release, and disposal of Samples and Aliquots.

3.2.2.9 The Laboratory shall maintain custody information on the transfer of Samples, or portions thereof, to another Laboratory.

3.2.2.10 The laboratory shall adopt procedures for future retesting of samples that have tested negative and have been identified for retroactive testing by the state horseracing authority.

3.2.3 Sampling and Preparation of Aliquots for Analysis

3.2.3.1 The Laboratory shall maintain paper or electronic Laboratory Internal Chain of Custody procedures for control of and accountability for all Aliquots and other

subsamples and transfers from preparation through disposal. The procedures shall incorporate the concepts presented in the RMTC Technical Document for Laboratory Internal Chain of Custody.

3.2.3.2 Before the initial opening of a Sample bottle, the device used to ensure the integrity of the Sample (*e.g.,* security tape or a bottle sealing system) shall be inspected and the integrity documented.

3.2.3.3 The Aliquot preparation procedure for any Initial Testing Procedure or Confirmation Procedure shall ensure that no risk of contamination of the Sample or Aliquot exists.

3.2.4 Analytical Testing

3.2.4.1 Urine analysis for adulteration or manipulation

3.2.4.1.1 The Laboratory shall only note any unusual condition of the urine - for example: color, odor, turbidity or foam. Any unusual conditions should be recorded and included as part of the report to the State Horse Racing Authority.

3.2.4.1.2 The Laboratory shall measure the pH and specific gravity of sample(s) with an Adverse Analytical Finding. Other tests that may assist in the evaluation of adulteration or manipulation may be performed if deemed necessary.

3.2.4.2 Urine/Blood Initial Testing Procedure

3.2.4.2.1 The Initial Testing Procedure(s) shall detect the Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s), or Marker(s) of the Use of a Prohibited Substance or Prohibited Method for all substances covered by the ARCI Uniform Classification Guidelines for Foreign Substances for which there is a method that is Fit-for-purpose. The RMTC may make specific exceptions to this section for specialized techniques that are not required to be within the scope of accreditation of all Laboratories.

3.2.4.2.2 The Initial Testing Procedure shall be performed with a Fit-for-purpose method for the Prohibited Substance or Prohibited Method being tested. A characteristic of the Initial Testing Procedure is to obtain information about the potential presence of Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s), or Marker(s) of the Use of a Prohibited Substance or Prohibited Method.

3.2.4.2.3 All batches undergoing the Initial Testing Procedure shall include appropriate negative and positive controls in addition to the Samples being tested.

3.2.4.2.4 For Threshold Substances, appropriate controls near the threshold shall be included in the Initial Testing Procedures. Initial Testing Procedures are not required to consider uncertainty of measurement.

3.2.4.3 Urine/Blood Confirmation Procedure
All Confirmation Procedures shall be documented. The objective of the Confirmation Procedure is to accumulate additional information to support an Adverse Analytical Finding. A Confirmation Procedure shall have equal or greater selectivity/discrimination than the Initial Testing Procedure.

3.2.4.3.1 "A" Sample Confirmation

3.2.4.3.1.1 A Presumptive Analytical Finding from an Initial Testing Procedure of a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method shall be confirmed using an additional Aliquot(s) taken from the original "A" Sample.

3.2.4.3.1.2 Mass spectrometry (MS) coupled to either gas (GC) or liquid chromatography (LC) is the analytical technique of choice for confirmation of Prohibited Substances, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method.

3.2.4.3.1.3 The Laboratory shall have a policy to define those circumstances where the Confirmation Procedure for an "A" Sample may be repeated (*e.g.,* batch quality control failure) and the first test result shall be nullified. Each repeat confirmation shall be documented and be completed on a new Aliquot of the "A" Sample.

3.2.4.3.1.4 If more than one Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method is identified by the Initial Testing Procedures, the Laboratory is not required to confirm every Presumptive Analytical Finding. The decision on the prioritization on order of confirmation(s) should be made in cooperation with the State Horse Racing Authority and the decision documented.

3.2.4.3.1.5 The mean value of the results of at least two Aliquots for the "A" Sample finding for Threshold Substances minus the value of the measurement uncertainty determined by the Laboratory must exceed the relevant Threshold. Adverse Analytical Finding or Atypical Finding decisions shall be based on the mean of the measured concentrations, taking into account the measurement uncertainty with the coverage factor, k, and a level of confidence of 95%. Reports and documentation shall give the mean concentration with the associated uncertainty, unless otherwise specified by the racing authority.

3.2.5 Results Management

3.2.5.1 Review of results

3.2.5.1.1 A minimum of two certifying scientists shall independently review all Adverse Analytical Findings and Atypical Findings before a report is issued. The review process

shall be recorded.

3.2.5.1.2 At a minimum, the review shall include:

- Laboratory Internal Chain of Custody documentation;
- Validity of the analytical initial and confirmatory data and calculations;
- Quality control data;
- Completeness of documentation supporting the reported analytical findings.

3.2.5.1.3When an Adverse Analytical Finding is rejected, the reason(s) shall be recorded.

3.2.6 Documentation and Reporting

3.2.6.1 The Laboratory shall have documented procedures to ensure that it maintains a coordinated record related to each Sample analyzed. In the case of an Adverse Analytical Finding, the record shall include the data necessary to support the conclusions reported. In general, the record should be such that in the absence of the analyst, another competent analyst could evaluate what tests had been performed and interpret the data.

3.2.6.2 Each step of testing shall be traceable to the staff member who performed that step.

3.2.6.3 Significant variance from the written procedure shall be documented as part of the record (*e.g.,* memorandum for the record).

3.2.6.4 Where instrumental analyses are conducted, the operating parameters for each run shall be included as part of the record.

3.2.6.5 Reporting of "A" Sample results should occur within fourteen (14) calendar days of receipt of the Sample. The reporting time required for specific Events may be substantially less than fourteen days. The reporting time may be altered by agreement between the Laboratory and the State Horse Racing Authority.

3.2.6.6 A single, distinct Test Report shall be generated to document the Adverse Analytical Finding(s) of an individual Sample. The Laboratory Test Report may include, in addition to the items stipulated in ISO/IEC 17025:2005, the following:

- Client Sample identification code;
- Laboratory identification code;
- Type of test (Out of Competition/In-Competition);
- Date of receipt of Sample;
- Date of report;
- Sex of the horse;
- Type of Sample (urine, blood, etc.);

- Test results (for Threshold Substances: the mean value, units, uncertainty details, and reporting threshold shall be included);
- Signature of authorized individual;
- Other information as specified by the State Horse Racing Authority and/or a properly designated independent oversight body.

At a minimum, labeling and information provided by the Laboratory related to the type of test, test results (including comments/opinions) and client to whom the report is addressed shall also be provided on the test report.

3.2.6.7 The Laboratory is not required to measure or report a concentration for Prohibited Substances in urine/blood Samples. The Laboratory shall report the actual Prohibited Substance(s), Metabolite(s) of the Prohibited Substance(s) or Prohibited Method(s), or Marker(s) detected in the Sample.

For Threshold Substances in urine/blood Samples, the Laboratory report shall establish that the Prohibited Substance or its Metabolite(s) or Marker(s) of a Prohibited Method is present at a concentration greater than the threshold concentration (taking into consideration the value of measurement uncertainty for the "A" Sample confirmation only).

3.2.6.8 The Laboratory should qualify the result(s) in the Test Report as an Adverse Analytical Finding or "No Prohibited Substance(s) on Test menu detected".

3.2.6.9 The Laboratory shall have a policy regarding the provision of opinions and interpretation of data which has been approved in writing by the State Horse Racing Authority. An opinion or interpretation may be included in the Test Report provided that the opinion or interpretation is clearly identified as such. The basis upon which the opinion has been made shall be documented. Note: An opinion or interpretation may include, but need not be limited to, recommendations on how to use results, information related to the pharmacology, metabolism and pharmacokinetics of a substance, whether the observed results may suggest the need for additional Testing and whether an observed result is consistent with a set of reported conditions.

3.2.6.10 The Laboratory, upon request by Testing Authorities, may be asked to review data from longitudinal studies. Following review of the applicable data, a report and recommendation shall be made by the Laboratory to the State Horse Racing Authority as to whether the data support an Adverse Analytical Finding or not.

3.2.6.11 The Laboratory Documentation Package should be provided by the Laboratory only to the relevant result management authority upon request and should be provided within 10 working days of the request. Laboratory Documentation Packages shall contain material specified in the RMTC Technical Document on Laboratory Documentation Packages (Appendix C).

3.3 Quality Management Processes

3.3.1 Organization

3.3.1.1 Within the framework of ISO/IEC 17025:2005, the Laboratory shall be considered as a testing Laboratory.

3.3.1.2 The administrative and operational activities of the Laboratory, as well as the hosting facility, should be independent from the Drug and Medication Control Organization(s) providing support (*e.g.,* financial, Samples, facilities) to the Laboratory.

3.3.1.3 The Laboratory Director shall have the responsibilities of the Chief Executive, unless otherwise noted.

3.3.2 Quality Policy and Objectives

3.3.2.1 The Quality Policy and implementation shall meet the requirements of ISO/IEC 17025:2005 Section 4.2 Management System and shall include a Quality Manual that describes the quality system.

3.3.2.2 A single staff member should be appointed as the Quality Manager and shall have responsibility and authority to implement and ensure compliance with the quality system.

3.3.3 Document Control

The control of documents that make up the Management System shall meet the requirements of ISO/IEC 17025:2005 Section 4.3 Document Control.

3.3.3.1 The Laboratory Director (or designee) shall approve the Quality Manual and all other documents used by staff members in completing testing.

3.3.3.2 The Management System shall ensure that the contents of the RMTC Technical Documents are incorporated into the appropriate manuals by the effective date and that training is provided and recorded. If this is not possible, the RMTC shall be contacted with a written request for an extension.

3.3.4 Review of requests, tenders, and contracts

Review of legal documents or agreements related to testing shall meet the requirements of ISO/IEC 17025:2005 Section 4.4.

The Laboratory shall ensure that the State Horse Racing Authority is informed concerning the Prohibited Substances that can be detected under the scope of accreditation in Samples submitted for analysis.

3.4.4 Test Methods and Method Validation

3.4.4.1 Selection of Methods

Standard methods are generally not available for Drug and Medication Control analyses. The Laboratory shall develop, validate, and document methods for the detection of substances present on the ARCI Uniform Classification Guidelines for Foreign Substance and for associated Metabolites or Markers or related substances.

Note that for many substances, the associated Metabolites are detected, thereby confirming the metabolism and the administration of a Prohibited Substance to the horse from which the sample was collected. The methods shall be selected and validated so they are Fit-for-purpose. RMTC shall supply feedback to the Laboratories regarding the suitability of the assay principle.

3.4.4.1.1 Non-Threshold Substances

Laboratories are not required to measure or report a concentration for Non-Threshold Substances.

The Laboratory shall develop, as part of the method validation process, acceptable standards for identification of Prohibited Substances.

The Laboratory shall demonstrate the ability to successfully identify 100% of the time representative substances in the class of Prohibited Substances at the Minimum Required Performance Levels (*e.g.,* twenty urine samples supplemented at the MRPL). The Laboratory shall establish, in routine practice, the use of control samples containing representative substance(s) at the MRPL if the appropriate standards are available. A Reference Collection may be used for identification and in such cases an estimate of the detection capability for the method may be provided by assessing a representative substance.

3.4.4.1.2Threshold Substances

The Laboratory shall develop methods that are Fit-for-purpose. The method shall be capable of determining both the concentration and the identity of the Prohibited Substance or Metabolite(s) or Marker(s).

Confirmation methods for Threshold Substances shall be performed on two Aliquots. If insufficient Sample volume exists to analyze two Aliquots, the determination should be based on the measurement of one Aliquot. Adverse Analytical Finding decisions shall be based on the mean of the measured concentrations, taking into account the measurement uncertainty with the coverage factor, k, and a level of confidence of 95%. Reports and documentation, where necessary, shall report the mean concentration.

3.4.4.2 Validation of Methods

3.4.4.2.1Confirmation methods for Non-Threshold Substances shall be validated. Factors to be investigated to demonstrate that a method is Fit-for-purpose include but are not limited to:

- Specificity. The ability of the assay to detect only the substance of interest shall be determined and documented. The assay shall be able to discriminate between compounds of closely related structures;
- Identification capability. Since the results for NonThreshold Substances are not quantitative, the Laboratory should establish criteria for ensuring that a substance representative of the class of Prohibited Substances can be repeatedly identified and detected as present in the Sample at the MRPL;
- Robustness. The method shall be determined to produce similar results with respect to minor variations in analytical conditions. Those conditions that are critical to reproducible results shall be controlled;
- Carryover. The conditions required to eliminate carryover of the substance of interest from Sample to Sample during processing or instrumental analysis shall be determined and implemented;
- Matrix interferences. The method should avoid interference in the detection of Prohibited Substances or their Metabolites or Markers by components of the Sample matrix;
- Standards. Reference Materials should be used for identification, if available. If there is no reference standard available, the use of data or Sample from a validated Reference Collection is acceptable.

3.4.4.2.2 Confirmation methods for Threshold Substances shall be validated. Factors to be investigated to demonstrate that a method is Fit-for-purpose include but are not limited to:

- Specificity. The ability of the assay to detect only the substance of interest shall be determined and documented. The assay shall be able to discriminate between compounds of closely related structures;
- Intermediate Precision. The method shall allow for the reliable repetition of the results at different times and with different operators performing the assay.
- Intermediate Precision at the threshold shall be recorded;
- Robustness. The method shall be determined to produce similar results with respect to minor variations in analytical conditions. Those conditions that are critical to reproducible results shall be controlled;
- Carryover. The conditions required to eliminate carryover of the substance of interest from Sample to Sample during processing or instrumental analysis shall be determined and implemented;
- Matrix interferences. The method shall limit interference in the measurement of the concentration of Prohibited Substances or their Metabolites or Markers by components of the Sample matrix;
- Standards. Reference Materials should be used for quantification, if available;

- Limit of quantitation (LOQ). The Laboratory shall demonstrate that a threshold method has an established LOQ of no more than 50% of the threshold value for Threshold Substances;
- Linearity shall be documented at 50% to 200% of the threshold value, unless otherwise stipulated in a Technical Document.

3.4.4.3 Estimate of Uncertainty of Method

In most cases, an identification of a Prohibited Substance, its Metabolite(s) or Marker(s), is sufficient to report an Adverse Analytical Finding.

3.4.4.3.1Uncertainty in identification

The appropriate analytical characteristics shall be documented for a particular assay. The Laboratory shall establish criteria for identification of a compound at least as rigorous as stated in the relevant Technical Document.

3.4.4.3.2Uncertainty in establishing that a substance exceeds a threshold.

The purpose of threshold reporting in Drug and Medication Control is to establish that the Prohibited Substance or its Metabolite(s) or Marker(s) is present at a concentration greater than the threshold value taking into consideration the applicable uncertainty. The method, including selection of standards and controls, and estimation of uncertainty shall be Fit-for-purpose.

3.4.4.3.2.1 Uncertainty of quantitative results, particularly at the threshold value, shall be addressed during the validation of the assay.

3.4.4.3.2.2 The expression of uncertainty shall use the expanded uncertainty using a coverage factor, k, to reflect a level of confidence of 95 %.

3.4.4.3.2.3 Uncertainty may be further addressed in Technical Documents in order to reflect the purpose of analysis for the specific substances.

3.4.4.4 Control of Data

3.4.4.4.1Data and Computer Security

3.4.4.4.1.1 All reasonable measures and best efforts shall be taken to prevent intrusion and copy of data from computer systems.

3.4.4.4.1.2 Access to computer terminals, computers, servers or other operating equipment shall be controlled by physical access and by multiple levels of access controlled by passwords or other means of employee recognition and identification. These include, but are not limited to, account privileges, user identification codes, disk access, and file access control.

3.4.4.4.1.3 The operating software and all files shall be backed up on a regular basis and a current copy shall be either stored in a fire and water proof environment or kept off site at a secure location.

3.4.4.4.1.4 The software shall prevent the changing of results unless there is a system to document the Person doing the editing and that editing can be limited to users with proper level of access.

3.4.4.4.1.5 All data entry, recording of reporting processes and all changes to reported data shall be recorded with an audit trail. This shall include the date and time, retention of original data, reason for change to original data, and the individual performing the task.

3.4.5 Equipment

3.4.5.1 A List of available equipment is to be established and maintained.

3.4.5.2 As part of a quality system, the Laboratory shall operate a program for the maintenance and calibration of equipment according to ISO/IEC 17025:2005 Section 5.5.

3.4.5.3 General service equipment that is not used for making measurements should be maintained by visual examination, safety checks, and cleaning as necessary. Calibrations are only required where the setting can significantly affect the test result. A maintenance schedule, at least to manufacturer's recommendations or local regulations, if available, shall be established for items such as fume hoods, centrifuges, evaporators, etc, which are used in the test method.

3.4.5.4 Equipment or volumetric devices used in measuring shall have periodic performance checks along with servicing, cleaning, and repair.

3.4.5.5 Qualified subcontracted vendors may be used to service, maintain, and repair measuring equipment.

3.4.5.6 All maintenance, service, and repair of equipment shall be documented.

3.4.6 Measurement Traceability

3.4.6.1 Reference Materials

When available, reference drug or drug Metabolite(s) traceable to a national standard or certified by a body of recognized status, such as USP, BP, Ph.Eur. or WHO, should be used. At a minimum, an analysis report must be obtained.

When a Reference Material is not certified, the Laboratory shall verify its identity and

purity by comparison with published data or by chemical characterization.

3.4.6.2 Reference Collections

A collection of Sample or isolates may be obtained from a biological matrix following an authentic and verifiable administration of a Prohibited Substance or Prohibited Method, providing that the analytical data are sufficient to justify the identity of the relevant chromatographic peak or isolate as a Prohibited Substance or Metabolite of a Prohibited Substance or Marker of a Prohibited Substance or Prohibited Method.

3.4.7 Assuring the quality of test results

3.4.7.1 The Laboratory shall participate in the Horse Testing Laboratory External Quality Assurance Program (EQAP).

3.4.7.2 The Laboratory shall have in place a quality control system, including the submission of masked quality control samples that challenges the entire scope of the analytical process (i.e., Sample receipt and accessioning through result reporting).

3.4.7.3 Analytical performance shall be monitored by operating quality control schemes appropriate to the type and frequency of testing performed by the Laboratory. The range of quality control activities should include:

- Positive and negative controls analyzed in the same analytical run as the Presumptive Analytical Finding Sample;
- The use of deuterated or other internal standards or standard addition;
- Comparison of mass spectra or ion ratios from selected ion monitoring (SIM) to a Reference Material or Reference Collection Sample analyzed in the same analytical run;
- Confirmation of the "A" and "B" Split Samples;
- For Threshold Substances, quality control charts referring to appropriate control limits depending on the analytical method employed (e.g., ± 10 % of the target value; ± 3SD), should be used;
- The quality control procedures shall be documented by the Laboratory.

Terms and definitions

Adverse Analytical Finding: A report from a Laboratory or other approved Testing entity that identifies in a Specimen the presence of a Prohibited Substance or its Metabolites or Markers (including elevated quantities of endogenous substances) or evidence of the Use of a Prohibited Method.

Aliquot: A portion of the Sample of biological fluid or tissue (e.g., urine, blood, etc.) obtained from the horse and used in the analytical process.

Analytical Testing: The parts of the Drug and Medication Control process involving Sample handling, analysis and reporting following receipt in the Laboratory.

Atypical Finding: A report from a Laboratory that requires further investigation as provided by the National Standard for Laboratories or related Technical Documents before determination of an Adverse Analytical Finding.

Batch: A set of samples processed as a group.

Certified Reference Material: Reference Material characterized by a metrologically valid procedure for one or more specified properties, accompanied by a certificate that provides the value of the specified property, its associated uncertainty, and a statement of metrological traceability.

Competition: A horse race. The distinction between a Competition and an Event will be provided in the rules of the applicable organization.

Confirmation Procedure: An analytical test procedure whose purpose is to identify the presence or concentration of one or more specific Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Method in a Sample. A Confirmation Procedure may also indicate a concentration of Prohibited Substance greater than a threshold concentration plus the measurement uncertainty in a Sample.

Coverage factor k: The coverage factor k is a numerical value from statistical tables or computation that is used to compute measurement uncertainty. For example,, a coverage factor of 3 confers a certain level of statistical certainty for the measurement uncertainty value. Larger values of the “coverage factor k” increase the certainty of the measurement uncertainty estimate.

Designated Special Event: A series of individual national Competitions conducted together under an organizing body (e.g., TOBA Graded Stakes Committee, Triple Crown Productions, the Breeders’ Cup Limited) and for which a significant increase of resources and sample testing capacity is required to conduct Drug and Medication Control for the Event as determined by the RMTC.

Drug and Medication Control: The process including test distribution planning, sample collection and handling, laboratory analysis, results management, hearings and appeals.

Event: A series of individual Competitions (e.g., Breeders' Cup races) conducted under the supervision of one organizing body.

Fit for Purpose: Suitability of a test to meet testing objectives.

Horse: For purposes of Drug and Medication Control, any horse entered in an officially recognized competition conducted under the rules of racing of State Horse Racing Authority.

In-Competition: For purposes of differentiating between In-competition and Out-of-Competition Testing, unless provided otherwise in the rules of a relevant State Horse Racing Authority, an In-Competition test is a test wherein a horse is selected for Testing in the period immediately before or after completion of a Competition.

Initial Testing Procedure (Screen Testing Procedure): An analytical test procedure whose purpose is to identify those Samples which may contain a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method or the quantity of a Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method in excess of a defined threshold.

Intermediate Precision: Variation in results observed when one or more factors, such as time, equipment, and operator are varied within a Laboratory.

International Standard: A standard adopted by the RMTC in support of the Code. Compliance with a National Standard (as opposed to another alternative standard, practice or procedure) shall be sufficient to conclude that the procedures covered by the National Standard were performed properly.

Laboratory: An accredited laboratory applying test methods and processes to provide evidentiary data for the detection and, if applicable, quantification of a Threshold Substance on the Prohibited List in urine, blood, and other biological Samples.

Laboratory Documentation Package: The material produced by the Laboratory to support the finding of an Adverse Analytical Finding as set forth in the RMTC Technical Document for Laboratory Documentation Packages (Appendix C).

Laboratory Internal Chain of Custody: Documentation of the sequence of Persons in possession of the Sample and any Aliquot of the Sample taken for Testing. [Comment: Laboratory Internal Chain of Custody is generally documented by a written record of the date, location, action taken, and the individual performing an action with a Sample or Aliquot.]

Marker: A compound, group of compounds, or biological parameters that indicates the Use of a Prohibited Substance or a Prohibited Method.

Measurement Uncertainty: The Measurement Uncertainty (MU) is a parameter associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the concentration of the analyte. The MU is different from the error associated with the measurement since the error is the difference between the measured value and the true value whereas the measurement uncertainty is a range of values that could reasonably be attributed to the measured concentration.

Metabolite: Any substance produced by a biotransformation process.

Minimum Required Performance Level (MRPL): concentration of a Prohibited Substance or Metabolite of a Prohibited Substance or Marker of a Prohibited Substance or Method that a Laboratory is expected to reliably detect and confirm in the routine daily operation of the Laboratory. See Technical Document Minimum Required Performance Standards for Detection of Prohibited Substances.

National Standard for Laboratories (NSL): The National Standard applicable to Laboratories as set forth herein.

Non-Threshold Substance: A substance listed on the Prohibited List for which the documentable detection of any concentration is considered a Drug and Medication Control rule violation.

Out-of-Competition: Any Drug and Medication Control which is not In-Competition.

Person: A natural person or an organization or other entity.

Presumptive Analytical Finding: The status of a Sample test result for which there is a suspicious result in the Initial Testing Procedure, but for which a confirmation test has not yet been performed.

Prohibited List: The List identifying the Prohibited Substances and Prohibited Methods.

Prohibited Method: Any method or practice so described under RCI Model Rules, Section ARCI-011-015.

Prohibited Substance: Any substance not specifically permitted by state statute or by the rules promulgated by the State Horse Racing Authority.

Publicly Disclose or Publicly Report: To disseminate or distribute information to the general public or Persons beyond those Persons entitled to earlier notification in accordance with Article 14.

Quality Manual: The Quality Manual is a document that describes the Laboratory's quality system. The Quality Manual shall include an Introduction, statement of the Scope, a section on Definitions and Terminology, a section on Management Requirements, and a section on Technical Requirements. The Management Requirements shall include sections on Organization, the Management System, Document control, Review of Contracts, Subcontracting, Purchasing, Service to the customer, Complaints, Control of Non-Conforming Work, Improvement, Corrective Actions, Preventive Actions, Control of Quality Records, Internal Audits, and Management Review. The Technical Requirements shall include sections on Personnel, Accommodations, Test Methods and Validation, Equipment, Measurement Traceability, Sampling, Handing of Test Items, Quality Control, and Reports and Calibration Certificates.

Reference Collection: A collection of samples of known origin that may be used in the determination of the identity of an unknown substance. For example, a well characterized sample obtained from a verified administration study in which scientific documentation of the identity of Metabolite(s) can be demonstrated.

Reference Material: Material, sufficiently homogeneous and stable with respect to one or more specified properties, which has been established to be fit for its intended use in a measurement process.

Repeatability, sr: Variability observed within a laboratory, over a short time, using a single operator, item of equipment, etc.

Reproducibility, sR: Variability obtained when different laboratories analyze the same Sample.

Revocation: The permanent withdrawal of a Laboratory's RMTC accreditation.

Sample/Specimen: Any biological material collected for the purposes of Drug and Medication Control.

Split Sample: Division of a Sample taken for testing into two portions at collection, usually designated "A" and "B".

State Horse Racing Authority: The entity(ies) designated by each state as possessing the primary authority and responsibility to adopt and implement Drug and Medication

Control rules, direct the collection of Samples, the management of test results, and the conduct of hearings, all at the state level.

Suspension: The temporary withdrawal of a Laboratory's RMTC accreditation.

Tampering: Altering for an improper purpose or in an improper way; bringing improper influence to bear; interfering improperly to alter results or prevent normal procedures from occurring.

Testing: The parts of the Drug and Medication Control process involving test distribution planning, Sample collection, Sample handling, and Sample transport to the Laboratory.

Threshold Substance: A substance listed in the Prohibited List for which the detection and quantification of the substance at a concentration in excess of a stated threshold concentration plus the measurement uncertainty is considered an Adverse Analytical Finding.

Trainer: For purposes of Drug and Medication Control, the Trainer is the Person who is the absolute insurer of the condition of the Horse.

Use: The application, ingestion, inhalation, injection or consumption by any means whatsoever of any Prohibited Substance or Prohibited Method.