Anti-Doping and Medication Control Protocol (Not Submitted to FTC)

1 DEFINITION OF ANTI-DOPING AND MEDICATON CONTROL RULE VIOLATIONS

1.1 Medication control rule violations are defined as the occurrence of one or more violations of Article 2.15 or one or more violations of Articles 2.4 or 2.5 involving only Secondary Substances. Medication control rule violations must also be Minor Infractions. Anti-Doping rule violations are defined as the occurrence of one or more of the violations set forth in Article 2.4 through Article 2.15 that are not medication control rule violations.

2 ANTI-DOPING AND MEDICATION CONTROL RULE VIOLATIONS

2.1 The purpose of Article 2 is to specify the circumstances and conduct which constitute anti-doping and medication control rule violations. Cases will be initiated based on the assertion that one or more of these specific rules have been violated

2.10 Possession of a Primary Substance or a Primary Method by a Covered Person

2.11 Trafficking or Attempted Trafficking in any Prohibited Substance or Prohibited Method by a Covered Person

2.12 Administration

2.12 (a) Administration or Attempted Administration to any Covered Horse of any Primary Substance or any Primary Method by a Covered Person.

2.12 (b) Administration or Attempted Administration to any Covered Horse of any Secondary Substance or any Secondary Method by a Covered Person where the circumstances as a whole demonstrate that such Prohibited Substances are not intended for genuine and legal therapeutic purposes or are intended to impact sport performance.

2.12 (c) Administration or Attempted Administration to any Covered Horse of any Secondary Substance or any Secondary Method by a Covered Person during the Race Period restricted period specified in the Prohibited List.

2.13 Complicity or Attempted Complicity by a Covered Person

2.13 (a) Assisting, encouraging, aiding, abetting, conspiring, covering up or any other type of intentional complicity or Attempted complicity involving an anti-doping or medication control rule violation, Attempted anti-doping or medication control rule violation, or violation of Article 10.12 (a) by a Covered Person.

2.14 Acts by a Covered Person to Discourage or Retaliate Against Reporting to Authorities

2.14 (a) Where such conduct does not otherwise constitute a violation of Article 2.9:

2.14 (a) (1) Any act which threatens or seeks to intimidate another Person with the intent of discouraging the Person from the good faith reporting of information that relates to an alleged anti-doping or medication control rule violation or alleged non-compliance with the Protocol to the Agency, the Authority, a State Racing Commission, law enforcement, a regulatory or professional disciplinary body, an Article 8 or Article 11 adjudication body, or any Person conducting an investigation for the Agency, the Authority, or a State Racing Commission.

2.14 (a) (2) Retaliation against a Person who, in good faith, has provided evidence or information that relates to an alleged anti-doping or medication control rule violation or alleged non-compliance with the Protocol to the Agency, the Authority, a State Racing Commission, law enforcement, regulatory or professional disciplinary body, an Article 8 or Article 11 adjudication body, or Person conducting an investigation for the Agency, the Authority, or a State Racing Commission.

2.14 (b) For purposes of Article 2.14, retaliation, threatening, and intimidation does not include an act taken against such Person in good faith and that is a proportionate response.

2.15 Medication Control Violation

2.15 (a) Covered Persons must ensure that all otherwise permitted medication administered to a Covered Horse in their care is the minimum necessary to address the diagnosed health concerns, recommended by a Veterinarian, justified by the Covered Horse's medical condition(s) as diagnosed by a Veterinarian, and given in the best interests of the Covered Horse's health and welfare.

2.15 (b) Possession of otherwise permitted medication for a Covered Horse by a Covered Person must be in compliance with state and federal law.

2.15 (c) The Responsible Person (or Owner, if there is no Responsible Person) is strictly liable for a violation of this Article 2.15, i.e., a medication control violation. Other Covered Persons have committed a medication control violation if they had knowledge or should have had knowledge that for 2.15 (a) the medication was not the minimum necessary to treat the diagnosed medical condition(s), was not recommended by a Veterinarian, was not justified by the Covered Horse's medical condition(s) as diagnosed by a Veterinarian, or was not given in the best interests of the Covered Horse's health and welfare and for 2.15 (b) the Possession of the medication was not in compliance with state or federal law.

2.2 The anti-doping and medication control rule violations described in this Article 2 may only be committed by Covered Persons. The Consequences of Anti-Doping and Medication Control Rule Violations under this Protocol shall apply to both Covered Persons and Covered Horses. Covered Persons shall be responsible for knowing what constitutes an anti-doping and medication control rule violation and the Prohibited Substances and Prohibited Methods which have been included on the Prohibited List.

2.3 To establish a Covered Person other than a Veterinarian committed a violation under this Protocol, other than an Article 2.4, 2.5, 2.7, or 2.15 violation, the Agency must demonstrate that the elements of a violation by a Covered Person have been established and the Covered Person intended the conduct that constituted or resulted in a violation. To establish a Veterinarian committed a violation, the Agency must demonstrate the elements of a violation and that the Veterinarian knew or should have known that their conduct constituted a rule violation

2.4 Presence of a Prohibited Substance or its Metabolites or Markers in a Covered Horse's Sample

2.4 (a) It is the Responsible Persons' duty to ensure that no Prohibited Substance enters their Covered Horses' bodies. Responsible Persons are responsible for any Prohibited Substance or its Metabolites or Markers found to be present in Covered Horses' Samples. Responsible Persons are strictly liable for the presence of a Prohibited Substance, or its Metabolites or Markers, in their Covered Horse. Accordingly, it is not necessary that intent, Fault, negligence or knowing Use be demonstrated in order to establish an anti-doping or medication control rule violation under Article 2.4 by a Responsible Person. In the event there is no Responsible Person for a Covered Horse, the responsibilities and principle of Strict Liability described under Article 2.4 shall be applied to the Covered Horse's Owner.

2.4 (b) Sufficient proof of an anti-doping or medication control rule violation under Article 2.4 is established by any of the following:

2.4 (b) (1) presence of a Prohibited Substance or its Metabolites or Markers in the Covered Horse's A Sample where the Responsible Person (or Owner, if there is no Responsible Person) waives analysis of the B Sample and the B Sample is not analyzed;

2.4 (b) (2) where the Covered Horse's B Sample is analyzed and the analysis of the B Sample confirms the presence of the Prohibited Substance or its Metabolites or Markers found in the A Sample; or

2.4 (b) (3) when the Laboratory splits the A or B Sample into two parts in accordance with the Laboratory Standards and the analysis of the second part of the split Sample confirms the presence of the Prohibited Substance or its Metabolites or Markers found in the first part of the split Sample or the Responsible Person (or Owner, if there is no Responsible Person) waives analysis of the second part of the split Sample.

2.4 (c) Subject to the terms of Article 2.4 (a)

2.4 (c) (1) sufficient proof of an anti-doping or medication control rule violation under Article 2.4 by a Covered Person who is not a Responsible Person (or Owner if there is no Responsible Person) is established by any of the criteria set forth in Article 2.4 (b)

2.4 (c) (2) demonstration by the Agency that the Covered Person had knowledge or should have had knowledge that a Prohibited Substance was administered or was planned to be administered to a Covered Horse

2.4 (d) Excepting those substances for which a Minimum Reporting Level, Threshold, or Decision Limit is specifically identified in the Prohibited List or a Technical Document, the presence of any reported quantity of a Prohibited Substance or its Metabolites or Markers in a Covered Horse's Sample shall constitute an anti-doping or medication control rule violation.

2.4 (e) As an exception to the general rule of Article 2.4, the Prohibited List, Policies, or Technical Documents may establish special criteria for reporting or the evaluation of certain Prohibited Substances.

2.4 (f) In the event a Responsible Person discloses to the Agency or Authority the Use or Attempted Use of any Prohibited Substance or Prohibited Method prohibited at all times by a horse in accordance with Article 5.4, then the presence or evidence of Use of such disclosed substance or method in the Covered Horse's Sample shall not be considered an anti-doping or medication control rule violation if it is determined by the Agency to have resulted from Use of the Prohibited Substance or Prohibited Method prior to the horse becoming a Covered Horse.

2.5 Use or Attempted Use in a Covered Horse of a Prohibited Substance or a Prohibited Method

2.5 (a) It is a Responsible Person's duty to ensure that no Prohibited Substance enters their Covered Horses' bodies and that no Prohibited Method is Used. Responsible Persons are responsible for any Use of a Prohibited Substance or Method in a Covered Horse. Responsible Persons are strictly liable for the Use of a Prohibited Substance in their Covered Horse. Accordingly, it is not necessary that intent, Fault, negligence or knowledge of Use be demonstrated in order to establish an anti-doping or medication control rule violation for Use of a Prohibited Substance or a Prohibited Method with respect to Responsible Persons. In the event there is no Responsible Person for a Covered Horse, the responsibilities and principle of Strict Liability described under Article 2.5 shall be applied to the Owner.

2.5 (b) Subject to the terms of Article 2.5 (a), to establish an anti-doping or medication control rule violation for Use of a Prohibited Substance or a Prohibited Method in a Covered Horse, by the Covered Person who is not a Responsible Person (or Owner if there is no Responsible Person), the Agency must demonstrate that the Covered Person had knowledge or should have had knowledge of the Use of the Prohibited Substance in the Covered Horse.

2.5 (c) The impact of the Use or Attempted Use of a Prohibited Substance or Prohibited Method as it relates to the Covered Horse's performance is not material. It is sufficient that the Prohibited Substance or Prohibited Method was Used or Attempted to be Used for an anti-doping or medication control rule violation to be committed.

2.6 Evading, Refusing or Failing to Submit a Covered Horse to Sample Collection

2.6 (a) Evading Sample collection or refusing or failing to submit the Covered Horse to Sample collection by a Covered Person without compelling justification.

2.6 (b) If a Covered Horse is intractable, and thereby fails to provide the Sample sought, no violation will be found on this basis, but the Covered Horse shall not be permitted to participate in a Race until the Responsible Person notifies the Agency that the Covered Horse is no longer intractable, and the Agency successfully collects a Sample. [see end note 1]

2.7 Whereabouts Failures regarding a Covered Horse

2.7 (a) Any combination of three Whereabouts Failures, as defined in the Whereabouts Policy, within a twelve-month period regarding a single Covered Horse constitutes an anti-doping rule violation for the Responsible Person and results in Ineligibility for the Covered Horse as described in 10.1 (b)

2.7 (a) (1) If the Responsible Person changes with respect to a Covered Horse with Whereabouts Failures, the Whereabouts Failures of the Covered Horse remain with the Covered Horse for purposes of Article 2.7 (a) but do not count against the Whereabouts Failures for the new Responsible Person as described in Articles 2.7 (a) and 2.7 (b)

2.7 (a) (2) In the circumstance described in Article 2.7 (a) (1) if a Covered Horse accrues three Whereabouts Failures in a twelve-month period but the new Responsible Person has not accrued three Whereabouts Failures with respect to that Covered Horse, an Article 2.7 (a) violation has been committed and the Agency shall initiate the case against the new Responsible Person on behalf of the Covered Horse. However, such Responsible Person shall not receive a violation or period of Ineligibility. The Covered Horse shall receive Consequences consistent with the Protocol.

2.7 (b) Any combination of six Whereabouts Failures, as defined in the Whereabouts Policy, within a twelve-month period for every 50 Covered Horses per Responsible Person on average annually, as described more fully in the Whereabouts Policy, constitutes an anti-doping rule violation.

2.7 (c) It is the Responsible Person's responsibility to provide accurate and up to date whereabouts information regarding a Covered Horse in accordance with the Whereabouts Policy and this Protocol unless the Covered Horse has no Responsible Person, in which case all whereabouts responsibilities shall be applied to the Owner of the Covered Horse.

2.8 Failure by a Covered Person to Cooperate with the Agency

2.9 Tampering or Attempted Tampering with any part of Doping Control by a Covered Person

3 PROOF OF DOPING AND MEDICATION CONTROL

3.1 Burdens and Standards of Proof

3.1 (a) The Agency shall have the burden of establishing that an anti-doping or medication control rule violation has occurred. The standard of proof shall be whether the Agency has established an anti-doping or medication control rule violation by a preponderance of the evidence. This standard of proof in all cases shall be that the Article 8 or Article 11 (except as otherwise described in the Act) adjudication body must be satisfied that, based on the evidence, the occurrence of the anti-doping or medication control rule violation was more probable than not. Similarly, where the Protocol places the burden of proof upon the Covered Person alleged to have committed an anti-doping or medication control rule violation to rebut a presumption or establish specified facts or circumstances the standard of proof also shall be by a preponderance of the evidence.

3.2 Methods of Establishing Facts and Presumptions

3.2 (a) Facts related to anti-doping or medication control rule violations may be established by any reliable means, including admissions. The following rules of proof shall be applicable in doping and medication control cases:

3.2 (a) (1) Analytical Methods, Minimum Reporting Levels, Thresholds, Screening Limits, Decision Limits, or any other Laboratory reporting requirements approved by the Commission are presumed to be scientifically valid and shall not be subject to challenge unless required by applicable law.

3.2 (a) (2) Laboratories are presumed to have conducted Sample analysis and custodial procedures in accordance with the Laboratory Standards. A Covered Person may rebut this presumption by establishing that a departure from the Laboratory Standards occurred that could reasonably have caused the Adverse Analytical Finding.

3.2 (a) (2) (i) If the Covered Person rebuts the preceding presumption by showing that a departure from the Laboratory Standards occurred which could reasonably have caused the Adverse Analytical Finding, then the Agency shall have the burden to establish that such departure did not cause the Adverse Analytical Finding.

3.2 (a) (3) Departures from any other Standards or procedures of the Agency shall not invalidate analytical results or other evidence of an anti-doping or medication control rule violation, and shall not constitute a defense to an anti-doping or medication control rule violation; provided, however, if the Covered Person establishes that a departure from one of the specific Standards listed below could reasonably have caused an anti-doping or medication control rule violation, then the Agency shall have the burden to establish that such departure did not cause the Adverse Analytical Finding or other anti-doping or medication control rule violation, as follows:

3.2 (a) (3) (i) a departure from the Testing and Investigations Standards related to Sample collection or Sample handling that could reasonably have caused an anti-doping or medication control rule violation based on an Adverse Analytical Finding, in which case the Agency shall have the burden to establish that such departure did not cause the Adverse Analytical Finding;

3.2 (a) (3) (ii) a departure from this Protocol or Testing and Investigations Standards related to an Adverse Passport Finding which could reasonably have caused an anti-doping or medication control rule violation, in which case the Agency shall have the burden to establish that such

departure did not cause the anti-doping or medication control rule violation;

3.2 (a) (3) (iii) a departure from this Protocol related to the requirement to provide notice to the Responsible Person and Owner of the B Sample opening which could reasonably have caused an anti-doping rule violation based on an Adverse Analytical Finding, in which case the Agency shall have the burden to establish that such departure did not cause the Adverse Analytical Finding; or

3.2 (a) (3) (iv) a departure from this Protocol related to Responsible Person and Owner notification which could reasonably have caused an anti-doping rule violation based on a Whereabouts Failure, in which case the Agency shall have the burden to establish that such departure did not cause the Whereabouts Failure.

3.2 (a) (4) Non-appealable and final factual findings of a court, or administrative body of competent jurisdiction shall be irrebuttable evidence against the Covered Person to whom the decision pertained of those facts unless the Covered Person establishes that the decision violated principles of due process.

3.2 (a) (5) The Steward, arbitrator, or hearing body under Article 11 reviewing an alleged anti-doping or medication control rule violation may draw an inference adverse to the Covered Person who is asserted to have committed an anti-doping or medication control rule violation based on the Covered Person's refusal to Cooperate with the Agency and/or their failure to appear and respond to questioning by the Agency, arbitrator, and hearing body (as applicable) at any hearing contemplated under the Protocol. This inference is independent from the Covered Person being found to have committed a violation for failing to Cooperate.

4 THE PROHIBITED LIST

4.1 Publication and Revision of the Prohibited List

4.1 (a) This Protocol hereby incorporates by reference the Prohibited List. Unless provided otherwise in the Prohibited List and/or a revision thereof, the Prohibited List and revisions shall go into effect under this Protocol three months after approval by the Commission and publication, without requiring any further action. Revisions will be made from time to time. All Covered Person shall be bound by the Prohibited List and any revisions thereto, from the date they go into effect, without further formality. It is the responsibility of all Covered Persons to familiarize themselves with the most up-to-date version of the Prohibited List and all revisions thereto.

4.2 Prohibited Substances and Prohibited Methods Identified on the Prohibited List

4.2 (a) Prohibited Substances and Prohibited Methods

4.2 (a) (1) The Prohibited List shall identify those Prohibited Substances and Prohibited Methods which are prohibited at all times because the Commission has determined in its sole discretion that the medical, veterinary, or other scientific evidence or experience supports: [see end note 2]

4.2 (a) (1) (i) Their actual or potential to impact performance in future Covered Horseraces;

4.2 (a) (1) (ii) Their actual or potential masking properties; and/or

4.2 (a) (1) (iii) Their actual or potential detrimental impact on horse welfare.

4.2 (a) (2) The Prohibited List applies whether Prohibited Substances and Prohibited Methods are used alone or in combination with other substances or methods. The Prohibited List further identifies those substances and methods which are prohibited on Race Day. Substances and methods prohibited on Race Day are also prohibited from Administration and Attempted Administration during the Race Period.

4.2 (a) (3) Prohibited Substances and Prohibited Methods may be included in the Prohibited List by general category (e.g., anabolic agents) or by specific reference to, or example of, a particular substance or method.

4.2 (b) Primary Substances, Secondary Substances, Primary Methods, and Secondary Methods

4.2 (b) (1) For purposes of application of Articles 7.4 and 10, the Prohibited List shall identify which Prohibited Substances are Primary Substances or Secondary Substances and which Prohibited Methods are Primary Methods or Secondary Methods

4.3 The Prohibited List

4.3 (a) The Commission's approval of the Prohibited Substances and Prohibited Methods that will be included on the Prohibited List, the classification of substances and methods into categories on the Prohibited List, the classification of a substance or method as prohibited at all times, prohibited on Race Day only and prohibited from Administration and Attempted Administration during the Race Period, the classification of a substance or method as a Primary Substance or Secondary Substance, or as a Primary Method or Secondary Method are presumed valid, final, and not subject to any challenge by a Covered Person based on an argument that the substance or method did not have the potential to be a masking agent, did not have the potential to impact performance, or did not have the potential to impact the horse's welfare.

4.4 Monitoring Program

4.4 (a) The Authority may approve a monitoring program regarding substances which are not on the Prohibited List, but which the Agency wishes to monitor in order to detect potential patterns of misuse in horseracing. In addition, the monitoring program may include substances that are on the Prohibited List, but which are to be monitored under certain circumstances—e.g., Use at all times of some substances prohibited on Race Day only or the combined Use of multiple substances at low doses ("stacking")—in order to establish prevalence of Use or to be able to implement adequate decisions in regard to their analysis by Laboratories or their Prohibited List status. Laboratories will report the instances of reported Use or detected presence of these substances to the Agency. Nothing in this paragraph prevents a Laboratory from sharing information with the Agency requested for any anti-doping or medication control purpose or other purpose authorized by the Act. The monitoring program list of substances should be reviewed annually.

5 TESTING AND INVESTIGATIONS

5.1 Purpose of Testing and Investigations

5.1 (a) Testing and investigations may be undertaken for any anti-doping or medical control purpose, including for identifying the horse, or other purpose authorized by the Act.

5.2 Authority to Test

5.2 (a) Any Covered Horse may be required by the Agency to provide a Sample at any time and at any place by the Agency.

5.2 (b) The Agency may delegate Testing authority to third parties, including but not limited to State Racing Commissions that elect to enter into an agreement to carry out such Testing. Such third parties shall follow the Testing and Investigations Standards

5.2 (c) The Agency may Test or direct the Testing of any Covered Horse which has not retired via official notification of retirement provided to the Agency. A Covered Horse that has been fatally injured or dies prior to retirement remains subject to Agency jurisdiction, including Sample collection.

5.2 (d) The Agency may test or direct the Testing of any Covered Horse during a Covered Horse's period of Ineligibility.

5.3 Testing Requirements

5.3 (a) The Agency shall conduct Test distribution planning and Testing as required by the Testing and Investigations Standards.

5.4 Disclosure Requirements

5.4 (a) The prospective Responsible Person (or Responsible Person) shall at the time of registering with the Authority (and prior to competing in any Race) declare in writing to the Agency or Authority all Use or Attempted Use of Prohibited Substances and Prohibited Methods prohibited at all times prior to a horse becoming a Covered Horse. The Agency may request Treatment records for the horse prior to it becoming a Covered Horse. Upon declaration of a Prohibited Substance or Prohibited Method prohibited at all times, the Agency, in its sole discretion, may require the Covered Horse to sit out (i.e., not compete in a Race) for a period up to the period of Ineligibility applicable for the Prohibited Substance or Prohibited Method for Covered Horses and provide one or more negative Samples. [see end note 3]

5.5 Covered Horse Whereabouts Information

5.5 (a) Whereabouts information for Covered Horses shall be provided in the manner specified in the Whereabouts Policy and shall be subject to Consequences for Article 2.7 violations as provided in Article 10.3 (a) (2). The Agency shall coordinate the identification of such Covered Horses and the collection of their whereabouts information. Whereabouts information shall be maintained by the Agency in accordance with the Whereabouts Policy.

5.6 Retired Covered Horses Returning to Covered Horseraces

5.6 (a) If an Owner wishes to retire a Covered Horse, then written notice of such retirement shall be provided to the Agency. If a Covered Horse is retired and then the Owner wishes to return the Covered Horse to active participation in Covered Horseraces, the Covered Horse shall not be entered in a Covered Horserace until the Covered Horse has been made available for Testing, by giving six months prior written notice to the Agency.

5.6 (b) If a Covered Horse is retired from horseracing while subject to a period of Ineligibility, the Owner must notify the Agency in writing of such retirement. If the Owner then wishes to return the Covered Horse to active competition in Covered Horseraces, the Owner shall provide the Agency with six months written notice and the Covered Horse shall not be entered in Covered Horseraces until the Covered Horse has been made available for Testing for at least six months or the remainder of the Covered Horse's period of Ineligibility, whichever is longer.

5.7 Investigations and Intelligence Gathering

5.7 (a) The Agency shall have the capability to conduct, and shall conduct, investigations and gather intelligence as required by the Testing and Investigations Standards.

6 ANALYSIS OF SAMPLES

6.1 Samples collected pursuant to this Protocol and the Testing and Investigations Standards shall be the property of the Agency. No Covered Person or any third party shall have a right to access or use of a Sample. Samples shall be analyzed in accordance with the following principles:

6.1 (a) Use of Accredited, Approved Laboratories, and Other Laboratories

6.1 (a) (1) For purposes of directly establishing an Adverse Analytical Finding under Article 2.4, Samples shall be analyzed only in Laboratories. The choice of the Laboratory used for the Sample analysis shall be determined in accordance with the Testing and Investigations Standards and Laboratory Standards.

6.1 (a) (2) As provided in Article 3.2, facts related to anti-doping or medication control rule violations may be established by any reliable means. This would include, for example, reliable Laboratory or other forensic Testing conducted outside of accredited or approved laboratories.

6.1 (b) Purpose of Analysis of Samples and Data

6.1 (b) (1) Samples, related analytical data, and Doping Control information shall be analyzed to detect Prohibited Substances and Prohibited Methods identified on the Prohibited List and other substances as may be directed pursuant to Article 4.4, or to assist the Agency in profiling relevant parameters in a Covered Horse's urine, blood, hair, or other matrix, including for DNA or genomic profiling, or for any other legitimate anti-doping or medical control purpose.

6.1 (c) Research on Samples and Data

6.1 (c) (1) Samples, related analytical data, and Doping Control information may be used for anti-doping or medication control research purposes. Samples and related analytical data or Doping Control information used for research purposes shall first be processed in such a manner as to prevent Samples and related analytical data or Doping Control information being traced back to a particular Covered Horse or Covered Person.

6.1 (d) Standards for Sample Analysis and Reporting

6.1 (d) (1) Laboratories shall analyze Samples and report results in conformity with the Laboratory Standards.

6.1 (d) (2) At the time of initial analysis, laboratories at their own initiative and expense may analyze Samples for Prohibited Substances or Prohibited Methods prohibited at all times that are not included on the Agency's standard Sample analysis menu, or as requested by the Agency. For all other Prohibited Substances and Prohibited Methods laboratories must notify and receive approval from the Agency prior to reporting an Adverse Analytical Finding for a substance not included on the Agency's standard Sample analysis menu. Results from any analysis for substances prohibited at all times or approved analysis for all other substances shall be reported to the Agency and have the same validity and Consequences as any other analytical result.

6.1 (e) Further Analysis of a Sample

6.1 (e) (1) There shall be no limitation on the authority of a Laboratory to conduct repeat or additional analysis on a Sample at any time, whether

6.1 (e) (1) (i) prior to the time the Agency notifies a Covered Person that the Sample is the basis for an Article 2.4 anti-doping or medication control rule violation or that the Sample is negative or

6.1 (e) (1) (ii) after a Sample has been reported as negative or has otherwise not resulted in an anti-doping or medication control rule violation. In any case, once a Sample has been collected by the Agency, it may be stored and subjected to Further Analyses for the purpose of Article 6.1 (b) at any time exclusively at the direction of the Agency. Further Analysis of Samples shall conform with the requirements of the Laboratory Standards.

6.1 (f) Split of A or B Sample

6.1 (f) (1) Where the Agency and/or a Laboratory (with approval from the Agency) wishes to split an A or B Sample for the purpose of using the first part of the split Sample for an A Sample analysis and the second part of the split Sample for B confirmation, then the procedures set forth in the Laboratory Standards shall be followed.

7 RESULTS MANAGEMENT

7.1 Results Management for Testing initiated by the Agency

7.1 (a) Results Management for Tests initiated by the Agency or its designee shall proceed as set forth below. The results from all analyses must be sent to the Agency via secure transmission, in a report signed by an authorized representative of the Laboratory. All communication must be conducted confidentially.

7.1 (b) Adverse Analytical Finding Reports

7.1 (b) (1) Upon receipt of an A Sample Adverse Analytical Finding, the Agency shall conduct a review to determine whether there is any apparent departure from the Testing and Investigations Standards or Laboratory Standards that caused the Adverse Analytical Finding. Subject to Article 7.1 (b) (2) the Agency may, but need not, communicate with the Responsible Person and Owner during such review.

7.1 (b) (2) If the initial review of an Adverse Analytical Finding under Article 7.1 (b) (1) does not reveal a departure that caused the Adverse Analytical Finding, then the Agency shall, promptly give written notice of the potential anti-doping rule violation to the Responsible Person, Owner, Authority, and applicable State Racing Commission after the State Racing Commission elects to enter into an agreement incorporating the confidentiality provisions of Article 12.2 (a) Written notice from the Agency pursuant to this Article 7.1 (b) (2) shall include the information described in Article 12.1 (a) (1) (i), as well as notify the Responsible Person and Owner of:

7.1 (b) (2) (i) the Adverse Analytical Finding;

7.1 (b) (2) (ii) the specific potential Protocol violation;

7.1 (b) (2) (iii) the Responsible Person's and Owner's opportunity to promptly provide an explanation regarding the Adverse Analytical Finding within a short deadline;

7.1 (b) (2) (iv) for those substances identified in the Laboratory Standards or Technical Documents for which immediate analysis of the B Sample is authorized in order to preserve the scientific integrity of the Sample in accordance with the Laboratory Standards, that the B Sample has been Tested;

7.1 (b) (2) (v) if the B Sample has not been Tested, the date, time, and place where the B Sample will be Tested and amount the Responsible Person or Owner must pay to have the B Sample tested and Laboratory Documentation Package prepared, failing such payment by the date indicated by the Agency, the B Sample analysis may be deemed irrevocably waived in the Agency's sole discretion; and

7.1 (b) (2) (vi) any Provisional Suspension imposed. The Agency shall promptly provide the Responsible Person and Owner an abbreviated A Sample documentation package at no charge. Upon receipt of the complete A Sample documentation package from the Laboratory, the Agency shall provide such to the Responsible Person and Owner, containing all information required by the Laboratory Standards.

7.1 (b) (3) Except for when the B Sample has been analyzed in accordance with Article 7.1 (b) (2) (iv), where paid for by the Responsible Person, Owner, or the Agency, arrangements shall be made for Testing the B Sample within the time-period specified in the Laboratory Standards, or such longer time as may be reasonably required under the circumstances without undue delay. A Responsible Person and Owner accept the A Sample analytical results by waiving the requirement for B Sample analysis. If waived, the Agency may nonetheless elect to proceed with the B Sample analysis.

7.1 (b) (4) If the B Sample proves negative, then, unless the Agency takes the case as an anti-doping or medication control rule violation under Article 2.5, the entire Test shall be considered negative, and the Responsible Person and Owner shall be so informed.

7.1 (b) (5) If a Prohibited Substance or the Use of a Prohibited Method is identified (i.e., if the B Sample analysis confirms the presence—and quantity, if applicable—of a Prohibited Substance or Prohibited Method in the Sample), or the B Sample analysis is waived (in accordance with this Protocol), the Responsible Person (or Owner, if no Responsible Person) shall be charged with an anti-doping rule violation and the Responsible Person and Owner shall be given written notice of:

7.1 (b) (5) (i) the Protocol violation being asserted;

7.1 (b) (5) (ii) the basis of that assertion,

7.1 (b) (5) (iii) the additional information set forth in Article 12.1 (a) (1) (i);

7.1 (b) (5) (iv) the maximum Consequences that the Agency may seek to impose;

7.1 (b) (5) (v) the Responsible Person's (or Owner's, if no Responsible Person) right within ten calendar days [see end note 4] of the notice, to challenge the violation and Consequences in accordance with the Arbitration Procedures; and

7.1 (b) (5) (vi) that, if the Responsible Person(or Owner, if no Responsible Person) does not request review by a steward or arbitrator within the time limit indicated in subsection 7.1 (b) (5) (v)

of this Article, the Consequences will be imposed immediately. If not already provided to the Responsible Person and Owner, once received by the Agency, the Agency shall promptly provide the Responsible Person and Owner with copies of the complete A and B Sample Laboratory Documentation Packages that include all information required by the Laboratory Standards. The Agency shall not be required to provide the complete A and B Sample documentation if the Responsible Person and Owner waive analysis of its B Sample. The Agency shall send a copy of the charge to the Authority and to the applicable State Racing Commission upon the State Racing Commission electing to enter into an agreement incorporating the confidentiality provisions of Article 12.2 (a)

7.1 (b) (6) If the B Sample analysis does not confirm the presence of a Prohibited Substance or Prohibited Method in the Sample, the Agency may, under appropriate circumstances (e.g., evidence the B Sample did not confirm due to microbial degradation), still charge Covered Person with an anti-doping rule violation under Article 2.5 and the Agency shall notify the applicable Covered Person in accordance with Article 7.1 (b) (5).

7.1 (b) (7) After notification of a potential anti-doping rule violation, if at any point during the Results Management process described in Article 7.1, the Agency decides not to move forward with an anti-doping rule violation charge, it will notify the Covered Person, State Racing Commission (if prior notice was given), and the Authority of the Agency's decision.

7.1 (b) (8) Notification to a Covered Person by the Agency, for all purposes of this Protocol, may be accomplished either through actual or constructive notice. Constructive notice is sufficient for all purposes for which notification is required under this Protocol and shall be effective when delivered by third-party courier or U.S. postal mail to the Covered Person's most recent mailing address on file with the Authority or by email to the Covered Person's most recent email address on file with the Authority. Actual notice may be accomplished by any other means.

7.1 (c) Atypical Findings Reports

7.1 (c) (1) When a Sample analysis is reported as an Atypical Finding, then the Agency shall do an investigation and decide whether to treat the Atypical Finding as an Adverse Analytical Finding. The Agency may, but need not, communicate with the Responsible Person and Owner during such investigation. If the Agency decides to not treat the matter as an Adverse Analytical Finding, then the Agency may, but need not, communicate with the applicable Responsible Person and Owner. If the Agency decides to move forward with the matter as an Adverse Analytical Finding, then the Agency shall communicate with the Responsible Person and Owner as set forth in Article 7.1 above.

7.1 (d) Atypical Passport Findings and Adverse Passport Findings Reports (when available)

7.1 (d) (1) Review of Atypical Passport Findings and Adverse Passport Findings shall take place as provided in this Protocol and the Laboratory Standards.

7.1 (d) (2) At such time as the Agency is satisfied that an anti-doping or medication control rule violation has occurred, it shall promptly charge the Responsible Person (or Owner, if no Responsible Person) as provided in Article 7.1 (b) (5), as applicable. The Agency shall also send the Owner a copy of the charge sent to the Responsible Person.

7.2 Results Management for Anti-Doping and Medication Control Rule Violations Not Covered by Article 7.1

7.2 (a) The Agency shall conduct any follow-up investigation required into any potential anti-doping or medication control rule violation not covered by Article 7.1. At such time as the Agency is satisfied that an anti-doping or medication control rule violation has occurred, it shall promptly charge the applicable Covered Person, providing information as identified in Article 7.1 (b) (5) as applicable.

7.3 Identification of Prior Anti-Doping and Medication Control Rule Violations

7.3 (a) Before giving a Covered Person written notice of an asserted anti-doping or medication control rule violation as provided above, the Agency shall attempt to determine whether any prior anti-doping or medication control rule violation under this Protocol exists.

7.4 Provisional Suspensions

7.4 (a) Provisional Suspension.

7.4 (a) (1) For each alleged violation of Articles 2.4 and/or 2.5 involving a Primary Substance or Primary Method and in connection with one or more Covered Horses, the Agency shall, at the time of notification (or charge, if no notification), impose a Provisional Suspension on such Covered Horses for no longer period than the Ineligibility period designated for the particular substance or category of substance in the Prohibited List.

7.4 (a) (2) For each alleged Article 2.7 violation in which a Covered Horse accrues three Whereabouts Failures in a twelve-month period, the Agency may impose a Provisional Suspension on such Covered Horse.

7.4 (a) (3) For each alleged violation of Articles 2.4 and/or 2.5 involving a Primary Substance or Primary Method, the Agency shall, at the time of notification (or charge, if no notification), impose a Provisional Suspension on Covered Person who were notified of the alleged violation (or charged, if no notification) against them.

7.4 (a) (4) For all other violations, the Agency may impose a Provisional Suspension on the Covered Person who was notified of the alleged violation (or charge, if no notification) against them.

7.4 (b) Where a Provisional Suspension is imposed pursuant to Article 7.4 (a), the applicable Covered Person, which is the Responsible Person with respect to a Covered Horse, shall be given either: (a) an opportunity for a Provisional Hearing either before or on a timely basis after imposition of the Provisional Suspension; or (b) an opportunity for an expedited final adjudication in accordance with Article 8 on a timely basis after imposition of the Provisional Suspension.

7.4 (b) (1) Provisional Hearings shall be conducted by a single arbitrator for a Major Infraction or a member of the Anti-Doping Stewards Panel for a Minor Infraction and heard via telephone or video conference call within the time frame specified by the Agency and in accordance with the Arbitration Procedures. The sole issue to be determined by the arbitrator at such a hearing will be whether the Agency's decision that a Provisional Suspension should be imposed shall be upheld.

7.4 (b) (2) The Agency's decision to impose a Provisional Suspension shall be upheld if probable cause exists for the Agency to proceed with a charge of an anti-doping or medication control rule violation against a Covered Person. It shall not be necessary, however, for any B Sample analysis to have been completed in order to establish probable cause.

7.4 (c) If a Provisional Suspension is imposed based on an A Sample Adverse Analytical Finding and subsequent analysis of the B Sample does not confirm the A Sample analysis, then the Covered Horse and Covered Person shall not be subject to any further Provisional Suspension on account of a violation of Article 2.4.

7.4 (d) In all cases where a Covered Person has been notified of an anti-doping or medication control rule violation (or charged, if no notification), but a Provisional Suspension has not been imposed on them, the Covered Person shall be offered the opportunity to accept a Provisional Suspension voluntarily pending the resolution of the matter.

7.5 Resolution or Imposition of Consequences

7.5 (a) A Covered Person against whom an anti-doping or medication control rule violation is asserted may admit that violation at any time, expressly waive their right to adjudicate the matter pursuant to Article 8 and Article 11 and accept the Consequences that have been offered by the Agency.

7.5 (b) Alternatively, if the Covered Person against whom an anti-doping or medication control rule violation is asserted fails to inform the Agency in writing that they dispute a charged anti-doping or medication control rule violation within ten calendar days of the Agency sending the charge, then the Covered Person shall be deemed to have admitted the violation, to have waived their rights under Article 8 and Article 11, and to have accepted the Consequences that have been offered by the Agency.

7.5 (c) In cases where Article 7.5. (a) or Article 7.5 (b) applies, an adjudication under Article 8 shall not be required. Instead, the Agency shall promptly issue a release confirming the commission of the anti-doping

and/or medication control rule violation(s) and the Consequences imposed as a result and setting out a brief summary of the reasons for any period of Ineligibility imposed unless doing so could compromise an ongoing investigation or proceeding. The Agency shall Publicly Disclose that release in accordance with Article 12.2 (b)

7.6 Retirement

7.6 (a) If a Covered Horse is retired or is deceased or a Covered Person retires or otherwise becomes unlicensed while the Agency is conducting the Results Management process, including the investigation of any Adverse Analytical Finding, Atypical Finding, Atypical Passport Finding, or potential non-analytical violation, the Agency retains jurisdiction to complete its Results Management process. If a Covered Horse is retired or is deceased or a Covered Person retires before any Results Management process has begun, and the Agency had jurisdiction over the Covered Horse or Covered Person at the time the anti-doping or medication control rule violation was committed, the Agency has authority to conduct Results Management in respect of that anti-doping or medication control rule violation.

8 RIGHT TO A FAIR PROCESS AND REASONED DECISION

8.1 For any Covered Person who is asserted to have committed an anti-doping or medication control rule violation, the Agency shall provide the Covered Person the opportunity for resolution before an impartial steward or arbitrator as set forth below. A timely reasoned decision specifically including an explanation of the reason(s) for any period of Ineligibility and Disqualification of results shall be Publicly Disclosed as provided in Article 12.2.

8.2 Procedures for Minor Infractions

8.2 (a) Where a Covered Person is alleged to have committed a Minor Infraction under this Protocol, the Covered Person shall be entitled to submit in writing all arguments and evidence to a member of the Anti-Doping Stewards Panel in compliance with this Protocol and accompanying Arbitration Procedures. The member of the Anti-Doping Review Steward Panel shall issue a reasoned decision, including the period of Ineligibility and other Consequences imposed, if any, to the Agency and the Covered Person within fourteen calendar days after the final written submission. Subject to the terms of Article 11, decisions rendered pursuant to this Article 8.2 shall be final and binding.

8.3 Procedures for Major Infractions

8.3 (a) Where a Covered Person is alleged to have committed a Major Infraction under this Protocol, the Covered Person shall be entitled to a hearing before an impartial arbitrator as set forth in this Protocol and accompanying Arbitration Procedures. The arbitrator's reasoned hearing decision, including the period of Ineligibility and other Consequences imposed, if any, shall be provided by the arbitrator to the Agency and the Covered Person within fourteen calendar days after the conclusion of the Major Infraction hearing. Subject to the terms of Article 11, decisions rendered pursuant to this Article 8.3 shall be final and binding.

8.4 Expedited Matters

8.4 (a) For matters involving Major Infractions or Minor Infractions and for which the Covered Horse or Covered Person is not Provisionally Suspended and the Covered Horse or Covered Person that is not Provisionally Suspended is likely to participate in a Covered Horserace within forty-five calendar days, the Agency may address the case in an expedited basis and shorten any deadlines in this Protocol and/or Arbitration Procedures proportionately to ensure resolution of the matter prior to the Covered Horserace.

9 AUTOMATIC DISQUALIFICATION OF COVERED HORSE'S RESULTS

9.1 An anti-doping or medication control rule violation, arising from a Race Day Test or that occurred on the Race Day or for purposes of Prohibited Method M5 only in the fourteen calendar days preceding Race Day, automatically leads to Disqualification of the result in the Race obtained by the Covered Horse(s) connected with the violation with all resulting Consequences, including forfeiture of any trophies, points, rankings, prizes, purses, and other compensation.

10 SANCTIONS

10.1 Ineligibility of Covered Horses

10.1 (a) For each violation involving any Prohibited Substance or Prohibited Method involving a Covered Horse, such Covered Horse shall be Ineligible for the time designated for the particular substance or category of substance in the Prohibited List and may be required to submit a negative Sample prior to returning from Ineligibility. Unless otherwise indicated in the Prohibited List, there shall be no Ineligibility for Covered Horses based on violations involving one or more Secondary Substances or Secondary Methods.

10.1 (b) For a violation of Article 2.7 in which a Covered Horse accrues three Whereabouts Failures in a twelve-month period or a violation of Article 2.6 regarding a specific Covered Horse, such Covered Horse shall be Ineligible for twelve months and may be required to submit a negative Sample prior to returning from Ineligibility.

10.1 (c) Under this Protocol, the Responsible Person is the sole representative of interests in a Covered Horse with respect to Ineligibility and/or retaining competitive results and shall be the sole party representing the interests of the Covered Horse in any adjudication under Article 8 or Article 11.

10.10 Allocation of Collected Forfeited Purses

10.10 (a) If a Covered Horse has results Disqualified under the Protocol, all purses, other prizes, and trophies must be repaid or surrendered as applicable to the Race organizer and the other Covered Horses' positions adjusted accordingly.

10.11 Multiple Violations for Covered Persons

10.11 (a) Second or Third Major Infractions

10.11 (a) (1) For a Covered Person's second Major Infraction that qualifies in accordance with Article 10.11 (d), the period of Ineligibility shall be the greater of:

10.11 (a) (1) (i) a six-month period of Ineligibility; or

10.11 (a) (1) (ii) a period of Ineligibility in the range between: i.) the sum of the period of Ineligibility imposed for the first violation plus the period of Ineligibility otherwise applicable to the second violation treated as if it were a first violation, not taking into account any reduction under Article 10.7 for either violation, and ii.) twice the period of Ineligibility otherwise applicable to the second violation treated as if it were a first violation, not taking into account any reduction under Article 10.7.

10.11 (a) (2) The period of Ineligibility within its range shall be determined based on the entirety of the circumstances and the Covered Person's degree of Fault with respect to the second violation.

10.11 (a) (3) A third (or greater) Major Infraction will result in a period of Ineligibility of a minimum of double the period of Ineligibility that would apply if it were a second violation up to a lifetime Ineligibility.

10.11 (a) (4) The period of Ineligibility established may then be further reduced by the application of Article 10.7.

10.11 (b) Multiple Minor Infractions

10.11 (b) (1) A Covered Person's second and third Minor Infraction that qualifies shall be treated the same as a first violation. The Agency in its discretion may require additional education for Covered Persons who have committed one or more Minor Infractions.

10.11 (b) (2) A Covered Person's fourth Minor Infraction that qualifies shall be treated as a first Major Infraction for all purposes under this Protocol and each subsequent Minor Infraction shall be treated as an additional Major Infraction for all purposes under this Protocol. And a Covered Person's Minor Infraction for which the Agency alleges Aggravating Circumstances shall be treated as a Major Infraction for all purposes under this Protocol.

10.11 (c) Additional Rules for Certain Potential Multiple Violations

10.11 (c) (1) For purposes of imposing sanctions under Article 10, an anti-doping or medication control rule violation will only be considered a second violation if the Agency can establish that the Covered Person committed the additional anti-doping or medication control rule violation after they received notice of the first anti-doping or medication control rule violation pursuant to Article 7, or after the Agency made reasonable efforts to give notice of the first anti-doping or medication control rule violation. If the Agency cannot establish this, the violations shall be considered together as one single first violation, and the sanction imposed shall be based on the violation that carries the more severe sanction.

10.11 (c) (2) If, after the imposition of a sanction for a first anti-doping or medication control rule violation, the Agency discovers facts involving an anti-doping or medication control rule violation by the Covered Person that occurred prior to notification regarding the first anti-doping or medication control rule violation, then the Agency may seek imposition of an additional sanction based on the sanction that could have been imposed if the two violations had been adjudicated at the same time. Results in all Races dating back to the earlier anti-doping or medication control rule violation will be Disqualified as provided in Article 10.9.

10.11 (d) Multiple Anti-Doping or Medication Control Rule Violations Qualification

10.11 (d) (1) For purposes of Article 10, each Major Infraction must take place within the same ten-year period in order to be considered multiple violations, and each Minor Infraction must take place within the same five-year period in order to be considered multiple violations.

10.12 Status During Ineligibility or Provisional Suspension

10.12 (a) Prohibition against Participation during Ineligibility or Provisional Suspension [see end note 6]

10.12 (a) (1) No Covered Horse which has been declared Ineligible or is the subject of a Provisional Suspension may, during a period of Ineligibility or Provisional Suspension, participate in any capacity in a Race, Workout, and any activity at a Racetrack. [see end note7]

10.12 (a) (2) No Covered Person who has been declared Ineligible or is subject to a Provisional Suspension may, during a period of Ineligibility or Provisional Suspension participate in any capacity in a Race, Workout, any activity (other than authorized anti-doping education or rehabilitation programs) at a Racetrack, and any activity involving Covered Horses or have an individual participate in any capacity on their behalf in any prohibited activity.

10.12 (a) (3) Covered Horses shall remain subject to Testing and the requirement to provide whereabouts information during a period of Ineligibility.

10.12 (b) Violation of the Prohibition of Participation during Ineligibility or Provisional Suspension

10.12 (b) (1) Where a Covered Horse or Covered Person which has been declared Ineligible violates the prohibition against participation during Ineligibility described in Article 10.12 (a), the results of such participation shall be Disqualified and a new period of Ineligibility equal in length to the original period of Ineligibility shall be added to the end of the original period of Ineligibility for the Covered Horse and the Covered Person.

10.12 (b) (2) If a Covered Horse violates the prohibition against participation during Ineligibility, the Responsible Person for the Covered Horse shall also receive a new period of Ineligibility equal in length to the original period of Ineligibility added to the end of the original period of Ineligibility. If the original period of Ineligibility already expired, the new period of Ineligibility shall start on the date of acceptance or imposition. If the Responsible Person did not serve an original period of Ineligibility, the period of Ineligibility for violating the prohibition against participation shall range from a reprimand to one year.

10.12 (b) (3) The new period of Ineligibility, including, but not limited to, a reprimand and no period of Ineligibility, may be adjusted based on the Covered Person’s degree of Fault and other circumstances of the case. The determination of whether there has been a violation of the prohibition against participation, and whether an adjustment is appropriate, shall be made by the Agency. This decision may be appealed under Article 11.

10.12 (c) A Covered Horse or Covered Person which violates the prohibition against participation during a Provisional Suspension described in Article 10.12 (a) shall receive no credit for any period of Provisional Suspension served and the results of such participation shall be Disqualified.

10.12 (d) Where a Covered Person other than the Responsible Person assists a Covered Horse or Covered Person in violating the prohibition against participation during Ineligibility or a Provisional Suspension, the Agency shall impose sanctions for a violation of Article 2.13 for such assistance.

10.13 Automatic Publication of Sanction

10.13 (a) A mandatory part of each sanction shall include automatic publication, as provided in Article 12.2.

10.2 Ineligibility of Covered Person for Presence, Use, or Attempted Use or Possession of a Prohibited Substance or Prohibited Method

10.2 (a) The period of Ineligibility for a violation of Article 2.4, 2.5, or 2.10 shall be as follows, subject to potential elimination, reduction, or suspension pursuant to Article 10.8, 10.9, or 10.10.

10.2 (a) (1) The period of Ineligibility shall be two years where:

10.2 (a) (1) (i) The anti-doping rule violation involves a Primary Substance or Primary Method.

10.2 (a) (1) (ii) The anti-doping rule violation involves a Secondary Substance or Secondary Method, and the Agency establishes the existence of Aggravating Circumstances pursuant to Article 10.4

10.2 (a) (1) (iii) The anti-doping rule violation involves a Secondary Substance or Secondary Method, and it is the Covered Person's fourth (or greater) violation pursuant to Article 10.11 (b).

10.2 (a) (2) If Article 10.2.(a) does not apply, the Consequences shall range between a reprimand, a Fine, and no period of Ineligibility and a Fine and a 30-day period of Ineligibility as described in Article 10.6 (a) (2).

10.3 Ineligibility of Covered Person for Other Anti-Doping and Medical Control Rule Violations

10.3 (a) The period of Ineligibility for anti-doping and medication control rule violations other than as provided in Article 10.1 shall be as follows, subject to potential reduction pursuant to Articles 10.6 and 10.7:

10.3 (a) (1) For violations of Article 2.6 2.9, 2.11, 2.12 (a), 2.12. (b), 2.13, or 2.14, the period of Ineligibility shall be two years.

10.3 (a) (2) For violations of Article 2.7, the period of Ineligibility shall be one year.

10.3 (a) (3) For violations of Article 2.8, 2.12 (c), or 2.15, the period of Ineligibility shall be the same as described in 10.2, except not subject to elimination pursuant to Article 10.5. For purposes of applying Article 10.2, a medication control violation shall be treated the same as if it was a violation involving a Secondary Substance or Secondary Method.

10.4 Aggravating Circumstances

10.4 (a) If the Agency establishes in an individual case that Aggravating Circumstances are present that justify the imposition of a period of Ineligibility greater than the standard sanction, then the period of Ineligibility otherwise applicable for a Major Infraction shall be increased by an additional period of Ineligibility of up to two years depending on the seriousness of the violation and the nature of the Aggravating Circumstances, and if Aggravating Circumstances are alleged in a Minor Infraction case, that case shall be processed as if it was a Major Infraction.

10.5 No Violation where there is No Fault or Negligence

10.5 (a) If a Covered Person establishes in an individual case that they bear No Fault or Negligence, then there shall be no violation. Notwithstanding the foregoing, the Covered Horse shall still be Ineligible in accordance with Article 10.1 and have results Disqualified in accordance with Article 9 even where the Covered Person is determined to be without Fault. [see end note 5]

10.6 Reduction of a Covered Person's Period of Ineligibility based on degree of Fault

10.6 (a) Reduction of Sanctions for Violations of Articles 2.4, 2.5, and 2.10 Based on Degree of Fault

10.6 (a) (1) Where an anti-doping rule violation involves a Primary Substance, Primary Method, or Aggravating Circumstances, the period of Ineligibility shall range between three months and two years, depending on the Covered Person's degree of Fault.

10.6 (a) (2) Where an anti-doping rule violation involves a Secondary Substance and no Aggravating Circumstances, the period of Ineligibility shall range between a reprimand and Fine and a 30-day period of Ineligibility, depending on the Covered Person's degree of Fault.

10.6 (a) (3) Contaminated Products: In cases where the Covered Person establishes that the Prohibited Substance came from a Contaminated Product, then the period of Ineligibility shall be in the range between a reprimand and a one-year period of Ineligibility, depending on the Covered Person's degree of Fault.

10.6 (b) Reduction of Sanctions for Other Anti-Doping and Medication Control Rule Violations Based on Fault

10.6 (b) (1) Article 2.7 Violations

10.6 (b) (1) (i) Where the anti-doping rule violation is based on Article 2.7 (Whereabouts Failures), the period of Ineligibility shall range between six months and one year, depending on the Responsible Person's degree of Fault. The flexibility regarding the period of Ineligibility in this Article is not available to a Responsible Person where a pattern of last-minute whereabouts changes or other conduct raises a serious suspicion that the Responsible Person was trying to avoid the Covered Horse being available for Testing

10.6 (b) (2) Other Anti-Doping and Medication Control Rule Violations

10.6 (b) (2) (i) The period of Ineligibility for anti-doping and medication control rule violations not covered by Article 10.6 (a) and 10.6 (b) (1) may be reduced from two years to six months based on the Covered Person's degree of Fault.

10.6 (b) (2) (ii) Contaminated Products: In cases where the Covered Person establishes that the Prohibited Substance came from a Contaminated Product, then the period of Ineligibility shall be in the range between a reprimand and a one-year period of Ineligibility, depending on the Covered Person's degree of Fault.

10.7 Elimination, Reduction, or Suspension of Period of Ineligibility or Other Consequences for a Covered Person for Reasons Other than Fault

10.7 (a) Substantial Assistance in Discovering or Establishing Other Violations

10.7 (a) (1) The Agency, in its sole discretion, may suspend all or part of the period of Ineligibility imposed on a Covered Person in a case where the Covered Person has provided Substantial Assistance to the Agency, a criminal authority, or a professional disciplinary body, including without limitation the Authority or a State Racing Commission, which results in:

10.7 (a) (1) (i) the Agency discovering or bringing forward an anti-doping or medication control rule violation by another Covered Person; or

10.7 (a) (1) (ii) which results in a criminal or disciplinary body discovering or bringing forward a sport-related criminal offense or the breach of professional or sports rules by another Person, including without limitation, offenses arising out of a sport integrity violation or sport safety violation, or the violation of any rule or requirement in the Act, and the information provided by the Covered Person providing Substantial Assistance is made available to the Agency or as directed to a third party by the Agency; or

10.7 (a) (1) (iii) which results in the Agency initiating a proceeding against a Laboratory for non-compliance with the Protocol, a Policy, or Technical Document. The extent to which the otherwise applicable period of Ineligibility may be Suspended shall be based on the seriousness of the anti-doping or medication control rule violation committed by the Covered Person and the significance of the Substantial Assistance provided by the Covered Person described in subsections (i) – (iii) above. If the Covered Person fails to continue to Cooperate and provide the complete, accurate, and credible Substantial Assistance upon which a suspension of the period of Ineligibility was based, the Agency shall reinstate the original period of Ineligibility and other Consequences. The Agency's decisions in the context of this Article 10.7.1 are not subject to challenge.

10.7 (a) (2) Admission of an Anti-Doping or Medication Control Rule Violation in the Absence of Other Evidence

10.7 (a) (2) (i) Where a Covered Person voluntarily admits the commission of an anti-doping or medication control rule violation before having received notice of a Sample collection which could establish an anti-doping or medication control rule violation (or, in the case of an anti-doping or medication control rule violation other than Article 2.4, before receiving first notice of the admitted violation pursuant to Article 7) and that admission is the only reliable evidence of the violation at the time of admission, then the period of Ineligibility may be reduced, but not below one-half of the period of Ineligibility otherwise applicable after reduction pursuant to Article 10.6.

10.8 Commencement of Ineligibility Period

10.8 (a) Except as provided below, the period of Ineligibility shall start on the date of the Article 8 decision providing for Ineligibility or on the date Ineligibility is accepted or otherwise imposed. Where a Covered Person or Covered Horse is already serving a period of Ineligibility for an anti-doping or medication control rule violation, any new period of Ineligibility shall commence on the first day after the current period of Ineligibility has been served. All competitive results achieved during the period of Ineligibility, including retroactive Ineligibility, shall be Disqualified.

10.8 (a) (1) Credit for Provisional Suspension or Period of Ineligibility Served

10.8 (a) (1) (i) If a Provisional Suspension is imposed on, or voluntarily accepted by, a Covered Person/Covered Horse and that Provisional Suspension is respected by the Covered Person/Covered Horse, then the Covered Person/Covered Horse shall receive a credit for such period of Provisional Suspension against any period of Ineligibility which may ultimately be imposed.

10.8 (a) (1) (ii) Except as provided for in 10.8 (a) (2), no credit against a period of Ineligibility shall be given for any time period before the effective date of the Provisional Suspension regardless of whether the Covered Person/Covered Horse elected not to participate.

10.8 (a) (2) Where there have been substantial delays in the adjudication process or other aspects of Doping Control that go well beyond the standard timeframes for Laboratory analyses and the timeframes for Results Management set forth in the applicable rules, and the Covered Person (which is the Responsible Person with respect to a Covered Horse) can establish that such delays are not attributable to the Covered Person, the body imposing the sanction may start the period of Ineligibility at an earlier date commencing as early as the date of Sample collection or the date on which an alleged anti-doping or medication control rule violation last occurred.

10.9 Disqualification of Results in Races Subsequent to Sample Collection or Commission of an Anti-Doping or

Medication Control Rule Violation

10.9 (a) In addition to the automatic Disqualification of the results in the Race provided for under Article 9, all other competitive results of the Covered Horse obtained from the date an anti-doping or medication control rule violation first occurred (which for a violation under Article 2.7 is the date of the third Whereabouts Failure) through the commencement of any Provisional Suspension or Ineligibility period for the Covered Horse, shall, unless fairness requires otherwise, be Disqualified with all of the resulting Consequences including forfeiture of any trophies, points, rankings, prizes, purses, and other compensation.

11 APPEAL OF ARTICLE 8 DECISIONS

11.1 Decisions Subject to Review

11.1 (a) Any final decision by a Steward or arbitrator under Article 8 may be appealed by the Covered Person found to have committed the anti-doping or medication control rule violation or by the Responsible Person on behalf of the Covered Horse which has been given a period of Ineligibility. Decisions made under this Protocol may be appealed as set forth below in Articles 11.2 - 11.3 or as otherwise provided in the Protocol or Policies. Such decisions shall remain in effect while under appeal unless the appellate body orders otherwise.

11.2 Review by Administrative Law Judge

11.2 (a) With respect to the decisions described in Article 11.1, on application which shall include the opening brief by the Commission, the Agency, or the Covered Person not later than 30 calendar days after the date on which the decision was issued, the decision shall be subject to de novo review by an administrative law judge. All administrative law judge hearings shall be conducted within 30 calendar days of a request for review pursuant to this Article 11. The administrative law judge shall determine whether a Covered Person has engaged in the anti-doping or medication control rule violation asserted, whether the Covered Person's conduct violates this Protocol or the Act, and whether the decision rendered pursuant to Article 8 was arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. The administrative law judge's reasoned hearing decision, including the decision to affirm, reverse, modify, set aside, or remand for further proceedings, in whole or in part, shall be provided to the Agency and the Covered Person within 60 calendar days after the conclusion of the hearing. Subject to the terms of Article 11.3 below, decisions rendered by the administrative law judge pursuant to this Article 11.2 shall be final and binding.

11.3 Review by the Commission

11.3 (a) The Commission may, on its own motion not later than 30 calendar days after the date on which the administrative law judge issues his or her decision, or on petition for Commission review by the Agency or the Covered Person not later than 30 calendar days after the date on which the administrative law judge issues his or her decision, review the administrative law judge's decision which was rendered pursuant to Article 11.2. If the Commission denies an application for review by the Agency or the applicable Covered Person, which the Commission may do in its discretion, the decision of the administrative law judge shall constitute the final decision of the Commission. In considering whether to review the administrative law judge's decision, the Commission shall consider whether any of the following circumstances exists:

11.3 (a) (1) a prejudicial error was committed in the conduct of the proceeding conducted pursuant to Article 11.2,

11.3 (a) (2) the decision involved an erroneous application of the Protocol, or

11.3 (a) (3) an exercise of discretion or a decision of law or Policy warrants review by the Commission. In the event the Commission decides a review pursuant to this Article 11.3 is warranted, such de novo review shall be conducted on the record before the administrative law judge as it relates to the factual findings and conclusions of law made by the administrative law judge. By motion of the Commission on its own accord or at the request of the Agency or Covered Person who is the subject of the anti-doping or medication control rule violation, the Commission may consider additional evidence which is material and for which reasonable grounds exist for the failure by a party to submit such evidence. The Commission may accept such additional evidence in writing or through testimony, or the Commission may remand the proceeding to the administrative law judge for the consideration of such additional evidence, in the Commission's discretion. The Commission's reasoned decision, including the decision to affirm, reverse, modify, set aside, or remand for further proceedings, in whole or in part, the decision of the administrative law judge, shall be provided to the Agency and the Covered Person within 30 calendar days after the conclusion of any hearing conducted pursuant to this Article 11.3 or final written submission. Decisions rendered by the Commission pursuant to this Article 11.3 shall be final and

binding.

12 CONFIDENTIALITY AND REPORTING

12.1 Information Concerning Adverse Analytical Findings, Atypical Findings, and other Asserted Anti-Doping or Medication Control Rule Violations

12.1 (a) Notice of Anti-Doping or Medication Control Rule Violations to Covered Persons

12.1 (a) (1) Notice to Covered Person of anti-doping or medication control rule violations asserted shall occur under Articles 7 and 12.1 (a) (1) (i) of this Protocol.

12.1 (a) (1) (i) The contents of an anti-doping or medication control rule violation notice shall include, at a minimum, the Covered Horse's and Covered Person's name, whether the violation was in connection with a particular Race, whether the Test was conducted on Race Day or otherwise, the date of Sample collection, the analytical result reported by the Laboratory, or, for anti-doping or medication control rule violations other than Article 2.4, the rule violated and the basis of the asserted violation. The failure to properly identify the Race, if any, with which a violation may be connected shall not invalidate the notice or affect the Disqualification of results under this Protocol. Any defect in notification may be corrected by the Agency and shall not invalidate the notice or affect the Disqualification of results under this Protocol.

12.1 (b) Notice of Protocol Violations to State Racing Commissions

12.1 (b) (1) The Agency must notify the applicable State Racing Commission of the assertion of an anti-doping or medication control rule violation after the State Racing Commission elects to enter into an agreement incorporating the confidentiality provisions of Article 12.2 (a). The Agency may in its sole discretion delay notice to the State Racing Commission for case- or investigation-related reasons.

12.1 (c) Status Reports

12.1 (c) (1) When the Agency has given notice of an anti-doping or medication control rule violation under Article 12.1 (b) the Agency shall provide a written notice of the resolution of the matter to any State Racing Commission which has been notified and to the Authority.

12.2 Public Disclosure

12.2 (a) After notice of an anti-doping or medication control rule violation has been provided to the Covered Person in accordance with Article 7 and Article 12, the Agency or Covered Person may Publicly Disclose information about the alleged violation as it deems appropriate, including but not limited to:

12.2 (a) (1) the identity of any Covered Person who is notified of a potential anti-doping or medication control rule violation and the applicable Covered Horse,

12.2 (a) (2) the Prohibited Substance or Prohibited Method and nature of the violation involved, and

12.2 (a) (3) whether the Covered Person and Covered Horse are subject to a Provisional Suspension. The Authority and the State Racing Commission(s) shall not Publicly Disclose information about an alleged violation unless the information has been previously publicly disclosed by the Agency or Covered Person or the Agency gives written authorization for the Authority or State Racing Commission to publicly disclose the information.

12.2 (b) No later than twenty calendar days after a decision pursuant to Article 8, a resolution has been reached between the Agency and Covered Person, the assertion of an anti-doping or medication control rule violation has not otherwise been timely challenged, or a new period of Ineligibility or reprimand has been

imposed under Article 10.12 (b) the Agency must Publicly Disclose the disposition of the anti-doping or medication control matter including the anti-doping or medication control rule violated (if any), the name of the Covered Person who committed the violation and any Covered Horse affected by the violation, the Prohibited Substance or Prohibited Method involved (if any), the Consequences imposed, and reasoned decision under Article 8 (if any), unless doing so could compromise an ongoing investigation or proceeding. The Agency must also Publicly Disclose within twenty calendar days the results of appellate decisions concerning anti-doping or medication control rule violations, including the information described above.

12.2 (c) Publication shall be accomplished at a minimum by placing the required information on the Agency's website and leaving the information up for the period by which it may be the basis for multiple violations under Article 10.11.

12.3 Other Reporting

12.3 (a) The Agency may publish general statistical reports of its Doping Control activities. The Agency may also publish reports showing the name of any Covered Horses Tested and the date of each Testing.

12.4 Data Privacy

12.4 (a) The Agency may collect, store, process or disclose personal information relating to Covered Person and Covered Horses where necessary and appropriate to conduct their anti-doping and medication control activities under the Protocol but shall take appropriate steps to maintain its confidentiality and to maintain such information in compliance with applicable law.

13 APPLICATION AND RECOGNITION OF DECISIONS

13.1 Any decision regarding a violation of the Protocol shall be recognized by all Covered Person and such Covered Persons shall take all necessary action to render such decision under this Protocol effective. The Agency shall recognize and implement other anti-doping and medication control decisions rendered by organizations with jurisdiction over Covered Persons and Covered Horses if the Agency finds that the decision purports to be within the authority of that body and the anti-doping and medication control rules of that body in relevant part are otherwise consistent with this Protocol.

14 STATUTE OF LIMITATIONS

14.1 No anti-doping or medication control rule violation proceeding may be commenced unless the Covered Person has been notified of the anti-doping or medication control rule violation as provided in Article 7, or notification has been reasonably attempted, within ten years from the date the violation is asserted to have occurred; however, a Covered Person's past conduct that occurred more than ten years prior to an anti-doping or medication control charge may be admitted as pattern and practice evidence in connection with the anti-doping or medication control rule violation for conduct committed after the Effective Date.

15 EDUCATION

15.1 The Agency shall plan, implement, evaluate and monitor information, education, and prevention programs for responsible medication use and doping-free horseracing and shall support active participation by Covered Persons in such programs. Covered Persons are required to complete Agency provided education yearly prior to registration with the Authority.

16 ADDITIONAL ROLES AND RESPONSIBILITIES OF COVERED PERSONS

16.1 Owners' Responsibilities (when not also Responsible Person)

16.1 (a) No matter how many owners, there must be one representative on file with the Authority to receive communication on behalf of all ownership interests.

16.1 (b) Update changes in ownership interests prior to the effective date.

16.1 (c) Owners accept decisions made removing their Covered Horse from Races in accordance with these rules and delegate their interest in their Covered Horse adhering to these rules to the Responsible Person.

16.1 (d) Owners accept that the Responsible Person for the Covered Horse represents the owners' rights and interests in the adjudication of alleged anti-doping or medication control rule violations under these rules, stemming from one or more Prohibited Substances being found in their Covered Horse's Sample.

16.1 (e) Understand the anti-doping and medication control rules and what conduct constitutes an anti-doping or medication control rule violation.

16.1 (f) Cooperate with the Agency.

16.1 (g) Provide truthful information to the Authority and Agency in all interactions and filings.

16.1 (h) Not engage in improper, insulting, or obstructive behavior toward Agency personnel in relation to their duties.

16.1 (i) Not engage in any acts intended to intimidate, threaten, discourage, or retaliate against an individual who has or intends to report alleged violations of this Protocol to authorities or Cooperate with investigations regarding violations of this Protocol.

16.2 Responsible Persons' Responsibilities

16.2 (a) Update designations as to the identity of the Responsible Person for a Covered Horses prior to the effective date.

16.2 (b) Treatment Records: Keep updated Treatment records in an electronic database designated by the Agency or in any other form designated by the Agency. The records must include the name of the Covered Horse, and all Treatments administered to any of the Responsible Person's Covered Horse(s). The records must detail the date and time of Administration, the name of the substance, route of Administration, amount, duration (if multiple dosing), name of person administering and authorizing Administration, the reason for Administration (such as procedure and diagnosis), and any other information prudent to the health and welfare of the Covered Horse. These records must be updated within 24 hours of Administration and will be kept for at least a term determined at the Agency's sole discretion.

16.2 (c) Ensure that all treatments and medications administered to a Covered Horse for which they are responsible are given in the best interests of the Covered Horse's health and welfare, justified by the horse's medical condition upon advice from a licensed veterinarian, and do not contain a Prohibited Substance or Prohibited Method.

16.2 (d) File and update whereabouts information in accordance with the Whereabouts Policy for Covered Horses for which they are responsible.

16.2 (e) Ensure a Nominated Person is available when a Covered Horse is selected for Sample collection and ensure the Nominated Person is eighteen years or older and is a Covered Person or has the requisite information or education to adequately represent the Responsible Person through the Sample Collection Session.

16.2 (f) Provide truthful information to the Authority and Agency in all interactions and filings.

16.2 (g) Make Covered Horses for which they are responsible available for sample collection at any time and any place.

16.2 (h) Take responsibility for what a Covered Horse for which they are responsible ingest and Use.

16.2 (i) Ensure no Prohibited Substance or Prohibited Method is ingested or Used by their Covered Horse, and ensure no Prohibited Substance is found in their Covered Horses' Samples.

16.2 (j) Understand the anti-doping and medication control rules and what conduct constitutes an anti-doping or medication control rule violation.

16.2 (k) Immediately notify the Authority in writing with information on when a female Covered Horse has been bred, is determined to be pregnant, and is no longer pregnant.

16.2 (l) Immediately notify the Authority when a Covered Horse dies.

16.2 (m) Provide Agency access to treatment records on Covered Horses.

16.2 (n) Supervise assistance, keepers, subordinate Trainers by vetting at the time of hire, monitoring activities related to Covered Horses, ensuring they understand their responsibilities under the anti-doping and medication control rules, and creating and maintaining systems to ensure subordinates compliance with the anti-doping and medication control rules.

16.2 (o) Inform medical personnel, including without limitation Veterinarians, of their obligations to ensure that Use of Prohibited Substances and Prohibited Methods in Covered Horses for which they are responsible does not occur.

16.2 (p) Cooperate with the Agency.

16.2 (q) For all purposes under the Protocol, represent the interests in a Covered Horse for which they are responsible retaining competitive results and/or not receiving a period of Ineligibility.

16.2 (r) Not engage in improper, insulting, or obstructive behavior toward Agency personnel in relation to their duties.

16.2 (s) Not engage in any acts intended to intimidate, threaten, discourage, or retaliate against an individual who has or intends to report alleged violations of this Protocol to authorities or Cooperate with investigations regarding violations of this Protocol.

16.3 Veterinarians' Responsibilities

16.3 (a) Immediately notify the Authority in writing with information on when a female Covered Horse has been bred, is determined to be pregnant, and is no longer pregnant.

16.3 (b) Cooperate with the Agency.

16.3 (c) Treatment Records: Keep updated Treatment records in an electronic database designated by the Agency or in any other form designated by the Agency. The records must include the name of the Covered Horse, and all Treatments administered or prescribed to any Covered Horse by the Veterinarian. The records must detail the date and time of Administration (if applicable), the name of the substance, route of Administration, amount, duration, name of person administering (if applicable) and authorizing Administration, the reason for Administration (such as procedure and diagnosis), and any other information prudent to the health and welfare of the Covered Horse. These records must be updated within 24 hours of Administration and will be kept for at least a term determined at the Agency’s sole discretion.

16.3 (d) Provide Agency access to medical records on Covered Horses.

16.3 (e) Provide truthful information to the Authority and Agency in all interactions and filings.

16.3 (f) Understand the anti-doping and medication control rules and what conduct constitutes an anti-doping or medication control rule violation.

16.3 (g) Ensure that all Treatment and medication administered to a Covered Horse by or at the direction or approval of the Veterinarian is given in the best interests of the Covered Horse’s health and welfare and justified by the horse’s medical condition.

16.3 (h) Not engage in any acts intended to intimidate, threaten, discourage, or retaliate against an individual who has or intends to report alleged violations of this Protocol to authorities or Cooperate with investigations regarding violations of this Protocol.

16.4 Other Covered Persons’ Responsibilities

16.4 (a) Understand the anti-doping and medication control rules and what conduct constitutes an anti-doping or medication control rule violation.

16.4 (b) Cooperate with the Agency.

16.4 (c) Provide truthful information to the Authority and Agency in all interactions and filings.

16.4 (d) Ensure no Prohibited Substance or Prohibited Method is ingested or Used by a Covered Horse in their care.

16.4 (e) Not engage in improper, insulting, or obstructive behavior toward Agency personnel in relation to their duties.

16.4 (f) Make Covered Horses under their care available for sample collection at any time and any place.

16.4 (g) Not engage in any acts intended to intimidate, threaten, discourage, or retaliate against an individual who has or intends to report alleged violations of this Protocol to authorities or Cooperate with investigations regarding violations of this Protocol.

17 WAIVER AND RELEASE

17.1 As a condition of participating in or preparing for a Race or working with a Covered Horse which is participating in or preparing for a Race, Covered Persons agree to release and hold harmless the Agency, the Authority, and all other Equine Constituencies and their designees from any claim, demand or cause of action, known or unknown, now or hereafter arising, including attorney's fees, resulting from acts or omissions which occurred in good faith.

18 AMENDMENT AND INTERPRETATION OF THIS PROTOCOL

18.1 This Protocol, the Prohibited List, and the Policies may be amended from time to time by the Commission.

18.2 This Protocol shall be interpreted as an independent and autonomous text and not by reference to existing law or statutes.

18.3 The headings used for the various parts and Articles of this Protocol are for convenience only and shall not be deemed part of the substance of this Protocol or to affect in any way the language of the provisions to which they refer.

18.4 The World Anti-Doping Code ("Code"), the comments annotating various provisions of the Code, and Policies shall be used to interpret this Protocol. If there is a conflict, this Protocol shall prevail.

18.5 This Protocol shall not apply retroactively to matters pending before the Effective Date.

18.5 (a) A Presence violation after the Effective Date stemming from Use or Administration prior to the Effective Date shall not be a violation for the Covered Horse, the Responsible Person, and any related Covered Persons.

18.5 (b) The relevant State Racing Commission retains authority prior to the Effective Date.

19 TRANSITIONAL PROVISIONS

19.1 General Application of the 2022 Protocol

19.1 (a) The 2022 Protocol shall apply in full as of July 1, 2022 (the "Effective Date").

19.2 Additional Protocol Amendments

19.2 (a) Any additional Protocol amendments shall go into effect as provided in Article 18.1.

Prohibited List (Not Submitted to FTC)

20 Prohibited at All Times (Race Day and Out-of-Competition)

20.1 Prohibited Substance(s)

20.1 (a) S0 Non-approved Substances

20.1 (a) (1) Any pharmacological substance which is not addressed by any of the subsequent sections of the List and with no current approval by any governmental regulatory health authority for veterinary or human therapeutic use (e.g., drugs under pre-clinical or clinical development or discontinued, designer drugs) or any substance not universally recognized by veterinary regulatory authorities as a valid veterinary therapeutic Treatment is prohibited at all times.

20.1 (b) S1 Anabolic Agents - The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited.

20.1 (b) (1) Anabolic Androgenic Steroids (when administered exogenously), including but not limited to:

20.1 (b) (1) (i) 1-Androstenediol (5α-androst-1-ene-3β, 17β-diol)

20.1 (b) (1) (ii) 1-Androstenedione (5α-androst-1-ene-3, 17-dione)

20.1 (b) (1) (iii) 1-Androsterone (3α-hydroxy-5α-androst-1- ene-17-one)

20.1 (b) (1) (iv) 1-Epiandrosterone (3β-hydroxy-5α-androst- 1-ene-17-one)

20.1 (b) (1) (ix) 7α-hydroxy-DHEA

20.1 (b) (1) (l) Norethandrolone

20.1 (b) (1) (li) Oxabolone

20.1 (b) (1) (lii) Oxandrolone

20.1 (b) (1) (liii) Oxymesterone

20.1 (b) (1) (liv) Oxymetholone

20.1 (b) (1) (lix) Stenbolone

20.1 (b) (1) (lv) Prasterone (dehydroepiandrosterone, DHEA, 3β-hydroxyandrost-5-en-17-one)

20.1 (b) (1) (lvi) Prostanozol (17β-[(tetrahydropyran-2-yl) oxy]-1'H-pyrazolo[3,4:2,3]-5α-androstane)

20.1 (b) (1) (lvii) Quinbolone

20.1 (b) (1) (lviii) Stanozolol

20.1 (b) (1) (lx) Testosterone

20.1 (b) (1) (lxi) Tetrahydrogestrinone (17-hydroxy-18a- homo-19-nor-17α-pregna-4,9,11-trien-3-one)

20.1 (b) (1) (lxii) Tibolone

20.1 (b) (1) (lxiii) Trenbolone (17β-hydroxyestr-4,9,11-trien-3- one

20.1 (b) (1) (v) 1-Testosterone (17β-hydroxy-5α-androst-1- en-3-one)

20.1 (b) (1) (vi) 4-Androstenediol (androst-4-ene-3β,17β- diol)

20.1 (b) (1) (vii) 4-Hydroxytestosterone (4,17β-dihydroxyandrost-4-en-3-one)

20.1 (b) (1) (viii) 5-Androstenedione (androst-5-ene-3,17- dione)

20.1 (b) (1) (x) 7β-hydroxy-DHEA

20.1 (b) (1) (xi) 7-Keto-DHEA

20.1 (b) (1) (xii) 19-Norandrostenediol (estr-4-ene-3,17-diol)

20.1 (b) (1) (xiii) 19-Norandrostenedione (estr-4-ene-3,17- dione)

20.1 (b) (1) (xiv) Androstanolone (5α-dihydrotestosterone, 17β-hydroxy-5α-androstan-3-one)

20.1 (b) (1) (xix) Boldione (androsta-1,4-diene-3,17-dione)

20.1 (b) (1) (xl) Methyl-1-testosterone (17β-hydroxy-17α- methyl-5α-androst-1-en-3-one)

20.1 (b) (1) (xli) Methylclostebol

20.1 (b) (1) (xlii) Methyldienolone (17β-hydroxy-17α- methylestra-4,9-dien-3-one)

20.1 (b) (1) (xliii) Methylnortestosterone (17β-hydroxy-17α- methylestr-4-en-3-one)

20.1 (b) (1) (xliv) Methyltestosterone

20.1 (b) (1) (xlix) Norclostebol (4-chloro-17β-ol-estr-4-en-3- one)

20.1 (b) (1) (xlv) Metribolone (methyltrienolone, 17β-hydroxy- 17α-methylestra-4,9,11-trien-3-one)

20.1 (b) (1) (xlvi) Mibolerone

20.1 (b) (1) (xlvii) Nandrolone (19-nortestosterone)

20.1 (b) (1) (xlviii) Norboletone

20.1 (b) (1) (xv) Androstenediol (androst-5-ene-3β,17β-diol)

20.1 (b) (1) (xvi) Androstenedione (androst-4-ene-3,17- dione)

20.1 (b) (1) (xvii) Bolasterone

20.1 (b) (1) (xviii) Boldenone

20.1 (b) (1) (xx) Calusterone

20.1 (b) (1) (xxi) Clostebol

20.1 (b) (1) (xxii) Danazol ([1,2]oxazolo[4',5':2,3]pregna-4-en- 20-yn-17α-ol)

20.1 (b) (1) (xxiii) Dehydrochlormethyltestosterone (4-chloro- 17β-hydroxy-17α-methylandrosta-1,4-dien- 3-one)

20.1 (b) (1) (xxiv) Desoxymethyltestosterone (17α-methyl-5α- androst-2-en-17β-ol and 17α-methyl-5α- androst-3-en-17β-ol)

20.1 (b) (1) (xxix) Ethylestrenol (19-norpregna-4-en-17α-ol)

20.1 (b) (1) (xxv) Drostanolone

20.1 (b) (1) (xxvi) Epiandrosterone (3β-hydroxy-5α-androstan- 17-one)

20.1 (b) (1) (xxvii) Epi-dihydrotestosterone (17β-hydroxy-5β- androstan-3-one)

20.1 (b) (1) (xxviii) Epitestosterone

20.1 (b) (1) (xxx) Fluoxymesterone

20.1 (b) (1) (xxxi) Formebolone

20.1 (b) (1) (xxxii) Furazabol (17α-methyl [1,2,5] oxadiazolo[3',4':2,3]-5α-androstan-17β-ol)

20.1 (b) (1) (xxxiii) Gestrinone

20.1 (b) (1) (xxxiv) Mestanolone

20.1 (b) (1) (xxxix) Methasterone (17β-hydroxy-2α,17α- dimethyl-5α-androstan-3-one)

20.1 (b) (1) (xxxv) Mesterolone

20.1 (b) (1) (xxxvi) Metandienone (17β-hydroxy-17α- methylandrosta-1,4-dien-3-one)

20.1 (b) (1) (xxxvii) Metenolone

20.1 (b) (1) (xxxviii) Methandriol

20.1 (b) (2) Other Anabolic Agents, including but not limited to:

20.1 (b) (2) (i) Clenbuterol, Selective androgen receptor modulators [SARMs, e.g., andarine, LGD-4033 (ligandrol) enobosarm (ostarine), RAD140, AC-262536, GW 501516, YK-11, BMS-564,929, S-23, LGD-121071, LY-245247, GSK 2881078, LGD-2226, S-40503, TFM-4AS-1 and LGD-3033], Zeranol, Zilpaterol, Ractopamine

20.1 (c) S2 Peptide Hormones, Growth Factors, Related Substances, and Mimetics -The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited.

20.1 (c) (1) Erythropoietins (EPO) and Agents affecting erythropoiesis, including but not limited to:

20.1 (c) (1) (i) Erythropoietin-Receptor Agonists, including but not limited to: Darbepoetins (dEPO), Erythropoietins (EPO), EPO-based constructs [e.g., EPO-Fc, methoxy polyethylene glycol-epoetin beta (CERA)], EPO-mimetic agents and their constructs (e.g., CNTO-530, peginesatide)

20.1 (c) (1) (ii) Hypoxia-Inducible Factor (HIF) Activating Agents, including but not limited to: Cobalt, Daprodustat (GSK1278863), IOX2, Molidustat (BAY 85-3934), Roxadustat (FG-4592), Vadadustat (AKB-6548), Xenon, Argon

20.1 (c) (1) (iii) Exceptions: a.) Injectable Cobalt: maximum 1mg over 24 hours period (recognized, legitimate Treatment) b.) Oral Cobalt: maximum 5mg over 24 hours period (nutritional supplement)

20.1 (c) (1) (iv) GATA Inhibitors, including but not limited to: K-11706

20.1 (c) (1) (v) Transforming Growth Factor-beta (TGF-β) signalling inhibitors, including but not limited to: Luspatercept, Sotatercept

20.1 (c) (1) (vi) Innate Repair Receptor Agonists, including but not limited to: Asialo EPO, Carbamylated EPO (CEPO)

20.1 (c) (2) Peptide Hormones and their Releasing Factors, including but not limited to:

20.1 (c) (2) (i) Chorionic Gonadotrophin (CG) and Luteinizing Hormone (LH) and their Releasing Factors in Males and Geldings, including but not limited to: Buserelin, Deslorelin, Gonadorelin, Goserelin, Leuprorelin, Nafarelin, Triptorelin

20.1 (c) (2) (ii) Corticotrophins and their Releasing Factors, including but not limited to: Corticorelin

20.1 (c) (2) (iii) Growth Hormone (GH), its analogues and fragments, including but not limited to: Growth hormone analogues, e.g., lonapegsomatropin, somapacitan, and somatrogon; Growth hormone fragments, e.g., AOD-9604 and hGH 176-191

20.1 (c) (2) (iv) Growth hormone releasing factors, including but not limited to: Growth hormone-releasing hormone (GHRH) and its analogues, e.g., CJC-1293, CJC-1295, sermorelin and tesamorelin; Growth hormone secretagogues (GHS), e.g., lenomorelin (ghrelin) and its mimetics, MK-677 (ibutamoren), anamorelin, ipamorelin, macimorelin and tabimorelin; GH-releasing peptides (GHRPs), e.g., alexamorelin, GHRP-1, GHRP-2 (pralmorelin), GHRP-3, GHRP-4, GHRP-5, GHRP-6, and examorelin (hexarelin)

20.1 (c) (3) Growth factors and growth factor modulators, including but not limited to:

20.1 (c) (3) (i) Fibroblast growth factors (FGFs)

20.1 (c) (3) (ii) Hepatocyte growth factor (HGF)

20.1 (c) (3) (iii) Insulin-like growth factor 1 (IGF-1) and its analogues

20.1 (c) (3) (iv) Mechano growth factors (MGFs)

20.1 (c) (3) (v) Platelet-derived growth factor (PDGF)

20.1 (c) (3) (vi) Thymosin-β4 and its derivatives e.g., TB-500

20.1 (c) (3) (vii) Vascular endothelial growth factor (VEGF)

20.1 (c) (3) (viii) and other growth factors or growth factor modulators affecting muscle, tendon or ligament protein synthesis/degradation, vascularisation, energy utilization, regenerative capacity or fibre type switching.

20.1 (d) S3 Beta-2 Agonists - The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited.

20.1 (d) (1) All selective and non-selective beta-2 agonist, including all optical isomers, are prohibited, including but not limited to:

20.1 (d) (1) (i) Arformoterol

20.1 (d) (1) (ii) Fenoterol

20.1 (d) (1) (iii) Formoterol

20.1 (d) (1) (iv) Higenamine

20.1 (d) (1) (ix) Indacaterol

20.1 (d) (1) (v) Levosalbutamolt

20.1 (d) (1) (vi) Olodaterol

20.1 (d) (1) (vii) Procaterol

20.1 (d) (1) (viii) Reproterol

20.1 (d) (1) (x) Salbutamol

20.1 (d) (1) (xi) Salmeterol

20.1 (d) (1) (xii) Terbutaline

20.1 (d) (1) (xiii) Tretoquinol (trimetoquinol)

20.1 (d) (1) (xiv) Tulobuterol

20.1 (d) (1) (xv) Vilanterol

20.1 (d) (2) Exceptions:

20.1 (d) (2) (i) Inhaled beta-2 agonists e.g., albuterol (salbutamol) when prescribed by a veterinarian as a bronchodilator at an appropriate dose.

20.1 (e) S4 Hormone and Metabolic Modulators - The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited.

20.1 (e) (1) Aromatase Inhibitors, including but not limited to:

20.1 (e) (1) (i) 2-Androstenol (5α-androst-2-en-17-ol)

20.1 (e) (1) (ii) 2-Androstenone (5α-androst-2-en-17-one)

20.1 (e) (1) (iii) 3-Androstenol (5α-androst-3-en-17-ol)

20.1 (e) (1) (iv) 3-Androstenone (5α-androst-3-en-17-one)

20.1 (e) (1) (ix) 4-Androstene-3,6,17 trione (6-oxo)

20.1 (e) (1) (v) Aminoglutethimide

20.1 (e) (1) (vi) Anastrozole

20.1 (e) (1) (vii) Androsta-1,4,6-triene-3,17-dione (androstatrienedione)

20.1 (e) (1) (viii) Androsta-3,5-diene-7,17-dione (arimistane)

20.1 (e) (1) (x) Exemestane

20.1 (e) (1) (xi) Formestane

20.1 (e) (1) (xii) Letrozole

20.1 (e) (1) (xiii) Testolactone

20.1 (e) (2) Anti-estrogenic substances [Anti-estrogens and selective estrogen receptor modulators (SERMS)], including but not limited to:

20.1 (e) (2) (i) Bazedoxifene

20.1 (e) (2) (ii) Clomifene

20.1 (e) (2) (iii) Cyclofenil

20.1 (e) (2) (iv) Fulvestrant

20.1 (e) (2) (v) Ospemifene

20.1 (e) (2) (vi) Raloxifene

20.1 (e) (2) (vii) Tamoxifen

20.1 (e) (2) (viii) Toremifene

20.1 (e) (3) Agents preventing activin receptor IIB activation, including but not limited to:

20.1 (e) (3) (i) Activin A-neutralizing antibodies

20.1 (e) (3) (ii) Activin receptor IIB competitors such as: Decoy activin receptors (e.g., ramatercept (ACE-031), dalantercept (ACE-041))

20.1 (e) (3) (iii) Anti-activin receptor IIB antibodies (e.g., bimagrumab)

20.1 (e) (3) (iv) Myostatin inhibitors such as: Agents reducing or ablating myostatin expression, Myostatin-binding proteins (e.g., follistatin, myostatin propeptide), Myostatin-neutralizing antibodies (e.g., domagrozumab, landogrozumab, stamulumab)

20.1 (e) (4) Metabolic Modulators

20.1 (e) (4) (i) Activators of the AMP-Activated Protein Kinase (AMPK), including but not limited to: AICAR, SR9009, Peroxisome proliferator-activated receptor delta (PPARδ) agonists, e.g., 2-(2-methyl-4-((4-methyl-2-(4-(trifluoromethyl)phenyl)thiazol-5-yl)methylthio)phenoxy) acetic acid (GW1516, GW501516)

20.1 (e) (4) (ii) Insulins and Insulin-Mimetics

20.1 (e) (4) (iii) Meldonium

20.1 (e) (4) (iv) Trimetazidinet

20.1 (e) (5) Thyroid hormone and thyroid hormone modulators, including but not limited to:

20.1 (e) (5) (i) Thyroxine

20.1 (e) (5) (ii) Tetraiodothyronine

20.1 (e) (5) (iii) Triiodothyronine

20.1 (f) S5 Diuretics and Masking Agents

20.1 (f) (1) The following diuretics and masking agents are prohibited, as are other substances with a similar chemical structure or similar biological effect(s), including but not limited to:

20.1 (f) (1) (i) Acetazolamide

20.1 (f) (1) (ii) Amiloride

20.1 (f) (1) (iii) Bumetanide

20.1 (f) (1) (iv) Chlortalidone

20.1 (f) (1) (ix) Canrenone

20.1 (f) (1) (v) Desmopressin

20.1 (f) (1) (vi) Etacrynic acid

20.1 (f) (1) (vii) Indapamide

20.1 (f) (1) (viii) Metolazone

20.1 (f) (1) (x) Plasma expanders, e.g., intravenous Administration of albumin, dextran, hydroxyethyl starch and mannitol

20.1 (f) (1) (xi) Probenecid

20.1 (f) (1) (xii) Spironolactone

20.1 (f) (1) (xiii) Thiazides, e.g., bendroflumethiazide, chlorothiazide and hydrochlorothiazide

20.1 (f) (1) (xiv) Triamterene

20.1 (f) (1) (xv) Vaptans, e.g., tolvaptan

20.1 (f) (2) Exceptions:

20.1 (f) (2) (i) Drospirenone; pamabrom; and topical ophthalmic Administration of carbonic anhydrase inhibitors (e.g., dorzolamide, brinzolamide)

20.1 (f) (2) (ii) Furosemide

20.1 (f) (2) (iii) Trichlormethiazide for treatment of edema

20.1 (f) (2) (iv) Use of any S5 agent, such as plasma expanders for procedures performed for life-saving purposes.

20.1 (g) S6 Miscellaneous Substances - The following substances, and other substances with similar chemical structure or similar biological effect(s), are prohibited.

20.1 (g) (1) Bisphosphonates, including but not limited to:

20.1 (g) (1) (i) Alendronate

20.1 (g) (1) (ii) Clodronic acid

20.1 (g) (1) (iii) Ibandronate

20.1 (g) (1) (iv) Pamidronate

20.1 (g) (1) (v) Risedronate

20.1 (g) (1) (vi) Tiludronic acid

20.1 (g) (1) (vii) Zoledronic acid

20.1 (g) (1) (viii) Exceptions: Bisphosphonates administered for the purpose of diagnostic imaging (gamma scintigraphy).

20.1 (g) (2) Toxins & Venoms of any species or derivatives of them, and their synthetic analogues, including but not limited to:

20.1 (g) (2) (i) Alpha-cobratoxin

20.1 (g) (2) (ii) Dermorphin

20.1 (g) (2) (iii) Ziconotide

20.1 (g) (3) Altrenogest in Males or Geldings

20.1 (g) (4) Pitcher plant extract

20.2 Prohibited Method(s)

20.2 (a) M1 Manipulation of Blood and Blood Components

20.2 (a) (1) The Administration or reintroduction of any quantity of autologous, allogenic (homologous) or heterologous blood, or red blood cell products of any origin into the circulatory system.

20.2 (a) (2) Artificially enhancing the uptake, transport or delivery of oxygen. Including, but not limited to: Perfluorochemicals; efaproxiral (RSR13) and modified haemoglobin products, e.g., haemoglobin-based blood substitutes and microencapsulated haemoglobin products, excluding supplemental oxygen by inhalation.

20.2 (a) (3) Any form of intravascular manipulation of the blood or blood components by physical or chemical means.

20.2 (a) (4) Withdrawal of blood for any purpose other than for diagnostic/Laboratory Testing procedures.

20.2 (a) (5) Exceptions:

20.2 (a) (5) (i) Procedures performed for life-saving purposes.

20.2 (a) (5) (ii) Use of veterinary regenerative therapies (autologous conditioned serum or platelet-rich plasma), for the treatment of musculoskeletal injury or disease.

20.2 (b) M2 Chemical and Physical Manipulation

20.2 (b) (1) Tampering, or Attempted Tampering, to alter the integrity and validity of Samples collected during Doping Control, including, but not limited to, Sample substitution and/or adulteration, e.g., addition of proteases to Sample.

20.2 (b) (2) Use of chemical castration or immunocastration.

20.2 (c) M3 Gene and Cell Doping

20.2 (c) (1) The following, with the potential to enhance performance or modify the heritable genome, are prohibited:

20.2 (c) (1) (i) The use of nucleic acids or nucleic acid analogues that may alter genome sequences and/ or alter gene expression by any mechanism. This includes but is not limited to gene editing, gene silencing and gene transfer technologies.

20.2 (c) (1) (ii) The use of normal or genetically modified cells.

20.2 (c) (1) (iii) Modification of the heritable genome

21 Prohibited on Race Day

21.1 Medications administered by Official Veterinarians providing emergency medical care to a Covered Horse as a result of an injury sustained or other adverse health event during a Covered Horserace are not prohibited.

21.2 Substances prohibited on Race Day must not be Administered during the Race Period, which commences 48 hours prior to a Covered Horse's start in any Race or Workout.

21.3 Prohibited Substance(s)

21.3 (a) S7 Supplements and feed additives and substances capable at any time of causing an action or effect, or both an action and effect, within one or more of the following mammalian body systems:

21.3 (a) (1) the blood system

21.3 (a) (10) the urinary system

21.3 (a) (2) the cardiovascular system

21.3 (a) (3) the digestive system

21.3 (a) (4) the endocrine system

21.3 (a) (5) the immune system

21.3 (a) (6) the musculoskeletal system

21.3 (a) (7) the nervous system

21.3 (a) (8) the reproductive system

21.3 (a) (9) the respiratory system

21.3 (b) All substances, including all optical isomers, e.g., d- and l- where relevant.

21.3 (c) Metabolites, artifacts, and isomers of S7 substances.

21.3 (d) Exceptions:

21.3 (d) (1) Normal food and water.

21.3 (d) (10) Orally administered chondroitin sulphate.

21.3 (d) (11) Orally administered glucosamine.

21.3 (d) (12) Orally administered vitamins.

21.3 (d) (13) Ranitidine.

21.3 (d) (14) Registered vaccines against infectious agents.

21.3 (d) (2) Electrolytes sodium, potassium, and chloride only.

21.3 (d) (3) Altrenogest in female horses.

21.3 (d) (4) Antimicrobials (antibiotics) and other anti-infective agents, excluding procaine penicillin or other antimicrobial/anti-infective agents containing other Prohibited Substances.

21.3 (d) (5) Antiparasitic/anthelmintics approved and registered for use in horses, excluding levamisole or other antiparasitic/anthelmintics metabolising to and/or containing other Prohibited Substances.

21.3 (d) (6) Cimetidine.

21.3 (d) (7) Furosemide during Workouts

21.3 (d) (8) Furosemide administered during the Race Period in accordance with specific provisions of the Act and/or any guidance or exceptions approved by the Authority.

21.3 (d) (9) Omeprazole.

21.3 (e) S7 substances do not include substances for which there is no current approval by any governmental regulatory health authority for veterinary or human therapeutic use (e.g., drugs under pre-clinical or clinical development or discontinued, designer drugs) and any substance not universally recognized by veterinary regulatory authorities as a valid veterinary therapeutic Treatment that fall within S0 and are therefore prohibited at all times.

21.4 Prohibited Method(s)

21.4 (a) M4 Alkalinization

21.4 (b) Exceptions:

21.4 (b) (1) Furosemide during Workouts

22 Prohibited in Workouts

22.1 The Prohibited on Race Day portion of the List is applicable for Workouts except for furosemide. See Definition of Race Day in the Equine Program Definitions, including official timed workouts.

23 Other Prohibited Periods

23.1 Prohibited Substance(s)

23.1 (a) None

23.2 Prohibited Method(s)

23.2 (a) M5 Intra-articular Injection

23.2 (a) (1) Intra-articular injections are prohibited on Race Day, and the fourteen (14) calendar days preceding Race Day. The Covered Horse is Ineligible to race for fourteen (14) calendar days post Administration of the intra-articular injection.

24 Table of Ineligibility Periods for Covered Horse

24.1 S0 Non-approved Substances - 14 months

24.1 (a) Exception: human substances of abuse, e.g., cocaine, MDMA - 0 months

24.10 M3 Gene and Cell Doping - LIFE

24.11 S7 Supplements and feed additives and substances capable at any time of causing an action or effect, or both an action and effect, within one or more of the following mammalian body systems: the nervous system; the cardiovascular system; the respiratory system; the digestive system; the urinary system; the reproductive system; the musculoskeletal system; the blood system; the endocrine system; the immune system - 0 months

24.12 M4 Alkalinization - 0 months

24.2 S1 Anabolic Agents - 14 months

24.2 (a) Exception: zilpaterol/ractopamine where established no Fault (feed contamination) - 6 months

24.3 S2 Peptide Hormones, Growth Factors, Related Substances, and Mimetics - 6 months

24.4 S3 Beta-2 Agonists - 14 months

24.5 S4 Hormone and Metabolic Modulators - 3 months

24.6 S5 Diuretics and Masking Agents - 0 months

24.7 S6 Miscellaneous Substances

24.7 (a) Bisphosphonates - LIFE

24.7 (b) Other - 0 months

24.8 M1 Manipulation of Blood and Blood Components - 6 months

24.9 M2 Chemical and Physical Manipulation - 0 months

Lab Standards (Not Submitted to FTC)

47 Introduction and Scope

47.1 The Agency Laboratory Standards

47.1 (a) Equine Standards for Laboratories (ESL)

47.1 (a) (1) In the introduction to the Horseracing Anti-Doping and Medication Control Protocol (Protocol), the purpose and implementation of the Horseracing Anti-Doping and Medication Control Program are summarized as follows:

47.1 (a) (2) As provided in the Horseracing Integrity and Safety Act of 2020, the purpose of the Horseracing Anti-Doping and Medication Control Program and this Protocol is to improve the integrity and safety of Horseracing by requiring a uniform Anti-Doping and Medication Control Program to be developed and enforced by an independent Horseracing Anti-Doping and Medication Control Authority

47.1 (a) (3) The main purpose of the ESL is

47.1 (a) (3) (i) to ensure that Laboratories report valid test results based on reliable evidentiary data; and

47.1 (a) (3) (ii) to facilitate harmonization in Analytical Testing of Samples by Laboratories.

47.1 (a) (4) The ESL sets out the requirements to be followed by Laboratories that wish to demonstrate that they are technically competent, operate within an effective Management System, and can produce forensically valid results. The ESL includes, inter alia, requirements for obtaining and maintaining HISA Equine Analytical Laboratory (HEAL) accreditation, operating standards for the performance of Laboratories, and a description of the accreditation and approval processes. The ESL also sets out requirements and guidance in relation to Sample custody and storage, Analytical Testing, and some aspects of Results Management.

47.1 (a) (5) Compliance with the ESL in effect at the time of Sample analysis (as opposed to another alternative standard, practice, or procedure) shall be sufficient to conclude that the procedures covered

by the ESL were performed properly. A failure by a Laboratory to follow a requirement in effect at the time of Analytical Testing, which has subsequently been eliminated from this ESL or applicable Technical Document(s) or Technical Letter(s) at the time of a hearing, shall not serve as a defense to an anti-doping rule violation.

47.1 (b) Technical Documents

47.1 (b) (1) Technical Documents are drafted by the Laboratory Expert Group and Agency and circulated for stakeholder consultation before being finalized. Technical Documents are approved by the Agency, and Authority as appropriate and published on the Agency website. Once approved, a Technical Document becomes an integral part of the ESL and supersedes any previous publication on a similar topic, including Technical Letter(s) and/or the ESL.

47.1 (b) (2) Implementation of the requirements detailed in a Technical Document may occur prior to the effective date for implementation specified in the Technical Document in accordance with the provisions below and shall occur no later than the effective date.

47.1 (b) (3) A failure by a Laboratory to implement a Technical Document or Technical Letter by the effective date may result in the imposition of an Analytical Testing Restriction against the Laboratory for that Analytical Testing Procedure, or a Suspension of the Laboratory's HEAL accreditation, respectively, as determined by the Agency

47.1 (b) (4) If a Laboratory is not able to implement a new Technical Document by its effective date, it shall inform the Agency as soon as possible. The Laboratory shall send a written request to the Agency for an extension beyond the applicable effective date, providing the reason(s) for the delayed implementation of the Technical Document, any measures taken to ensure that Samples received in the Laboratory will be subject to Analytical Testing in compliance with the new Technical Document (for example, by subcontracting the analysis to another Laboratory as applicable), as well as plans for the implementation of the new Technical Document

47.1 (b) (5) The implementation of the Technical Documents requirements into the Laboratory's Management System is mandatory for obtaining and maintaining HEAL accreditation or approval, respectively, and for the application of the relevant Analytical Testing Procedure(s) to the analysis of Samples

47.1 (b) (6) In cases when a newly approved version of a Technical Document lowers a Threshold for a Threshold Substance, a Minimum Reporting Level for a Non-Threshold Substance, or any other limit, as applicable, the revised limits specified in the new Technical Document shall not be applied to the reporting of analytical results for Samples collected before the effective date of the Technical Document;

47.1 (b) (7) Where the above revised limit specification does not apply, Laboratories may implement a Technical Document as soon as it is approved by the Agency and Authority, as appropriate, provided that the requirements of the Technical Document have been implemented and documented appropriately by the Laboratory

47.1 (b) (8) The most recently approved Technical Document shall be applied to the Analytical Testing of Samples prior to the effective date if it would lead to a result that benefits the Covered Person and Covered Horse (e.g., increase of the Threshold for a Threshold Substance or of the Minimum Reporting Level for a Non-Threshold Substance, or any other limit, establishment of more stringent identification criteria for chromatographic-mass spectrometric or other Confirmation Procedures). Therefore, in the case where an analytical finding does not meet the reporting criteria defined in the new Technical Document, it shall be reported as a Negative Finding

47.1 (c) Technical Letters

47.1 (c) (1) Technical Letters are issued in letter format on an ad-hoc basis to provide direction to the Laboratories on particular issues on the analysis, interpretation and reporting of results for specific Prohibited Substance(s) and/or Prohibited Method(s) or on the application of specific Laboratory procedures. Technical Letters are modified and/or withdrawn by the Agency as appropriate;

47.1 (c) (2) Technical Letters are drafted and approved by the Agency and Authority, in consultation with relevant scientific experts, and published on the Agency's website. Technical Letters become effective immediately, unless otherwise specified by the Agency;

47.1 (c) (3) Once approved, a Technical Letter becomes an integral part of the ESL and supersedes any previous publication on a similar topic, including Technical Document(s) and/or the ESL;

47.1 (c) (4) The implementation of the requirements of relevant Technical Letters into the Laboratory's

Management System is mandatory for obtaining and maintaining HEAL accreditation or approval, respectively, and for the application of the relevant Analytical Testing Procedure(s) to the analysis of Samples.

47.1 (d) Laboratory Guidelines

47.1 (d) (1) Laboratory Guidelines are issued to provide direction to the Laboratories on new Analytical Methods or procedures approved by the Agency. Laboratory Guidelines are modified and/or deleted by the Agency, as appropriate;

47.1 (d) (2) Laboratory Guidelines are approved by the Laboratory Expert Group (LabEG) and are published on the Agency website;

47.1 (d) (3) Implementation of Laboratory Guidelines is not mandatory. However, Laboratories are encouraged to follow, to the fullest extent possible, the recommendations of best practice included in relevant Laboratory Guidelines.

47.1 (e) Technical Notes

47.1 (e) (1) Technical Notes are issued to Laboratories to provide detailed technical guidance on the performance of specific Analytical Methods or procedures;

47.1 (e) (2) Technical Notes are approved by the LabEG. Technical Notes are provided to Laboratories only and are not published on the Agency website;

47.1 (e) (3) Implementation of the recommendations detailed in Technical Notes is not mandatory. However, Laboratories are encouraged to follow, to the fullest extent possible, the technical guidance included in Technical Notes.

47.2 Sample Analysis

47.2 (a) Sample analysis is part of the Analytical Testing process and involves the detection, identification, and in some cases demonstration of the presence above a Threshold of Prohibited Substance(s) and/or their Metabolite(s), or Marker(s) of Use of Prohibited Substances or Prohibited Methods in an equine Sample

47.2 (b) Laboratories may accept samples for other forms of analysis, subject to the provisions of the ESL Code of Ethics (see Article 56), which are not under the scope of HEAL accreditation. Any such testing shall not be covered by the Laboratory's HEAL accreditation and, therefore, shall not be subject to the requirements of the ESL, Technical Documents or Technical Letters. Test reports or other documentation or correspondence from Laboratories shall not declare or represent that any such testing is covered under their HEAL accreditation status.

48 Protocol provisions

48.1 Several articles in the Protocol are directly relevant to the ESL, they can be obtained by referring to the Protocol itself.

49 Definitions and Interpretations

49.1 Definitions

49.1 (a) See Definitions.

49.2 Interpretation

49.2 (a) The comments annotating various provisions of the ESL shall be used to guide its interpretation

49.2 (b) Unless otherwise specified, references to Sections and Articles are references to Sections and Articles of the ESL

49.2 (c) Where the term “days” is used in the ESL, it shall mean calendar days unless otherwise specified

49.2 (d) The Annexes to the ESL have the same mandatory status as the rest of the ESL

50 Racing Medication and Testing Consortium (RMTC) Accredited Laboratories

50.1 This ESL will replace current RMTC accreditation, although a transition phase which may include RMTC conducting the accreditation program may be agreed between the Agency and RMTC.

50.2 Where a laboratory has current RMTC accreditation, any information required as part of the HEAL application process which has already been provided as part of their RMTC accreditation, and which the laboratory checks to confirm it is still current and valid, may with the agreement of the parties be provided to the Agency.

51 Process and Requirements for HEAL Laboratory Accreditation

51.1 This section describes the specific requirements that a laboratory shall fulfill in the process of applying for, obtaining, and maintaining HEAL accreditation.

51.2 Applicant Laboratory for HEAL accreditation

51.2 (a) In principle, any laboratory that satisfies the criteria listed below may apply to become a candidate laboratory for HEAL accreditation.

51.2 (b) Submit Initial Application Form

51.2 (b) (1) The applicant laboratory shall submit a completed Application Form, provided by the Agency, duly signed by the Laboratory Director (or equivalent position) and, if relevant, by the Director (or equivalent position) of the host organization (e.g., university, hospital, public institution).

51.2 (c) Provision of Business Plan

51.2 (c) (1) The Agency shall request the applicant laboratory to submit a business plan summary, which shall include market considerations (clients, number of Samples, maintenance costs, prices for analysis etc.), facility, instrumental, staffing and training needs, and shall make a reasonable guarantee the long-term provision of adequate financial and human resources to the laboratory.

51.3 Candidate Laboratory for HEAL accreditation

51.3 (a) The application shall be evaluated by the Agency to determine whether the applicant laboratory will be granted the Agency candidate laboratory status and thereby continue within the HEAL accreditation process. Additional supporting documentation may be requested by, and at the discretion of the Agency.

51.3 (b) Description of the Candidate Laboratory

51.3 (b) (1) Once approved by the Agency, the candidate laboratory shall complete a detailed questionnaire and submit it to the Agency. The questionnaire will include, but is not limited to, the following:

51.3 (b) (10) Status and scope of ISO/IEC 17025 accreditation, according to ILAC-G7 specifications;

51.3 (b) (11) A description of how the principles of the Code of Ethics are integrated into the laboratory Management System. A letter of compliance with the Code of Ethics signed by the laboratory Director shall be provided.

51.3 (b) (12) The Agency may require an update of this documentation during the process of accreditation.

51.3 (b) (2) Staff list and their qualifications, including description of any relevant anti-doping experience

and a list of relevant scientific publications by laboratory staff;

51.3 (b) (3) Relevant memberships and engagement with professional societies, such as the Association of Official Racing Chemists (AORC), World Association of Anti-Doping Scientists (WAADS), Society of Forensic Toxicologists (SOFT) and The International Association of Forensic Toxicologists (TIAFT);

51.3 (b) (4) Description of the physical laboratory facilities, including a description of the security considerations for Samples and records. The laboratory facilities shall include ample analytical and administrative space to allow separate, restricted and dedicated areas for analytical and administrative operations

51.3 (b) (4) (i) Physical Security: specific measures to maintain secure and restricted access to the laboratory facility and a controlled internal laboratory environment (e.g., dedicated and restricted Sample storage areas, CCTV monitoring);

51.3 (b) (4) (ii) IT Security: implementation of firewalls and other cyber security measures consistent with best practice and any applicable governmental regulations (see Article 53.2 (c) (5));

51.3 (b) (4) (iii) Information Technology (IT) infrastructure: implementation of a data and information management system (e.g., LIMS), central server/intranet which allows secure data handling (see Article 53.2(c) (5)).

51.3 (b) (5) List of actual and proposed instrumental resources and equipment, including year of purchase and conditions for technical support (e.g., contract/access to instrument manufacturer maintenance services);

51.3 (b) (6) List of validated Initial Testing Procedure(s) and Confirmation Procedures, including target Analytes and Limits of Detection (LODs), Limits of Identification (LOIs) and, where applicable, Limits of Quantification (LOQs) and estimates of Measurement Uncertainty (MU);

51.3 (b) (7) Status of method development and validation, including, at minimum, all mandatory Analytical Methods and method validation reports (if completed and currently in use);

51.3 (b) (8) List of available Reference Materials and Reference Collections, or plans to acquire Reference Materials or obtain Reference Collections;

51.3 (b) (9) Plans to ensure compliance with laboratory independence and impartiality requirements before receiving HEAL accreditation (see Article 51.4 (b) (4));

51.3 (c) Payment of Initial Accreditation Fee

51.3 (c) (1) Prior to entering the probationary period, the candidate laboratory shall pay the Agency a one-time non-refundable fee to cover the costs related to the initial accreditation process. This fee shall be determined by the Agency and disclosed to the laboratory prior to the accreditation process commencing. If the fee is not agreed the accreditation process will not commence.

51.3 (d) Compliance with the Code of Ethics

51.3 (d) (1) The candidate laboratory shall implement and comply with the provision(s) of the Code of Ethics. Candidate laboratories shall not accept Samples directly from individual Covered Persons or from individuals or organizations acting on their behalf.

51.3 (e) Pre-Probationary Testing and On-Site Assessment

51.3 (e) (1) If this is covered by other accreditation such as ISO/IEC 17025, the laboratory may refer to this.

51.3 (e) (2) Prior to entering the probationary accredited period, the Agency shall conduct a pre-probationary testing (PPT) and on-site assessment of the candidate laboratory at the candidate Laboratory's expense. The purpose of this assessment is to obtain information about different aspects of the laboratory’s competence and to clarify any issues regarding the accreditation process, which are relevant for the HEAL accreditation.

51.3 (e) (3) As part of the PPT, the candidate laboratory shall be required to analyze at least ten (10) blind EQAS samples arranged by the Agency. The general composition and content of the blind EQAS samples and the evaluation of laboratory EQAS results are described in Part Three and Five, respectively.

51.3 (e) (4) The candidate laboratory shall report the results for the PPT blind EQAS samples to, and in a form designated by, the Agency (in compliance with Article 52.4 (e)) within fifteen (15) days, unless otherwise requested by the laboratory and agreed to by the Agency.

51.3 (e) (4) (i) Upon request, the candidate laboratory shall provide the Agency with a Laboratory Documentation Package for selected EQAS samples for which there is an Adverse Analytical Finding. Additional data may be required upon the Agency's request. This documentation shall be submitted within ten (10) days of the request or as otherwise indicated by the Agency;

51.3 (e) (4) (ii) For selected EQAS samples with Negative Findings, the Agency may request all or a portion of the Initial Testing Procedure(s) data

51.3 (e) (5) After receiving the PPT EQAS results, the Agency shall inform the candidate laboratory of the evaluation of its performance and provide guidance for improvement. Corrective actions, if any, shall be conducted and reported by the candidate laboratory to the Agency within thirty (30) days, or as otherwise indicated by the Agency.

51.3 (e) (6) In addition, the Agency shall provide an Assessment Report regarding the outcomes of the on-site assessment, including any identified nonconformity(-ies), to allow the candidate laboratory to implement the necessary improvements. Corrective actions, if requested, shall be conducted, and reported by the candidate laboratory to the Agency within thirty (30) days, or as otherwise indicated by the Agency.

51.3 (e) (7) The nonconformities identified in the Agency Assessment Report shall be satisfactorily addressed and the recommendations for improvement should be implemented before the candidate laboratory can be accepted as an Agency probationary laboratory. The candidate Laboratory's performance in the PPT and on-site assessment will be considered in the overall review of the candidate laboratory's application and may affect the timeliness of the candidate laboratory's entry into the probationary phase of accreditation.

51.3 (f) Obtaining ISO/IEC 17025 Accreditation by the Laboratory

51.3 (f) (1) Before the Agency grants HEAL accreditation, the candidate laboratory shall obtain ISO/IEC 17025 accreditation as an animal testing laboratory from an Accreditation Body, or its equivalent as specified in ILAC-G7, with primary reference to the interpretation and application of the ISO/IEC 17025 requirements to the analysis of Samples (see Part Four). The Accreditation Body shall be an International Laboratory Accreditation Cooperation (ILAC) full member that is a signatory to the ILAC Mutual Recognition Arrangement (ILAC MRA) and must comply with all requirements of the current ILAC-G7 document (Accreditation Requirements and Operating Criteria for Horseracing Laboratories).

51.3 (f) (2) The candidate laboratory shall prepare and establish the required documentation and Management System according to the requirements of ISO/IEC 17025 applicable to the analysis of Samples (see Part Four). Based on this, the laboratory shall initiate and prepare for the accreditation process by consulting with an Accreditation Body. The candidate laboratory shall correct and document any identified nonconformities with the ISO/IEC 17025 standard within the defined timelines.

51.3 (f) (3) The Accreditation Body should send a summary of the Assessment Report and any corrective/preventive action documentation addressing nonconformities, to the Agency. Should the candidate laboratory prefer to send the information directly to the Agency, the laboratory shall do so within a reasonable timeline.

51.3 (f) (4) The ISO/IEC 17025 accreditation is a critical and mandatory pre-requisite for obtaining HEAL accreditation.

51.3 (g) Analytical Testing Procedures

51.3 (g) (1) Before the Agency grants accreditation, candidate laboratories shall provide documentation to the Agency demonstrating that all mandatory Test Methods have been validated and included in the Laboratory's Scope of ISO/IEC 17025 accreditation. See Technical Documents.

51.3 (h) Laboratory Independence and Impartiality

51.3 (h) (1) Before the Agency grants accreditation, probationary laboratories shall provide documentation to the Agency demonstrating compliance with the requirements of Laboratory independence and impartiality established in Article 51.4 (b) (4).

51.3 (i) Professional Liability Insurance Coverage

51.3 (i) (1) Before the Agency grants accreditation, probationary laboratories shall provide documentation to the Agency demonstrating that they have adequate provisions for self-insuring, or professional liability risk insurance coverage has been obtained to cover liability of no less than two (2) million USD annually.

51.4 The Agency-Accredited Laboratory

51.4 (a) Obtaining HEAL Accreditation

51.4 (a) (1) The Agency Probationary HEAL Accreditation

51.4 (a) (1) (i) Upon satisfactory completion of the candidate laboratory requirements (as per Article 51.3), as determined by the LabEG, a candidate laboratory can be considered for entry to the probationary phase of HEAL accreditation as an Agency probationary laboratory. Once the Agency has determined that the laboratory has successfully completed the requirements of a candidate laboratory, the Agency can grant the laboratory probationary accreditation status.

51.4 (a) (1) (ii) A probationary laboratory must comply with the requirements of accredited laboratories, including the requirements for maintaining accreditation.

51.4 (a) (1) (iii) The probationary period is two (2) years, or following the analysis of 2,500 samples, whichever comes later.

51.4 (a) (2) The Agency Pre-Final Accreditation

51.4 (a) (2) (i) Once the Agency has determined that the laboratory has successfully completed the requirements of the probationary period, the Laboratory can be granted final accreditation status. At the Agency's discretion, as part of the final accreditation process, a Final Accreditation Test (FAT) and/or on-site assessment may be conducted by the Agency. Costs associated with the Agency on-site assessment and FAT shall be disclosed and agreed to with the probationary laboratory.

51.4 (a) (2) (ii) As part of the FAT, the probationary laboratory shall analyze a minimum of fifteen (15) blind EQAS samples selected from the routine EQAS program. The general composition and content of the blind EQAS samples and the evaluation of laboratory EQAS results are described in Part Three and Five, respectively.

51.4 (a) (2) (iii) Compliance with the defined requirements in the Application of ISO/IEC 17025 to the analysis of Samples, the ESL and other Agency Laboratory Standards (Technical Documents, Technical Letters), and the practice and documentation of the laboratory will be assessed. The FAT shall assess both the scientific competence and the capability of the probationary laboratory to manage multiple Samples.

51.4 (a) (2) (iv) The probationary laboratory shall successfully report the results for the blind EQAS samples in the FAT to the Agency in accordance with Article 52.4 (e) within fifteen (15) days of opening the samples, unless otherwise requested by the laboratory and agreed to by the Agency:

51.4 (a) (2) (v) Upon request, the probationary laboratory shall provide the Agency with a Laboratory Documentation Package for selected EQAS samples for which there is an Adverse Analytical Finding. Additional data may be required upon the Agency's request. This documentation shall be submitted within ten (10) days of the Agency request or as otherwise indicated by the Agency;

51.4 (a) (2) (vi) For EQAS samples with Negative Findings, the Agency may request all or a

portion of the Initial Testing Procedure(s) data.

51.4 (a) (2) (vii) After receiving the FAT EQAS results, the Agency shall inform the probationary laboratory of the evaluation of its performance. Corrective actions, if any, shall be conducted and reported by the probationary laboratory to the Agency within thirty (30) days, or as otherwise indicated by the Agency.

51.4 (a) (2) (viii) The Agency shall provide an Assessment Report with the outcomes of the accreditation assessment, including any identified nonconformities for the probationary laboratory to implement the necessary improvements. Corrective actions, if any, shall be conducted and reported by the probationary laboratory to the Agency within thirty (30) days, or as otherwise indicated by the Agency. The nonconformities identified in the FAT EQAS and the Assessment Report shall be satisfactorily addressed by the laboratory and the recommendations for improvement should be implemented before accreditation can be granted.

51.4 (a) (3) The Agency Recommendation for Accreditation

51.4 (a) (3) (i) Based on the relevant documentation received from the probationary laboratory, the Assessment Report(s) from the Agency and from the relevant Accreditation Body, the Agency shall evaluate the probationary laboratory's progress in meeting all the requirements outlined in Articles 51.3 and 51.4.

51.4 (a) (3) (ii) Once as determined by the Agency in the Agency's sole discretion that all accreditation requirements have been satisfactorily met by the probationary laboratory, the Agency will grant accreditation to the laboratory.

51.4 (a) (3) (iii) However, if following the FAT and on-site assessment, and the review of any resulting Corrective Action Reports submitted by the probationary laboratory, the Agency determines that the probationary laboratory should not be accredited, the laboratory will have a maximum of six (6) additional months to correct and improve any pending nonconformity(-ies). The provision of documentation, the analysis of additional EQAS samples and/or an additional assessment (on-site, remotely or as a documentary audit, as determined by the Agency), may be required, and conducted at the probationary laboratory's expense. A probationary laboratory that fails to provide satisfactory improvements, as determined by the Agency after six (6) months may be required to renew its candidacy as described in Article 51.3 or to re- start the probationary phase of accreditation in accordance with Article 51.4 (a) (1).

51.4 (a) (4) Issuing and Publishing of HEAL Accreditation Certificate

51.4 (a) (4) (i) An Accreditation Certificate signed by a duly authorized representative of the Agency shall be issued in recognition of the HEAL accreditation. It shall specify probationary or final accreditation status. Such Accreditation Certificate shall specify the name of the Laboratory and the period for which the Accreditation Certificate is valid. Accreditation Certificates may be issued after the effective date, with retroactive effect. A list of HEAL accredited laboratories, together with internationally approved laboratories, shall be published on the Agency's website.

51.4 (b) Maintaining HEAL accreditation

51.4 (b) (1) Maintain ISO/IEC 17025 Accreditation

51.4 (b) (1) (i) The Laboratory shall maintain accreditation to ISO/IEC 17025, with primary reference to the analysis of Samples, granted by a relevant Accreditation Body, which is an ILAC full member and signatory to the ILAC MRA for testing activities as defined in ISO/IEC 17025.

51.4 (b) (1) (ii) Flexible Scope of ISO/IEC 17025 Accreditation is highly desired upon HEAL accreditation, but in any event is required by 1 January 2025.

51.4 (b) (10) Laboratory Analytical Testing Procedures and services

51.4 (b) (10) (i) Laboratories shall provide to the Agency an up-to-date list of Analytical Testing Procedures and services, to assist the Agency in developing Test Distribution Plans. Upon request, Laboratories should Cooperate with the Agency by providing other relevant information

regarding Testing plans (e.g., Laboratory analytical capabilities).

51.4 (b) (11) Participating in the Agency / Accreditation Body Re-assessments and Continuous Assessments during the Accreditation Cycle

51.4 (b) (11) (i) Accreditation Body Re-assessment and/or Continuous Assessment during the Accreditation

51.4 (b) (11) (i) (A) The assessment team shall include at least one ESL-trained assessor selected by the Accreditation Body for the assessment/re-assessment.

51.4 (b) (11) (i) (B) The relevant Accreditation Body, or the Laboratory, should send copies of a summary of the Assessment Report, as well as the Laboratory responses in a timely fashion to the Agency. Should the Laboratory prefer to provide the Assessment Report summary directly to the Agency, it shall do so within thirty (30) days from receiving the Accreditation Body's Assessment Report.

51.4 (b) (11) (i) (C) The Laboratory shall provide the Agency with an updated copy of the ISO/IEC 17025 Certificate and Scope of ISO/IEC 17025 Accreditation as soon as it is obtained from the Accreditation Body.

51.4 (b) (11) (ii) The Agency Laboratory Assessment

51.4 (b) (11) (ii) (A) The Agency reserves the right to conduct documentary audits as well as inspect and assess the Laboratory through on-site or remote (on-line) assessments at any time, at the Agency's expense. The notice of the Agency assessment will be made in writing to the Laboratory Director. In exceptional circumstances, and at the Agency's discretion, the assessment may be unannounced.

51.4 (b) (11) (ii) (B) As part of an announced or unannounced Laboratory assessment, the Agency retains the right to request copies of Laboratory documentation and/or request Further Analysis of selected "A" and/or "B" Samples either on-site or in a Laboratory(-ies) chosen by the Agency.

51.4 (b) (2) Flexible Scope of ISO/IEC 17025 Accreditation

51.4 (b) (2) (i) A Laboratory may modify or add Analytes to Analytical Testing Procedures, which are included within its Scope of ISO/IEC 17025 Accreditation or develop new Analytical Testing Procedure(s) that involve technology already included within the Scope of ISO/IEC 17025 Accreditation, without the need for approval by the Accreditation Body that provides the ISO/IEC 17025 accreditation of that Laboratory.

51.4 (b) (2) (ii) The Laboratories are not eligible to apply a Flexible Scope of ISO/IEC 17025 Accreditation to the analysis of Samples in the following scenarios:

51.4 (b) (2) (iii) - New Analytical Testing Procedures: Any Analytical Testing Procedure, which is new to the field of anti-doping analysis, shall be approved as Fit-for-Purpose by the Agency prior to implementation by any Laboratory. The Agency shall use whatever means deemed appropriate, including formal consultations with scientific expert working groups, publication(s) in peer-reviewed scientific journal(s), or participation in an inter-laboratory collaborative study or the Agency-organized EQAS round to evaluate whether the test is Fit-for-Purpose prior to providing approval. Before applying such a new Analytical Testing Procedure to the analysis of Samples, a Laboratory shall obtain an extension of the Scope of ISO/IEC 17025 Accreditation by the relevant Accreditation Body and may be required to successfully participate in an Agency EQAS, if available;

51.4 (b) (2) (iv) The Agency-specific Analytical Testing Procedures: The Agency may require an extension of the Scope of ISO/IEC 17025 Accreditation to include specific Analytical Testing Procedures before application to the analysis of Samples, even if the analytical technique involved is already incorporated in the Laboratory's Scope of ISO/IEC 17025 Accreditation. The Agency will communicate to the Laboratories and to the Accreditation Bodies which Analytical Testing Procedures are included in this category. In such cases, the Analytical Testing Procedure shall be validated by the Laboratory. The Laboratory may also be required to successfully participate in an inter-laboratory collaborative study or the Agency-organized EQAS round to obtain an extension to

the Scope of ISO/IEC 17025 Accreditation by a relevant Accreditation Body before introducing the Analytical Testing Procedure to the analysis of Samples. However, once included within the scope, limited changes to these Analytical Testing Procedures may be allowed within the boundaries of a Flexible Scope of ISO/IEC 17025 Accreditation. Nonetheless, this flexibility does not allow the Laboratories to introduce new Analytes within these Analytical Testing Procedures if specific method performance and compliance decision criteria (e.g., Decision Limits) are needed and those criteria are not yet defined in an applicable Technical Document (e.g., new target compound(s) for GC/C/IRMS analysis).

51.4 (b) (2) (v) Inclusion of an Analytical Testing Procedure within the Laboratory's Scope of ISO/IEC 17025 Accreditation establishes that the Analytical Testing Procedure is Fit-for-Purpose, and the Laboratory shall not be required to provide Analytical Method validation documentation or EQAS performance data in support of an analytical finding.

51.4 (b) (2) (vi) Laboratories are expected to include Analytical Testing Procedures within their Scope of ISO/IEC 17025 Accreditation prior to application to the analysis of Samples. However, under exceptional circumstances, a Laboratory may apply a method, which has been validated in accordance with applicable Technical Document(s), Technical Letter(s) or Laboratory Guidelines, to the analysis of Samples before inclusion into the Laboratory's Scope of ISO/IEC 17025 Accreditation. However, in such cases, the Laboratory does not automatically benefit from the presumption that the method is Fit-for-Purpose, as would otherwise be the case if the Analytical Testing Procedure is included within the Laboratory's Scope of ISO/IEC 17025 Accreditation. Consequently, any Adverse Analytical Findingreported by applying a Test Method, which is not within the Laboratory's Scope of ISO/IEC 17025 Accreditation, may require the Laboratory to provide method validation documentation or EQAS performance data in support of that Adverse Analytical Finding.

51.4 (b) (2) (vii) Laboratories shall not apply an Agency-specific Analytical Testing Procedure to the analysis of Samples until such method is included in the Laboratory's Scope of ISO/IEC 17025 Accreditation.

51.4 (b) (3) Participate in the Agency EQAS Program

51.4 (b) (3) (i) Laboratories are required to participate in the Agency EQAS on a continuous basis and meet the performance requirements of the EQAS as described in Part Three.

51.4 (b) (4) Laboratory Independence and Impartiality

51.4 (b) (4) (i) The Laboratory shall be administratively and operationally independent from any organization or person(s) that could exert undue pressure on the Laboratory and affect the impartial execution of its tasks and operations.

51.4 (b) (4) (ii) In order to be administratively independent, the Laboratory cannot be administered by, connected or subject to a State Racing Commission, sport organization or other government body responsible for sport performance, including their Board Members, staff, State Racing Commission members or officials. This is necessary to avoid potential conflicts of interest and ensure full confidence in the Laboratory's competence, impartiality, judgment and operational integrity, in compliance with ISO/IEC 17025.

51.4 (b) (4) (iii) In order to be operationally independent, the Laboratory shall manage its own affairs without hindrance, interference or direction from any Person. The Laboratory shall, without limitation, control: the allocation of its budget, the procurement of equipment and other resources, Laboratory personnel decisions, the research conducted by the Laboratory and all Sample Analytical Testing and reporting of results. The Laboratory shall not accept money from any Covered Person.

51.4 (b) (4) (iv) The Laboratory shall have a dedicated budget allowing the implementation of an efficient approval process for the timely procurement of necessary Reference Materials, reagents, consumables and essential equipment, as well as independent Laboratory management decisions concerning the recruitment, retention and training of staff, participation in scientific meetings and symposia, etc. This does not prevent the Laboratory from receiving research grants or other financial support from their host organization (e.g., university, hospital, public institution), Anti-Doping Organizations, sport organizations, government, or other sponsors, while following applicable accounting regulations in connection with the receipt and management of those funds.

51.4 (b) (4) (v) In accordance with ISO/IEC 17025, the Laboratory shall be a legal entity, or a defined part of a legal entity, which is legally responsible for its activities.

51.4 (b) (5) Document Compliance with the Agency Laboratory Code of Ethics

51.4 (b) (5) (i) The Laboratory shall comply with the provision(s) of the Code of Ethics.

51.4 (b) (5) (ii) The Laboratory shall annually provide to the Agency a letter of compliance with the provisions of the Code of Ethics, signed by the Laboratory Director. All staff employed at the Laboratory, permanent or temporary, shall also read, agree to, and sign the Code of Ethics. The Laboratory may be asked to provide documentation of compliance with the provisions of the Code of Ethics.

51.4 (b) (5) (iii) The Laboratory shall establish a system requiring Laboratory staff to report any alleged breaches of the Code of Ethics to the Laboratory Director, which the Laboratory Director shall report to the Agency. However, if Laboratory staff suspect that the Laboratory Director may have breached the Code of Ethics, the Laboratory staff shall report the alleged breaches of the Code of Ethics directly to the Agency. The Laboratory Director and/or the Agency, as applicable, shall immediately and thoroughly investigate any alleged breach of the Code of Ethics.

51.4 (b) (5) (iv) If the Laboratory's investigation determines that a breach of the Code of Ethics occurred, the Laboratory Director shall immediately inform the Agency of the results of the investigation and the disciplinary actions taken. The Agency may also impose penalties as a result of its own investigations. Penalties may range from a personal reprimand to the expulsion of the implicated Laboratory staff member(s), the reporting of the breach to the pertinent authorities (e.g., law enforcement), the Suspension or Revocation of the Laboratory's HEAL accreditation, or any other follow up measures the Agency determines to be appropriate.

51.4 (b) (6) Document Implemented Research and Development Activities

51.4 (b) (6) (i) The Laboratory shall develop and maintain a plan for research and development in the field of anti-doping science. The research activities can either be conducted by the Laboratory alone or in cooperation with other Laboratories or other research organizations.

51.4 (b) (6) (ii) The Laboratory shall supply an annual progress report to the Agency documenting research and development results in the field of anti-doping science. The Laboratory shall also relate research and development plans for the following year.

51.4 (b) (6) (iii) The annual research summary will be evaluated and scored by the LabEG. The Laboratory must, except where otherwise agreed by the Agency, achieve the minimum requirement to meet accreditation research requirements (Article 57).

51.4 (b) (7) Document Implemented Sharing of Knowledge

51.4 (b) (7) (i) The Laboratory shall demonstrate its willingness and ability to share knowledge with other Laboratories. The Laboratory shall disseminate the results of its research and development activities to other Laboratories. The Laboratory are encouraged to make at least one (1) annual contribution to an anti-doping symposium or conference. Laboratories are encouraged to participate in collaborative research projects with other Laboratories, and to exchange experience, protocols, arrange for visits of specialists and provide training to other Laboratories and probationary laboratories in specific areas of Analytical Testing.

51.4 (b) (7) (ii) The Laboratory shall supply a report on sharing of knowledge with other Laboratories to the Agency, if requested. A description of sharing of knowledge is provided in the Code of Ethics.

51.4 (b) (8) Maintain Professional Liability Insurance Coverage

51.4 (b) (8) (i) Laboratories shall provide documentation to the Agency including evidence that professional liability risk insurance coverage is maintained of no less than two (2) million USD annually (for example, evidence of timely payment of applicable fees and premiums).

51.4 (b) (9) Maintain Minimum Number of Samples

51.4 (b) (9) (i) To maintain proficiency in Analytical Testing, Laboratories are required to analyze a

minimum of 2,500 Samples provided annually by the Agency. The Agency will monitor the number of Samples tested by the Laboratory. If the number of Samples falls below the minimum, the Laboratory's HISA accreditation may be Suspended in accordance with 55.3.

51.4 (b) (9) (ii) It is recognized that specific circumstances may affect a Laboratory's ability to analyze the minimum Samples annually, such as when the Laboratory is not operational for the full calendar year. In such cases, the Agency shall require that the Laboratory implement measures to maintain proficiency in Analytical Testing, for example by strengthening its internal Quality Assurance Scheme (iQAS) and internal audits program. The Agency may also provide additional EQAS samples and/or conduct a documentary audit and/or an on-site or remote (on-line) assessment, at its discretion, to assess the status of the Laboratory's operations.

51.5 The Agency Monitoring of Accreditation Status

51.5 (a) The Agency shall regularly review the compliance of Laboratories with the requirements listed in the ESL and related Technical Documents and Technical Letters. In addition, the Agency shall also conduct an annual review of EQAS results and of relevant routine Analytical Testing issues to assess the overall performance of each Laboratory and to decide its accreditation status.

51.5 (b) Maintenance of HEAL accreditation

51.5 (b) (1) Compliance with all the requirements established in Article 51.4 (b), including satisfactory performance by a Laboratory in the EQAS and in routine Analytical Testing, as determined by the Agency, is a critical requirement for the maintenance of the Laboratory's HEAL accreditation.

51.5 (c) Issuing and Publication of Accreditation Certificate

51.5 (c) (1) On an annual basis, when maintenance of accreditation is approved by the Agency, the Laboratory shall receive a HEAL accreditation Certificate, signed by a duly authorized representative of the Agency, which is issued in recognition of such accreditation. The Accreditation Certificate shall specify the name of the Laboratory and the period for which the Accreditation Certificate is valid. HEAL accreditation Certificates may be issued after the effective date, with retroactive effect. The list of the HEAL -accredited Laboratories is maintained on the Agency's{53}} website.

52 The Agency External Quality Assessment Scheme (EQAS)

52.1 The Agency regularly distributes External Quality Assessment Scheme (EQAS) samples to Laboratories and, when applicable, to probationary laboratories. The Agency EQAS is designed to continually monitor the capabilities of the Laboratories and probationary laboratories, to evaluate their proficiency, and to improve test result uniformity between Laboratories. EQAS samples are used to assess Laboratory routine analytical capacity and performance, reporting turn-around times and overall compliance with the Agency Laboratory standards (e.g., ESL, Technical Documents and Technical Letters), as well as other, non-analytical performance criteria. At the same time, the EQAS also represents, via its educational components, a source of continuous improvement for the effectiveness of the Analytical Testing Procedures.

52.2 Types of EQAS

52.2 (a) Blind EQAS

52.2 (a) (1) The Laboratory will be aware that the sample is an EQAS sample since it is delivered by the Agency's EQAS sample provider. However, the Laboratory will not know the content of the sample.

52.2 (b) Double-Blind EQAS

52.2 (b) (1) The Laboratory will not be aware that the sample is an EQAS sample since it is delivered by the Agency and is indistinguishable from routine Samples.

52.2 (c) Educational EQAS

52.2 (c) (1) Educational EQAS samples may be provided as open (in which case the content of the EQAS sample is known), blind or double-blind samples. This approach is used for educational purposes or for data gathering.

52.2 (c) (2) As part of the educational EQAS, the Agency may provide Laboratories with new Reference Materials, Reference Collections, or quality control (QC) samples for a prompt implementation of existing or new Analytical Testing Procedures.

52.2 (c) (3) The Agency may require the successful participation of Laboratories in an educational EQAS for the Agency-specific Analytical Testing Procedures for Laboratories to seek an extension of the Laboratory's Scope of ISO/IEC 17025 Accreditation by an Accreditation Body (see Article 51.4 (b) (ii)) before the subsequent application of the Analytical Testing Procedure to the routine analysis of Samples.

52.3 EQAS Sample Number and Composition

52.3 (a) Number of EQAS Samples

52.3 (a) (1) The actual composition and number of EQAS samples supplied to different Laboratories may vary; however, within any calendar year, all Laboratories participating in the EQAS are expected to have analyzed the minimum total number of EQAS samples.

52.3 (a) (2) Each year, the EQAS program will consist of:

52.3 (a) (2) (i) At least fifteen (15) blind EQAS samples, distributed by the Agency in multiple rounds;

52.3 (a) (2) (ii) At least five (5) double-blind EQAS samples distributed by the Agency in several rounds;

52.3 (a) (2) (iii) At least three (3) of the above EQAS samples will contain Threshold Substances.

52.3 (a) (3) As part of the Agency's Laboratory monitoring activities, and with the main purpose of assisting Laboratories in their continuous improvement of performance, the Agency may increase the number of annual EQAS samples (mainly for educational purposes) for certain Laboratories, according, but not limited, to the following criteria:

52.3 (a) (3) (i) Monitoring the effectiveness of corrective action implementation after questionable or unsatisfactory performance in the Agency EQAS or in routine Analytical Testing;

52.3 (a) (3) (ii) Substantiated intelligence information received by the Agency indicating questionable or unsatisfactory Laboratory performance;

52.3 (a) (3) (iii) Laboratories which do not receive enough Samples (< 100 annual Samples) for a specific Analytical Testing Procedure, which is not part of the Laboratory's routine Analytical Testing menu;

52.3 (a) (3) (iv) As part of the Agency Laboratory assessments.

52.3 (b) Composition of EQAS Samples

52.3 (b) (1) EQAS Samples may or may not contain Prohibited Substance(s) and/or Metabolite(s) of Prohibited Substance(s) and/or Marker(s) of Prohibited Substance(s) or Prohibited Method(s).

52.3 (b) (2) 6.2.2.1 Blank EQAS Samples

52.3 (b) (2) (i) EQAS Samples may or may not contain Prohibited Substance(s) and/or Metabolite(s) of Prohibited Substance(s) and/or Marker(s) of Prohibited Substance(s) or

Prohibited Method(s).

52.3 (b) (3) Adulterated EQAS Samples

52.3 (b) (3) (i) Adulterated EQAS Samples are those which have been deliberately adulterated by the spiking of non-characteristic Metabolite(s) or by the addition of extraneous substances designed to dilute or concentrate the sample, degrade or mask the Analyte prior to or during the analytical determination. Adulterated EQAS samples may also be obtained from the controlled Administration or the addition of non-prohibited substances, which share common Metabolite(s) with Prohibited Substance(s).

52.3 (b) (4) EQAS Samples Containing Prohibited Substance(s), their Metabolite(s) or Marker(s), or the Marker(s) of Prohibited Method(s)

52.3 (b) (4) (i) The concentration(s) of selected Analyte(s) are those that may be encountered in the urine or blood after Use of Prohibited Substance(s) or Prohibited Method(s). For some Analytes, the EQAS Sample may contain the parent Prohibited Substance and/or its Metabolite(s) and/or its Marker(s).

52.3 (b) (4) (ii) EQAS Samples may be spiked with Prohibited Substance(s) and/or their Metabolite(s) or Marker(s) but would be preferably prepared from controlled Administration studies. The EQAS sample composition shall reflect as closely as possible the expected target Analyte Metabolite pattern and concentrations usually found in Samples.

52.3 (b) (4) (iii) A EQAS Samples may contain more than one Prohibited Substance, Metabolite(s), or Marker(s) of a Prohibited Substance or Prohibited Method. It may also contain multiple Metabolites or Markers of a single Prohibited Substance or Markers of a Prohibited Method, which would represent the presence of a single Prohibited Substance or the Use of a single Prohibited Method.

52.3 (b) (4) (iv) Double-blind EQAS samples should be representative of Samples. Therefore, to the extent possible (in consideration, for example, of technical or ethical constraints, availability of the pharmaceutical grade substance, etc.), double-blind EQAS samples containing Prohibited Substance(s) and/or Metabolite(s) of Prohibited Substance(s) and/or Marker(s) of Prohibited Substance(s) or Prohibited Method(s) should be prepared from controlled Administration studies performed in equine subjects. However, if this is not possible, then the double-blind EQAS sample(s) may be prepared by spiking expected target Analyte(s) in the Sample matrix in consideration of the representative metabolic profile(s).

52.3 (b) (4) (v) For Non-Threshold Substances, the concentration in the EQAS sample will be guided by, but not limited to, one of the following criteria: Concentrations of the Prohibited Substance and/or its Metabolite(s) or Marker(s) equal to or greater than (≥) the applicable MRPL; Concentrations of the Prohibited Substance and/or its Metabolite(s) or Marker(s) between 50% of the MPRL and the MRPL (applicable only to Non-Threshold Substances prohibited at all times and with no Minimum Reporting Levels); Non-Threshold Substances with Minimum Reporting Levels or other limits controlling them (e.g., substances prohibited on Race Day only), will normally be present in estimated concentrations greater than (>) 120% of the applicable Minimum Reporting Level; Concentrations of the Prohibited Substance and/or its Metabolite(s) or Marker(s) below (<) 50% of the applicable MRPL (for Non-Threshold Substances prohibited at all times with no Minimum Reporting Levels, for educational purposes).

52.3 (b) (4) (vi) For Threshold Substances, the concentration in the EQAS sample will be guided by, but not limited to, one of the following criteria: Greater than (>) 10% of the Threshold as established in the relevant Technical Document(s) or Laboratory Guidelines; At less than (<) 50% of the Threshold for those Threshold Substances specified in the TD DL whose presence shall be reported if detected in the presence of diuretics or masking agents.

52.3 (b) (5) Laboratory Analytical Testing Procedures Used in EQAS

52.3 (b) (5) (i) All procedures associated with the Analytical Testing of the EQAS samples by the Laboratory are to be conducted in a manner similar to that applied to routine Samples, unless otherwise specified by the Agency. No effort shall be made to optimize instrument (e.g., change multipliers or chromatographic columns) or method performance prior to analyzing the EQAS samples unless it is a scheduled maintenance activity. Only validated, Fit-for-Purpose Analytical Testing Procedures described in the Laboratory's SOPs are to be employed in the analysis of EQAS samples (i.e., using the Initial Testing Procedure(s)s and Confirmation Procedures applied

in routine Analytical Testing).

52.4 Reporting of EQAS results

52.4 (a) The purpose of the EQAS program is to ensure that all Laboratories maintain proficiency in the performance of their Analytical Testing Procedures and report valid results to the Agency in a timely manner.

52.4 (b) In the spirit of the EQAS program, a Laboratory shall not communicate with other Laboratories regarding the identity or content of substances present in or absent from blind EQAS samples prior to the submission of EQAS results to the Agency. This prohibition also applies to Laboratory requests for second opinions, which shall not be requested for blind EQAS samples.

52.4 (c) Contact between Laboratories regarding any aspect of blind EQAS analysis (including the results obtained) prior to reporting by all Laboratories to The Agency will be considered an attempt to circumvent the quality assessment.

52.4 (d) For double-blind EQAS samples, which are indistinguishable from routine Samples, consultation between Laboratories before reporting such EQAS results to the Agency may occur. However, such consultation shall not involve identifying the sample as an Agency double-blind EQAS sample (in cases when, for any reason, the Laboratory identifies the EQAS nature of the sample).

52.4 (e) Reporting Blind EQAS Results

52.4 (e) (1) The Laboratory shall report the results of blind EQAS samples to the Agency in the same manner as specified for routine Samples (see Article 53.7 (g)) unless otherwise notified by the Agency. For some blind EQAS samples or sample sets, additional information may be requested from the Laboratory (e.g., LODs, LOQs, MU estimations).

52.4 (e) (2) The results of the blind EQAS shall be submitted to the Agency on or before the specified reporting date unless an extension is granted by the Agency for valid reasons. Failure to report results of blind EQAS samples will be considered a false Negative Finding(s).

52.4 (f) Reporting Double-Blind EQAS Results

52.4 (f) (1) The Laboratory shall report the results of double-blind EQAS samples as per Article 53.7 (g)

52.4 (f) (2) Reporting of double-blind EQAS results should occur within the same timeframe as specified for routine Samples, unless an extension is granted by the Agency for valid reasons

52.4 (f) (3) Failure to report double-blind EQAS results within this timeframe or, subject to an extension of this deadline granted by the Agency based on valid reasons, within the agreed or the Agency-approved deadline, will be considered a false Negative Finding(s).

52.4 (g) Reporting Educational EQAS Results

52.4 (g) (1) The Laboratory shall report the results of open or blind educational EQAS samples on or before the specified reporting deadline and in a format specified by the Agency. Results received after the deadline will not be included in the assessment of EQAS results nor in the subsequent educational EQAS report and will be considered a false Negative Finding(s).

52.4 (g) (2) For open educational and blind EQAS samples, the Laboratory shall report the LODs of the identified Non-Threshold Substance(s) and/or Metabolite(s) and/or Marker(s), or of the identified Marker(s) of Prohibited Method(s), as estimated during method validation of the Initial Testing Procedure(s)

52.4 (h) Reporting Results for EQAS Samples Containing Non-Threshold Substances

52.4 (h) (1) Unless otherwise specified by the Agency (for example, for an educational EQAS), the report of EQAS results for Non-Threshold Substances shall include all the Analytes whose presence in the EQAS sample has been confirmed by the Laboratory in accordance with applicable Technical

Document(s), including the Prohibited Substance(s) (e.g., parent compound(s), if applicable) and all identified Metabolite(s) and/or Marker(s) of the Prohibited Substances or Marker(s) of Prohibited Method(s). The Agency may also require that the Laboratory report the estimated concentrations of the confirmed Analyte(s).

52.4 (i) Reporting Results for EQAS Samples Containing Threshold Substances

52.4 (i) (1) For educational and blind EQAS samples, the report of EQAS results for Threshold Substances shall include the values measured for each Aliquots analyzed, whenever the measured mean value of all replicates is greater than or equal to (≥) 50% of the applicable Threshold.

52.4 (i) (2) For double-blind EQAS samples, the Laboratory shall report the quantitative results to, and in a form designated by, the Agency has done for routine Samples, in accordance with the relevant Technical Document(s), Technical Letter(s) or Laboratory Guidelines.

53 Application of ISO/IEC 17025 to the Analysis of Samples

53.1 Introduction and Scope

53.1 (a) This section of the ESL is intended as an extension of the application of ISO/IEC 17025 and ILAC-G7 to the field of Doping Control. Any aspect of Analytical Testing or management not specifically discussed in this document or in the relevant Technical Documents, Technical Letters or Laboratory Guidelines shall be governed by ISO/IEC 17025. 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 Laboratory and are therefore significant in the evaluation and accreditation process.

53.1 (b) This section introduces the specific performance standards for a Laboratory, as applicable. The conduct of Laboratory Analytical Testing is considered a process within the definitions of ISO 17000. Performance standards are defined according to a process model where the Laboratory practice is structured into three (3) main categories of processes:

53.1 (b) (1) Structural and Resource Requirements

53.1 (b) (2) Process Requirements

53.1 (b) (3) Management Requirements

53.10 Storage of Samples

53.10 (a) Storage of Urine Samples

53.10 (a) (1) All urine Samples retained for storage in the Laboratory shall be stored frozen in a secure location under continuous chain of custody. The Laboratory shall keep all chain of custody and other records (either as hard-copy or in digital format) pertaining to those Samples.

53.10 (a) (1) (i) Urine Sample(s) without an Adverse Analytical Findingor Atypical Finding: The Laboratory shall retain the "A" and "B" urine Sample(s) without an Adverse Analytical Findingor Atypical Finding for a minimum of three (3) months after reporting the final analytical result to the Agency, and may be discarded after this time, unless the long-term storage of the Sample(s) has been requested, in writing or electronically, by the Agency and unless the Agency requests the Laboratory retain the Sample for a longer period.

53.10 (a) (1) (ii) Urine Samples with Irregularities: The Laboratory shall retain the "A" and "B" urine Sample(s) with irregularities for a minimum of three (3) months after reporting to the Agency, or for a longer period as determined by the Agency.

53.10 (a) (1) (iii) Urine Sample(s) with an Adverse Analytical Findingor Atypical Finding: The Laboratory shall retain the "A" and "B" urine Sample(s) with an Adverse Analytical Findingor Atypical Finding for a minimum of six (6) months after reporting the final analytical result (for the "A" or the "B" Sample, as applicable to, the Agency and shall not dispose without approval by the

Agency.

53.10 (a) (1) (iv) Urine Samples under challenge, dispute or investigation: If the Laboratory has been informed by the Agency (in writing and within the applicable storage period as defined in this Article 53.10 (a)) that the analysis of a urine Sample is challenged, disputed or under investigation, the Laboratory shall retain both the “A” and “B” Samples until further notice by the Agency, as applicable.

53.10 (b) Storage of Blood Samples

53.10 (b) (1) Samples for which Analytical Testing has been performed on blood serum/plasma fraction only (not on cellular components):

53.10 (b) (2) All serum or plasma Samples retained for storage in the Laboratory shall be stored frozen according to established protocols in a secure location under continuous chain of custody. The Laboratory shall keep all chain of custody and other records (either as hard-copy or in digital format) pertaining to those Samples.

53.10 (b) (2) (i) Serum/plasma “A” and “B” Samples without an Adverse Analytical Findingor Atypical Finding: The Laboratory shall retain the serum/plasma “A” and “B” Samples without an Adverse Analytical Findingor Atypical Finding for a minimum of three (3) months after reporting the final analytical result to the Agency, or for a maximum of ten (10) years after the Sample collection date, if the long-term storage of the Sample(s) has been requested by the Agency and unless the Agency requests the Laboratory retain the Sample for a longer period.

53.10 (b) (2) (ii) Serum/plasma “A” and “B” Samples without an Adverse Analytical Findingor Atypical Findings, analyzed only for TCO2 shall be retained for a minimum of one (1) month, unless otherwise requested by the Agency.

53.10 (b) (2) (iii) Serum/plasma Samples with irregularities: The Laboratory shall retain the serum/plasma Samples with irregularities for a minimum of three (3) months after reporting the final analytical result to the Agency, or for a longer period as determined by the Agency.

53.10 (b) (2) (iv) Plasma/serum “A” and “B” Sample(s) with an Adverse Analytical Findingor Atypical Finding: The Laboratory shall retain “A” and “B” plasma/serum Sample(s) with an Adverse Analytical Finding or Atypical Finding for a minimum of six (6) months after reporting the final analytical result (for the “A” or the “B” Sample, as applicable) to the Agency and shall not dispose without approval by the Agency.

53.10 (b) (2) (v) Plasma/serum “A” and “B” Sample(s) under challenge, dispute or investigation: If the Laboratory has been informed by the Agency (in writing and within the applicable storage period as defined in this Article 53.10 (b)) that the analysis of a serum/plasma Sample is challenged, disputed or under investigation, the Laboratory shall retain both the “A” and “B” Samples until further notice by the Agency, as applicable.

53.10 (b) (3) Samples for which Analytical Testing has been performed on cellular fractions of whole blood.

53.10 (b) (3) (i) Whole blood “A” and “B” Samples without an Adverse Analytical Findingor Atypical Finding: The Laboratory shall retain the whole blood Samples without an Adverse Analytical Finding or Atypical Finding for a minimum of one (1) month after reporting the final analytical result to the Agency.

53.10 (b) (3) (ii) Whole blood Samples with irregularities: The Laboratory shall retain the whole blood Samples with irregularities for a minimum of one month after reporting the final analytical results to the Agency, or for a longer period as requested by the Agency.

53.10 (b) (3) (iii) Whole blood “A” and “B” Sample(s) with an Adverse Analytical Findingor Atypical Finding: The Laboratory shall retain “A” and “B” whole blood Sample(s) with an Adverse Analytical Finding or Atypical Finding for a minimum of three (3) months after reporting the final analytical result (for the “A” or the “B” Sample, as applicable) to the Agency and shall not dispose without approval by the Agency.

53.10 (b) (3) (iv) Whole blood “A” and “B” Sample(s) under challenge, dispute or investigation: If the Laboratory has been informed by the Agency (in writing and within the applicable storage period as defined in this Article 53.10 (b)) that the analysis of a whole blood Sample is challenged,

disputed or under investigation, the Laboratory shall retain both the “A” and “B” Samples until further notice by the Agency, as applicable.

53.10 (c) Storage of Hair Samples

53.10 (c) (1) All hair Samples retained for storage in the Laboratory shall be stored in a secure location under continuous chain of custody.

53.10 (d) Storage of Other Samples

53.10 (d) (1) All other Samples should be stored in optimal conditions based on the available information applicable to the Sample type, and at the direction of the Agency. They shall be stored in a secure location under continuous Chain of Custody.

53.10 (e) Long-term Storage of Samples

53.10 (e) (1) At the direction of the Agency, any urine, serum/plasma, hair or other Sample may be stored in long-term storage after the Sample collection date for the purpose of Further Analysis, subject to the conditions set out in Articles 53.5 (i) (22), 53.10 (a) and 53.10 (b)

53.10 (e) (2) Sample(s) may be stored in long-term storage under the custody of either a Laboratory or another Fit-for-Purpose facility under the responsibility of the Agency, which has ownership of the Sample(s) pursuant to the Equine Testing and Investigations Standards. the Agency shall retain the Sample collection records pertaining to all stored Samples for the duration of Sample storage.

53.10 (e) (3) Laboratories as Sample Custodians:

53.10 (e) (3) (i) The Laboratory shall ensure that Samples are stored according to established protocols in a secure location in the Laboratory’s permanent controlled zone and under continuous Chain of Custody. The written request from the Agency for long-term storage of Samples shall be properly documented.

53.10 (e) (3) (ii) Samples may also be transported for long-term storage to a specialized, secure Sample storage facility, which is located outside the Laboratory’s permanent controlled zone and is under the responsibility of the Laboratory or may be transported to another Laboratory. If the external Sample storage facility is not covered by the Laboratory’s ISO/IEC 17025 accreditation, then the subcontracted external storage facility shall be Fit-for-Purpose and have its own ISO accreditation or certification (e.g., 17025, 20387, 9001). The transfer of the Samples to the external long-term storage facility or Laboratory shall be recorded.

53.10 (e) (3) (iii) If Sample(s) are to be transported for storage at a location outside the secured area of the Laboratory that first analyzed the Sample(s), the Laboratory shall secure the “A” Sample(s) to be shipped either by re-sealing individual “A” Sample container(s) with a Tamper Evident sealing system, which has similar capabilities for security and integrity as the original sealing system, or by sealing the box in which the Sample(s) are shipped in a manner that maintains Sample integrity and Chain of Custody.

53.10 (e) (3) (iv) “B” Sample(s) to be shipped shall be individually sealed, either in the original, sealed “B” Sample container(s) or, if previously opened, by re-sealing the individual “B” Sample container(s) with a Tamper Evident sealing system, which has similar capabilities for security and integrity as the original sealing system.

53.10 (e) (3) (v) During transport and long-term storage, Sample(s) shall be stored at a temperature appropriate to maintain the integrity of the Sample(s). In any anti-doping rule violation case, the issue of the Sample’s transportation or storage temperature shall be considered where failure to maintain an appropriate temperature could have caused the Adverse Analytical Findingor other result upon which the anti-doping rule violation is based.

53.10 (e) (3) (vi) The Laboratory shall retain all Laboratory Internal Chain of Custody and technical records (as per ISO/IEC 17025) pertaining to a stored Sample for the duration of Sample storage, either as hard-copy or in digital format. In addition, the Laboratory may retain Sample analytical data which would allow retrospective analysis of such data, for example, for the purpose of identifying signals for novel Metabolite(s) of Prohibited Substance(s) or Marker(s) of Prohibited Substance(s) or Prohibited Method(s) (e.g., full-scan mass spectrometry data) as detailed in

Article 53.5 (i) (22).

53.10 (e) (3) (vii) If Sample(s) are transported to another Laboratory for long-term storage, the Sample's external Chain of Custody and other non-analytical records (e.g., Sample collection documentation), available to the transferring Laboratory, shall also be transferred, immediately or upon later request, to the Laboratory storing the Samples or to the Agency, either as originals or copies.

53.10 (e) (4) the Agency as Sample Custodians:

53.10 (e) (4) (i) Sample(s) may also be transported for long-term storage to a Fit-for-Purpose, secure Sample storage facility, which is under the responsibility of the Agency. In such cases, the external storage facility shall have its own ISO accreditation or certification (e.g. 17025, 20387, 9001) and shall maintain security requirements comparable to those applicable to a Laboratory. The Agency shall ensure that Samples are stored according to established protocols in a secure location under continuous Chain of Custody.

53.10 (e) (4) (ii) The written request from the Agency for the transfer of the Sample(s) to long-term storage shall be properly documented. The transfer of the Samples to the external long-term storage facility shall also be recorded. The Laboratory shall secure the Sample(s) for transportation to the long-term storage facility as described above.

53.10 (e) (4) (iii) The Laboratory shall retain all Laboratory Internal Chain of Custody and technical records (as per ISO/IEC 17025) pertaining to all Samples transferred for long-term storage for the duration of Sample storage, either as hard-copy or in digital format. In addition, the Laboratory may retain Sample analytical data which would allow retrospective analysis of such data. The Laboratory shall transfer the Sample's external Chain of Custody and other non-analytical records to the Agency, either as originals or copies, immediately or upon request.

53.11 Secondary Use or Disposal of Samples and Aliquots

53.11 (a) The Laboratory shall maintain SOP(s) pertaining to the secondary use of Samples or Aliquotss for research or quality assurance, as well as for the disposal of Samples and Aliquots.

53.11 (b) If the Laboratory has discretion to dispose of a Sample, the Laboratory shall do one of the following with the Sample(s) and Aliquots as soon as practicable:

53.11 (c) Disposal of the Sample(s) and Aliquotss

53.11 (c) (1) Disposal of Samples and Aliquots shall be recorded under the Laboratory Internal Chain of Custody.

53.11 (d) Secondary use of Samples and Aliquots for Research and Quality Assurance

53.11 (d) (1) Samples and Aliquots shall be anonymized to ensure that any subsequent results cannot be traced back to a particular Covered Person or Covered Horse (see Protocol). Only after anonymization, may a Sample or Aliquot be used for:

53.11 (d) (1) (i) Anti-doping research. The Covered Person or their representative's consent is not required for these purposes.

53.11 (d) (1) (ii) Quality assurance, quality improvement of existing Test Methods, development or evaluation of Analytical Testing Procedures for Prohibited Substances or Prohibited Methods included in the Prohibited List at the time of Sample collection, or to establish reference population ranges or Thresholds or other statistical purposes. The Covered Person or their representative's consent is not required for these purposes.

53.11 (e) The use of Samples and Aliquots for the purposes of this Article 53.11 (d) is subject to the following

conditions:

53.11 (e) (1) The Laboratory must respect the Protocol and the ESL Code of Ethics requirements related to research, types of permitted research, and respect of ethical standards for research or quality assurance studies involving equine subjects;

53.11 (e) (2) The Laboratory must not make any attempt to re-identify a Covered Person and/or Covered Horse from Samples or Aliquots used for the purposes of this Article 53.11 (d) or data arising from any research or quality assurance analysis;

53.11 (e) (3) The Laboratory must consult the applicable national regulations, guidance, or authorities to determine whether a study should be considered as falling under Article 53.11 (d) (1) (i) or Article 53.11 (d) (1) (ii));

53.11 (e) (4) In the event the Laboratory wishes to transfer Sample(s) or Aliquots to be used for the purposes of this Article 53.11 (d) to another Laboratory or a third-party research institution or group, or wishes to partner with another Laboratory or research institution or group for the purpose of an Article 53.11 (d) (1) (i) study, the Laboratory shall subject the receiving party to the conditions described in this Article 53.11 (d) (1) (i) by way of a written agreement and shall prohibit the receiving party from further transferring any Sample(s) or Aliquots or related data to another party.

53.12 Management Requirements

53.12 (a) Organization

53.12 (a) (1) Within the framework of ISO/IEC 17025, the Laboratory shall be considered as a testing laboratory.

53.12 (a) (2) Management Reviews

53.12 (a) (2) (i) Management reviews will be conducted to meet the requirements of ISO/IEC 17025.

53.12 (b) Document Control

53.12 (b) (1) The control of documents that make up the Management System shall meet the requirements of ISO/IEC 17025. The Laboratory Director (or designee) shall approve the Management System documentation and all other documents used by Laboratory staff members involved in Analytical Testing.

53.12 (c) Control and Storage of Technical Records

53.12 (c) (1) The Laboratory shall keep a copy of all Sample records to the extent needed to produce Laboratory Documentation Packages or Certificates of Analysis, in accordance with the Technical Document, in a secure storage until Sample disposal or anonymization (see Article 53.11 (d)).

53.12 (d) Cooperation with the Agency

53.12 (d) (1) Cooperation with the Agency shall be handled in accordance with ISO/IEC 17025.

53.12 (d) (2) Ensuring Responsiveness to the Agency

53.12 (d) (3) The Laboratory Director or their designee shall:

53.12 (d) (3) (i) Ensure adequate communication with the Agency in a timely manner;

53.12 (d) (3) (ii) Provide complete, appropriate and timely explanatory information as requested by the Agency;

53.12 (d) (3) (iii) Report to the Agency any unusual circumstances or information with regard to

Analytical Testing, patterns of irregularities in Samples, or potential Use of new substances;

53.12 (d) (3) (iv) Provide documentation to the Agency [e.g., Management System documentation, SOPs, contracts (not including commercial or financial information) or Delegated Third Parties working on behalf of the Agency upon request to ensure conformity with the rules established under the Protocol as part of the maintenance of HEAL accreditation. This information shall be treated in a confidential manner.

53.12 (d) (4) The Laboratory Director shall be familiar with the Protocol and the Prohibited List.

53.12 (d) (5) The Laboratory Director shall interact with the Agency in regard to specific timing, report information, or other support needs. These interactions should occur in a timely manner and should include, but are not limited to, the following:

53.12 (d) (5) (i) Communicating with the Agency concerning any significant question of Analytical Testing needs or any unusual circumstance in the Analytical Testing process (including delays in reporting);

53.12 (d) (5) (ii) Providing complete, timely and unbiased explanations to the Agency when requested or when there is a potential for misunderstanding of any aspect of the Analytical Testing process, Laboratory Test Report, Certificate of Analysis or Laboratory Documentation Package;

53.12 (d) (5) (iii) If requested by the Agency, the Laboratory shall provide advice and/or opinion regarding the Prohibited Substances and Prohibited Methods included in the Analytical Testing Procedures;

53.12 (d) (5) (iv) Providing evidence and/or expert testimony on any test result or report produced by the Laboratory as required in administrative, arbitration, or legal proceedings. The requests from such expert testimonies shall originate, in writing, from the Agency or adjudication bodies as part of the Results Management process. The Laboratory shall not provide expert testimony to Covered Persons or their representatives, including their legal counsels;

53.12 (d) (5) (v) Responding to any complaint submitted by the Agency concerning the Laboratory and its operation.

53.12 (d) (5) (vi) As required by ISO/IEC 17025, the Laboratory shall actively monitor the quality of the services provided to the Agency, including the introduction of an annual questionnaire to clients to assess their satisfaction (or otherwise) with the performance of the Laboratory. There should be documentation that the Agency's concerns have been incorporated into the Laboratory's Management System where appropriate

53.2 Structural and Resource Requirements

53.2 (a) General

53.2 (a) (1) General structure and resource requirements shall be provided in accordance with the requirements of ISO/IEC 17025.

53.2 (a) (2) The Laboratory shall have available the personnel, facilities, equipment, systems and support services necessary to manage and perform its Laboratory activities.

53.2 (b) Laboratory Personnel

53.2 (b) (1) The Laboratory Director is responsible for ensuring that the Laboratory personnel are adequately trained and have the experience and skills necessary to perform their duties.

53.2 (b) (2) All personnel shall have a thorough knowledge of their responsibilities including the security of the Laboratory, the Code of Ethics, confidentiality of Analytical Testing results, Laboratory Internal Chain of Custody protocols, and the Standard Operating Procedures (SOPs) for any Analytical Testing Procedure that they perform

53.2 (b) (3) The Laboratory shall have access to records for every Person employed by, or under

contract with, the Laboratory including a curriculum vitae or qualification form(s)/certificate(s), a job description, records of completed and ongoing training and records of authorization to perform their defined duties.

53.2 (b) (4) Specific criteria shall be met by the Laboratory Director, Laboratory Quality Manager, Laboratory Certifying Scientists, and Laboratory Supervisory Personnel, as outlined below.

53.2 (b) (5) Laboratory Director

53.2 (b) (5) (i) The Laboratory shall have a qualified Person as the Laboratory Director, whose priority is to assume and focus on the professional, organizational, educational, operational and administrative responsibilities of the Laboratory's operations. The Laboratory Director plays an essential role in the anti-doping Laboratory's operations and the HEAL accreditation is delivered based upon such qualification as well as on the Laboratory's operational performance. A suitably qualified person with a Doctoral degree or equivalent would be desirable, in any event they shall possess the necessary expertise relevant equine anti-doping and medication control.

53.2 (b) (5) (ii) Any personnel changes to the position of Laboratory Director shall be communicated to the Agency no less than one (1) month, or as soon as practicable, prior to the scheduled date the Laboratory Director vacates their position.

53.2 (b) (6) Laboratory Quality Manager

53.2 (b) (6) (i) The Laboratory shall have a single staff member appointed as the Laboratory Quality Manager. The Quality Manager shall have responsibility and authority to implement and ensure compliance with the Management System. The Quality Manager's priority and functions shall be focused on quality assurance and quality control activities. The Quality Manager should remain independent, as much as possible, from routine Laboratory analytical activities. By 1 January 2025 the Quality Manger shall be independent from routine Laboratory analytical activities. Quality control activities including ISO/IEC 17025.

53.2 (b) (7) Laboratory Certifying Scientists

53.2 (b) (7) (i) The Laboratory shall have qualified personnel to serve as Certifying Scientists to review all pertinent analytical data, Analytical Method validation results, quality control results, Laboratory Documentation Packages, and to attest to the validity of the Laboratory's test results.

53.2 (b) (8) Laboratory Supervisory Personnel

53.2 (b) (8) (i) The Laboratory shall have qualified personnel to serve as Laboratory Supervisors. All Laboratory Supervisors shall have a thorough understanding of the Laboratory's Management System including the review, interpretation and reporting of test results, the maintenance of Laboratory Internal Chain of Custody, and proper implementation of corrective and preventive actions in response to analytical problems

53.2 (c) Laboratory Facilities and Environmental Conditions

53.2 (c) (1) Laboratory Facilities

53.2 (c) (1) (i) The Laboratory shall have Fit-for-Purpose facilities including sufficient space for dedicated administrative, Sample handling, Sample storage and analytical areas, which comply with the security requirements outlined below:

53.2 (c) (1) (ii) A Person shall be assigned as the security officer, who has overall knowledge of the security system and/or serves as the liaison Person with the security services of the host organization (e.g., university, hospital, research institute);

53.2 (c) (1) (iii) The Laboratory shall have a policy for the security of its facilities, equipment and systems against unauthorized access, which may include a threat and risk assessment performed by expert(s) in the relevant field;

53.2 (c) (1) (iv) Two (2) main levels of access shall be defined in the Management System and

evaluated in the threat assessment plan:

53.2 (c) (1) (iv) (A) Reception Zone: An initial point of control beyond which unauthorized individuals shall not be permitted. The Laboratory shall have a system to register visitors and authorized individuals to the Laboratory. They shall be supplied with an identification badge while in the Laboratory facilities.

53.2 (c) (1) (iv) (B) Controlled Zones: Access to these areas shall be monitored (e.g., through the use of electronic access system(s) such as biometric and/or personal identification cards) and records of access by visitors shall be maintained; Access to the Laboratory Controlled Zones shall be monitored and restricted to Laboratory staff and temporarily approved/authorized personnel (e.g., maintenance engineers, auditing teams). All other visitors to the Laboratory Controlled Zones shall be continuously escorted by Laboratory staff member(s). Access to the Laboratory Controlled Zones shall be defined in the Laboratory's Management System.

53.2 (c) (1) (ix) Samples may be transported for long-term storage to a third-party, secure Sample storage facility, which is located outside the Laboratory's permanent controlled zone, to another Laboratory, or to another Fit-for-Purpose facility under the responsibility of the Agency, which has ownership of the Sample(s). Long-term storage facilities shall maintain security requirements comparable to the security requirements applicable to a Laboratory's short-term storage of Samples. If the external Sample storage facility is not covered by the Laboratory's ISO/IEC 17025 accreditation, then the subcontracted external storage facility shall have its own ISO accreditation or accredited certification (i.e., 17025, 20387, 9001). The transfer of the Samples to the long-term storage facility shall be recorded. The Laboratory may implement additional security measures, which should be assessed on a case-by-case basis.

53.2 (c) (1) (v) The Laboratory shall have a dedicated and restricted area within the Controlled Zone for Sample receipt and Aliquot preparation;

53.2 (c) (1) (vi) Access to the Laboratory's Sample receipt and Aliquot preparation area shall be restricted to authorized personnel, based on a risk assessment by the Laboratory.

53.2 (c) (1) (vii) The Laboratory shall have a dedicated and restricted Sample storage area;

53.2 (c) (1) (viii) Access to stored Samples shall be restricted to authorized personnel, based on a risk assessment by the Laboratory.

53.2 (c) (1) (x) Environmental Control

53.2 (c) (2) Relocation of Laboratory Facilities

53.2 (c) (2) (i) In cases where a Laboratory is to relocate to a new physical space, on a permanent or temporary basis, a report containing the following information shall be provided to the Agency no later than three (3) months prior to the relocation:

53.2 (c) (2) (ii) Description of the circumstances for moving Laboratory operations into a new space and anticipated effect on capabilities;

53.2 (c) (2) (iii) Relocation date(s) including date of closing of existing facility operations and date of opening of future facility operations;

53.2 (c) (2) (iv) Expected date(s) of assessment of the new facilities by the Accreditation Body (evidence of continued accreditation and/or acceptance of suitability of the new Laboratory facilities required when made available by the Accreditation Body); and

53.2 (c) (2) (v) New Laboratory contact information and coordinates

53.2 (c) (3) Environmental Control

53.2 (c) (3) (i) The Laboratory shall have a written safety policy and compliance with Laboratory safety policies shall be enforced.

53.2 (c) (3) (ii) The Laboratory's storage and handling of controlled substances shall comply with applicable national legislation.

53.2 (c) (3) (iii) The Laboratory shall: Ensure appropriate safeguards to electrical service (for example, by provision of an alternative power supply such as a UPS system and/or power generators, due to costs and complexity, this could be laboratory-wide and/or instrument-specific) and environmental conditions (space, temperature, humidity, as applicable) for all Laboratory instrumentation and equipment critical to Laboratory operations, such that service is reasonably maintained and any damage is minimized should there be a power interruption. Have policies in place to ensure the integrity of refrigerated and/or frozen stored Samples in the event of an electrical or freezer/refrigerator equipment failure.

53.2 (c) (4) Confidentiality of Data, Information and Operations

53.2 (c) (4) (i) The Laboratory should either file securely any confidential or sensitive information or properly destroy it before disposal. Laboratory staff shall be appropriately trained to comply with confidentially requirement.

53.2 (c) (4) (ii) To minimize any attempts of fraud or counterfeit, the Laboratory should implement a policy to ensure that discarded urine and blood Sample containers, cannot be collected by unauthorized Persons or recovered after disposal (for example, bottles should be recycled or destroyed, or trash containers should be properly secured).

53.2 (c) (5) Control and Security of Electronic Data and Information

53.2 (c) (5) (i) The Laboratory shall implement all reasonable measures, based on a thorough risk and vulnerability assessments (e.g., by a competent third party), to prevent and to detect unauthorized access and copying of Laboratory data and information from local and/or cloud-based computerized systems. Laboratories shall implement technical and organizational safeguards consistent with best practice and any applicable governmental regulations.

53.2 (c) (5) (ii) Access to Laboratory computer terminals, computers, servers or other operating equipment shall be restricted to authorized personnel (e.g., by using access passwords).

53.2 (c) (5) (iii) The Laboratory shall implement a data and information management system, a software-based solution that supports and maintains proper traceability of Laboratory operations (e.g., a Laboratory Information Management System, LIMS) with secure and restricted access to stored electronic data by authorized personnel as well as information and data exchange capabilities including between the Laboratory and the Agency.

53.2 (c) (5) (iv) The Laboratory shall utilize a secure data storage system that prevents unauthorized access and data loss (e.g., failed hard drive, fire, flooding). The Laboratory shall ensure that at least two (2) independent, regularly backed-up copies of all relevant analytical/LIMS/instrument software files are available. If the Laboratory is utilizing a non-cloud-based system, then at least one backup copy shall be stored in a restricted and secure environment either in the Laboratory (e.g., fire and waterproof safe) or in a secure off-site location (e.g., in a mirrored server that guarantees the integrity of the server and the stored data); If the Laboratory is using a cloud-based system, the Laboratory data shall be, at a minimum, replicated in two different physical locations (e.g., between two different availability zones within the same region or between different regions) in order to minimize the possibility of data loss.

53.2 (c) (5) (v) The software utilized by the Laboratory shall prevent the changing of data and test results, unless there is a system to record the change with audit trail capabilities which is limited to users with authorized access. The audit trail shall record the Person performing the editing task, the date and time of the edit, the reason(s) for the change to the original data and allow the retention of the original data.

53.2 (c) (5) (vi) If the Laboratory utilizes third-party computerized systems or software, the Laboratory shall ensure the provider or operator complies with all applicable requirements of the Protocol and the ESL and shall implement and maintain technical and organizational controls necessary to safeguard Laboratory data.

53.2 (d) Laboratory Equipment

53.2 (d) (1) The Laboratory shall have access to equipment that is required for the correct performance of Analytical Testing activities. The Laboratory shall maintain sufficient instrumental capacity to minimize the risk of operational delays and meet the analytical and results reporting obligations. A list of available

equipment shall be established and maintained. All maintenance, service, and repair of equipment shall be recorded.

53.2 (d) (2) As part of its Management System, the Laboratory shall operate a program for the maintenance and calibration of equipment according to ISO/IEC 17025. Calibrations are only required where the setting can change the test result. A maintenance schedule, at least in accordance with the manufacturer's recommendations or local regulations, if available, shall be established for general Laboratory equipment that is used in Analytical Testing Procedure(s).

53.2 (d) (3) General Laboratory equipment (fume hoods, centrifuges, evaporators, etc.) that is not used for analytical measurements should be maintained by visual examination, safety checks, performance verification and cleaning, as necessary.

53.2 (d) (4) Equipment or volumetric devices used in measuring shall have periodic performance checks and/or calibrations along with servicing, cleaning, and repair.

53.2 (e) Metrological Traceability

53.2 (e) (1) Reference Materials

53.2 (e) (1) (i) When available, Reference Materials of substances traceable to a national standard or certified by a body of recognized status (e.g., USP, BP, Ph.Eur. WHO) or a Reference Material producer accredited to ISO 17034 should be used.

53.2 (e) (1) (ii) When a Reference Material is not certified, the Laboratory shall verify its identity and check its purity by comparison with published data and/or by chemical characterization.

53.2 (e) (2) Reference Collections

53.2 (e) (2) (i) Samples or isolates may be obtained from in vitro or in vivo sources [e.g., (i) an external quality control sample, (ii) an isolate from a urine or blood sample after an authenticated Administration, or (iii) an "in-vitro" incubation with liver cells, microsomes or biological fluids] and be used as Reference Collections.

53.2 (e) (2) (ii) Reference Collections shall be traceable to a Prohibited Substance or a Prohibited Method, and the analytical data shall be sufficient to establish the identity of the Analyte.

53.2 (f) Subcontracting of Analysis

53.2 (f) (1) A Laboratory shall perform all work with qualified personnel and equipment within its accredited facility.

53.2 (f) (2) A Laboratory may subcontract an analysis to another Laboratory, in consultation and following written approval from the Agency. The conditions that justify subcontracting include, for example:

53.2 (f) (3) A specific technology or Analyte(s) that are not within the Laboratory's Scope of ISO/IEC 17025 Accreditation;

53.2 (f) (3) (i) An Analytical Testing Restriction decision;

53.2 (f) (3) (ii) Other justifications such as a need for higher sensitivity or specific equipment or expertise, temporary workload or technical incapacity;

53.2 (f) (3) (iii) In exceptional circumstances, the Agency may elect to grant specific authorization to subcontract analyses using specific methods to an ISO/IEC 17025-accredited laboratory approved by the Agency, which has the necessary technique within its Scope of ISO/IEC 17025 Accreditation (for example, DNA analysis or genomic profiling);

53.2 (f) (3) (iv) Other specific investigations, such as, without limitation, forensic examinations which need to be performed in the course of the Analytical Testing process may also be subcontracted by the Laboratory.

53.2 (f) (4) In all such cases, the Laboratory subcontracting the analysis is only responsible for the maintenance of the appropriate chain of custody up to Sample reception by the subcontracted Laboratory. Such arrangements shall be clearly recorded as part of the Sample's documentation and included in the Laboratory Documentation Package, if applicable.

53.2 (g) Purchasing of Services and Supplies

53.2 (g) (1) Chemicals and reagents shall be Fit-for-Purpose and be of appropriate purity. Documentation indicating the purity of Reference Materials/Standards shall be obtained when available and retained in the Management System documentation. Chemicals, reagents and kits labelled (e.g., "Research Only" or "Forensic Use Only") may be utilized for the purposes of Doping Control as long as they are demonstrated to be Fit-for-Purpose by the Laboratory and/or the Agency.

53.2 (g) (2) In the case of rare or difficult to obtain Reference Materials, or Reference Collections for use in qualitative Analytical Testing Procedures, the expiration date can be extended if adequate documentation exists confirming that no significant deterioration has occurred or that appropriate purification or verification of Fitness-for-Purpose has been performed. The process to extend the expiration date of a Reference Material, Reference Collection, or solution shall be described in the Laboratory's Management System documentation.

53.2 (g) (3) The Laboratory shall maintain control and proper records of use of controlled chemicals and reagents in accordance with national laws and other relevant regulations.

53.2 (g) (4) Waste disposal shall be in accordance with national laws and other relevant regulations. This includes biohazard materials, chemicals, controlled substances, and radioisotopes, if used.

53.2 (g) (5) Environmental health and safety policies shall be in place to protect the staff, the public, and the environment.

53.3 Process Requirements

53.3 (a) The Laboratory shall maintain paper or (ideally) electronic Laboratory Internal Chain of Custody in compliance with the TD.

53.3 (b) Reviewing of Requests, Tenders and Contracts

53.3 (b) (1) Review of legal documents or agreements related to Analytical Testing shall meet the requirements of ISO/IEC 17025.

53.3 (c) Reception, Registration and Handling of Samples

53.3 (c) (1) The Laboratory may receive Samples, which have been collected, sealed and transported to the Laboratory according to the Equine Testing and Investigations Standards.

53.3 (c) (2) The transfer of the Samples from the courier or other delivery Person shall be recorded including, at a minimum, the date, the time of receipt, the initials or (electronic) signature of the Laboratory representative receiving the Samples and the courier company tracking number, if applicable. This information shall be included into the Laboratory Internal Chain of Custody record(s) of the Sample(s).

53.3 (c) (3) The Sample transport container & each individual sample shall be inspected, and any irregularities recorded (see Article 53.3 (e)). However, Samples transferred for long-term storage purposes are not subject to an individual inspection by the receiving Laboratory until a Sample has been selected for Further Analysis.

53.3 (c) (4) 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 information.

53.3 (d) Acceptance of Samples for Analysis

53.3 (d) (1) The Laboratory shall analyze each Sample received, unless, unless otherwise instructed by the Agency.

53.3 (d) (2) If justified by the Sample irregularities observed (see Article 53.3 (e)), the Laboratory shall seek instructions from the Agency on the performance of Analytical Testing on the Sample. The Agency shall inform the Laboratory in writing whether a Sample with noted irregularities should be analyzed or not, and/or of any further measures to be taken (e.g., splitting the Sample in accordance with Article 53.3 (f), forensic analysis, DNA analysis), or that the Sample should be stored for Further Analysis. The communication between the Laboratory and the Agency shall be recorded as part of the Sample's documentation.

53.3 (e) Samples with Irregularities

53.3 (e) (1) The Laboratory shall observe and document conditions that exist at the time of Sample reception or registration that may adversely impact on the integrity of a Sample or on the performance of Analytical Testing Procedures. Only unusual conditions shall be recorded.

53.3 (e) (2) Irregularities to be noted by the Laboratory may include, but are not limited to:

53.3 (e) (2) (i) Sample transport conditions (e.g., delivery time, temperature), which may impact the integrity of the Sample for Analytical Testing, as determined by the Laboratory;

53.3 (e) (2) (ii) Sample collection information (including Sample identification Protocol), which is necessary to conduct the requested Analytical Testing menu, is not provided, e.g., missing or incomplete Sample collection documentation;

53.3 (e) (2) (iii) Sample identification is questionable. For example, the number on the Sample container does not match the Sample identification number on the Sample collection documentation;

53.3 (e) (2) (iv) Covered Person or Covered Horse information is visible on the Laboratory copy of the Sample collection documentation or any other document transferred to the Laboratory;

53.3 (e) (2) (ix) The Sample contains foreign objects, such as insects;

53.3 (e) (2) (v) Sample identification numbers are different between the "A" and the "B" Sample containers of the same Sample;

53.3 (e) (2) (vi) Tampering or adulteration of the Sample is evident;

53.3 (e) (2) (vii) Sample is not sealed with Tamper-Evident device or not sealed upon receipt;

53.3 (e) (2) (viii) Sample volume does not meet the suitable volume for analysis or is otherwise inadequate to perform the requested Analytical Testing menu;

53.3 (e) (2) (x) The Sample condition(s) is unusual – for example: color, odor, presence of turbidity or foam in a urine Sample; color, hemolysis, freezing or clotting of a blood Sample; unusual differences in Sample appearance (e.g., color and/or turbidity) between the "A" and the "B" Samples.

53.3 (e) (3) When an analysis on a Sample with documented irregularities is performed, the Laboratory shall record the irregularities in the Test Report.

53.3 (f) Sample Splitting Procedure

53.3 (f) (1) In cases when either the "A" or "B" Sample is not suitable for the performance of the analyses (e.g., there is insufficient Sample volume; the Sample container has not been properly sealed or has been broken; the Sample's integrity has been compromised in any way; the Sample is heavily contaminated, the "A" or "B" Sample is missing), the Laboratory shall notify and seek authorization from the Agency to split the other Sample container ("A" or "B", as applicable), provided that it is properly sealed. The Agency shall inform the Laboratory of its decision in writing within three (3) days of notification by the Laboratory. If the Agency decides not to proceed with the Sample splitting procedure, then the Laboratory shall report the Sample as Not Analyzed to, and in a form designated by, the Agency, including the noted Sample irregularities and the documented reasons if provided by the Agency.

53.3 (f) (2) The first fraction of the split Sample shall be considered as the "A" Sample and shall be used for the Initial Testing Procedure(s), unless the Initial Testing Procedure(s) have already been performed,

and the “A” Confirmation Procedure(s), if necessary. The second fraction, considered as the “B” Sample, shall be resealed and stored frozen for “B” Confirmation Procedure(s), if necessary.

53.3 (f) (3) The process of opening and splitting the Sample and resealing of the remaining second fraction shall be conducted in accordance with Article 53.5 (i) (13) for a customary “B” Sample opening.

53.3 (f) (4) When the splitting procedure concerns blood Samples, which have been collected for Analytical Testing on the blood serum/plasma fraction, the sealed, intact (“A” or “B”) Sample shall be centrifuged as soon as practical after Laboratory reception to obtain the serum or plasma fraction. The centrifuged Sample shall be stored frozen in the sealed Sample collection tube according to established protocols until the Sample opening/splitting procedure can be conducted. The opening of the Sample for the splitting of the serum/plasma fraction and resealing of the second fraction shall be carried out as described immediately above.

53.3 (g) Initial Storage and Sample Aliquoting for Analysis

53.3 (g) (1) The Aliquot preparation procedure for any Initial Testing Procedure(s) or Confirmation Procedure shall minimize the risk of contamination of the Sample or Aliquot. The Laboratory shall use new material(s) (e.g., new test tubes, disposable pipettes or pipettes with disposable, non-reusable tip) to take Aliquots for Confirmation Procedures.

53.3 (g) (2) Urine Samples

53.3 (g) (2) (i) In order to maintain the stability and integrity of the urine Samples, the Laboratory shall implement Sample storage procedures that minimize storage time at room and refrigerated temperatures as well as Sample freeze/thaw cycles.

53.3 (g) (2) (ii) For urine Samples, the Laboratory shall obtain, following proper homogenization of the Sample, an initial Aliquot containing enough Sample volume for all analytical procedures (all Initial Testing Procedure(s) or all intended Confirmation Procedures, as applicable), by decanting the Aliquot from the urine Sample container into a secondary container (e.g., a Falcon tube). Procedure-specific Aliquot(s) shall then be taken from the secondary container.

53.3 (g) (2) (iii) The Laboratory shall measure the pH and Specific Gravity of urine Samples once, using one Aliquot, during the Initial Testing Procedure(s) and the Confirmation Procedure(s) (“A” and “B” Samples). Other tests that may assist in the evaluation of adulteration or manipulation may be performed if deemed necessary by the Laboratory.

53.3 (g) (2) (iv) Urine “A” Samples should be frozen after Aliquots are taken for the Initial Testing Procedure(s) to minimize risks of Sample microbial degradation. Urine “B” Samples shall be stored frozen after reception until analysis, if applicable.

53.3 (g) (3) Blood Samples

53.3 (g) (3) (i) The Laboratory shall follow the applicable Technical Document(s) and Technical Letter(s) for handling and storing blood Samples.

53.4 Selection and Validation of Analytical Testing Procedures

53.4 (a) The Laboratory shall select, validate, and document Analytical Testing Procedures, which are Fit-for-Purpose for the analysis of representative target Analytes of Prohibited Substances and Prohibited Methods.

53.4 (b) Validation results for Analytical Testing Procedures shall be summarized in a Validation Report and supported by the necessary documentation and analytical data. The Validation Report shall indicate whether the Analytical Testing Procedure is Fit-for-Purpose and shall be included in a Laboratory Scope of Accreditation.

53.4 (c) The Laboratory shall define and document the conditions that would trigger the revalidation of an Analytical Testing Procedure (e.g., change of internal standard, modified extraction procedure or chromatographic methodology, change in detection technique) or a partial re-assessment of the validation process (e.g., replacement or upgrade of instrument, addition of new Analyte to the Analytical Method).

53.4 (d) Validation of Analytical Testing Procedures for Non-Threshold Substances

53.4 (d) (1) The Laboratory shall develop, as part of the method validation process, appropriate standard solutions for detection and/or identification and estimation of the concentration of Non-Threshold Substances. In the absence of suitable Reference Materials, Reference Collections may be used for detection and identification.

53.4 (d) (2) Validation of Initial Testing Procedure(s) for Non-Threshold Substances

53.4 (d) (2) (i) The Laboratory shall validate the Selectivity, carryover, reliability of detection at the MRPL and Limit of Detection (LOD) for the Initial Testing Procedure(s) from the analysis of an adequate number of representative samples prepared in the appropriate matrix of analysis. For chromatographic-mass spectrometric Analytical Methods, the Initial Testing Procedure shall allow the detection of each Non-Threshold Substance or its representative Metabolite(s) or Marker(s) at 50% or less of the Minimum Required Performance Levels (MRPL).

53.4 (d) (2) (ii) For Non-Threshold Substances with Minimum Reporting Levels (MRL), the Laboratory shall validate and document the concentration levels that will require a Confirmation Procedure.

53.4 (d) (2) (iii) If there is no available Reference Material, an estimate of the detection capability of the Initial Testing Procedure(s) (i.e., the LOD) for the Non-Threshold Substance or its representative Metabolite(s) or Marker(s) may be provided by assessing a representative substance from the same class of Prohibited Substances with a similar chemical structure.

53.4 (d) (3) Validation of Confirmation Procedures for Non-Threshold Substances

53.4 (d) (3) (i) Factors to be investigated in the method validation procedure to demonstrate that a Confirmation Procedure for Non-Threshold Substances is Fit-for-Purpose include, but are not limited to:

53.4 (d) (3) (ii) Selectivity: The ability of the Confirmation Procedure to detect and identify the Analyte of interest, taking into account interference(s) from the matrix or from other substance(s) present in the Sample. Selectivity shall be determined and documented from the analysis of an adequate number of representative samples prepared in the matrix of Sample analysis, in compliance with the applicable Technical Document, Technical Letter or Laboratory Guidelines. The Confirmation Procedure shall be able to discriminate between Analytes of closely related structures;

53.4 (d) (3) (iii) Limit of Identification (LOI): When the analyses of Non-Threshold Substances are based on chromatographic-mass spectrometric techniques, the Laboratory shall determine the lowest concentration at which each Non-Threshold Substance or its representative Metabolite(s) or Marker(s), for which a Reference Material is available, is identified at no more than 5% false negative rate (in compliance with the applicable Technical Document, Technical Letter or Laboratory Guidelines). The LOI shall be lower than the applicable MRPL;

53.4 (d) (3) (iv) Robustness: The Confirmation Procedure shall be demonstrated to produce similar results with respect to minor variations in analytical conditions, which may affect the results of the analysis. Those conditions that are critical to ensuring Reproducible results shall be considered;

53.4 (d) (3) (v) Carryover: The conditions required to eliminate carryover of the substance of interest from Sample to Sample during processing or instrumental analysis.

53.4 (e) Validation of Analytical Testing Procedures for Threshold Substances

53.4 (e) (1) As part of the validation process for chromatography-mass spectrometric Analytical Methods applied to the analysis of Threshold Substances, the Laboratory shall develop acceptable standard solutions for identification of Threshold Substances. For Confirmation Procedures, Certified Reference Materials should be used for quantification, if available.

53.4 (e) (2) For the application of affinity-binding assays, or other methods as applicable, to the analysis of Threshold Substances, the Laboratory shall follow the applicable Technical Document and should follow applicable Laboratory Guidelines.

53.4 (e) (3) Validation of Initial Testing Procedure(s) for Threshold Substances

53.4 (e) (3) (i) The Laboratory shall validate Initial Testing Procedure(s) that are Fit-for-Purpose, in accordance with relevant Technical Document(s), Technical Letter(s) or Laboratory Guidelines

53.4 (e) (3) (ii) For chromatographic-mass spectrometric Initial Testing Procedure(s), the Laboratory shall validate the Selectivity, LOD and dynamic range from the analysis of an adequate number of representative samples prepared in the appropriate matrix of analysis, unless otherwise specified.

53.4 (e) (3) (iii) Unless otherwise specified, the Laboratory shall validate and document the concentration levels which will require quantitative Confirmation Procedure(s).

53.4 (e) (3) (iv) In order to account for a possible underestimation of concentrations of Threshold Substances during non-quantitative Initial Testing Procedure(s), the Laboratory shall establish, and document in the Test Method's SOP, criteria (e.g., concentration levels), determined during the Initial Testing Procedure method validation, to evaluate initial results as Presumptive Adverse Analytical Findings and ensure that all potentially positive Samples are subjected to quantitative Confirmation Procedures.

53.4 (e) (3) (v) The estimation of Measurement Uncertainty (MU) is not required during the validation of Initial Testing Procedure(s), unless otherwise specified.

53.4 (e) (4) Validation of Confirmation Procedures for Threshold Substances

53.4 (e) (4) (i) Factors to be investigated during the method validation to demonstrate that a quantitative Confirmation Procedure for a Threshold Substance is Fit-for-Purpose include but are not limited to:

53.4 (e) (4) (ii) Selectivity, LOI, Robustness, Carryover (see Article 53.4 (d));

53.4 (e) (4) (iii) Limit of Quantification (LOQ): The Laboratory shall demonstrate that a quantitative Confirmation Procedure has an established LOQ of no more than 50% of the Threshold value or in accordance with the LOQ values required in relevant Technical Document(s) or in consideration of Laboratory Guidelines;

53.4 (e) (4) (iv) Dynamic Range: The range of the quantitative Confirmation Procedure shall be documented from at least 50% to 200% of the Threshold value;

53.4 (e) (4) (v) Repeatability (sr): The quantitative Confirmation Procedure shall allow for the reliable repetition of the results over a short time, using a single operator, item of equipment, etc. Repeatability at levels close to the Threshold shall be determined;

53.4 (e) (4) (vi) Intermediate Precision (sw): The quantitative Confirmation Procedure shall allow for the reliable repetition of the results at different times and with different operators and instruments, if applicable, performing the assay. Intermediate Precision at levels close to the Threshold shall be determined;

53.4 (e) (4) (vii) Bias (b): The Bias of the measurement procedure shall be evaluated either using Certified Reference Materials or traceable Reference Materials, if available, or from comparison with a reference method or with the consensus values obtained from an inter-Laboratory comparison study or EQAS participation. Bias at the levels close to the Threshold shall be determined;

53.4 (e) (4) (viii) Measurement Uncertainty (MU): The MU associated with the results obtained with the quantitative Confirmation Procedure shall be estimated in accordance with the applicable Technical Document, Technical Letter or Laboratory Guidelines. At least, MU at levels close to the Threshold shall be addressed during the validation of the quantitative Confirmation Procedure.

53.4 (e) (5) Confirmation Procedure method validation data (including the estimation of MU) is evaluated during the assessment process for inclusion of the quantitative Confirmation Procedure within the Laboratory's Scope of ISO/IEC 17025 Accreditation. Therefore, for those Confirmation Procedures that are included within the Laboratory's Scope of ISO/IEC 17025 Accreditation, the Laboratory is not required to produce method validation data, SOPs, or other evidence of method validation in any legal proceeding.

53.5 Sample Analysis

53.5 (a) Laboratories shall analyze Samples collected by the Agency using Race Day or Out-of-Competition Analytical Testing menus to detect the presence of Prohibited Substances or Prohibited Methods only (as defined in the Prohibited List).

53.5 (b) Covered Persons and their representatives are not permitted to be present for any aspect of Sample analysis or processing described in the ESL, Technical Documents, Technical Letters, Laboratory Guidelines, or Laboratory SOPs. In addition, Covered Persons are not permitted to have a Sample transferred to be tested at a laboratory.

53.5 (c) Laboratories may analyze Samples for the following, in which case the results of the analysis shall not be reported as an Atypical Finding or an Adverse Analytical Finding:

53.5 (c) (1) Non-prohibited substances or methods that are included in the Agency Monitoring Program (see Protocol);

53.5 (c) (2) Non-prohibited substances for results interpretation purposes (e.g., non-prohibited substances that share Metabolite(s) or degradation products with Prohibited Substances), if applicable;

53.5 (c) (3) Non-prohibited substances or methods requested as part of a Results Management process by an adjudicatory body or the Agency;

53.5 (c) (4) Non-prohibited substances or methods requested by the Agency as part of its safety Protocol, Protocol of conduct or other regulations (see comments to Protocol); or

53.5 (c) (5) Additional analyses for quality assurance/quality improvement/method development or research purposes, in accordance with the requirements indicated in Article 53.11 (d).

53.5 (d) At minimum, all Laboratories are required to implement all mandatory Analytical Testing Procedures, as determined by the Agency in compliance with relevant Technical Document(s) and Technical Letter(s). Laboratories may implement additional methods for the analysis of particular Prohibited Substances or Prohibited Methods.

53.5 (e) Analytical Testing Procedure(s) included in the Laboratory's Scope of ISO/IEC 17025 Accreditation shall be considered as Fit-for-Purpose and therefore the Laboratory shall not be required to provide method validation documentation, SOPs or EQAS performance data in support of an Adverse Analytical Finding.

53.5 (f) However, if the Analytical Testing Procedure has not been included yet in the Laboratory's Scope of ISO/IEC 17025 Accreditation, the Laboratory shall validate the procedure in compliance with the ESL and the applicable Technical Document(s), Technical Letter(s) or Laboratory Guidelines prior to its application to the analysis of Samples. In such cases, the Laboratory may be required to provide method validation documentation or EQAS performance data in support of an Adverse Analytical Finding(see Article 51.4 (b) (ii)).

53.5 (g) Laboratories may, on their own initiative and prior to reporting a test result, apply additional Analytical Testing Procedures to analyze Samples for Prohibited Substances or Prohibited Methods not included in the standard Analytical Testing menu, provided that the additional work is conducted at the Laboratory's expense and does not significantly affect the possibility to submit the Sample, as identified by the Agency, to Further Analysis. Results from any such analysis shall be reported to, and in a form designated by, the Agency and have the same validity and Consequences as any other analytical result.

53.5 (h) Application of Initial Testing Procedure(s)

53.5 (h) (1) The objective 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. Results from Initial Testing Procedure(s) can be included as part of longitudinal studies (e.g., endogenous steroid), provided that the method is Fit-for-Purpose.

53.5 (h) (2) The Initial Testing Procedure(s) shall fulfil the following requirements:

53.5 (h) (2) (i) The Initial Testing Procedure(s) shall be Fit-for-Purpose;

53.5 (h) (2) (ii) The Initial Testing Procedure(s) shall be performed on Aliquot(s) taken from the container identified as the "A" Sample;

53.5 (h) (2) (iii) The Initial Testing Procedure(s) shall be recorded, as part of the Sample (or Sample batch) record, each time it is conducted;

53.5 (h) (2) (iv) All batches undergoing an Initial Testing Procedure(s) shall include appropriate negative and positive quality controls prepared in the matrix of analysis, unless otherwise specified;

53.5 (h) (2) (v) The Initial Testing Procedure(s) for Non-Threshold Substances shall include appropriate controls of representative substance(s) at or below the MRPL;

53.5 (h) (2) (vi) The Initial Testing Procedure(s) for Threshold Substances shall include appropriate controls close to the Threshold, unless otherwise specified;

53.5 (h) (2) (vii) Results from Initial Testing Procedure(s) are not required to consider the associated MU, unless otherwise specified;

53.5 (h) (2) (viii) The Laboratory shall establish criteria, based on its method validation and in accordance with its SOP, to evaluate results from an Initial Testing Procedure(s) as a Presumptive Adverse Analytical Finding, which would trigger confirmation analyses.

53.5 (i) Application of Confirmation Procedures

53.5 (i) (1) The objective of the Confirmation Procedure is to obtain a result, which supports or does not support the reporting of an Adverse Analytical Findingor Atypical Finding.

53.5 (i) (10) Repetition of the “A” Confirmation Procedure

53.5 (i) (10) (i) The Laboratory may repeat the Confirmation Procedure for an “A” Sample, if appropriate, (e.g., quality control failure, chromatographic peak interferences, inconclusive “A” confirmation results). In that case, the previous test result shall be nullified. Each repeat confirmation shall be performed using a new Aliquot(s) taken from the “A” Sample container and shall be recorded.

53.5 (i) (11) “A” Confirmation Procedure for Non-Threshold Substances

53.5 (i) (11) (i) For Non-Threshold Substances without Minimum Reporting Levels, Adverse Analytical Findingor Atypical Finding decisions for the “A” Sample shall be based on the identification of the Non-Threshold Substance or its characteristic Metabolite(s) or Marker(s), as applicable, in compliance with the relevant Technical Document, Technical Letter or in consideration of Laboratory Guidelines.

53.5 (i) (11) (ii) For Non-Threshold Substances with Minimum Reporting Levels as specified in the TD, Adverse Analytical Finding decisions for the “A” Sample should be based on the identification of the Non-Threshold Substance or its characteristic Metabolite(s) or Marker(s), in compliance with the TD, at an estimated concentration greater than the Minimum Reporting Level, unless there is justification for reporting the finding at levels below the Minimum Reporting Level (e.g., if the analysis forms part of an ongoing investigation).

53.5 (i) (12) “A” Confirmation Procedure for Threshold Substances

53.5 (i) (12) (i) For Threshold Substances, Adverse Analytical Findingor Atypical Finding decisions for the “A” Sample shall be based on the confirmed identification (in accordance with the TD, applicable to Confirmation Procedures based on chromatography-mass spectrometry) of the Threshold Substance and/or its Metabolite(s) or Marker(s) and their quantitative determination in the Sample at a level exceeding the value of the relevant Decision Limit, which is specified in the TD DL or other applicable Technical Document(s) or Laboratory Guidelines.

53.5 (i) (12) (ii) Quantitative Confirmation Procedures for Threshold Substances shall be based on the determination of the mean of measured analytical values (e.g., concentrations, chromatogram peak heights or areas) or the ratio/score calculated from the mean(s) of the measured analytical values of three (3) “A” Sample Aliquots, unless otherwise specified. If there is not enough Sample volume to analyze three (3) Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.

53.5 (i) (12) (iii) By determining that the test result exceeds the Decision Limit, the quantitative Confirmation Procedure establishes that the Threshold Substance or its Metabolite(s) or Marker(s)

is present in the Sample at a level greater than the Threshold, with a statistical confidence of at least 95% (for more information, refer to the TD DL).

53.5 (i) (12) (iv) For Threshold Substances, Markers of the “steroid profile”, or any other Prohibited Substance that may be produced endogenously at low levels, Adverse Analytical Findingdecisions for the “A” Sample may also be based on the application of any Fit-for-Purpose Confirmation Procedure that establishes the exogenous origin of the Prohibited Substance or its Metabolite(s) or Marker(s). Atypical Findings may result from non-conclusive determinations of the origin (endogenous vs. exogenous) of the Prohibited Substance or its Metabolite(s) or Marker(s).

53.5 (i) (13) “B” Confirmation Procedure:

53.5 (i) (14) Testing Laboratory

53.5 (i) (14) (i) The “B” Confirmation Procedure shall be performed in the same Laboratory as the “A” Confirmation Procedure, unless there are exceptional circumstances, as determined by the Agency and with the Agency’s prior written approval, which prevent the “B” Confirmation Procedure from being performed in the same Laboratory. A different analyst must perform the “B” analytical procedure. The same individual(s) that performed the “A” analysis may perform instrumental set up and performance checks and verify results.

53.5 (i) (15) Notification and Timing of “B” Confirmation Procedure

53.5 (i) (15) (i) The “B” Confirmation Procedure shall only be performed by the Laboratory upon request by the Agency.

53.5 (i) (15) (ii) The Agency should inform the Laboratory, in writing, within fifteen (15) days following the reporting of an “A” Sample Adverse Analytical Findingby the Laboratory, whether the “B” Confirmation Procedure shall be conducted. This includes situations when the Covered Person does not request the “B” Sample analysis or expressly or implicitly waives their right to the analysis of the “B” Sample, but the Agency decides that the “B” Confirmation Procedure shall still be performed.

53.5 (i) (15) (iii) If the “B” Confirmation Procedure is to be performed, either upon the request of and payment by the Covered Person in accordance with the Protocol or the Agency, it should be performed as soon as possible after the Agency has provided such notice to the Laboratory.

53.5 (i) (15) (iv) The timing of the “B” Confirmation Procedure may be strictly fixed within a very short period of time and without any possible postponement, if circumstances so justify it. This can notably and without limitation be the case when a postponement of the “B” Sample analysis could significantly increase the risk of Sample degradation and/or inadequately delay the decision-making process in the given circumstances (e.g., and without limitation, during or in view of a Covered Horserace requiring rapid completion of the Sample analysis).

53.5 (i) (16) Opening, Aliquoting and Resealing of “B” Sample

53.5 (i) (16) (i) The “B” Confirmation Procedure shall be performed using Aliquot(s) taken from the container defined as the “B” Sample.

53.5 (i) (16) (ii) If the “B” Sample container was not properly sealed and/or showed signs of Tampering, or if the identifying numbers did not match those on the Sample collection documentation, the Laboratory shall not proceed with the “B” Confirmation Procedure and will inform the Agency immediately to obtain instructions. In such cases, the “B” Confirmation Procedure may have to be re-scheduled.

53.5 (i) (16) (iii) The Laboratory shall ensure that the “B” Sample container is opened and Aliquots for the “B” Confirmation Procedure are taken.

53.5 (i) (16) (iv) The Laboratory shall also ensure that, after opening and taking Aliquots for the “B” Confirmation Procedure, the “B” Sample is properly resealed.

53.5 (i) (16) (v) At a minimum, the Laboratory Director or representative shall sign another part of the Laboratory documentation attesting that the “B” Sample opening and aliquoting procedures and that the “B” Sample was properly resealed.

53.5 (i) (17) Target Analyte(s)

53.5 (i) (17) (i) If more than one (1) Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method has been confirmed in the “A” Confirmation Procedure, the Laboratory shall confirm as many of the Adverse Analytical Findings as possible given the “B” Sample volume available. The decision on the prioritization for the confirmation(s) shall be made to prioritize the analysis of the Prohibited Substance(s) or Prohibited Method(s) that carry the longest potential period of Ineligibility. The prioritization decision should be made in consultation with the Agency and documented.

53.5 (i) (18) Repetition of the “B” Confirmation Procedure

53.5 (i) (18) (i) The Laboratory may repeat the Confirmation Procedure for a “B” Sample, if appropriate, (e.g., quality control failure, chromatographic peak interferences, inconclusive “B” confirmation results). In that case, the previous test result shall be nullified. The Laboratory may repeat the “B” Confirmation Procedure using the remaining volume of the same Aliquot initially taken from the “B” Sample container. However, if there is not enough volume left of the initial Aliquot, then the Laboratory shall use a new Aliquot(s) taken from the re-sealed “B” Sample container. Each Aliquot used shall be documented.

53.5 (i) (19) “B” Confirmation with Negative Results

53.5 (i) (19) (i) If the final “B” confirmation results are negative, the Analytical Testing result shall be considered a Negative Finding. The Laboratory shall notify the Agency immediately. If requested by the Agency, the Laboratory shall conduct an internal investigation of the causes of the discrepancy between the “A” and “B” Sample results.

53.5 (i) (2) A Confirmation Procedure for a Non-Threshold Substance with a Minimum Reporting Level, or other control limit may also be performed if the result estimated from the Initial Testing Procedure(s) is lower than the applicable Minimum Reporting Level, as determined by the Laboratory in accordance with the method’s validation results, or as specifically required by the Agency.

53.5 (i) (20) “B” Confirmation Procedure for Non-Threshold Substances and exogenous Threshold Substances

53.5 (i) (20) (i) For Non-Threshold Substances (including those with Minimum Reporting Levels as specified in the TD) and exogenous Threshold Substances, the “B” Sample results shall only confirm the presence of the Prohibited Substance(s) or its Metabolite(s) or Marker(s) identified in the “A” Sample (in compliance with the TD) for the Adverse Analytical Findingto be valid, unless otherwise specified. No quantification or estimation of concentrations of such Prohibited Substance, or its Metabolite(s) or Marker(s) is necessary.

53.5 (i) (21) “B” Confirmation Procedure for Threshold Substances

53.5 (i) (21) (i) For Threshold Substances, Adverse Analytical Findingdecisions for the “B” Sample results shall be based on the confirmed identification (in accordance with the TD), applicable to Confirmation Procedures based on chromatography-mass spectrometry) of the Threshold Substance or its Metabolite(s) or Marker(s) and their quantitative determination in the Sample at a level exceeding the value of the relevant Threshold as specified in Technical Document(s) or Laboratory Guidelines. Comparison of the measured value of the “B” Sample to the measured value of the “A” Sample is not necessary to establish “B” Sample confirmation. The “B” Sample value is only required to exceed the applicable Threshold.

53.5 (i) (21) (ii) Quantitative “B” Confirmation Procedures for Threshold Substances shall be based on the determination of the mean of measured analytical values (e.g., concentrations, chromatogram peak heights or areas) or the ratio/score calculated from the mean(s) of the measured analytical values of three (3) “B” Sample Aliquots, unless otherwise specified. If there is not enough Sample volume to analyze three (3) Aliquots, the maximum number of Aliquots that can be prepared should be analyzed.

53.5 (i) (21) (iii) For Threshold Substances or any other Prohibited Substance that may be produced endogenously at low levels, Adverse Analytical Findingdecisions for the “B” Sample results may also be based on the application of any Fit-for-Purpose Analytical Testing Procedure

that establishes the exogenous origin of the Prohibited Substance and/or its Metabolite(s) or Marker(s). Atypical Findings may result from non-conclusive determinations of the origin (endogenous vs. exogenous) of the Prohibited Substance or its Metabolite(s) or Marker(s).

53.5 (i) (22) Further Analysis:

53.5 (i) (23) Further Analysis of stored Samples shall, as a matter of principle, be aimed at detecting all the Prohibited Substance(s) or Metabolite(s) of Prohibited Substance(s), or Marker(s) of the Use of a Prohibited Substance or Prohibited Method included in the Prohibited List in force at the time of the collection of the Sample(s).

53.5 (i) (24) Selection of Samples and Laboratories for Further Analysis:

53.5 (i) (24) (i) Stored Samples may be selected for Further Analysis at the discretion of the Agency.

53.5 (i) (24) (ii) The choice of which Laboratory will conduct the Further Analysis will be made by the Agency. Requests to the Laboratory for Further Analysis shall be made in writing and be recorded as part of the Sample's documentation.

53.5 (i) (24) (iii) When a Sample has been reported as a Negative Finding or Atypical Finding, there is no limitation on the Agency to conduct Further Analysis on the Sample.

53.5 (i) (24) (iv) Further Analysis may also be performed on stored Samples, which were previously reported as Adverse Analytical Findings. Any Prohibited Substance or Prohibited Method detected, which was prohibited at the time of Sample collection, shall be reported.

53.5 (i) (24) (v) Previously acquired Initial Testing Procedure(s) data may also be re-evaluated for the presence of Prohibited Substances or their Metabolite(s) or Marker(s) of Prohibited Substances or Prohibited Methods, at the initiative the Agency or the Laboratory itself. The results of such re-evaluation, if suspicious, shall be communicated to the Agency, and may lead to Further Analysis.

53.5 (i) (25) Analytical Testing Procedures for Further Analysis of Stored Samples:

53.5 (i) (25) (i) Further Analysis of stored Samples shall be performed under the ESL, Technical Documents, Technical Letters in effect at the time the Further Analysis is performed. Any Laboratory Guidelines may also be referenced.

53.5 (i) (25) (ii) Further Analysis of stored Samples includes, notably, but without limitation, the application of newly developed or more sensitive Analytical Testing Procedures and/or the analysis of new target Analytes of Prohibited Substance(s) or Prohibited Method(s) [e.g., Metabolite(s) and/or Marker(s)], which were not known or not included in the initial Analytical Testing of the Sample.

53.5 (i) (25) (iii) Depending on the circumstances, and to ensure an effective and targeted use of the available Sample volume, priorities may be set, and/or the scope of the Further Analysis restricted to specific analyses (in particular, but without limitation, to analyses based on new or improved Analytical Testing Procedures).

53.5 (i) (26) Further Analysis of Stored Samples Process

53.5 (i) (27) Use of the "A" Sample:

53.5 (i) (27) (i) The Agency may instruct the Laboratory to use the "A" Sample for both the Initial Testing Procedure(s) and the "A" Confirmation Procedure(s), to use it only for the Initial Testing Procedure(s) or not to use the "A" Sample for Further Analysis at all.

53.5 (i) (27) (ii) If the Laboratory has been instructed to perform only Initial Testing Procedure(s) on the "A" Sample, any suspicious analytical result obtained from the "A" Sample shall be considered as a Presumptive Adverse Analytical Finding, irrespective of the Analytical Testing Procedure applied, and shall be confirmed using the split "B" Sample (see below).

53.5 (i) (27) (iii) When a Confirmation Procedure is performed on the "A" Sample and an Adverse Analytical Findingis reported on this basis, the "B" Confirmation Procedure shall be applicable (as per Article 53.7 (g)).

53.5 (i) (28) Use of the split “B” Sample:

53.5 (i) (28) (i) When the “A” Sample is used only for the Initial Testing Procedure(s) or is not used at all during Further Analysis, the “B” Sample shall be split and used for analysis. The “B” Sample shall be split into two fractions, in accordance with Article 53.3 (f).

53.5 (i) (28) (ii) In the event an Adverse Analytical Findingis notified based on the results of a Confirmation Procedure of the first fraction of the “B” Sample, the second split fraction of the “B” Sample shall be deemed as the “B” Sample. If applicable, a “B” confirmation shall be decided and performed in accordance with Article 53.7 (g).

53.5 (i) (29) Alternative Biological Matrices

53.5 (i) (29) (i) Any negative Analytical Testing results obtained from hair, hoof, saliva or other biological material shall not be used to counter Adverse Analytical Findings or Atypical Findings from urine or blood (including whole blood, plasma or serum).

53.5 (i) (3) A result obtained in the Initial Testing Procedure(s) for a Threshold Substance higher than the Threshold requires a Confirmation Procedure. A Confirmation Procedure may also be performed if the result obtained in the Initial Testing Procedure is lower than the Threshold, as determined by the Laboratory or as specifically required by the Agency.

53.5 (i) (4) Irregularities in the Initial Testing Procedure(s) shall not invalidate an Adverse Analytical Finding, which is adequately established by a Confirmation Procedure.

53.5 (i) (5) The Confirmation Procedure(s) shall fulfil the following requirements:

53.5 (i) (5) (i) The Confirmation Procedure(s) shall be Fit-for-Purpose, including the estimation of the MU associated with a quantitative Confirmation Procedure;

53.5 (i) (5) (ii) The Confirmation Procedure(s) shall be recorded, as part of the Sample (or Sample batch) record, each time it is conducted;

53.5 (i) (5) (iii) The Confirmation Procedure shall have equal or greater Selectivity than the Initial Testing Procedure(s) and shall provide accurate quantification results (applicable to Threshold Substances). The Confirmation Procedure should incorporate, when possible and adequate, a different Sample extraction protocol and/or a different analytical methodology, unless otherwise specified;

53.5 (i) (5) (iv) All batches undergoing a Confirmation Procedure shall include appropriate negative and positive quality controls prepared in the matrix of analysis.

53.5 (i) (6) Confirmation Procedure Methods

53.5 (i) (6) (i) Mass spectrometry (MS) coupled to chromatographic separation (e.g., gas or liquid chromatography) is the analytical technique of choice for confirmation of most Prohibited Substances, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method. These are acceptable methods for both the Initial Testing Procedure(s) and the Confirmation Procedure.

53.5 (i) (7) “A” Confirmation Procedure:

53.5 (i) (8) Aliquots

53.5 (i) (8) (i) The “A” Confirmation Procedure shall be performed using new Aliquot(s) taken from the container identified as the “A” Sample. At this point, the link between the Sample external Protocol as shown in the Sample container and the Laboratory internal Sample Protocol shall be verified.

53.5 (i) (9) Target Analyte(s)

53.5 (i) (9) (i) If the presence of more than one (1) Prohibited Substance, Metabolite(s) of a Prohibited Substance, or Marker(s) of the Use of a Prohibited Substance or Prohibited Method is detected by the Initial Testing Procedure(s), the Laboratory shall confirm as many of the Presumptive Adverse Analytical Findings as reasonably possible (such decision should consider the volumes available in the “A” and “B” Samples). The confirmation(s) shall prioritize the identification and/or quantification of the Prohibited Substance(s) or Prohibited Method(s) that carry the longest potential period of Ineligibility. The prioritization decision shall be made in consultation with the Agency and documented.

53.6 Assuring the Validity of Analytical Results

53.6 (a) The Laboratory shall monitor its analytical performance and the validity of test results by operating quality control schemes, which are appropriate to the type and frequency of Analytical Testing performed by the Laboratory. The resulting data should be recorded in such a way that trends are detectable and, where practicable, statistical techniques should be applied to review the results.

53.6 (b) All quality control procedures shall be documented by the Laboratory. The range of quality control activities include, but are not limited to:

53.6 (b) (1) Use of appropriate quality control samples (QCs)

53.6 (b) (1) (i) Appropriate positive and negative QCs shall be included in every analytical run both for the Initial Testing Procedure(s) and Confirmation Procedure(s), unless otherwise specified.

53.6 (b) (1) (ii) Appropriate internal standard(s) shall be used for chromatographic methods.

53.6 (b) (1) (iii) For Threshold Substances, quality control charts (QC-charts) referring to appropriate control limits depending on the Analytical Testing Procedure employed (e.g., +/- 2SD; +/- 3SD; +/- U95%), shall be regularly used to monitor method performance and inter-batch variability (when applicable).

53.6 (b) (2) Implementation of an Internal Quality Assurance Scheme (iQAS)

53.6 (b) (2) (i) The Laboratory shall establish a functional and robust iQAS program, in accordance with the requirements of ISO/IEC 17025, which challenges the entire scope of the Analytical Testing process (i.e., from Sample accessioning through result reporting). The Laboratory shall implement a procedure that prevents the submission of iQAS results to the Agency.

53.6 (b) (2) (ii) The iQAS plan shall include and evaluate as many Laboratory procedures as possible, including the submission of a sufficient number of test samples on a regular basis (e.g., monthly) and shall incorporate as many categories of Prohibited Substances and Prohibited Methods as possible.

53.6 (b) (2) (iii) The Laboratory shall have a dedicated SOP for the iQAS program, which incorporates a detailed procedure for the planning, preparation, (blind and/or double-blind) introduction of the iQAS samples and management of the iQAS results (reviewing and follow-up of nonconformities).

53.6 (b) (3) Mandatory participation in the Agency EQAS (see relevant Section).

53.6 (b) (4) Implementation of Internal Audits:

53.6 (b) (4) (i) Internal audits shall be conducted in accordance with the requirements of ISO/IEC 17025, and shall have a dedicated SOP incorporating a detailed procedure for the planning and performance of the audits, the training and selection of internal auditors, specification of their auditing activities, as well as for management of the internal audit conclusions (reviewing and follow-up of nonconformities).

53.6 (b) (4) (ii) Internal audit responsibilities may be shared amongst personnel provided that any Laboratory staff member does not audit their own area.

53.6 (b) (4) (iii) Internal audits shall be carried out by qualified Laboratory staff members. In addition, qualified members of the Laboratory's host organization (e.g., university, institute, company) may also be included in the internal auditing teams.

53.6 (b) (5) Implementation of External Audits

53.6 (b) (5) (i) Laboratories may also consider having their procedures and systems audited by other Laboratory Directors or external auditors. However, this shall not replace the performance of internal audits by the Laboratory.

53.7 Results Management

53.7 (a) Review of Results

53.7 (b) The Laboratory shall conduct a minimum of one (1) independent review of all Initial Testing Procedure(s) raw data and results. The review process shall be recorded.

53.7 (c) A minimum of two (2) Certifying Scientists shall conduct an independent review of all Adverse Analytical Findings and Atypical Findings before a test result is reported. Evidence of the review and approval of the analytical run/batch shall be recorded.

53.7 (c) (1) Second Opinion

53.7 (c) (1) (i) The Laboratory may request a second opinion from other Laboratory(-ies) before reporting an Adverse Analytical Findingor Atypical Finding. Such requests for second opinions may be required by specific Technical Document(s) or Technical Letters, required by the Agency from certain Laboratory(-ies) for all or for specific Analytical Testing Procedures under certain conditions (e.g., following the recent obtaining of HEAL accreditation or after a period of Suspension or Analytical Testing Restriction), or requested at the discretion of the Laboratory (e.g., for firstly detected Analytes or for difficult to interpret findings). In any case, the request for a second opinion shall be made in writing and the second opinion received shall be recorded as part of the Sample’s documentation. Any transfer of data and information necessary for the second opinion shall be made securely and respecting the confidentiality of the analytical data and any other information.

53.7 (c) (1) (ii) The Laboratory that performed the analysis is responsible for the result and for issuing the final Test Report.

53.7 (c) (2) Laboratory Review of Adverse Analytical Findings and Atypical Findings

53.7 (c) (2) (i) At a minimum, the review of Adverse Analytical Findings and Atypical Findings shall include:

53.7 (c) (2) (ii) Documentation linking the Sample (as specified in the Sample collection documentation) to the Laboratory Internal Chain of Custody Documentation;

53.7 (c) (2) (iii) Laboratory Internal Chain of Custody documentation;

53.7 (c) (2) (iv) Initial Testing Procedure(s) and Confirmation Procedure(s) analytical data and calculations;

53.7 (c) (2) (v) Quality control data;

53.7 (c) (2) (vi) Completeness of technical and analytical documentation supporting the reported findings; Compliance of test data with the Analytical Testing Procedure’s validation results (e.g., MU);

53.7 (c) (2) (vii) Assessment of the existence of significant data or information that would cast doubt on or refute the Laboratory findings;

53.7 (c) (3) When the Confirmation Procedure result(s) are not determined to be Adverse Analytical Finding(s) or Atypical Finding(s) based on the results review, the reason(s) for the rejection shall be recorded, in the laboratory test report.

53.7 (d) Traceability of Results and Documentation

53.7 (e) The Laboratory shall have documented procedures to ensure that it maintains a record related to each Sample analyzed. In the case of an Adverse Analytical Findingor Atypical Finding, the record shall include the data necessary to support the conclusions reported as set forth in and limited by the TD.

53.7 (e) (1) Each step of Analytical Testing shall be traceable to the staff member who performed that step;

53.7 (e) (2) Significant deviation from a written SOP shall be recorded;

53.7 (e) (3) Where instrumental analyses are conducted, the operating parameters for each run shall be included as part of the record;

53.7 (e) (4) Requests for information by the Agency to a Laboratory shall be made in writing;

53.7 (e) (5) Laboratory Documentation Packages and Certificates of Analysis shall be in compliance with the TD LDOC. Laboratories are not required to produce a Laboratory Documentation Package for a Sample in which no Prohibited Substance or Prohibited Method or their Metabolite(s) or Marker(s) was detected, unless requested by an adjudication body as part of a Results Management process or Laboratory disciplinary proceedings.

53.7 (f) Confidentiality of the Analytical Data and Covered Person and/or Covered Horse's Identity

53.7 (f) (1) The Laboratory shall not make any attempt to identify a Covered Person linked to and/or the Covered Horse that has provided a Sample.

53.7 (f) (2) Information sent by a facsimile is acceptable provided that the correct facsimile number is verified prior to transmission and the receipt is verified after the facsimile has been transmitted.

53.7 (f) (3) Secure emails or documents shall be used for reporting or discussion of Adverse Analytical Findings or Atypical Findings if the Covered Person and/or Covered Horse can be identified or if any information regarding the identity of the Covered Person and/or Covered Horse is included.

53.7 (g) Reporting Test Results

53.7 (h) Reporting Times

53.7 (h) (1) Reporting of all "A" Sample results should occur to, and in a form designated by, the Agency no later than twenty (20) days of receipt of the Sample. The reporting time required for specific occasions may be substantially less than twenty (20) days. The reporting time may be altered by agreement between the Laboratory and the Agency. The Agency should be informed of any delay in the reporting of "A" Sample results.

53.7 (h) (2) In order to expedite the Results Management process, an Abbreviated Laboratory Documentation Package should be provided at the time of reporting an Adverse Analytical Findingto the Agency unless the Agency indicates an Abbreviated Laboratory Documentation Package is not necessary. The Laboratory Documentation Packages and/or Certificates of Analysis should be provided by the Laboratory only to the Agency upon request and should be provided as soon as practicable and no later than five (5) days of the request, unless a different deadline is agreed upon with the Agency.

53.7 (i) Reporting Requirements

53.7 (i) (1) The Laboratory shall record the test result for each individual Sample from the Agency to, and in a form designated by, the Agency.

53.7 (i) (2) When reporting test results to, and in a form designated by, the Agency, the Laboratory shall include, in addition to the mandatory information stipulated to, and in a form designated by, the Agency, in the relevant Technical Document(s) or Technical Letter(s), and in the ISO/IEC 17025 standard, the

following:

53.7 (i) (2) (i) The Specific Gravity of the Sample, if applicable (Initial Testing Procedure(s) and “A” and “B” Confirmation Procedures);

53.7 (i) (2) (ii) Relevant comments, if necessary, for proper interpretation of the test result or recommendations to the Agency (for example, for Target Testing of the Covered Horse);

53.7 (i) (2) (iii) Specific tests performed, in addition to the Laboratory routine Analytical Testing menu (e.g., EPO, bisphosphonates, hGH, DNA, genomic profiling);

53.7 (i) (2) (iv) Any irregularities noted on Samples;

53.7 (j) The Laboratory is not required to provide any additional Test Report, either in hard-copy or digital format, other than the submission of test results to, and in a form designated by, the Agency. Upon request by the Agency, the Laboratory shall report a summary of the results of analyses performed in a format specified by the Agency. In addition, the Laboratory shall also provide any information requested by the Agency in relation to the Monitoring Program (Protocol).

53.7 (k) The Laboratory shall qualify the result(s) of the analysis in the Agency’s Test Report as:

53.7 (k) (1) Adverse Analytical Finding;

53.7 (k) (2) Atypical Finding;

53.7 (k) (3) Negative Finding; or

53.7 (k) (4) Not Analyzed

53.7 (l) Any Sample received at the Laboratory and not subject to Analytical Testing for a valid, documented reason (as instructed by or agreed with the Agency) such as Sample irregularities, intermediate Samples of a Sample Collection Session, etc. (see Article 53.3 (d)).

53.7 (m) Test Report for Non-Threshold Substances

53.7 (m) (1) “A” Sample Test Report

53.7 (m) (1) (i) The Laboratory is not required to report concentrations for Non-Threshold Substances. The Laboratory shall report the actual Prohibited Substance(s) and/or its Metabolite(s), or Marker(s) of the Use of Prohibited Substance(s) or Prohibited Method(s) present (i.e., identified, as per the TD) in the Sample and in accordance with the reporting requirements established in the TD. [Comment: When applicable, the Laboratory shall record in the form designated by the Agency Test Report the specific Metabolite(s) or Marker(s) of the Non-Threshold Substance that were identified in the Sample.]

53.7 (m) (1) (ii) However, the Laboratory shall provide estimated concentrations when possible and for information purposes only, upon request by the Agency, if the detected level of the Non-Threshold Substance(s), its Metabolite(s), or Marker(s) may be relevant to the Results Management of an anti-doping case. In such instances, the Laboratory should indicate the estimated concentration while making it clear to the Agency that the concentration was obtained by an Analytical Testing Procedure, which has not been validated for quantitative purposes.

53.7 (m) (2) “B” Sample Test Report

53.7 (m) (2) (i) For Non-Threshold Substances, irrespective of whether they have a Minimum Reporting Level, the Laboratory result for the “B” Sample shall only establish the presence (i.e., the identity) of the Prohibited Substance(s) or its Metabolite(s) or Marker(s) in accordance with the applicable Technical Document(s). The Laboratory is not required to quantify or estimate the concentration of such Prohibited Substance, or its Metabolite(s) or Marker(s).

53.7 (n) Test Report for Threshold Substances

53.7 (n) (1) “A” & “B” Sample Test Report

53.7 (n) (1) (i) For Threshold Substances, the Laboratory Test Report for the “A” Sample shall establish that the identified Prohibited Substance(s) or its Metabolite(s) or Marker(s) is present at a concentration and/or ratio and/or score of measured analytical values greater than the Threshold, and/or that the Prohibited Substance(s) or its Metabolite(s) or Marker(s) is of exogenous origin.

53.8 Control of Nonconformities in Analytical Testing

53.8 (a) The Laboratory shall have policies and procedures that shall be implemented when any aspect of its Analytical Testing does not comply with set requirements.

53.8 (b) Any nonconformities in Analytical Testing shall be recorded and kept as part of the documentation of the Sample(s) involved.

53.8 (b) (1) Risk Minimization

53.8 (b) (1) (i) Laboratories shall take corrective actions in accordance with ISO/IEC 17025 for Corrective Action Investigation and Reporting.

53.8 (b) (1) (ii) When conducting a corrective action investigation, the Laboratory shall perform and record a thorough Root Cause Analysis of the nonconformity.

53.8 (b) (2) Improvement

53.8 (b) (2) (i) The Laboratory shall maintain, and when appropriate improve, the effectiveness of its Management System in accordance with ISO/IEC 17025.

53.9 Complaints

53.9 (a) Complaints shall be handled in accordance with ISO/IEC 17025.

54 EQAS Overview

54.1 The Agency system of Laboratory EQAS and routine Analytical Testing performance (see Article 57) has been developed with the objective of setting a transparent and balanced procedure for evaluation of Laboratory operations. It is focused on maintaining and improving Laboratory’s Analytical Testing capabilities under their HEAL accreditation, or probationary accreditation. It is ultimately aimed at maintaining the confidence in and strengthening of the anti-doping Laboratory system to benefit clean Covered Horses.

54.10 Overall Laboratory Evaluation

54.10 (a) The Agency shall evaluate Laboratory EQAS performance for each EQAS round, as well as Laboratory performance for routine Analytical Testing, and assign penalties, including corrective actions or other follow up measures in the Agency’s sole discretion.

54.10 (b) When a Laboratory’s HEAL accreditation is Suspended:

54.10 (b) (1) If a Laboratory under Suspension as a result of EQAS performance is not capable of correcting the issue(s) before the end of the Suspension period, then the Agency may extend the Laboratory’s Suspension for up to an additional six (6) months or until such a time when the Laboratory can satisfactorily correct all the issues identified;

54.10 (b) (2) If the Laboratory under Suspension fails to satisfy performance criteria during an extended period of Suspension (beyond the initial six (6) months), then the Agency may Revoke the Laboratory's accreditation;

54.10 (c) When a Laboratory is subject to an Analytical Testing Restriction:

54.10 (c) (1) Laboratories under an Analytical Testing Restriction remain operational (except for the activity(-ies) under the Analytical Testing Restriction) and, therefore, are evaluated during the Analytical Testing Restriction as any other, fully operational Laboratory.

54.11 Probationary Period and Probationary Laboratory Evaluation

54.11 (a) The probationary EQAS is a part of the initial evaluation of a probationary laboratory seeking HEAL accreditation. Successful participation in the Agency probationary EQAS is required before a probationary laboratory is eligible to be considered for full HEAL accreditation. The Agency may decide, based on its evaluation of the overall performance of the probationary laboratory, to extend the probationary period of accreditation.

54.11 (b) Overall Probationary Laboratory Evaluation

54.11 (b) (1) The Agency will evaluate probationary laboratory EQAS performance.

54.11 (b) (2) Serious and repeated issues in the probationary EQAS shall result in the removal of the laboratory's status as a probationary laboratory by the Agency.

54.11 (b) (3) Any false Adverse Analytical Findingor false Negative Finding of a technical/methodological nature reported automatically suspends a probationary laboratory from further consideration for HEAL accreditation.

54.11 (b) (4) A Suspended probationary laboratory wishing to re-enter the probationary EQAS is required to provide documentation of corrective and preventive action(s) no later than thirty (30) days prior to the end of the Suspension period (unless otherwise indicated by the Agency). Failure to do so will preclude the laboratory from participating in the probationary EQAS.

54.11 (b) (5) Lifting of the Suspension occurs only when proper corrective and preventive actions have been implemented and reported to the Agency. The Agency may choose, at its sole discretion, to submit additional EQAS samples to the laboratory and/or to require that the laboratory be re-assessed, at the expense of the laboratory. Laboratories re-entering the probationary EQAS shall be considered as candidate laboratories and are subject to provide the applicable accreditation fee and the required documentation to the Agency (see Article 51.3).

54.12 Removal of Samples by the Agency

54.12 (a) Removal of Samples for Analysis or Further Analysis

54.12 (a) (1) Within the context of an investigation or Laboratory performance monitoring activity (for example, during an on-site Agency Laboratory assessment), the Agency, initially at its expense, may remove Sample(s) from a Laboratory to conduct Further Analysis, or analysis of the Sample if the analytical results for that Sample have not yet been reported, for the purpose described in Protocol. The Agency shall retain the right to request analysis or Further Analysis, at its expense, as permitted by Protocol.

54.12 (a) (2) The Agency may delegate an observer to monitor the removal of the Samples, which shall be implemented in accordance with the Agency's instructions. During the removal of Samples, the Agency shall be responsible for maintaining proper Sample Chain of Custody documentation and the safety and integrity of the Samples until receipt by the other Laboratory(-ies).

54.12 (a) (3) The Agency may also require that the Laboratory transfer the Samples. In such situations, the Laboratory shall be responsible for maintaining proper Chain of Custody documentation for all transferred Samples and the safety and integrity of the Samples until receipt by the receiving Laboratory(-ies).

54.12 (a) (4) In connection with its monitoring of Laboratory performance, the Agency may direct Further Analysis of a Sample which has resulted in a Protocol anti-doping rule violation without consent of the Covered Person or approval from an adjudication body as provided in Protocol.

54.12 (b) Removal of Samples for Laboratory Quality Assessment

54.12 (b) (1) The Agency may also direct the re-analysis of anonymized Samples, which have met the conditions described in Article 53.11 (d), for purposes of Laboratory quality assurance and education, including the implementation of a system of transfer of Samples reported as Negative Findings between Laboratories. In this regard, the number of Samples directed by the Agency for re-analysis may vary.

54.12 (b) (2)

54.2 The Agency shall inform a Laboratory in writing about the imposition of penalty, and/or corrective action and/or other follow up measures.

54.3 Technical or methodological error

54.3 (a) If the Laboratory is able to remedy the technical or methodological error through the implementation of satisfactory corrective actions in a timely manner, as determined by the Agency, the Laboratory will not face any additional penalty.

54.4 Clerical/Administrative Error

54.4 (a) If the Laboratory is able to remedy the clerical or administrative error through the implementation of satisfactory corrective actions in a timely manner, as determined by the Agency, the Laboratory will not face any additional penalty.

54.5 Corrective Action Report

54.5 (a) A Corrective Action Report may be requested by the Agency. Where requested it shall be submitted within the timeframe specified by the Agency in written notification about the unsatisfactory result. Failure to submit a satisfactory Corrective Action Report or the late submission of the Corrective Action Report without prior approval by the Agency may result in a penalty.

54.5 (b) Corrective Action Reports related, for example, to nonconformities detected during the Agency Laboratory assessments, or to procedural or reporting nonconformities with the ESL, Technical Documents or Technical Letters, or unsatisfactory performance in the analysis of EQAS samples (not related to a false Adverse Analytical Findingor false Negative Finding), shall be submitted to the Agency within thirty (30) days of the Agency's notification to the Laboratory.

54.5 (c) Unless otherwise agreed with the Agency, the corrective and preventive action(s) reported to and approved by the Agency shall be implemented in the routine operations of the Laboratory immediately.

54.5 (d) Corrective Action Report Review

54.5 (d) (1) The Corrective Action Report will be reviewed by the Agency as soon as practicable. If applicable, it will establish the source of the incorrect result as either a technical/methodological error or a clerical/administrative error.

54.5 (e) Satisfactory Corrective Action Report

54.5 (e) (1) Corrective Action Report will be considered as satisfactory when it meets the following criteria, as determined by the Agency.

54.5 (e) (1) (i) Properly and concisely identifies the root cause(s) of the nonconformity, following an appropriate investigation into all the factors that may have caused the problem (Root Cause Analysis);

54.5 (e) (1) (ii) Leads to the documented implementation of effective corrective action(s) to solve

the problem; and

54.5 (e) (1) (iii) Leads to the documented implementation of appropriate preventive actions, if applicable, to minimize the risk of recurrence of the problem.

54.5 (e) (2) A satisfactory Corrective Action Report shall include only the necessary supporting documentation (e.g., raw analytical data, data review files, evidence of procurement of Reference Materials) which demonstrates the implemented actions described in the Corrective Action Report.

54.5 (f) Unsatisfactory Corrective Action Report

54.5 (f) (1) If the Laboratory's Corrective Action Report is considered unsatisfactory by the Agency, the Agency shall provide feedback to the Laboratory and provide it with the opportunity to resubmit a revised Corrective Action Report within seven (7) days (or as otherwise agreed with the Agency).

54.5 (f) (2) If the Laboratory is unable to submit a satisfactory revised Corrective Action Report in a timely manner, as determined by the Agency, the Agency may impose a penalty.

54.6 Laboratory Self-Reporting

54.6 (a) If the Laboratory must identify and report all errors in Sample analysis resulting in a false Adverse Analytical Findingor false Negative Finding. Self-reporting will be taken into consideration by the Agency.

54.7 Evaluation of EQAS Results

54.7 (a) Satisfactory EQAS performance in single EQAS round and over a consecutive twelve (12)- month period is necessary for maintaining HEAL accreditation.

54.7 (b) EQAS Samples for Educational Samples

54.7 (b) (1) Unsatisfactory performance in an educational EQAS for a new or the Agency-specific Analytical Testing Procedure may prevent the Laboratory from seeking an extension of the Laboratory's Scope of ISO/IEC 17025 Accreditation for the Analytical Testing Procedure and from its application in routine Analytical Testing (see Article 51.4 (b) (ii)). In such circumstances, the Laboratory may only apply the new Agency-approved method or procedure for routine Sample analysis when it properly corrects the deficiencies identified in the educational EQAS (as determined by the Agency) and the method is included in the Laboratory's Scope of ISO/IEC 17025 Accreditation.

54.7 (c) EQAS Samples Containing Non-Threshold Substances

54.7 (c) (1) When a qualitative determination of a Non-Threshold Substance has been reported, the Laboratory result will be evaluated on the basis of the correct reporting of the finding (e.g., Adverse Analytical Finding, Negative Finding) as intended in the preparation of the EQAS sample.

54.7 (c) (2) The results for any Non-Threshold Substance and/or its Metabolite(s) and/or Marker(s) at concentrations greater than (>) the MRPL (or exceeding 120% of the Minimum Reporting Level, when applicable) shall be evaluated.

54.7 (c) (3) The results for any Non-Threshold Substance and/or its Metabolite(s) and/or Marker(s) at concentrations between 50% of the MRPL and the MRPL (or less than 120% of the Minimum Reporting Level, when applicable) may require an internal investigation and Corrective Action Report from the Laboratory.

54.7 (c) (4) The results for any Non-Threshold Substance and/or its Metabolite(s) and/or Marker(s) at concentrations below (<) 50% of the applicable MRPL in an EQAS sample should report their finding(s) if the analyses are compliant with its validation data, SOPs, the ESL and the TD IDCR. Laboratories unable to report such substance(s) are encouraged, on receipt of the EQAS report, to consider re-assessment of their Analytical Testing Procedure.

54.7 (d) EQAS Samples Containing Threshold Substances

54.7 (d) (1) For EQAS samples containing Threshold Substances at levels greater than (>) 50% of the Threshold, the quantitative determination will be statistically evaluated (e.g., z- score, degree of equivalence analysis) to determine the compatibility of the reported result with the assigned value (reference, nominal or consensus value, as applicable).

54.7 (d) (2) A Laboratory is to achieve a satisfactory statistical evaluation of quantitative results reported based on the mean of three (3) replicate determinations. The overall evaluation of the quantitative performance is based on the criteria indicated in the effective version of the TD DL or other relevant Technical Document, Technical Letter or Laboratory Guidelines.

54.7 (d) (3) The main criterion applied for the evaluation of EQAS results for the quantification of Threshold Substances is the compatibility of the reported Laboratory result with the assigned value. Therefore, the incorrect reporting of an EQAS sample as a Negative Finding or as an Adverse Analytical Finding, as applicable, when the assigned value of the Threshold Substance in the EQAS sample is close to the Threshold, is not considered as a false Negative Finding or false Adverse Analytical Finding, respectively, if the absolute z-score (truncated to one (1) decimal place) for the Laboratory's quantitative result is < 3.0.

54.7 (e) Unsatisfactory Quantitative Result for Threshold Substances (absolute z-score ≥ 3.0)

54.7 (e) (1) The Laboratory shall provide the Agency with a Corrective Action Report for an unsatisfactory quantitative result.

54.7 (f) Questionable Quantitative Result (absolute z-score > 2.0 and < 3.0)

54.7 (f) (1) The Laboratory shall perform an internal investigation to determine the root cause(s) of the questionable result and implement appropriate corrective measures to resolve them.

54.7 (g) EQAS Evaluation of Laboratory Performance

54.7 (g) (1) Where an EQAS result is reported incorrectly the Laboratory shall provide the Agency with a Corrective Action Report.

54.7 (h) Double-blind, Blind EQAS & Educational EQAS samples

54.7 (h) (1) Failure to report accurately, in accordance with criteria, three (3) Blind or Double-blind EQAS, or Educational EQAS results within a continuous 12-month period may result in penalties imposed by the Agency, including, but not limited to, potential Suspension or Revocation of HEAL accreditation, or Analytical Testing Restrictions.

54.8 Evaluation of Laboratory Performance

54.8 (a) 8.6.1 False Adverse Analytical Findingor False Negative Finding

54.8 (a) (1) If the Laboratory discovers that it reported a false Adverse Analytical Findingor false Negative Finding, the Laboratory shall inform the Agency immediately.

54.8 (a) (2) When the false Adverse Analytical Findingor false Negative Finding is identified by the Agency, through the Agency’s own Results Management activities or through any other means, the Agency shall inform the Laboratory as soon as practicable.

54.8 (a) (3) The Agency, considering the nature of the error that caused the false Adverse Analytical Findingor false Negative Finding, may impose a penalty, including, but not limited to, potential Suspension or Revocation of HEAL accreditation, or Analytical Testing Restrictions against the Laboratory for a particular Analytical Testing Procedure or for the analysis of a particular class of Prohibited Substances or Prohibited Methods, as applicable or other follow up measures. For example, The Laboratory may be required by the Agency to analyze EQAS samples and/or to review the relevant

analytical results and to re-analyze any relevant and available Samples previously reported as Adverse Analytical Findings during the preceding twelve (12) months (or during a period otherwise determined by the Agency) within seven (7) days (unless informed otherwise by the Agency). Depending on the nature of the error that caused the false Adverse Analytical Finding or false Negative Finding, this re-analysis may be limited to one Analyte, a class of Prohibited Substances or Prohibited Methods, or may include any Prohibited Substance or Prohibited Method. A statement signed by the Laboratory Director shall record this re-analysis.

54.8 (a) (3) (i) During the period of Suspension, the Laboratory shall follow the instructions provided in Article 55.6 (b)in regard to Samples in the Laboratory's Possession at the time of Suspension. Alternatively, if an Analytical Testing Restriction has been imposed, the Laboratory shall subcontract the affected analyses as provided in Articles 55.6 (a) and 53.2 (f).

54.8 (a) (3) (ii) During the Suspension or Analytical Testing Restriction period, the Agency will conduct an assessment (preferably on-site) of the Laboratory, including the analysis of further EQAS samples.

54.8 (a) (3) (iii) The Suspension or Analytical Testing Restriction of the Laboratory shall be lifted only when the aforementioned conditions are satisfactorily completed, and the Laboratory provides sufficient evidence, as determined by the Agency and in the Agency's sole discretion, that appropriate steps have been taken to remedy the issue(s) that resulted in the Suspension or Analytical Testing Restriction.

54.9 Further Procedural Evaluations

54.9 (a) If the Agency considers that a Corrective Action Report is unsatisfactory, and the Laboratory is not able to provide a satisfactory revised Corrective Action Report within a reasonable time frame after receiving feedback from the Agency, the Laboratory may receive a penalty at the Agency's discretion.

55 Withdrawal of HEAL accreditation

55.1 A Laboratory's HEAL accreditation may be Suspended or Revoked, or subject to an Analytical Testing Restriction, whenever the Laboratory fails to comply with the ESL and/or Technical Documents and/or Technical Letters, or where the Suspension, Revocation or Analytical Testing Restriction is otherwise required to protect the integrity of the Samples, the Analytical Testing process or the interests of the Anti- Doping Community.

55.2 The imposition of an Analytical Testing Restriction or the Suspension of a Laboratory's HEAL accreditation should not imply the automatic withdrawal of its ISO/IEC 17025 accreditation. The status of the Laboratory's ISO/IEC 17025 accreditation is to be independently assessed by the relevant Accreditation Body.

55.3 Suspension of Accreditation and Analytical Testing Restriction

55.3 (a) The Agency may suspend a Laboratory's HEAL accreditation or impose an Analytical Testing Restriction against a Laboratory if the Agency identifies a noncompliance with the ESL and/or Technical Documents and/or Technical Letters based on the Laboratory's performance during the EQAS or during routine Analytical Testing.

55.3 (b) Penalties as determined by the Agency.

55.3 (b) (1) The Laboratory may not challenge the penalty imposed by the Agency.

55.4 Noncompliance with the ESL

55.4 (a) Noncompliance with the ESL that may lead to an Analytical Testing Restriction, Suspension, Revocation of HEAL accreditation, or other follow up measures include, but are not limited to:

55.4 (a) (1) Suspension, or withdrawal of ISO/IEC 17025 accreditation;

55.4 (a) (10) Analysis of Samples from the Agency in violation of a Suspension or Analytical Testing Restriction decision;

55.4 (a) (11) Failure to Cooperate with the Agency in providing documentation;

55.4 (a) (12) Noncompliance with the Code of Ethics; or

55.4 (a) (13) Any other cause that materially affects the ability of the Laboratory to ensure the full reliability and accuracy of Analytical Testing and the accurate reporting of test results.

55.4 (a) (2) Failure to establish and/or maintain administrative and operational independence as described in Article 51.3 (h);

55.4 (a) (3) Failure to analyze the minimum number of Samples indicated in Article 51.4 (b) (9);

55.4 (a) (4) Reporting of false Adverse Analytical Findings and/or false Negative Findings;

55.4 (a) (5) Failure to implement a Technical Document or Technical Letter by the effective date without prior approval by the Agency;

55.4 (a) (6) Failure to Comply with any of the requirements or standards listed in the ESL and/or Technical Documents and/or Technical Letters;

55.4 (a) (7) Noncompliance with results reporting timelines (see Article 53.7 (g));

55.4 (a) (8) Failure to take appropriate corrective action after an unsatisfactory performance during routine Analytical Testing or in a blind EQAS or double-blind EQAS round;

55.4 (a) (9) Failure to take appropriate corrective action for ESL and/or Technical Document and/or Technical Letter noncompliance(s) identified from the Agency Laboratory assessment(s);

55.4 (b) Laboratory staff and/or management issues, including but not limited to:

55.4 (b) (1) Major changes in senior Laboratory management positions (e.g., Laboratory Director, Quality Manager) without proper and timely notification (usually within a month) to the Agency;

55.4 (b) (2) Failure to appoint a permanent Laboratory Director or other senior management positions (e.g., Quality Manager) within a reasonable timeline;

55.4 (b) (3) Failure to guarantee the competence and/or proper training of scientific staff including, for example, the qualification of analysts as Certifying Scientists and Laboratory Supervisory Personnel (see Articles 53.2 (b) (7) and 53.2 (b) (8));

55.4 (b) (4) Significant loss or lack of experienced staff (e.g., Certifying Scientists) that affects, as determined by the Agency, the Laboratory's ability to ensure the full reliability and accuracy of Analytical Testing and reporting of test results;

55.4 (b) (5) Conviction of any key personnel for any criminal offence that is determined by the Agency to impact the operations of the Laboratory;

55.4 (b) (6) Loss of sufficient Laboratory support and resources that affects, as determined by the Agency, the quality and/or viability of the Laboratory; or

55.4 (b) (7) Failure to Cooperate in any Agency enquiry in relation to the activities of the Laboratory.

55.4 (c) Notification of Penalty Decision

55.4 (c) (1) The Agency shall provide the Laboratory with written notice of its decision regarding penalties. This notice shall state the following:

55.4 (c) (1) (i) That the Laboratory's HEAL accreditation has been maintained (including warnings, if applicable); or

55.4 (c) (1) (ii) That the Laboratory's HEAL accreditation has been Suspended or Revoked or that an Analytical Testing Restriction has been imposed against the Laboratory. Such notice shall include:

55.4 (c) (1) (iii) The reason(s) for Suspension or Revocation or the imposition of an Analytical

Testing Restriction;

55.4 (c) (1) (iv) The terms of the Suspension, Revocation, or Analytical Testing Restriction; and

55.4 (c) (1) (v) The period of Suspension or of Analytical Testing Restriction, if applicable.

55.4 (c) (1) (vi) Any corrective actions or other follow up requirements.

55.4 (d) Effective Date and Appeals

55.4 (d) (1) A Revocation, Suspension, or Analytical Testing Restriction is effective immediately upon receipt of notification of the decision.

55.4 (d) (2) The Agency's decision is not subject to appeal.

55.5 Public Notice

55.5 (a) The Agency shall publicly announce a change in a Laboratory's accreditation status on its website as soon as practicable after the Laboratory is notified by the Agency of its decision.

55.5 (b) The Agency's website shall be updated regarding a Laboratory's accreditation status when the Laboratory's HEAL accreditation is reinstated following a Suspension.

55.6 Consequences of Suspended or Revoked Accreditation or Analytical Testing Restriction

55.6 (a) Analytical Testing Restriction

55.6 (a) (1) If the Agency determines that the noncompliance(s) are limited to a class of Prohibited Substances or Prohibited Methods or to a specific Analytical Testing Procedure, which are not included in the standard Analytical Testing menu for Race Day or Out-of-Competition Samples received by the Laboratory, the Agency may impose an Analytical Testing Restriction for that class of Prohibited Substance(s) or Prohibited Method(s) or for the specific Analytical Testing Procedure in which the noncompliance(s) occurred.

55.6 (a) (2) If the reason for the Analytical Testing Restriction was related to the reporting of false Adverse Analytical Finding(s), all analyses employing the affected Analytical Testing Procedure(s) shall cease immediately.

55.6 (a) (3) The Laboratory shall transfer the following Samples ("A" and "B" Samples) in the Laboratory's custody, which involve the analysis of the same class of Prohibited Substances or Prohibited Methods and/or the application of the affected Analytical Testing Procedure(s) subjected to the Analytical Testing Restriction, to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures (unless otherwise instructed by the Agency):

55.6 (a) (3) (i) Samples, which had been previously reported as an Adverse Analytical Finding(as requested by the Agency);

55.6 (a) (3) (ii) Samples, which had been opened and were undergoing analysis for the Initial Testing Procedure(s) at the time of the Analytical Testing Restriction decision;

55.6 (a) (3) (iii) Samples for which, at the time of the Analytical Testing Restriction decision, Initial Testing Procedure(s) had been completed and had produced Presumptive Adverse Analytical Findings requiring Confirmation Procedures, or Samples that are the subject of other Confirmation Procedures;

55.6 (a) (3) (iv) Samples for which the "A" or "B" Confirmation Procedures had been completed, but results of the analysis had not been reported by the Analytical Testing Restriction date, or Samples which were undergoing "A" or "B" Confirmation Procedures at the time of the imposition of the Analytical Testing Restriction;

55.6 (a) (3) (v) Samples which had been reported as Adverse Analytical Findings based on the "A" Confirmation Procedure prior to the imposition of the Analytical Testing Restriction. These

Samples shall be kept in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions. Should a “B” Confirmation Procedure be requested during the period of the Analytical Testing Restriction, both “A” and “B” Samples shall be transferred6 to another Laboratory(-ies) for the “A” Confirmation Procedure to be performed again and for the performance of the “B” Confirmation Procedure, if applicable.

55.6 (a) (4) If the Analytical Testing Restriction was caused by the reporting of false Negative Finding(s), and further investigation reveals that other Negative Finding(s) had been reported for Samples that are still stored in the Laboratory, the Laboratory shall inform the Agency. In such cases, both the “A” and “B” containers of the relevant Samples shall be transferred to another Laboratory(-ies) for Further Analysis, as determined by the Agency. These re-analyses may be applied to the class of Prohibited Substances and/or Prohibited Methods or to the Analytical Testing Procedure(s) that were associated with the Negative Finding(s), as determined by the Agency.

55.6 (b) Suspension

55.6 (b) (1) A Laboratory whose HEAL accreditation has been Suspended is Ineligible to perform Analytical Testing of Samples.

55.6 (c) Suspension for Violation of the Code of Ethics

55.6 (c) (1) If the reason for the Suspension was related to a violation of the Code of Ethics, all Analytical Testing in the suspended Laboratory shall cease immediately and the Laboratory shall transfer 7 all Samples (both the “A” and “B” Samples) in the Laboratory’s custody to other Laboratory(-ies) chosen by the Agency.

55.6 (d) Suspension for Reporting of False Adverse Analytical Finding(s)

55.6 (d) (1) If the reason for the Suspension was related to the reporting of false Adverse Analytical Finding(s), all Analytical Testing shall cease immediately. In addition, the Laboratory shall transfer the following Samples (“A” and “B” Samples) in the Laboratory’s custody to another Laboratory(-ies) for the performance of the “A” and, if needed, the “B” Confirmation Procedures, unless otherwise instructed by the Agency:

55.6 (d) (1) (i) Samples, which had been previously reported as an Adverse Analytical Findingfor the same class of Prohibited Substances or Prohibited Methods when applying the same Confirmation Procedure (as requested by the Agency);

55.6 (d) (1) (ii) Samples for which, at the time of the Suspension decision, Initial Testing Procedure(s) had been completed and had produced Presumptive Adverse Analytical Findings requiring Confirmation Procedures, or Samples that are the subject of other Confirmation Procedures;

55.6 (d) (1) (iii) Samples, which had been opened and were undergoing analysis for the Initial Testing Procedure(s) at the time of the Suspension;

55.6 (d) (1) (iv) Samples which had been received at the Laboratory but had not been opened at the time of the Suspension [these Samples shall be kept sealed in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions until transfer to another Laboratory(-ies)].

55.6 (d) (1) (v) Samples for which “A” or “B” Confirmation Procedures had been completed, but results of the analysis had not been reported by the Suspension date, or Samples which were undergoing “A” or “B” Confirmation Procedures at the time of the Suspension;

55.6 (d) (1) (vi) Samples which had been reported as Adverse Analytical Findings based on the “A” Confirmation Procedure prior to the Suspension.

55.6 (e) Suspension for Other Reasons

55.6 (e) (1) A Laboratory that has had its HEAL accreditation Suspended for reasons other than a violation of the Code of Ethics or the reporting of false Adverse Analytical Findings(s) shall take the following steps with the Samples in the Laboratory's custody, unless otherwise instructed by the Agency:

55.6 (e) (2) Samples which had been analyzed and reported as a Negative Finding, and which have either been stored in the Laboratory for a period of less than three (3) months or have been placed in long-term storage upon request by the Agency.

55.6 (e) (3) These Samples shall be kept in the Laboratory under proper Laboratory Chain of Custody and appropriate storage conditions. The Laboratory shall inform the Agency of such actions including the provision of the Sample Protocols.

55.6 (e) (4) If the Suspension was caused by the reporting of false Negative Finding(s), and further investigation reveals that other Negative Finding(s) had been reported by the Laboratory, the Laboratory shall inform the Agency. In such cases, both the "A" and "B" containers of the relevant Samples shall be transferred to another Laboratory(-ies) for Further Analysis, as determined by the Agency. These analyses may be applied for all the Prohibited Substances and Prohibited Methods included in the requested Analytical Testing menu or be limited to the class of Prohibited Substances and/or Prohibited Methods or to the Analytical Testing Procedure(s) that were associated with the Negative Finding(s), as determined by the Agency.

55.6 (e) (5) Samples for which Initial Testing Procedure(s) had been completed, but results had not been reported at the time of the Suspension:

> 55.6 (e) (5) (i) If the Initial Testing Procedure(s) produced Presumptive Adverse Analytical Finding(s) or other Confirmation Procedures were required, both the "A" and "B" Samples shall be transferred7 to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures.
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> 55.6 (e) (5) (ii) In addition, if the Suspension was caused by the reporting of false Negative Finding(s) and the Initial Testing Procedure(s) had produced negative results, both the "A" and "B" Samples shall also be transferred to another Laboratory(-ies) for the repetition of the Initial Testing Procedure(s) and, if needed, the performance of Confirmation Procedures. These analyses may be applied for all the Prohibited Substances and Prohibited Methods included in the requested Analytical Testing menu or be limited to the class of Prohibited Substances and/or Prohibited Methods or to the Analytical Testing Procedure(s) that were associated with the Negative Finding, as determined by the Agency.
>
> 55.6 (e) (5) (iii) If the reason for the Suspension was not related to the reporting of false Negative Findings and the Initial Testing Procedure(s) had produced negative results, the Sample(s) shall be reported to the Agency as Negative Finding(s). These Samples shall be kept in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions until further notice by the Agency. The Laboratory shall inform the Agency of such actions including the provision of the Sample Protocols.

55.6 (e) (6) Samples which had been opened and were undergoing analysis for the Initial Testing Procedure(s) at the time of the Suspension:

> 55.6 (e) (6) (i) If the reason for Suspension was not related to the reporting of false Negative Finding(s), the Laboratory shall continue to analyze the relevant Samples until all Initial Testing Procedure(s) are completed. If the Initial Testing Procedure(s) produce Negative Findings, the Laboratory shall report these findings to, and in a form designated by, the Agency and these Samples shall be kept in the Laboratory under proper Laboratory Chain of Custody and appropriate storage conditions until further notice by the Agency. The Laboratory shall inform the Agency of such actions including the provision of the Sample Protocols.
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> 55.6 (e) (6) (ii) However, if the Initial Testing Procedure(s) produced a Presumptive Adverse Analytical Finding, both the "A" and "B" Samples shall be transferred7 to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures.
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> 55.6 (e) (6) (iii) If the Suspension was caused by the reporting of false Negative Finding(s), then the Laboratory shall cease all Analytical Testing and have the "A" and "B" Samples transferred7 to another Laboratory(-ies) for the performance of the "A" and, if needed, the "B" Confirmation Procedures.
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> 55.6 (e) (6) (iv) Samples which had been received at the Laboratory but had not been opened yet at the time of the Suspension:
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> 55.6 (e) (6) (v) These Samples shall be kept sealed in the Laboratory under proper Laboratory Chain of Custody and appropriate storage conditions until transfer to another Laboratory(-ies) for

Analytical Testing.

55.6 (e) (7) Samples for which “A” or “B” Confirmation Procedures had been completed, but results of analysis had not been reported by the Suspension date, or Samples which were undergoing “A” or “B” Confirmation Procedures at the time of the Suspension:

55.6 (e) (7) (i) Both the “A” and “B” Samples shall be transferred7 to another Laboratory(- ies) for the repetition of the “A” and, if applicable, the “B” Confirmation Procedures.

55.6 (e) (8) Samples which had been reported as an Adverse Analytical Findingbased on the “A” Confirmation Procedure prior to the Suspension:

55.6 (e) (8) (i) These Samples shall be kept in the Laboratory under proper Laboratory Internal Chain of Custody and appropriate storage conditions. Should a “B” Confirmation Procedure be requested during the Suspension, both “A” and “B” Samples shall be transferred7 to another Laboratory(-ies) for the “A” Confirmation Procedure to be performed again and for the performance of the “B” Confirmation Procedure, if applicable.

55.6 (e) (8) (ii) During a Suspension or Analytical Testing Restriction period, the Laboratory shall continue to participate in the Agency EQAS program. The Agency may require the Laboratory to analyze additional blind EQAS samples and/or perform a Laboratory assessment, at any time and at the expense of the Laboratory, in order to evaluate the Laboratory’s status.

55.6 (f) Revocation

55.6 (f) (1) A laboratory whose HEAL accreditation has been Revoked is Ineligible to perform Analytical Testing of Samples. The Laboratory Internal Chain of Custody maintained by a Revoked laboratory for stored Samples is valid until such time that arrangements can be made, in consultation with the Agency, for the transfer of relevant Samples to a Laboratory(-ies).

55.6 (f) (2) A laboratory whose HEAL accreditation has been Revoked shall arrange the transfer of Samples in the laboratory’s custody to a Laboratory(-ies) chosen by the Agency, respectively, within thirty (30) days of being notified of the decision revoking its HEAL accreditation. In such circumstances, the Samples to be transferred shall be selected the Agency. The laboratory transferring the Samples shall inform the Agency and provide the relevant Sample Protocols and the chosen Laboratory(-ies). In addition, the revoked laboratory shall assist with the transfer of the relevant Sample data and records to the Laboratory(-ies) that have been selected to receive the Samples.

55.6 (f) (3) The Revoked laboratory shall transfer all Samples in its custody for which the Analytical Testing process has not been completed at the time of the Revocation. The Agency may also choose to transfer additional Samples retained in the laboratory in accordance with Articles 53.10 (a)-53.10 (d), or other Samples for which it is the owner pursuant to the Testing and Investigations Standards and that had been analyzed and were in long-term storage at the time of the Revocation of the laboratory’s HEAL accreditation. In addition, the Agency may identify and request that Samples be transferred to another Laboratory(-ies).

55.6 (g) Reinstatement of Suspended Accreditation or Lifting of the Analytical Testing Restriction

55.6 (g) (1) The Agency shall lift the Suspension of the Laboratory’s HEAL accreditation or lift the Analytical Testing Restriction only when the Laboratory provides satisfactory evidence, as determined by the Agency, that appropriate steps have been taken to remedy the noncompliance(s) that resulted in the Suspension of the Laboratory’s HEAL accreditation or the imposition of the Analytical Testing Restriction, and that proper measures have been implemented to satisfactorily address the condition(s) specified, if any, for reinstatement of HEAL accreditation.

55.6 (h) Extension of Suspension or Analytical Testing Restriction

55.6 (h) (1) If a Laboratory whose HEAL accreditation has been Suspended or has been the subject of an Analytical Testing Restriction has not satisfactorily corrected the ESL and/or Technical Document(s) and/or Technical Letter(s) noncompliance(s) that resulted in the Suspension or Analytical Testing

Restriction, or if the Agency identifies any additional ESL and/or Technical Document(s) and/or Technical Letter(s) noncompliance(s) during an Agency Laboratory assessment conducted during the initial Suspension or Analytical Testing Restriction period, either the Suspension of the Laboratory's HEAL accreditation or Analytical Testing Restriction may be further extended or the Laboratory's accreditation shall be Revoked, as determined by the Agency. The Suspension or Analytical Testing Restriction period may be extended up to an additional six (6) months, if the Laboratory provides justifiable explanation(s) for the delay, as determined by the Agency, in addressing the conditions to lift the Suspension or Analytical Testing Restriction (including the submission of satisfactory corrective actions).

55.6 (h) (2) If applicable, a delay in the delivery of the ISO/IEC 17025 accreditation to the Laboratory by the relevant Accreditation Body may also constitute grounds to extend the Suspension of the Laboratory's HEAL accreditation.

55.6 (h) (3) The decision to extend the Suspension of a Laboratory's HEAL accreditation or the period of the Analytical Testing Restriction shall be made in the Agency's sole discretion.

55.6 (h) (4) If, in accordance with the terms of the extension of the Suspension of the Laboratory's HEAL accreditation or the terms of the extension of the Analytical Testing Restriction, the Laboratory provides evidence determined to be satisfactory by the Agency that all of the identified ESL and/or Technical Document and/or Technical Letter noncompliance(s) have been corrected, the Laboratory's accreditation shall be re-instated or the Analytical Testing Restriction may be lifted by decision of the Agency.

55.6 (h) (5) If the Laboratory has not provided evidence determined to be satisfactory by the Agency at the end of the extended Suspension or extended Analytical Testing Restriction period, the Agency may Revoke the Laboratory's accreditation.

55.6 (h) (6) The Agency will notify the Laboratory of its decision to revoke the Laboratory's HEAL accreditation in accordance with Article 55.4 (c).

55.6 (i) Revoked Accreditation

55.6 (i) (1) If a laboratory whose HEAL accreditation has been Revoked wishes to seek a new HEAL accreditation, it must apply for HEAL accreditation as a new laboratory in accordance with Article 51.2.

55.6 (i) (2) When seeking a new HEAL accreditation, the laboratory may request that the Agency expedite the laboratory re-accreditation procedure, which may be approved by the Agency. To do so the laboratory shall provide the Agency, as part of its application for a new accreditation, information that it considers constitutes "exceptional circumstances" as justification for modifying the requirements of Articles 51.2 and 51.3 to expedite the entry of the laboratory into, and/or shortening the duration of, the probationary phase of accreditation. At its sole discretion, the Agency may determine whether such modifications are justified, and which steps must be followed prior to granting approval to the laboratory to enter the probationary phase of accreditation.

55.6 (j) Voluntary Cessation of Laboratory Operations

55.6 (j) (1) A Laboratory may decide to voluntarily cease its anti-doping Analytical Testing operations on either a temporary or permanent basis despite not having been found to have committed any analytical failures or other ESL noncompliance(s) and not having been subject to an Analytical Testing Restriction or Suspension or Revocation of its HEAL accreditation.

55.6 (j) (2) In such circumstances, the Laboratory shall inform the Agency and provide, in writing, the reason(s) for the cessation of anti-doping Analytical Testing operations as soon as the decision is taken to cease its operations and no later than three (3) months prior to the date on which its decision shall take effect. The Laboratory shall also take all necessary measures to notify all its clients of the decision to cease its operations and to arrange, in consultation with its clients, to transfer Samples to another Laboratory(-ies) in accordance with Article 55.6 (b) (temporary closure) or 55.6 (f) (permanent closure).

55.6 (j) (3) If a Laboratory voluntarily ceases its anti-doping Analytical Testing operations on a temporary basis, the Laboratory shall maintain satisfactory performance in the analysis of EQAS samples during the period of inactivity. The period of temporary cessation of Analytical Testing activities shall not exceed six (6) months, with one possible extension of up to six (6) months (as determined by the Agency). If the Laboratory is unable to resume its Analytical Testing operations within a twelve (12)-month period, the Agency shall revoke the Laboratory's accreditation, unless otherwise approved by the Agency.

55.6 (j) (4) If a Laboratory decides to cease its operations on a permanent basis, the Laboratory shall

assist the Agency with the transfer of relevant Sample data and records to the Laboratory(-ies) that have been selected to receive the Samples.

56 CODE OF ETHICS FOR LABORATORIES

56.1 Confidentiality

56.1 (a) Directors of Laboratories, their delegates and all Laboratory staff shall respect and comply with ESL and Protocol.

56.2 Research in Support of Doping Control

56.2 (a) Laboratories shall participate in research programs, provided that the Laboratory Director is satisfied with their bona fide nature and the program(s) have received proper ethical approval, if applicable. The Laboratory shall not engage in any research activity that undermines or is detrimental to the purposes of the Act.

56.2 (b) The Laboratories are expected to develop a research and development program to support and expand the scientific foundation of Doping Control. This research may consist of the development of new methods or technologies, the pharmacological characterization of a new doping agent, the characterization of a masking agent or method, and other topics relevant to the field of Doping Control.

56.2 (c) Research on Equine (and other animal species) Subjects

56.2 (d) Laboratories shall follow institutional animal care and use guidelines and requirements regarding the use of animal subjects in research.

56.2 (e) Covered Horses who may undergo Doping Control Testing shall not be the subjects of drug Administration studies that include Prohibited Substances or Prohibited Methods.

56.2 (f) Controlled Substances

56.2 (g) The Laboratories are expected to comply with the relevant and applicable national laws regarding the handling, storage and discarding of controlled (illegal) substances.

56.3 Analysis

56.3 (a) The Laboratory shall not engage in any analysis or activity that undermines or is detrimental to the purposes of the Act.

56.3 (b) Analytical Testing for Other Anti-Doping Organizations:

56.3 (c) The Laboratories shall accept Samples for Analytical Testing only if all the following conditions have been met:

56.3 (d) The Sample matrix is of the proper type (e.g., blood, urine, hair or other Samples) for the requested analyses;

56.3 (d) (1) The Samples have been collected, sealed and transported to the Laboratory in accordance with procedures equivalent to the Equine Testing and Investigations Standards; and

56.3 (d) (2) The collection is a part of a legitimate anti-doping and medication control program, as determined by the Agency, or satisfies any of the conditions for Sample analysis indicated in Article 53.5 (i).

56.4 Analytical Testing for Covered Persons or those acting of their behalf

56.4 (a) Laboratories shall not accept Samples directly from individual Covered Persons or from individuals or organizations acting on their behalf.

56.5 Other Analytical Activities

56.5 (a) The Laboratory shall not provide analytical services in a Doping Control adjudication, unless specifically requested by the Agency or an adjudication body.

56.5 (b) The Laboratory shall not engage in analyzing commercial material or preparations (e.g., dietary or herbal supplements), unless:

56.5 (b) (1) Specifically requested by the Agency or an adjudication body as part of a Results Management process;

56.5 (b) (2) If done as part of a legitimate anti-doping research program, as determined by the Agency; or

56.5 (b) (3) If a request is made by a Covered Person or their representative, the Laboratory may conduct the analysis if agreed by the Agency, which may also specify conditions that must be followed prior to or during the analysis (e.g., verification of original sealed packages, product batch number).

56.5 (c) The Laboratory shall not provide results, documentation or advice that, in any way, could be used as an endorsement of products or services.

56.5 (d) Analytical activities performed outside the Act will not fall under Agency-accredited status of the laboratory and shall not negatively affect the Analytical Testing of Samples from the Agency.

56.6 Sharing of Knowledge

56.6 (a) When information on new doping substance(s), method(s), or practice(s) is known to the Laboratory, such information shall be shared with the Agency within sixty (60) days. When possible, the Laboratories shall share information with the Agency regarding the detection of potentially new or rarely detected doping agents as soon as possible. Immediately after having been notified of the Use of a new substance or method as a doping agent, the Agency will inform all Laboratories.

56.6 (b) The Laboratory Director or staff shall participate in developing standards for best practice and enhancing uniformity of Analytical Testing in the HEAL-accredited laboratory system.

56.7 Duty to Preserve the Integrity of the Anti-Doping and Medication Control Program Contemplated in the Act and to Avoid any Detrimental Conduct

56.7 (a) The personnel of Laboratories shall not engage in conduct or activities that undermine or are detrimental to the anti-doping and medication control program contemplated in the Act. Such conduct could include, but is not limited to, fraud, embezzlement, perjury, etc. that would cast doubt on the integrity of the anti-doping and medication control program.

56.7 (b) All employees of Laboratories shall strictly respect the confidentiality of Analytical Testing results, as well as of all other Laboratory, including information provided by the Agency under confidentiality.

56.7 (c) No employee or consultant of Laboratories shall provide counsel, advice or information to Covered Persons or others regarding techniques or methods used to mask or avoid detection of, alter metabolism of, or suppress excretion of a Prohibited Substance or its Metabolite(s), or Marker(s) of a Prohibited Substance or Prohibited Method in order to avoid an Adverse Analytical Finding.

56.7 (d) No employee or consultant of Laboratories shall provide information about a Test Method to a Covered Person, or from individuals or organizations acting on their behalf, which could be used to avoid the detection of doping. They should instead be referred to the Agency.

56.7 (e) No staff of Laboratories shall assist a Covered Person in avoiding collection of a representative Sample (e.g., advice on masking strategies or detection windows).

56.7 (f) [This does not prohibit the publication and/or presentation of scientific research results, general presentations to educate Covered Persons, students, or others concerning anti-doping programs and Prohibited Substances or Prohibited Methods.]

56.7 (g) If a staff member of a Laboratory is requested to provide evidence in anti-doping proceedings, they

are expected to provide independent, scientifically valid expert testimony.

56.7 (h) The Laboratory shall not issue any statements related to its analytical processes or findings, unless otherwise provided in Protocol. The responsibility for evaluation of these findings with further action and publication, if considered necessary, shall be the sole responsibility of the responsible the Agency.

56.8 Breach and Enforceability

56.8 (a) A failure to respect any of the provisions of this Code of Ethics may result in the Laboratory being subject to Disciplinary Proceedings instituted by the Agency to either suspend or revoke its HEAL accreditation or its Agency approval, as applicable.

56.8 (b) In addition, a failure to respect any of the provisions of this Code of Ethics may result in staff of the Laboratory being subject to disciplinary action by the Laboratory, respectively, resulting in consequences beyond those stipulated under the ESL, including potential termination of employment or, where applicable, the imposition of criminal charges.

57 RESEARCH AND DEVELOPMENT ACTIVITY REQUIREMENTS

57.1 The Laboratory must receive a minimum score of ten (10) points annually.

57.1 (a) Five (5) points for each Peer-Reviewed Manuscript;

57.1 (b) Five (5) points for the production of educational materials

57.1 (c) Three (3) points for each Funded Research Project

57.1 (d) One (1) point for each Laboratory (Internal) Method Development. Note The validation or implementation of established anti-doping methods with only minor adjustments, or repetition of research previously published or presented by others, is not sufficient to be considered as a research and development activity

Testing & Investigations Standards (Not Submitted to FTC)

58 Equine Testing and Investigations Standards Introduction and Scope

58.1 The Equine Testing and Investigations Standards is developed pursuant to the Horseracing Integrity and Safety Act of 2020 and the Equine Anti-Doping and Medication Control Protocol (“Protocol”).

58.2 The first purpose of the Equine Testing and Investigations Standards (the “Testing and Investigations Standards”) is to plan for intelligent and effective Testing, both on Race Day and Out-of-Competition, and to maintain the integrity and identity of the Samples collected from the point of notification of a Covered Horse’s selection for Testing, to the point the Samples are delivered to a Laboratory for analysis. To that end, these Testing and Investigations Standards (including its Annexes) establish protocols for test planning (including collection and use of Covered Horse whereabouts information), notification of a Covered Horse’s selection for Testing, preparing for and conducting Sample collection, security/post-test Administration of Samples and documentation, and transport of Samples to Laboratories for analysis.

58.3 The second purpose of the Testing and Investigations Standards is to establish rules for the efficient and effective gathering, assessment, and use of anti-doping and medication control intelligence and for efficient and effective investigations into possible anti-doping and medication control rule violations.

58.4 Terms used in these Testing and Investigations Standards that are defined terms in the Equine Program Dictionary are italicized.

59 Standards for Testing

59.1 Planning Effective Testing

59.1 (a) Objective

59.1 (a) (1) The Agency is required to plan and implement intelligent Testing on Covered Horses over

which it has authority, and which is proportionate to the risk of doping, misuse of medication, and effective to detect and to deter such practices. The objective of this section is to set out the steps to develop a Risk Assessment in order to inform Testing plans that best ensure clean competition and protect the health and welfare of Covered Horses.

59.1 (a) (2) The Agency shall ensure that Covered Persons with a conflict of interest in the outcome of the Testing being contemplated are not involved in test planning or in the process of selection of Covered Horses for Testing.

59.1 (a) (3) The Agency should monitor, evaluate, and update its Risk Assessment during the year/cycle in light of changing circumstances and in implementing its Testing plans.

59.1 (b) Risk Assessment

59.1 (b) (1) The Risk Assessment shall be conducted in good faith, reviewed and updated as required, and should take into account (if available) the following information:

59.1 (b) (1) (i) Discipline, and individual factors that may result in a higher potential for adopting doping behavior and/or misuse of medication;

59.1 (b) (1) (ii) Available statistics and research on doping trends and/or misuse of medication, practices, and methods;

59.1 (b) (1) (iii) Reliable information received/intelligence developed on possible doping practices;

59.1 (b) (1) (iv) The outcomes of previous test planning cycles including past testing strategies;

59.1 (b) (1) (v) Optimal times to apply specific test types (including analysis) to maximize opportunities for detecting and deterring doping;

59.1 (b) (1) (vi) Given the structure of the racing season (including generic racing schedules and training patterns), at what time(s) during the year a horse is most likely to be administered Prohibited Substances or subjected to Prohibited Methods (to enhance or impair performance or impact welfare/soundness); and

59.1 (b) (1) (vii) The Agency shall consider in good faith any Risk Assessment carried out by a State Racing Commission or racing authority in another country and provided to the Agency for purposes of enhancing its Risk Assessment.

59.1 (c) Prioritizing between Covered Horses, Types of Testing, and Samples

59.1 (c) (1) Only the Agency has the authority to direct Testing on any Covered Horse. All Covered Horses shall be included in the Registered Testing Pool and therefore subject to whereabouts requirements. The Agency should consider various factors in prioritizing the allocation of Testing resources. In addition, the Agency will use Target Testing to focus Testing resources where they are most needed within the overall pool of Covered Horses.

59.1 (c) (2) Factors relevant to determining which Covered Horses should be subject of Target Testing may include (but are not limited to):

59.1 (c) (2) (i) Covered Horses serving a period of Ineligibility or a Provisional Suspension;

59.1 (c) (2) (ii) Covered Horses who were high priority for Testing before retirement and are now returning from retirement to active participation;

59.1 (c) (2) (iii) Covered Persons' prior anti-doping and medication control rule violations, Testing history, including any abnormal biological Sample data (e.g., Atypical Finding reported by a Laboratory);

59.1 (c) (2) (iv) Performance history, performance pattern, and/or high performance (e.g., Trainer strike rate) without a commensurate Testing record;

59.1 (c) (2) (ix) Association with a third party (such as a Trainer, Veterinarian, or Owner) with a history of involvement in doping;

59.1 (c) (2) (v) Repeated failure to meet whereabouts requirements;

59.1 (c) (2) (vi) Suspicious Whereabouts Filing patterns;

59.1 (c) (2) (vii) Moving to or training in a remote location;

59.1 (c) (2) (viii) Suspicious withdrawal or absence from expected Covered Horserace(s);

59.1 (c) (2) (x) Injury;

59.1 (c) (2) (xi) Age/stage of career;

59.1 (c) (2) (xii) Financial incentives for improved or degraded performance, such as purse size, unusual betting patterns, or upcoming claiming race; and/or

59.1 (c) (2) (xiii) Reliable information from a third party, or intelligence developed by or shared with the Agency.

59.1 (c) (3) Target Testing is a priority because random Testing, or even weighted random Testing, does not ensure that all of the appropriate Covered Horses will be sufficiently tested. Covered Horses can be tested at any time and at any place. The Protocol does not impose any reasonable suspicion or probable cause requirement for Target Testing or Testing.

59.1 (c) (4) Testing which is not Target Testing should be determined based on the Risk Assessment. Testing should be conducted using a documented system for such selection, such as weighted (where Covered Horses are ranked using pre-determined criteria to increase or decrease the chances of selection) or completely random (where no pre-determined criteria are considered, and Covered Horses are chosen arbitrarily from a list or pool of names). Testing that is weighted should be prioritized and be conducted according to defined criteria which may take into account the risk factors to ensure that a greater percentage of at risk Covered Horses are selected.

59.1 (c) (5) Based on the Risk Assessment and prioritization process described above, the Agency should determine to what extent each of the following types of Testing is required to detect and deter doping and medication abuse practices within the sport intelligently and effectively:

59.1 (c) (5) (i) Race Day Testing and Out-of-Competition Testing;

59.1 (c) (5) (ii) Testing of urine;

59.1 (c) (5) (iii) Testing of hair;

59.1 (c) (5) (iv) Testing of blood; and

59.1 (c) (5) (v) Testing involving other matrices or methodologies as available.

59.1 (d) Sample Analysis, Retention Strategy, and Further Analysis

59.1 (d) (1) The Agency shall ask Laboratories to analyze Samples at minimum for the standard analysis menu based on whether the Sample was collected on Race Day or Out-of-Competition. The Agency may also consider undertaking more extensive Sample analysis for Prohibited Substances or Prohibited Methods based on the risk or any intelligence that the Agency may receive (e.g., specific Prohibited Substances, gene doping).

59.1 (d) (2) The Agency should develop a system for retention of Samples and the documentation relating to the collection of such Samples to enable the Further Analysis of such Samples at a later date in accordance with Article 6.1 (e). Such a system should comply with the requirements of the Laboratory Standards and should take into account the purposes of analysis of Samples set out in Protocol Article 6.1 (b), as well as (without limitation) the following elements:

59.1 (d) (3) Laboratory and Equine Passport Management Unit (“EPMU”) recommendations (when available);

59.1 (d) (3) (i) The possible need for retroactive analysis in connection with the Equine Biological Passport program (when available);

59.1 (d) (3) (ii) New relevant detection methods to be introduced in the future;

59.1 (d) (3) (iii) Samples collected meeting some or all of the criteria set out at Article 4.4;

59.1 (d) (3) (iv) Any other information made available to the Agency such that it determines in its sole discretion based on that information or random selection that long-term storage or Further Analysis of Samples is appropriate.

59.1 (e) Coordinating with State Racing Commissions and Other Entities

59.1 (e) (1) Any Testing done must be initiated and directed by the Agency. The Agency may coordinate its Testing efforts with State Racing Commissions (subject to the applicable State Racing Commission electing to enter into an agreement with the Agency) by, for example, utilizing Sample Collection Personnel employed or designated by a State Racing Commission to collect Samples how and when directed by the Agency. Any state rule, law, or regulation preventing Sample Collection Personnel or potential Sample Collection Personnel employed or designated by a State Racing Commission from contracting with the Agency to collect Samples is preempted by this rule that allows for such arrangements. Regardless of who collects a Sample, only the Agency shall receive all Sample results directly from the Laboratory.

59.1 (e) (2) The Agency may contract with third parties to collect Samples on the Agency's behalf and third parties may contract with the Agency to collect additional Samples on Covered Horses consistent with the Act and the Protocol.

59.1 (e) (3) The Agency shall consult and coordinate with law enforcement and other relevant authorities, in obtaining, developing, and sharing information and intelligence that can be useful in informing test planning.

59.2 Notification

59.2 (a) Objective

59.2 (a) (1) The objective is to notify the Responsible Person or Nominated Person that their Covered Horse has been selected for Testing with no advance notice, except to grant immediate access to the Covered Horse; that the rights of those involved in the Sample collection are maintained; that the welfare of the Covered Horse is maintained; that there are no opportunities to manipulate the Sample; and that the notification is documented.

59.2 (b) Requirements Prior to Notification

59.2 (b) (1) No Advance Notice Testing should be the method for Sample collection save in exceptional and justifiable circumstances. Ideally, if the Responsible Person is with the Covered Horse at the time of notification, the Responsible Person should be the first Person notified that the Covered Horse has been selected for Sample collection. In order to ensure that Testing is conducted on a No Advance Notice Testing basis, the Agency shall ensure Testing selection decisions are only disclosed in advance of Testing to those who need to know in order for such Testing to be conducted. Any notification to a third party shall be conducted in a secure and confidential manner to minimize the risk that the Responsible Person or other Covered Person will receive any advance notice of a Covered Horse's selection for Sample collection.

59.2 (b) (2) The Agency shall appoint Doping Control Officers ("DCOs"), Chaperones, and other Sample Collection Personnel sufficient to ensure No Advance Notice Testing and continuous observation of the Covered Horse or confirmation the Covered Horse is in a secure location (a stall, for example) throughout the Doping Control process. Sample Collection Personnel must be trained for their assigned responsibilities, must not have a conflict of interest in the outcome of the Sample collection, and must not be minors. See Article 65 for more information.

59.2 (b) (3) Sample Collection Personnel shall have official documentation, provided by the Agency, evidencing their authority to collect a Sample from the Covered Horse, such as a credential. DCOs' credentials shall include their name, photograph, and date of expiration or a letter of authority from the Agency and a federal or state issued identification. The Agency may determine what information to include on other Sample Collection Personnel's credentials.

59.2 (b) (4) Information provided in the Covered Horse's Whereabouts Filing and registration with the

Authority, shall be used by Sample Collection Personnel to confirm the identity of the Covered Horse. Confirmation of the Covered Horse's identity by any other method or failure to confirm the identity of the Covered Horse, shall be documented, including through photographs, and reported to the Agency.

59.2 (b) (5) The DCO shall establish the location of the selected Covered Horse and plan the approach and timing of notification, taking into consideration the specific circumstances of the location, schedule, and the situation in question (e.g., Race Day, training).

59.2 (c) Requirements for Notification

59.2 (c) (1) Out-of-Competition Testing

59.2 (c) (1) (i) As soon as practical, the Sample Collection Personnel shall ensure that the Responsible Person or Nominated Person is informed:

59.2 (c) (1) (i) (A) That the Covered Horse is required to undergo a Sample collection;

59.2 (c) (1) (i) (B) That immediate access to the Covered Horse shall be granted, unless there are valid reasons for a delay (e.g., horse is currently being exercised, cooled down);

59.2 (c) (1) (i) (C) Of the responsibilities of the Responsible Person or Nominated Person with respect to the Covered Horse, including the requirement to: Provide a secure location where a Sample(s) can be collected from the Covered Horse like a stall or other safe and secure location; Ensure that the Covered Horse remains within continuous observation of Sample Collection Personnel at all times or is in a secure location (a stall, for example) until the completion of the Sample collection procedure; Not leave the Covered Horse unattended once Responsible Person or Nominated Person is notified and contact is made with the Covered Horse and until Sample(s) have been collected; Produce identification of the Responsible Person or Nominated Person if possible and identification of the Covered Horse if requested (pictures will be taken of the individual(s) and the Covered Horse if identification is requested and not provided); Comply with Sample collection procedures and Cooperate (and the Responsible Person or Nominated Person, if applicable, should be advised of the possible Consequences of a Failure to Comply); and Ensure the Covered Horse is not administered any medications or supplements until the completion of Sample collection, once Responsible Person or Nominated Person is notified and contact is made with the Covered Horse and until Sample(s) have been collected, unless there is a medical emergency as determined by a Veterinarian.

59.2 (c) (1) (ii) The Sample Collection Personnel shall have the Responsible Person or Nominated Person sign an appropriate form to acknowledge and accept the notification. If the Responsible Person or Nominated Person refuses to sign that they have been notified on behalf of the Covered Horse, or evades the notification, the Sample Collection Personnel shall, if possible, inform the Responsible Person or Nominated Person of the Consequences of a Failure to Comply, and the Sample Collection Personnel (if not the DCO) shall immediately report all relevant facts to the DCO. When possible, the Sample Collection Personnel shall continue to collect a Sample. The DCO shall document the facts in a detailed report and report the circumstances to the Agency. The Agency shall follow the steps for a review of a Possible Failure to Comply in Part Four below.

59.2 (c) (1) (iii) From the time that the Sample Collection Personnel are granted access to the Covered Horse until the end of the Sample Collection Session, a member of the Sample Collection Personnel shall keep the Covered Horse under observation at all times or confirm the Covered Horse is in a secure location (a stall, for example).

59.2 (c) (1) (iv) A Nominated Person may change during the Sample collection process upon reasonable request to the Sample Collection Personnel so long as the new Nominated Person (a) falls within the scope of the definition of Nominated Person, (b) completes the relevant portions of the Sample collection paperwork, and (c) does not interfere with the Sample collection process. Any changes of Nominated Person during the Sample collection process shall be documented by the Sample Collection Personnel.

59.2 (c) (2) Race Day Post-Race Testing

59.2 (c) (2) (i) A member of the Sample Collection Personnel will generally tag a Covered Horse selected for Doping Control after the Race is completed in the unsaddling area and Chaperone the Covered Horse from the point of tagging/notification for Doping Control. Notification should be prompt after the conclusion of a Race and in no case exceed one hour after the Race or winner's

circle activities are completed, if applicable.

59.2 (c) (2) (ii) While the Covered Horse is being unsaddled (or as soon as practical), a member of the Sample Collection Personnel should inform the Responsible Person or Nominated Person (who will normally be the Groom):

59.2 (c) (2) (ii) (A) That the Covered Horse is required to undergo a Sample collection;

59.2 (c) (2) (ii) (B) That the Covered Horse must immediately report to the Test Barn, unless there are valid reasons for a delay;

59.2 (c) (2) (ii) (C) The location of the Test Barn (if not known to the Responsible Person or Nominated Person);

59.2 (c) (2) (ii) (D) Of the responsibilities of the Responsible Person or Nominated Person with respect to the Covered Horse, including the requirement to: Ensure that the Covered Horse remains within continuous observation of the Sample Collection Personnel or in a secure location (a stall, for example) at all times until the completion of the Sample collection procedure; Confirm the water bucket, if provided by Sample Collection Personnel at the Test Barn, is clean and acceptable and only for that Covered Horse during that Covered Horse's Sample Collection Session; Not leave the Covered Horse unattended once the Responsible Person or Nominated Person is notified and contact is made with the Covered Horse and until Sample(s) have been collected; Produce identification of the Responsible Person or Nominated Person if possible and identification of the Covered Horse as described above (pictures will be taken of the individual(s) and the Covered Horse if no identification is provided); Comply with Sample collection procedures and Cooperate (and the Responsible Person or Nominated Person, if applicable, should be advised of the possible Consequences of a Failure to Comply); and Ensure the Covered Horse is not administered any medications or supplements until the completion of Sample collection, unless there is a medical emergency as determined by an Official Veterinarian.

59.2 (c) (2) (iii) The Sample Collection Personnel shall notify the Responsible Person or Nominated Person and document the time and the individual notified (e.g., by taking a photograph or by having the Responsible Person or Nominated Person sign an appropriate form) and the Responsible Person or Nominated Person must sign an appropriate form to acknowledge and accept the notification no later than once in the Test Barn or other secure location. If the Responsible Person or Nominated Person refuses to sign that they have been notified on behalf of the Covered Horse, or evades the notification, the Sample Collection Personnel shall, if possible, inform the Responsible Person or Nominated Person of the Consequences of a Failure to Comply, and the Sample Collection Personnel (if not the DCO) shall immediately report all relevant facts to the DCO. When possible, the Sample Collection Personnel shall continue to collect a Sample. The DCO shall document the facts in a detailed report and report the circumstances to the Agency. The Agency shall follow the steps for a review of a Possible Failure to Comply in Part Four below.

59.2 (c) (2) (iv) From the time that the Covered Horse is tagged until the end of the Sample Collection Session, the Sample Collection Personnel shall keep the Covered Horse under observation or ensure the Covered Horse is in a secure location (a stall, for example).

59.2 (c) (2) (v) A Nominated Person may change during the Sample collection process upon reasonable request to the Sample Collection Personnel so long as the new Nominated Person (a) falls within the scope of the definition of Nominated Person, (b) completes the relevant portions of the Sample collection paperwork, and (c) does not interfere with the Sample collection process. Any changes of Nominated Person during the Sample collection process shall be documented by the Sample Collection Personnel.

59.2 (c) (3) Requests for Delay

59.2 (c) (3) (i) The DCO may at their discretion consider any reasonable third-party request or any request by the Responsible Person or Nominated Person for permission to delay beginning the Sample collection process following acknowledgment and acceptance of notification. The DCO may grant such permission if the Covered Horse can be continuously chaperoned and kept under continuous observation by Sample Collection Personnel during the delay. Delayed reporting to the stall or Test Barn may be permitted for the following activities:

59.2 (c) (3) (i) (A) For Race Day Testing: Participation in winner's circle; Obtaining necessary medical Treatment if there is a medical emergency as determined by an Official Veterinarian; or Any other reasonable circumstances, as determined by the DCO, taking into account any instructions of the Agency.

59.2 (c) (3) (i) (B) For Out-of-Competition Testing: Completing a training session or a cool down; Receiving necessary medical Treatment if there is a medical emergency as determined by a Veterinarian; or Any other reasonable circumstances, as determined by the DCO, taking into account any instructions of the Agency.

59.2 (c) (3) (ii) The DCO shall reject a request for delay from a Responsible Person or Nominated Person if it will not be possible for the Covered Horse to be continuously observed or secured during such delay, unless there is a medical emergency as described above.

59.2 (c) (3) (iii) Sample Collection Personnel shall document any reasons for delay in reporting to the stall or Test Barn and/or reasons for leaving the stall or Test Barn that may require further investigation by the Agency.

59.2 (c) (3) (iv) If immediate access to the Covered Horse is not granted, the DCO shall report to the Agency a possible Failure to Comply. If at all possible, the DCO shall proceed with collecting a Sample. The Agency shall investigate a possible Failure to Comply in accordance with Part Four below.

59.3 Preparing for Sample Collection Session

59.3 (a) Objective

59.3 (a) (1) To prepare for the Sample Collection Session in a manner that ensures that the session can be conducted efficiently and effectively including with sufficient resources, e.g., personnel and equipment.

59.3 (b) Requirements for Preparing for the Sample Collection Session

59.3 (b) (1) The Agency should establish a system for obtaining all the information necessary to ensure that the Sample Collection Session can be conducted effectively.

59.3 (b) (2) For Race Day Testing that occurs post-Race, a Test Barn should be used that, where possible, is used solely as a Test Barn for the duration of the Doping Control and unauthorized persons should not be permitted. Should the DCO determine the Test Barn is unsuitable, they shall seek an alternative location.

59.3 (b) (3) Unless otherwise approved by the Agency, the Test Barn should be equipped with:

59.3 (b) (3) (i) A walk ring or area for Covered Horses to walk in or adjacent to the Test Barn that is large enough to accommodate several horses and allow for continuous observation of the Covered Horses;

59.3 (b) (3) (ii) Sufficient enclosed stalls (at least one) for the volume of Testing and that permit observation of the collection process and provide for the protection of Covered Horses undergoing Testing and space for Sample Collection Personnel and up to two Covered Persons per Covered Horse;

59.3 (b) (3) (iii) Facilities and equipment for the collection, identification, and storage of Samples including one refrigerator or cooler that can be locked or otherwise secured;

59.3 (b) (3) (iv) An area and appropriate facilities for a Covered Horse to be bathed;

59.3 (b) (3) (v) A table or other suitable surface;

59.3 (b) (3) (vi) Access to hot and cold running water;

59.3 (b) (3) (vii) Clean water buckets for each Covered Horse or space for a Covered Person to provide their own water bucket for their Covered Horse; and

59.3 (b) (3) (viii) A security officer to ensure no unauthorized person is permitted in the Test Barn.

59.3 (b) (4) For Out-of-Competition Testing, the DCO will determine a suitable location to be used for the Sample Collection Session. If at a stable, by default the Covered Horse's own stall should be used.

59.3 (b) (5) Sample Collection Personnel should ensure they have and use Sample Collection Equipment provided by or approved by the Agency.

59.3 (b) (6) Sample Collection Equipment for urine, blood, and hair Samples which should, at a minimum:

59.3 (b) (6) (i) Have a unique numbering system incorporated into all A and B bottles, containers, tubes, or other items used to seal the Sample;

59.3 (b) (6) (ii) Have a Tamper Evident sealing system;

59.3 (b) (6) (iii) Ensure the identity of the Responsible Person and Covered Horse are not evident from the equipment itself;

59.3 (b) (6) (iv) Ensure that all equipment is clean and sealed prior to use;

59.3 (b) (6) (ix) Have a built-in security identification feature(s) which allows verification of the authenticity of the equipment;

59.3 (b) (6) (v) Be constructed of a material and sealing system that is able to withstand the handling conditions and environment in which the equipment will be used or subjected to, including but not limited to transportation, Laboratory analysis, and long-term frozen storage up to the period of the statute of limitations;

59.3 (b) (6) (vi) Be constructed of a material and sealing system approved by the Agency that should:

59.3 (b) (6) (vi) (A) Maintain the integrity (chemical and physical properties) of the Sample for the analytical Testing;

59.3 (b) (6) (vi) (B) Withstand temperatures of -80 °C. Tests conducted to determine integrity under freezing conditions shall use the matrix that will be stored in the Sample bottles, containers, or tubes, (e.g., blood, urine);

59.3 (b) (6) (vi) (C) Be constructed of a material and with a sealing system that can withstand a minimum of three (3) freeze/thaw cycles;

59.3 (b) (6) (vii) The bottles, containers, and tubes shall be transparent or translucent so the Sample is visible;

59.3 (b) (6) (viii) Have a sealing system which allows verification by the Responsible Person or Nominated Person and the DCO that the Sample is correctly sealed in the bottles or containers;

59.3 (b) (6) (x) Be compliant with the standards published by the International Air Transport Association (IATA) for the transport of exempt specimens which includes urine and/or blood Samples in order to prevent leakage during transportation by air;

59.3 (b) (6) (xi) Have been manufactured under the internationally recognized ISO 9001 certified process which includes quality control management systems; and

59.3 (b) (6) (xii) Be able to be resealed after initial opening by a Laboratory to maintain the integrity of the Sample and Chain of Custody in accordance with the requirements for long-term storage of the Sample and Further Analysis.

59.3 (b) (6) (xiii) For urine Sample collections:

59.3 (b) (6) (xiii) (A) Have the capacity to contain a minimum of 100 mL volume of urine in each A and B bottle or container;

59.3 (b) (6) (xiii) (B) Have a visual marking on the A and B bottles or containers and the collection vessel, indicating: the minimum volume of urine (25 mL) required in each A and B bottle or containers; the maximum volume levels that allow for expansion when frozen without compromising the bottle, container, or the sealing system; and the level of suitable volume for urine for analysis on the collection vessel.

59.3 (b) (6) (xiv) For blood Sample collection:

59.3 (b) (6) (xiv) (A) Have the ability to collect, store and transport blood tubes in separate A and B containers;

59.3 (b) (6) (xiv) (B) For the analysis of Prohibited Substances or Prohibited Methods in whole blood or plasma and/or for profiling blood parameters, each A and B container must have the capacity to contain a minimum of 30 mL of blood (e.g., three 10mL tubes);

59.3 (b) (6) (xiv) (C) For the analysis of Prohibited Substances or Prohibited Methods in serum, each A and B tube must have the capacity to contain a minimum of 10mL of blood; and

59.3 (b) (6) (xiv) (D) For the transport of blood Samples, ensure the storage and transport device and temperature logger meet the requirements listed in Article 63 – Collection of Blood Samples.

59.3 (b) (7) Sample Collection Personnel should ensure they have the necessary equipment for hair Sample collection and any other approved Testing matrices or methodologies.

59.4 Conducting the Sample Collection Session

59.4 (a) Objective

59.4 (a) (1) To conduct the Sample Collection Session in a manner that ensures the integrity, security, and identity of the Sample and respects the humane treatment and welfare of the Covered Horse.

59.4 (b) Requirements for Sample Collection

59.4 (b) (1) The Agency shall be responsible for the overall conduct of the Sample Collection Session, with specific responsibilities delegated to the DCO.

59.4 (b) (10) At the conclusion of the Sample Collection Session the Responsible Person or Nominated Person and DCO shall sign appropriate documentation to indicate their satisfaction that the documentation accurately reflects the details of the Covered Horse's Sample Collection Session, including any concerns expressed by the Responsible Person or Nominated Person.

59.4 (b) (11) The Responsible Person shall be provided access to the Doping Control form for the Covered Horse's Sample Collection Session.

59.4 (b) (2) The following may be authorized and/or required to be present during the Sample Collection Session:

59.4 (b) (2) (i) Sample Collection Personnel sufficient to notify, Chaperone, and collect the required Samples;

59.4 (b) (2) (ii) The Responsible Person or Nominated Person must be present during the Sample Collection Session. If the Responsible Person or Nominated Person is not present this will be documented by the DCO;

59.4 (b) (2) (iii) At least one, but no more than two, Covered Persons may be present to assist during the Sample Collection Session except in exceptional circumstances as determined by the DCO;

59.4 (b) (2) (iv) Collection of Samples must only be performed by Sample Collection Personnel approved by the Agency; and

59.4 (b) (2) (v) Any Person authorized by the Agency who is involved in the training or supervision of Sample Collection Personnel.

59.4 (b) (3) Except as provided above, the Sample Collection Personnel shall coordinate with the Test Barn security officer to ensure that no unauthorized person is permitted in the Test Barn.

59.4 (b) (4) For Race Day post-Race Testing, the Covered Horse shall remain in the Test Barn through the end of the Sample Collection Session.

59.4 (b) (5) Samples shall be collected in a manner that ensures:

59.4 (b) (5) (i) the Sample is of a quality and quantity that meets the relevant Sample suitability and analytical requirements;

59.4 (b) (5) (ii) the Sample has not been manipulated, substituted, contaminated, or otherwise tampered with in any way;

59.4 (b) (5) (iii) the Sample is clearly and accurately identified; and

59.4 (b) (5) (iv) the Sample is securely sealed in a Tamper Evident kit.

59.4 (b) (6) The Sample Collection Personnel shall collect the Sample from the Covered Horse according to the following protocol(s) for the specific type of Sample collection:

59.4 (b) (6) (i) Article 62: Collection of Urine Samples;

59.4 (b) (6) (ii) Article 63: Collection of Blood Samples;

59.4 (b) (6) (iii) Article 64: Collection of Hair Samples;

59.4 (b) (7) Any anomalous behavior by the Responsible Person, Nominated Person, and/or Covered Persons associated with the Covered Horse or behavior with potential to compromise the Sample collection shall be recorded in detail by the Sample Collection Personnel. If appropriate, the Agency shall review the possible Failure to Comply in accordance with Part Four below.

59.4 (b) (8) The DCO shall provide the Responsible Person or Nominated Person with the opportunity to document any concerns they may have about how the Sample Collection Session was conducted.

59.4 (b) (9) The following information shall be recorded as a minimum in relation to the Sample Collection Session:

59.4 (b) (9) (i) Date, time of notification, name and signature of notifying Sample Collection Personnel;

59.4 (b) (9) (ii) If Race Day Testing, the arrival time of the Covered Horse to the Test Barn;

59.4 (b) (9) (iii) The name of the Covered Horse, Responsible Person, and Nominated Person (if applicable);

59.4 (b) (9) (iv) Any changes in Nominated Person during the Sample collection process;

59.4 (b) (9) (ix) The Sample code number(s);

59.4 (b) (9) (v) The gender of the Covered Horse (male, female, gelding);

59.4 (b) (9) (vi) The color of the Covered Horse;

59.4 (b) (9) (vii) Means by which the Covered Horse identity is validated (e.g., microchip number, tattoo or brand);

59.4 (b) (9) (viii) Nominated Person’s contact information (i.e., home address, email address, and telephone number), if not a Covered Person or if the Covered Person’s contact information is not readily available to the Sample Collection Personnel;

59.4 (b) (9) (x) Date and time of sealing of each Sample collected and date and time of completion of entire Sample collection process (i.e., the time when the Responsible Person or Nominated Person signs the declaration at the bottom of the Doping Control form);

59.4 (b) (9) (xi) Location of Doping Control (e.g., for Out-of-Competition barn name, city, and state;

for Race Day name of event, city, and state);

59.4 (b) (9) (xii) The type of the Sample (e.g., urine, blood, hair);

59.4 (b) (9) (xiii) The type of test (Race Day, Race Day TCO2, or Out-of-Competition);

59.4 (b) (9) (xiv) The name and signature of the Sample Collection Personnel catching the urine Sample and/or collecting hair and/or blood Sample (where applicable);

59.4 (b) (9) (xix) Any comments or concerns from the Responsible Person or Nominated Person regarding the conduct of the Sample Collection Session;

59.4 (b) (9) (xv) Whether furosemide was administered to the Covered Horse within 48 hours before the Race;

59.4 (b) (9) (xvi) Required Laboratory information on the Sample (e.g., for urine Sample, its volume; for hair Sample, mane/tail and pulled/cut);

59.4 (b) (9) (xvii) For a blood Sample, the DCO shall record the information as outlined in Article 63 – Collection of Blood Samples;

59.4 (b) (9) (xviii) Any irregularities in procedures for example, if advance notice was provided or if there were delays to arriving to the Test Barn;

59.4 (b) (9) (xx) Responsible Person or Nominated Person acknowledgment of the processing of Sample collection data and a description of such processing; and

59.4 (b) (9) (xxi) The name of additional Persons (if any) present during the Sample Collection Session.

59.5 Security/Post-Test Administration

59.5 (a) Objective

59.5 (a) (1) The objective is to ensure that all Samples and Sample collection documentation are securely stored prior to transport to the Laboratory.

59.5 (b) Requirements for Security/Post-Test Administration

59.5 (b) (1) Samples should be stored by Sample Collection Personnel in a manner that protects the integrity, identity, and security prior to transport to the Laboratory, as detailed in Article 62, 63, and 64.

59.5 (b) (2) Sample Collection Personnel are required to document who has custody of the Samples and/or is permitted access to the Samples.

59.5 (b) (3) The Agency shall develop a system for recording the Chain of Custody of Samples and receiving Sample Collection Session documentation to ensure that each Sample is securely handled and the documentation for each Sample is completed.

59.6 Transport of Samples and Documentation

59.6 (a) Objective

59.6 (a) (1) The objective is to ensure that Samples and related documentation arrive at the Laboratory that will be conducting the analysis in proper condition to do the necessary analysis and to ensure the Sample Collection Session documentation is sent to the Agency in a secure and timely manner.

59.6 (b) Requirements for Transport and Storage of Samples and Documentation

59.6 (b) (1) The Agency shall authorize a transport system that ensures Samples and documentation are transported in a manner that protects their integrity, identity, and security.

59.6 (b) (2) State Racing Commissions may select a Laboratory at which Samples collected in its state shall be analyzed. If specific analysis requested by the Agency cannot be performed at the selected Laboratory, the Agency may have the Sample sent to another Laboratory that can conduct the requested analysis. Each year the State Racing Commissions must make their Laboratory designation for all Samples collected within its state on or before September 30th of the year prior to the designation taking effect. If a State Racing Commission fails to select a Laboratory by this deadline, the Authority shall select the Laboratory for that particular state. The Agency may allow for a State Racing Commission to change its selection of Laboratory outside of the time-period set forth above if a reasonable request is made.

59.6 (b) (3) Samples (both A and B bottles) shall always be transported to the Laboratory using the Agency's authorized transport method, as soon as reasonably practicable after the completion of the Sample Collection Session. Samples shall be transported in a manner which minimizes the potential for Sample degradation due to factors such as delays and extreme temperature variations.

59.6 (b) (4) The Agency shall have the ability to confirm, if necessary, that both the Sample and Sample collection documentation arrived at their intended destinations. The Laboratory shall report any irregularities to the Agency on the condition of Samples upon arrival in line with the Laboratory Standards.

59.6 (b) (5) The Agency shall develop a system to ensure that, where required, instructions for the type of analysis to be conducted are provided to the Laboratory that will be conducting the analysis. In addition, the Agency shall provide the Laboratory with information as required for result reporting and statistical purposes and include whether long-term Sample storage is required.

59.6 (b) (6) Documentation identifying the Covered Horse and Responsible Person or Nominated Person shall not be included with the Samples or documentation sent to the Laboratory that will be analyzing the Samples.

59.6 (b) (7) If the Samples with accompanying documentation or the Sample Collection Session documentation are not received at their respective intended destinations, or if a Sample's integrity or identity may have been compromised during transport, the Agency shall consider whether the Samples should be voided. The decision to void a Sample is in the sole discretion of the Agency.

59.6 (b) (8) Documentation related to a Sample Collection Session and/or an anti-doping or medication control rule violation shall be stored by the Agency for a period of ten years or in accordance with the Agency's record retention policy.

59.7 Ownership of Samples

59.7 (a) Samples collected from a Covered Horse are owned by the Agency.

60 Standards for Intelligence Gathering

60.1 Objective

60.1 (a) The Agency shall ensure that it is able to obtain, assess, and process anti-doping and medication control intelligence from all available sources to help deter and detect doping and medication abuse; to inform effective, intelligent, and proportionate test planning; to plan Target Testing; and to conduct investigations as required by Protocol Article 5.6. The objective of this section is to establish standards for the efficient and effective gathering, assessment, and processing of such intelligence for these purposes.

60.2 Gathering Anti-Doping and Medication Abuse Intelligence

60.2 (a) The Agency should make every reasonable effort to ensure that it is able to capture or receive anti-doping and medication control intelligence from all available sources, including but not limited to Covered Persons (including through Substantial Assistance provided pursuant to Protocol Article 10.7 (a)) and members of the public (e.g., by means of a confidential tip platform), Sample Collection Personnel (whether via mission reports, incident reports, or otherwise), laboratories, pharmaceutical companies, the Authority,

State Racing Commissions, law enforcement, other regulatory and disciplinary bodies, and the media (in all its forms).

60.2 (b) The Agency shall ensure that anti-doping and medication control intelligence captured or received from a confidential source or in a non-public fashion is handled securely and confidentially, that sources of intelligence are protected, that the risk of leaks or inadvertent disclosure is properly addressed, and that intelligence shared with the Agency by law enforcement, other relevant authorities and/or other third parties in a matter intended to be confidential is processed, used, and disclosed only for legitimate legal, law enforcement, regulatory, anti-doping, or medication control purposes.

60.2 (c) The Agency shall facilitate and encourage whistleblowers.

60.3 Assessment and Analysis of Anti-Doping and Medication Abuse Intelligence

60.3 (a) The Agency should ensure that it is able to assess all anti-doping and medication control intelligence upon receipt for relevance, reliability, and accuracy, taking into account the nature of the source and the circumstances in which the intelligence has been captured or received.

60.3 (b) All relevant anti-doping and medication control intelligence captured or received by the Agency should be collated and analyzed to establish patterns, trends, and relationships that may assist the Agency in developing an effective anti-doping and medication control strategy and/or in determining (where the intelligence relates to a particular case) whether there is reasonable suspicion that an anti-doping or medication control rule violation may have been committed, such that further investigation is warranted.

60.4 Intelligence Outcomes

60.4 (a) Anti-doping and medication control intelligence may be used for the following purposes (without limitation): developing, reviewing, and revising Testing planning and/or in determining when to conduct Target Testing, and/or to create targeted intelligence files to be referred for investigation.

60.4 (b) The Agency may share intelligence, where appropriate with State Racing Commissions and/or law enforcement and/or other relevant regulatory or disciplinary authorities (e.g., if the intelligence suggests the possible commission of a crime or regulatory offence or breach of other rules of conduct).

61 Standards for Investigations

61.1 Objective

61.1 (a) The objective of this section is to establish standards for the efficient and effective conduct of investigations under the Protocol, including but not limited to:

61.1 (a) (1) The investigation of Atypical Findings, Atypical Passport Findings, and Adverse Passport Findings, and any other Sample abnormalities reported by the Laboratory;

61.1 (a) (2) The investigation of any other analytical or non-analytical information and/or intelligence where there is reasonable suspicion to suspect that an anti-doping or medication control rule violation may have been committed, such as a review of a possible Failure to Comply;

61.1 (a) (3) The investigation of the circumstances surrounding and/or arising from an Adverse Analytical Findingto gain further intelligence on the Responsible Person or other Covered Persons associated with the Covered Horse whose Sample was positive or other methods involved in doping or medication abuse; and

61.1 (a) (4) Where an anti-doping or medication control rule violation by a Covered Horse or Responsible Person is alleged, the investigation into whether other Covered Persons may have been involved in that violation.

61.1 (b) In each case, the purpose of the investigation is to achieve one of the following either:

61.1 (b) (1) to rule out a possible violation or involvement in an anti-doping or medication control rule violation;

61.1 (b) (2) to develop evidence that supports an anti-doping or medication control rule violation proceeding or the initiation of such a proceeding in accordance with Protocol Article 7; or

61.1 (b) (3) to provide evidence of a breach of the Protocol, applicable law, or regulation.

61.2 Investigating Possible Anti-Doping or Medication Control Rule Violations

61.2 (a) The Agency shall direct and manage all investigations under the Protocol. The Agency shall conduct all investigations under the Protocol unless specifically referred to a State Racing Commissions (subject to the applicable State Racing Commission electing to enter into an agreement with the Agency) whose investigators would continue to act at the direction of the Agency.

61.2 (b) The Agency and any State Racing Commissions to which the Agency refers investigatory tasks (subject to the applicable State Racing Commission electing to enter into an agreement with the Agency) shall ensure that investigations are conducted confidentially.

61.2 (c) The Agency should ensure that it effectively investigates any analytical or non-analytical information or intelligence that indicates there is reasonable suspicion that an anti-doping or medication control rule violation may have been committed or that indicates further inquiry might lead to the discovery of admissible evidence of such a violation.

61.2 (d) The Agency should gather and record all relevant information and documentation as soon as possible.

61.2 (e) The Agency shall ensure that investigations are conducted fairly, objectively, and impartially at all times. The conduct of investigations, the evaluation of information and evidence identified in the course of that investigation, and the outcome of the investigation, should be fully documented.

61.2 (f) Covered Persons are required under Protocol Articles 2.8 and 16 to Cooperate with investigations conducted by Agency. If they fail to do so, the Agency may bring proceedings against them for violating Protocol Article 2.8 (Failure of Covered Person to Cooperate with the Agency). If their conduct amounts to subversion of the investigation process (e.g., by providing false, misleading, or incomplete information, and/or by destroying potential evidence), the Agency may also bring proceedings against them for violating Protocol Article 2.11 (Tampering or Attempted Tampering).

61.2 (g) It shall not be a defense in a proceeding involving an anti-doping or medication control rule violation that an investigation should have been conducted more quickly or that any aspect of the Testing and Investigations Standards were not followed by the Agency or State Racing Commissions except as provided in the Protocol.

61.3 Obtaining Investigative Information

61.3 (a) The Agency should make use of all investigative resources reasonably available to it to conduct its investigation. This may include obtaining information and assistance from law enforcement and other relevant authorities, including other regulators, the Equine Biological Passport program (when available), investigative powers conferred under applicable rules (including inspection, examination, and seizure; production of documents; subpoenas; and interviews), and the power to suspend a period of Ineligibility imposed on a Covered Person in return for Substantial Assistance in accordance with Protocol Article 10.7 (a).

61.3 (b) Without limitation, the Agency may utilize the following investigative tools in relation to investigations and inquiries of possible violations of the Protocol:

61.3 (c) Inspection, Examination, and Seizure

61.3 (c) (1) The Agency may enter facilities, offices, stables, barns, or any other premises related to Covered Horses which are owned, controlled, or occupied by Covered Person(s) and:

61.3 (c) (1) (i) inspect and search the premises including any books, records or property, and to take Possession or a sample of any item or material believed to be, or that may lead to, evidence directly or indirectly of a violation of the Protocol;

61.3 (c) (1) (ii) search any Covered Person or Covered Horse on the premises;

61.3 (c) (1) (iii) access electronically stored data, including emails, computers, and mobile phones and devices without altering such data or device(s) other than to forward, back up, copy or make a mirror image of such data or device(s);

61.3 (c) (1) (iv) conduct identification and medication checks on any Covered Horse;

61.3 (c) (1) (v) inspect and take copies of any records the Covered Person is required to keep under the Protocol;

61.3 (c) (1) (vi) request a Sample from any Covered Person; and

61.3 (c) (1) (vii) examine any Covered Horse under the care of a Covered Person and take Samples from the Covered Horse for analysis.

61.3 (d) Production of Documents, Subpoenas

61.3 (d) (1) The Agency may:

61.3 (d) (1) (i) Require a Covered Person to provide any information, documents or records in such form as the Agency may require, and which are held by the Covered Person or within their power to obtain;

61.3 (d) (1) (ii) Require production of any mobile phones, computers, tablets, other electronic devices, books, documents and records (including telephone or financial records whether currently in the direct Possession of a Covered Person or a third person who may be directed by the Covered Person to provide the information) that may be relevant to any investigation, inquiry, hearing or proceeding;

61.3 (d) (1) (iii) Request the Authority issue a subpoena to a Person to appear or to answer questions and/or produce evidence related to anti-doping and medication control matters. A subpoena may direct the witness to appear at a specific time and place to testify; to produce designated evidence by a specific time; or to permit inspection of premises by the Agency at a specific time. A subpoena must be issued under the signature of a designated person from the Authority. If the Covered Person fails to comply with a subpoena, the Agency or Authority may seek enforcement of the subpoena in any of the district courts of the United States within the jurisdiction of which such inquiry is carried on. Additionally, the arbitrator, steward or administrative law judge considering a case arising under the Protocol may impose an adverse inference against a Covered Person who fails to comply with a valid subpoena, regardless of whether a court has been required to enforce the subpoena or has found the Covered Person in contempt.

61.3 (d) (1) (iv) This issuance of a subpoena and compliance therewith is independent of the Agency's powers to inspect and obtain evidence without a subpoena and Covered Persons' duty to Cooperate under the Protocol. In addition to a rule violation for refusal to Cooperate, a refusal to Cooperate can result in imposition of an adverse inference against a Covered Person by an arbitrator, steward or administrative law judge.

61.3 (d) (2) As a matter of efficient operation of the Agency's investigative program, the following considerations should be taken into account by the Agency (but should not be considered relevant by a reviewing court) in determining whether a subpoena should be requested to be issued by the Authority:

61.3 (d) (2) (i) The availability of and success in using alternative methods for obtaining the information in a timely manner;

61.3 (d) (2) (ii) The indispensability of the information to the success of the investigation or establishing a violation; and

61.3 (d) (2) (iii) The need to protect against the destruction of records or information and to protect the Agency's ability to bring forward a violation of the Protocol for such destruction.

61.3 (e) Interviews

61.3 (e) (1) Covered Persons must comply with a request to be interviewed by the Agency.

61.3 (e) (2) Only if the Agency requires a Covered Person to submit to an under oath transcribed interview, the Covered Person may request a short delay to the interview, if necessary, to seek legal

advice. However, such delay shall only encompass the time reasonably necessary to contact and retain counsel and shall in no case exceed seven days without the consent of the Agency.

61.3 (e) (3) An authorized Person may administer an oath or affirmation to a Covered Person appearing for an under oath interview.

61.3 (e) (4) The only basis for refusing to answer a question in an interview is an assertion of the attorney-client privilege or the Fifth Amendment privilege against self-incrimination.

61.3 (f) Investigation Outcomes

61.3 (f) (1) The Agency shall come to a decision efficiently and without undue delay as to whether proceedings should be brought against a Covered Person and/or Responsible Person on behalf of a Covered Horse asserting commission of an anti-doping or medication control rule violation.

61.3 (f) (2) Where the Agency concludes based on the results of its investigation that proceedings should be brought against a Covered Person or a Responsible Person independently or on behalf of a Covered Horse asserting commission of an anti-doping or medication control rule violation, it shall give notice of that decision in the manner set out in the Protocol.

61.3 (f) (3) Where the Agency concludes, based on the results of its investigation, that proceedings should not be brought against the Covered Person or Responsible Person independently or on behalf of a Covered Horse asserting commission of an anti-doping or medication control rule violation, it shall consider whether any of the intelligence obtained and/or lessons learned during the investigation should be used for test planning, to plan Target Testing, and/or should be shared with any other body or included in any report in accordance with these Testing and Investigations Standards.

61.3 (f) (4) The Agency may include information from its investigations in reports made to the Authority, Congress, State Racing Commissions, or other appropriate bodies regardless of whether the information relates to one or more rule violations. The fact that information was included in such a report shall not be a defense in any proceeding involving a potential rule violation.

62 Collection of Urine Samples

62.1 Urine Samples may be collected and analyzed for any anti-doping analytical matrix or methodology, including Equine Biological Passport, as determined by the Agency.

62.10 The volume of urine required for a full Sample is 50-100mL; however more should be collected if possible. On the initial attempt, if less than 50mL is obtained, the relevant Sample Collection Personnel should try to collect additional urine.

62.11 After reasonable attempts, if less than 50mL of urine is obtained, the entire Sample should be submitted to the Laboratory with best efforts for a 60/40 split between A and B bottles. In the event that less than 50 mL of urine is obtained, a blood Sample should also be collected from the Covered Horse.

62.12 Intractable Covered Horses will be handled in accordance with Protocol Article 2.6 (b).

62.13 Once the volume of urine provided by the Covered Horse is deemed sufficient, the relevant Sample Collection Personnel will bring the Sample to the designated processing area.

62.14 The relevant Sample Collection Personnel will select the Sample collection kit and will open, inspect, and confirm Sample codes numbers within the kit match and ask the Responsible Person or Nominated Person if they would like to confirm the same.

62.15 In view of the Responsible Person or Nominated Person, the relevant Sample Collection Personnel will pour and split urine Sample between A and B Sample collection bottles in accordance with the above capacity.

62.16 In view of the Responsible Person or Nominated Person, the relevant Sample Collection Personnel will seal the A and B bottles. Once closed, the relevant Sample Collection Personnel will check that the bottles have been properly sealed.

62.17 A DCO will complete all the required Sample collection documentation and provide the Responsible Person access to the Doping Control form for the Covered Horse’s Sample Collection Session.

62.18 Urine should only be discarded when both the A and B bottles or containers have been filled to the maximum

amount they can hold and have been sealed. Any excess urine should be disposed of into a drain (ground drain or sink) or into a bin or waste pile if necessary. The Responsible Person or Nominated Person shall be given the option to observe the disposal of any residual urine not sent to the Laboratory for analysis.

62.19 A DCO shall store the Sample in a manner that protects the integrity, identity, and security prior to transport to the Laboratory. Specifically, urine Samples should be transported to the Laboratory as soon as possible after the conclusion of the Sample Collection Session. If a Sample cannot be transported that same day, a DCO should store the Sample in a secure refrigerator and document in the Chain of Custody the location and time in and time out.

62.2 The Responsible Person or Nominated Person must be given reasonable opportunity to prepare the Covered Horse for Sample collection, for example by removing gear, washing off, and moving the Covered Horse to the collection area, while remaining in direct observation of the Sample Collection Personnel.

62.20 Comment: If the Responsible Person or Nominated Person is not satisfied with the chosen Sample Collection Equipment, this shall be recorded by a DCO. If a DCO does not agree with the Responsible Person or Nominated Person that the equipment is unsatisfactory, a DCO shall inform the Responsible Person or Nominated Person that the Sample Collection Session is proceeding. If a DCO agrees with the Responsible Person or Nominated Person that the equipment is unsatisfactory, a DCO shall use other available equipment that the DCO determines is satisfactory. If no such equipment is available, a DCO shall terminate the Sample Collection Session, and this shall be recorded by a DCO.

62.3 Where Testing is conducted at any location other than a Test Barn, the Responsible Person or Nominated Person must provide a suitable location where a Sample(s) can be collected from the Covered Horse.

62.4 The Responsible Person or Nominated Person will be instructed to examine the Sample collection vessel to ensure it will not affect the integrity of the urine Sample.

62.5 The relevant Sample Collection Personnel will retain control of the Sample collection vessel.

62.6 The relevant Sample Collection Personnel will then open and use the selected Sample collection vessel to collect the urine Sample in accordance with the instructions for the Sample collection vessel.

62.7 The relevant Sample Collection Personnel will wear a new pair of disposable gloves when handling the Sample collection vessel.

62.8 The relevant Sample Collection Personnel shall ensure as unobstructed view as possible of the Sample leaving the Covered Horse's body and shall continue to observe the Sample after provision until the Sample is securely sealed.

62.9 When the Covered Horse passes urine, the collection vessel should be positioned to collect as much urine as possible.

63 Collection of Blood Samples

63.1 Blood collection shall be conducted by a Blood Collection Officer ("BCO") who is a licensed veterinarian or veterinary technician.

63.10 Once a complete blood Sample is obtained, a BCO or DCO will properly seal the A and B bottles.

63.11 Intractable Covered Horses will be handled in accordance with Protocol Article 2.6 (b).

63.12 A BCO or DCO will complete all the required Sample collection documentation and provide the Responsible Person.

63.13 A DCO shall store the Sample in a manner that protects the integrity, identity, and security prior to transport to the Laboratory. Specifically, blood Samples should be transported to the Laboratory as soon as reasonably practical to do so after the conclusion of the Sample Collection Session. If a Sample cannot be transported that same day, a DCO should store the Sample in a secure refrigerator and document in the Chain of Custody the location and time in and time out. For Race Day Testing, urine Samples should be stored in a secure refrigerator until transport is possible.

63.14 Blood Samples shall be transported to the Laboratory in a device that maintains the integrity of Samples during transportation, in a cool and constant environment, recorded by a temperature logger. The transport device shall be transported securely via a transportation or shipping service authorized by the Agency.

63.15 Comment: If the Responsible Person or Nominated Person is not satisfied with the chosen Sample Collection Equipment, this shall be recorded by a DCO. If a DCO does not agree with the Responsible Person or Nominated Person that the equipment is unsatisfactory, a DCO shall inform the Responsible Person or Nominated Person that the Sample Collection Session is proceeding. If a DCO agrees with the Responsible Person or Nominated Person that the equipment is unsatisfactory, a DCO shall use other available equipment that the DCO determines is

satisfactory. If no such equipment is available, a DCO shall terminate the Sample Collection Session, and this shall be recorded by a DCO.

63.2 Certain blood collections might be required at specific times around a Race (e.g., TCO2 Testing). If so, Sample Collection Personnel will communicate this information to the Responsible Person or Nominated Person at the time of notification.

63.3 Blood Samples may be collected and analyzed for any anti-doping analytical matrix or methodology, including Equine Biological Passport, as determined by the Agency.

63.4 A DCO or BCO will select a Sample collection kit containing A and B bottles, collection tubes, and the other necessary equipment needed to collect a blood Sample (which will include a new needle).

63.5 Once the Sample collection kit has been selected, a BCO or DCO will open, inspect, and confirm Sample codes numbers within the kit match and ask the Responsible Person or Nominated Person if they would like to confirm the same.

63.6 A BCO will assess the most suitable location of venipuncture. A BCO will wear a new pair of disposable gloves.

63.7 A BCO shall dispose of used blood sampling equipment not required to complete the Sample Collection Session in accordance with the required local standards for handling used blood draw equipment.

63.8 A BCO will collect the amount of blood that will adequately satisfy the relevant analytical requirements for the Sample analysis to be performed. The minimum total volume requirement is 30mL whole blood for each A and B bottle, except when blood is collected solely for TCO2 analysis in which case a lesser volume may be appropriate in the Agency's discretion. Anything below 30mL should still be packaged and transported to the Laboratory.

63.9 If the amount of blood that can be removed from the Covered Horse at the first attempt is insufficient, a BCO shall repeat as necessary and appropriate to try and obtain the minimum total volume for a blood Sample, unless the Covered Horse is intractable. Should a BCO's attempts fail to produce a sufficient amount of blood, then a DCO shall terminate the blood Sample Collection Session and record the reasons for terminating. Other matrices should be considered for collection.

64 Collection of Hair Samples

64.1 Requirements

64.1 (a) A member of the Sample Collection Personnel should collect hair Samples in accordance with the following requirements:

64.1 (a) (1) Hair should (to the extent possible) be completely dry and free of visible dirt, debris, or foreign substances;

64.1 (a) (2) Mane hair should be collected unless tail hair is specifically requested. If for a particular reason a mane Sample cannot be obtained (such as hogged mane), tail hair may be collected;

64.1 (a) (3) An adequate Sample should be obtained for each of the A and B Samples;

64.1 (a) (4) If the mane is less than 10cm, an additional Sample of hair may be required to ensure a suitable volume is obtained for analysis;

64.1 (a) (5) The Sample should be secured tightly with an elastic band, or equivalent, and oriented to clearly mark the ends cut or pulled from the Covered Horse; and

64.1 (a) (6) Hair shafts should remain aligned so that the hair does not become knotted.

64.1 (b) A DCO will complete all the required Sample collection documentation and provide the Responsible Person a copy for their records.

64.1 (c) The Sample Collection Personnel shall store the Sample in a manner that protects the integrity, identity, and security prior to transport to the Laboratory.

65 Sample Collection Personnel Requirements

65.1 Objective

65.1 (a) To establish standards for training and accrediting Sample Collection Personnel to ensure that they have adequate qualifications, are free of conflicts of interest, and have experience to conduct Doping Control.

65.2 Requirements

65.2 (a) The Agency shall establish the necessary competence, eligibility, and qualification requirements for the positions of DCO, BCO, and Chaperone. As a minimum:

65.2 (a) (1) Sample Collection Personnel shall not be minors;

65.2 (a) (2) Sample Collection Personnel shall agree to undergo screening required by the Agency (e.g., background checks, conflicts of interest);

65.2 (a) (3) BCOs shall be a veterinarian or veterinary technician with the practical skills and knowledge to perform blood collection from a vein on a horse.

65.3 Conflicts

65.3 (a) The Agency shall ensure that all Sample Collection Personnel sign an agreement regarding conflicts of interest, confidentiality, and code of conduct.

65.3 (b) The Agency shall not appoint any Sample Collection Personnel to Testing where they have an interest in the outcome of the Doping Control process. At a minimum, Sample Collection Personnel are deemed to have such an interest if they are:

65.3 (b) (1) Involved, or have an immediate family member involved, in the participation or Administration of horse racing for which Doping Control is being conducted, excluding State Racing Commissions; however, over the first eighteen months of the program this provision will not apply to Sample Collection Personnel who are supervised and whose actions material to the Sample Collection Session are witnessed by Sample Collection Personnel who comply with this provision;

65.3 (b) (2) Related to, or involved in the personal affairs of, any Covered Horse and/or any Equine Constituencies, except State Racing Commissions;

65.3 (b) (3) Are engaged in business with, have a financial interest in, or have a personal stake in a Covered Horserace; and/or

65.3 (b) (4) Appear to have private or personal interests that detract from their ability to perform their duties with integrity and in an independent and purposeful manner.

65.4 Training

65.4 (a) The Agency shall establish or approve written training materials for Sample Collection Personnel that outline their respective responsibilities that adequately train them of their roles.

65.4 (b) The Agency shall ensure that DCOs have completed the necessary training program and are familiar with the requirements before giving a credential.

65.4 (c) The training program for DCOs should include, at a minimum:

65.4 (c) (1) Comprehensive theoretical training in those Doping Control activities relevant to the DCO position;

65.4 (c) (2) Observation of Doping Control activities that are the responsibility of the DCO as set out in these Standards, preferably on-site; and

65.4 (c) (3) The satisfactory performance of one complete Doping Control on-site under observation by a qualified DCO or similar.

65.4 (d) The training program for Sample Collection Personnel responsible for the collection of blood Samples shall also include standard precautions in veterinary settings.

65.4 (e) The training program for Chaperones shall include all relevant requirements of the Doping Control process to carry out their responsibilities including how to handle potential Failures to Comply. DCOs may direct a Chaperone to perform specified activities that fall within the scope of the Chaperone's authorized duties as determined by the Agency.

65.4 (f) The Agency should ensure that Sample Collection Personnel are adequately trained to carry out their responsibilities in a manner respectful of any Covered Persons who are of a different race, religion, sex, national origin, sexual orientation, age, citizenship, disability, gender identity or Veteran status to its Sample Collection Personnel.

65.4 (g) The Agency shall establish a system for credentialing and re-credentialing DCOs.

65.4 (h) Only Sample Collection Personnel who have a credential recognized by the Agency or letter of authority from the Agency shall be authorized to conduct Doping Control activities on behalf of the Agency.

65.4 (i) DCO credentials shall be valid for a maximum of two (2) years. DCOs should be subject to an assessment (theoretical and/or practical) before being re-credentialed. Any DCO who has not participated in any Doping Control activities within a year should be required to complete a re-training program.

65.4 (j) The Agency shall take steps to develop a system to monitor the performance of DCOs.

65.4 (k) The Agency shall maintain records of conflicts and training of all Sample Collection Personnel.

Arbitration Procedures (Not Submitted to FTC)

66 Applicability

66.1 These Arbitration Procedures for the Equine Anti-Doping and Medication Control Protocol (the "Adjudication Procedures") shall apply to adjudications arising out of the Equine Anti-Doping and Medication Control Protocol (the "Protocol"). Terms used in the Adjudication Procedures that are defined terms from the Protocol are written in italics.

67 Delegation of Duties

67.1 Major Infractions arising out of the Protocol shall be administered by an independent arbitral body (the "Arbitral Body") in accordance with the Protocol and the Adjudication Procedures. The Arbitral Body is selected by mutual agreement of the Authority and the Agency. Minor Infractions arising out of the Protocol shall be adjudicated by the National Stewards Panel member assigned to the case in accordance with the Protocol and the Adjudication Procedures. Notwithstanding the use of the terms "arbitrator" when referring to the impartial decision-maker in Major Infractions cases and "steward" when referring to the impartial decision-maker in Minor Infractions cases, all cases arising out the Protocol are intended to be arbitrations, subject to review as specified in the Protocol and the Act . Therefore, both arbitrators and stewards are to be considered arbitrators or umpires within the meaning of the Federal Arbitration Act, which applies arbitrations under the Protocol to the exclusion of any applicable state arbitration and to the extent not inconsistent with the Protocol and the Act.

68 Pool of Arbitrators

68.1 The pool of arbitrators for Major Infractions arising out of the Protocol shall consist of no more than ten members appointed by mutual agreement of the Authority and the Agency (the "Arbitrator Pool").

68.2 The arbitrators in the Arbitrator Pool shall be appointed for four-year terms. Candidates to serve as an arbitrator shall complete an application approved by the Authority and the Agency.

68.3 There shall be no absolute requirement that an arbitrator candidate be a member of any arbitral body or association of arbitrators prior to appointment. Candidates shall not be or have been in the previous two years an officer, director, trustee, employee, commission member, consultant or official or be in a policy making position for any Equine Constituencies or the Agency. A candidate shall be required to submit to a background check before appointment to the Arbitrator Pool. The Arbitral Body shall, if necessary, accept the candidate as a member on its roll of arbitrators, if necessary, upon appointment to the Arbitrator Pool.

68.4 Candidates shall commit in writing to accept appointment to all cases to which they are selected except (i) when they have been involved in the Provisional Hearing for the matter; (ii) for conflicts of interest; or (iii) for personal hardship and shall agree to not decline appointment for personal hardship in more than two cases in any 12-month

period.

68.5 In the event an arbitrator dies, resigns, becomes incapacitated during the arbitrator's term, or is removed by the Authority for an ethical breach or deficiencies in carrying out their duties, a new arbitrator shall be selected and appointed for a full four-year term, following the procedures set forth above. Incapacity of an arbitrator is determined solely by the Authority.

69 National Stewards Panel

69.1 The National Stewards Panel (the "Panel") consists of impartial stewards or otherwise qualified individuals ("stewards") appointed by mutual agreement of the Authority and the Agency to hear Minor Infractions. The Authority and the Agency may appoint as many individuals as necessary to resolve Minor Infractions in accordance with the Adjudication Procedures.

69.2 Prospective stewards shall be required to submit to a background check before appointment and shall commit in writing to accept appointment to all cases to which they are selected except: (i) when they have been involved in the Provisional Hearing for the matter; (ii) for conflicts of interest; or (iii) for personal hardship and shall agree to not decline appointment for personal hardship in more than two cases in any 12-month period. Stewards are appointed for four-year terms and outside appointment to the Panel shall not have any business or economic interest with a party in a case.

69.3 In the event a steward dies, resigns, becomes incapacitated during the steward's term (legal incapacity is not required), or commits an ethical breach, the Authority may remove the steward from the Panel. The Agency will publish a list of members of the Panel on its website.

70 Training of Arbitrators and Stewards

70.1 All arbitrators in the Arbitrator Pool and stewards on the Panel shall receive at least two hours of continuing education each year on issues related to proper and efficient handling of cases or the Protocol, Standards, Policies, or Technical Documents. The education must be approved by the Authority. Failure to complete this required continuing education is grounds for immediate dismissal by the Authority.

71 Initiation by USADA

71.1 Major Infractions: Arbitration proceedings shall be initiated with the Arbitral Body by the Agency after a hearing is requested by the Covered Person(s) in response to being charged with a Major Infraction under the Protocol. If both Major and Minor Infractions are charged against one or more Covered Persons, the procedures for Major Infractions apply. The parties to the proceeding shall be the Agency and the Covered Person(s) charged with at least one anti-doping or medication control rule violation(s) under the Protocol. The relevant Owner(s), provided they are not charged with a violation under the Protocol, and the Authority shall be invited to join in the proceeding as an observer. Subject to such limitations as may be imposed by the arbitrator, the hearing shall be open to the public via an audio/video or audio only feed that will be provided for members of the public, but technical issues in providing the feed shall not postpone or invalidate the hearing.

71.2 Minor Infractions: Proceedings shall be initiated with the appropriate Panel member by the Agency after the Covered Person(s) requests review by a steward in response to being charged with a Minor Infraction under the Protocol. The parties to the proceeding shall be the Agency and the Covered Person(s) charged with one or more anti-doping or medication control rule violations under the Protocol. The relevant Owner(s), provided they are not charged with a violation under the Protocol, and the Authority shall be invited to join in the proceeding as an observer and, if accepted, receive copies of the filings in the case.

72 Changes of Claim

72.1 After the filing of a claim, if the Agency desires to make any new or different claim, it shall be made in writing and filed with the other party or parties and the steward or arbitrator and Arbitral Body, as applicable. After the arbitrator or steward is appointed, however, no new or different claim may be submitted except with the arbitrator's or steward's consent. The deadlines set forth in Article 82 and Article 83 will reset provided the Covered Person requests review by a steward or arbitrator, as applicable, of the new or different claim.

73 Expedited Procedures

73.1 At the request of any party, any time period set forth in the Adjudication Procedures may be shortened by the arbitrator or steward when doing so is reasonably necessary to resolve any Covered Person's or Covered Horse's eligibility before a Covered Horserace, while continuing to protect the right of a Covered Person to a fair process.

73.2 The adjudication process shall be expedited according to the procedures in the Protocol and may be

expedited in such other instances where expediting is in the interest of justice. Pursuant to Article 8.3, the Agency may in its sole discretion shorten any deadlines within the Adjudication Procedures proportionately to ensure resolution prior to a Covered Horserace.

73.3 If a request to expedite the adjudication process is made based on circumstances that are not addressed in the Protocol and if the Agency does not agree to the process being expedited the arbitrator or steward shall determine whether the adjudication process shall be expedited and the schedule pursuant to which the process shall proceed.

74 Jurisdiction

74.1 An arbitrator or steward shall have the authority to rule on his or her own jurisdiction, including any objections with respect to the existence, scope, or validity of the applicable rules.

74.2 The arbitrator or steward shall have the authority to determine the existence or validity of a contract of which an arbitration clause forms a part. Such an arbitration clause shall be treated as an agreement independent of the other terms of the contract. A decision by the arbitrator that the contract is null and void shall not for that reason alone render invalid the arbitration clause.

74.3 A party must object to the jurisdiction of the arbitrator or steward or to the arbitrability of a claim by the Agency no later than the filing of the answering statement to the claim that gives rise to the objection. The arbitrator or steward may rule on such objections as a preliminary matter or as part of the final reasoned award.

75 Consolidation

75.1 Matters involving more than one Covered Person may, in the Agency's discretion, be consolidated into a single matter and if a Major Infraction is alleged by the Agency against any of the Covered Persons who are parties in the consolidated matter, the process for Major Infractions will be followed.

76 Location of Hearing for Major Infractions

76.1 All hearings on Major Infractions shall take place by telephone or video conference unless the parties and the arbitrator agree to an in-person hearing. Once the parties agree to an in-person hearing, consent to an in-person hearing can only be withdrawn upon mutual agreement of the parties.

76.2 The situs of arbitrations and locations of in-person hearings (if agreed to by the parties) shall be in the United States at locations determined by the arbitrator and set forth no later than in the first procedural order. The arbitrator shall give preference to the choice of the Covered Person unless outweighed by the interests of justice.

76.3 In the event it may be necessary for enforcement of an arbitration subpoena(s) (separate from an investigative subpoena under the Act) that the arbitrator conduct a hearing at a particular location(s) and receive live testimony or documents or other evidence, the arbitrator shall at the request of the party who is seeking enforcement of the subpoena travel to that location to conduct the hearing regardless of whether the parties are participating in the arbitration via telephone or video conference.

77 Qualifications of an Arbitrator

77.1 Any arbitrator or steward appointed pursuant to Article 78 shall be subject to Disqualification for the reasons specified in Section 79.

78 Appointment of the Arbitrators and Stewards to Adjudicate Cases

78.1 An arbitrator shall be appointed in the following manner: Immediately after the initiation of a proceeding by the Agency (as set forth in Article 71), the Arbitral Body shall appoint an arbitrator on a rotating basis from the Arbitrator Pool, after confirming the arbitrator will not decline appointment due to personal hardship. The arbitrator who handles the Provisional Hearing shall not serve as an arbitrator for the Covered Person's arbitration concerning the allegation that they have committed an anti-doping or medication control rule violation. The Arbitral Body shall communicate to the parties within three calendar days of initiation by the Agency the name of the arbitrator appointed to hear the matter.

78.2 A steward shall be appointed in the following manner: Immediately after the initiation of a proceeding by the Agency (as set forth in Article 71), the Agency's National Stewards Panel Coordinator shall contact a steward on a rotating basis from the National Stewards Panel except that for violations occurring during a Race Period, a steward should not be appointed in a particular case if they work for or previously worked for one or more years for the State Racing Commissions in the state where the Covered Horserace relevant to the alleged violation occurred. The steward's written acceptance of the case from the Agency's National Stewards Panel Coordinator constitutes

appointment to that case. The steward shall communicate to the parties within three calendar days of initiation by the Agency that the steward has accepted the case. The steward who handles the Provisional Hearing shall not serve as the steward determining the merits of the allegation that the Covered Person committed an anti-doping or medication control rule violation.

78.3 Once appointed, the arbitrator shall receive from the Arbitral Body a copy of or link to the charging letter, Adjudication Procedures, the Protocol, and the Billing Standards. Once appointed, the steward shall receive this same information from the Agency's National Stewards Panel Coordinator.

79 Disclosure and Challenge Procedure

79.1 An appointed arbitrator or steward in a particular case shall disclose to the parties any circumstance likely to affect impartiality, including any Bias or any financial or personal interest in the result of the case or any past or present relationship with the parties or their representatives.

79.2 Upon objection of a party to the continued service of an arbitrator, the Arbitral Body shall determine whether the arbitrator is evidently partial and the arbitrator should be Disqualified. The Arbitral Body shall inform the parties of its decision, which shall be final and not subject to interlocutory appeal.

79.3 Upon objection of a party to the continued service of a steward, the steward shall determine whether the steward is evidently partial and the steward should recuse themself from the case. The steward shall inform the parties of their decision, which shall be final and not subject to interlocutory appeal.

80 Communication with Arbitrator or Steward

80.1 Once appointed, no party and no one acting on behalf of any party shall communicate unilaterally concerning the case with an arbitrator or steward. All communications concerning the case shall include the other party or parties and for cases before an arbitrator, a representative from the Arbitral Body.

81 Vacancies

81.1 If for any reason following assignment to the case an arbitrator becomes unable to perform their duties in a particular case, the Arbitral Body may fill the vacancy on a rotating basis as described in these rules.

81.2 If for any reason following assignment to the case a steward becomes unable to perform their duties in a particular case, the Agency's National Stewards Panel Coordinator may contact a steward on a rotating basis from the National Stewards Panel to fill the vacancy.

82 Procedures for Major Infractions

82.1 For matters involving at least one alleged Major Infraction arising from an Adverse Analytical Finding(Presence and Use violations), each Covered Person's pre-hearing submission must be filed with the arbitrator on or before fourteen calendar days after submitting a request for a hearing, and the Agency's pre-hearing submission must be filed with the arbitrator on or before fourteen calendar days after the last Covered Person's pre-hearing submission. There shall be no reply pre-hearing submission, but each party may present rebuttal evidence at the hearing.

82.2 For matters involving at least one alleged Major Infraction and at least one alleged non-analytical violation (i.e., a violation other than Presence or Use), the Agency's initial pre-hearing submission must be filed with the arbitrator on or before fourteen calendar days after the last Covered Person requests a hearing or (only if a Covered Person in the same matter has already requested a hearing) after the last Covered Person's deadline passes with no request for a hearing, whichever is later. Each Covered Person's pre-hearing submission must be filed with the arbitrator on or before fourteen calendar days after the Agency's initial pre-hearing submission, and the Agency's reply pre-hearing submission must be filed with the arbitrator seven calendar days after the last Covered Person's pre-hearing submission.

82.3 A Covered Person's pre-hearing submission shall include a brief not to exceed 30 double-spaced pages and shall include all exhibits, schedules, expert reports, and all other evidence (except testimonial evidence, summaries, and demonstrative aides) the Covered Person intends to rely upon at the hearing. The Covered Person's pre-hearing submission shall include a designation of witnesses providing the identity of witnesses (or name of organization if an organization representative) expected to be called to testify at the hearing as well as a brief summary of the expected testimony. For expert witnesses, the pre-hearing submission shall include a C.V. and expert report, identifying all opinions to which they will testify and the facts and scientific methods upon which those opinions are based as well as to identify all scientific treatises, studies, or articles on which the expert relies in rendering their opinion(s), for each expert included in the witness designations.

82.4 The Agency's initial pre-hearing submission shall include a brief not to exceed thirty double-spaced pages for each Covered Person charged in the case and shall include all exhibits, schedules, expert reports, and all other

evidence (except testimonial evidence, impeachment evidence, summaries, and demonstrative aides) the Agency intends to rely upon at the hearing. The Agency's initial pre-hearing submission shall include a designation of witnesses providing the identity of witnesses (or name of organization if an organization representative) expected to be called to testify at the hearing as well as a brief summary of the expected testimony. For expert witnesses, the initial pre-hearing submission shall include a C.V. and expert report, identifying all opinions to which they will testify and the facts and scientific methods upon which those opinions are based as well as to identify all scientific treatises, studies, or articles on which the expert relies in rendering their opinion(s), for each expert included in the witness designations. The Agency's reply pre-hearing submission, when permitted under these Adjudication Procedures, shall include all additional evidence upon which it intends to rely for rebuttal (except testimonial evidence, impeachment evidence, summaries, and demonstrative aides) and a reply brief not to exceed fifteen double-spaced pages for each Covered Person charged in the case.

82.5 Each party is responsible for updating its disclosures as such information becomes available. If a party should have submitted evidence in their pre-hearing submission but did not, the arbitrator should not admit such evidence absent good cause shown.

82.6 The hearing shall take place forty-two calendar days from the date the last Covered Person requested a hearing in a particular case. If any of the dates described in Article 82 fall on a weekend or a federal holiday, the due date is the next business day.

82.7 At the request of any party or at the discretion of the arbitrator or the Arbitral Body, the arbitrator may schedule as soon as practicable a preliminary hearing with the parties and/or their representatives. The preliminary hearing should be conducted by telephone or video conference at the arbitrator's discretion. During the preliminary hearing, the parties and the arbitrator should discuss any preliminary matters to ensure compliance with the procedures herein.

82.8 Upon showing of exceptional circumstances, the arbitrator may extend any of the deadlines set forth in Article 82 for the minimum time necessary to address the circumstance. If all parties agree to an alternative schedule in a particular case, the arbitrator shall alter dates accordingly.

82.9 The arbitrator shall issue a reasoned award on or before fourteen calendar days after the close of the hearing.

83 Procedures for Minor Infractions

83.1 For matters involving alleged Minor Infractions arising from an Adverse Analytical Finding(Presence and Use violations) and no alleged Major Infraction, each Covered Person's submission must be filed with the arbitrator on or before seven calendar days after submitting a request for review by a steward, and the Agency's submission must be filed with the arbitrator on or before seven calendar days after the last Covered Person's submission. There shall be no reply submission.

83.2 For matters involving at least one alleged non-analytical Minor Infraction (i.e., a violation other than Presence or Use) and no alleged Major Infraction, the Agency's initial submission must be filed with the arbitrator on or before seven calendar days after the last Covered Person requests a review by a steward or (only if a Covered Person in the same matter has already requested a review by a steward) after the last Covered Person's deadline passes with no request for review by a steward, whichever is later. Each Covered Person's submission must be filed with the arbitrator on or before seven calendar days after the Agency's initial submission, and the Agency's reply submission must be filed with the arbitrator on or before seven days after the last Covered Person's submission.

83.3 A Covered Person's submission shall include a brief not to exceed 20 double-spaced pages and shall include all exhibits, schedules, diagrams, charts, expert reports, affidavits, and all other evidence on which the Covered Person relies. A C.V. and expert report, identifying all opinions to which they will testify and the facts and scientific methods upon which those opinions are based as well as to identify all scientific treatises, studies, or articles on which the expert relies in rendering their opinion(s), must be included for each expert relied upon by the Covered Person.

83.4 The Agency's initial submission shall include a brief not to exceed 20 double-spaced pages for each Covered Person charged in the case and shall include all exhibits, schedules, summaries, diagrams, charts, expert reports, affidavits, and all other evidence on which the Agency relies. A C.V and expert report, identifying all opinions to which they will testify and the facts and scientific methods upon which those opinions are based as well as to identify all scientific treatises, studies, or articles on which the expert relies in rendering their opinion(s), must be included for each expert relied upon by the Agency. The Agency's reply submission, when permitted under these Adjudication Procedures, shall include all additional evidence upon which it intends to rely for rebuttal and a brief not to exceed 10 double-spaced pages for each Covered Person charged in the case.

83.5 If any of the dates described in Article 83 fall on a weekend or a federal holiday, the due date is the next business day.

83.6 At the request of any party or at the discretion of the steward, the steward may, upon showing of exceptional circumstances, extend any of the deadlines set forth in Article 83 for the minimum time necessary to address the circumstance. If all parties agree to an alternative schedule in a particular case, the steward shall alter dates accordingly.

83.7 The steward shall render a decision based on the parties' written submissions described above, not a hearing, and shall issue a reasoned award on or before fourteen calendar days after the last written submission contemplated in Article 83.

84 Exchange of Information

84.1 Information shall be exchanged electronically, unless otherwise agreed by the parties. The arbitrator and steward are authorized to resolve any disputes concerning the exchange of information between the parties consistent with the expedited nature of the proceedings.

85 Participation

85.1 The steward, arbitrator, and the Arbitral Body shall maintain the confidentiality of the proceedings unless in cases before an arbitrator the hearing is open to the public as described in Article 71. An arbitrator's or a steward's review may proceed without the participation of any party or representative who, after due notice, fails to be present or make a submission. An award shall not be made solely on the default of a party. The arbitrator or steward shall require the party who is present to submit such evidence as the arbitrator or steward may require for the making of an award.

86 Representation

86.1 Any party may be represented by counsel. The representative shall provide a letter of representation notifying the other party and the steward or Arbitral Body of their name, phone number, email, and address. When such a representative requests a hearing by an arbitrator or review by a steward or responds for a party, notice is deemed to have been given. Parties are bound by the statements made or positions taken by their representatives.

87 Oaths

87.1 Before proceeding with the first preliminary hearing, or a merits hearing if no preliminary hearing, each arbitrator may take an oath of office and, if required by law, shall do so. An arbitrator may require witnesses to testify under oath administered by any duly qualified person and, if it is required by law or requested by any party, shall do so. Similarly, before issuing a reasoned award, each steward may take an oath of office and, if required by law, shall do so.

88 Stenographic Record

88.1 Any party desiring a stenographic record of all or a portion of the hearing shall notify the other parties of the request at least seven calendar days in advance of the start of the hearing or as required by the arbitrator. The Agency shall identify the court reporter to be used for transcription services, and the transcript must be provided to the arbitrator and made available to the other parties for inspection, at a date, time, and place determined by the arbitrator with the costs of the transcription divided equally between the parties.

89 Interpreters

89.1 All proceedings shall take place in English. Any party wishing to have an interpreter present during proceedings shall make all arrangements directly with the interpreter and shall assume the costs of the service. Interpreters shall have no prior relationship with a party or have any interest in the proceeding and the arbitrator must approve the interpreter. Any document which is not in English shall be officially translated by a certified translator paid for by the party offering or relying upon the document.

90 Conduct of Hearings for Major Infractions

90.1 The Agency shall present evidence to support its claim. The Covered Person(s) charged with an anti-doping or medication control rule violation shall then present evidence to support their defense. The Agency is then entitled to present rebuttal evidence. Witnesses for each party shall also submit to questions from the arbitrator and the adverse party. The arbitrator has the discretion to vary this procedure, provided that the parties are treated with equality and that each party has the right to be heard and is given a fair opportunity to present its case.

90.2 The arbitrator shall have the power to require the sequestration of any witness, other than a party or other essential person, during the testimony of any other witness. It shall be discretionary with the arbitrator to determine the propriety of the attendance of any other person other than (i) a party and its representatives and (ii) those entities identified in Article 71, which may attend the hearing as observers.

90.3 The arbitrator, exercising his or her discretion, shall conduct the proceedings with a view to resolving the dispute in accordance with Article 82 but may direct the order of proof, bifurcate proceedings, and direct the parties to focus their presentations on issues the decision of which could dispose of all or part of the case.

90.4 The parties may agree to waive oral hearings in any case.

91 Evidence

91.1 The parties may offer such evidence as is relevant and material to the dispute and, unless limited by the Protocol, Policies, Standards, or Technical Documents shall produce such evidence as the arbitrator may deem necessary to make a determination in a case.

91.2 An arbitrator or steward may only retain an expert or seek independent evidence if agreed to by the parties and (i) the parties agree to pay for the cost of such expert or independent evidence or (ii) the Authority agrees to pay for the cost of such expert or independent evidence. The parties shall have the right to examine any expert retained by the arbitrator and shall have the right to respond to any independent evidence obtained by the arbitrator.

91.3 An arbitrator or steward shall determine the admissibility, relevance, and materiality of the evidence offered, including hearsay evidence, and may exclude evidence deemed cumulative or irrelevant. Conformity to legal rules of evidence shall not be necessary but the federal rules of evidence may be used for guidance.

91.4 The arbitrator or steward shall apply relevant principles of legal privilege, including those involving the confidentiality of communications between a lawyer and client and investigative privilege.

91.5 An arbitrator or steward may issue subpoenas for witnesses, documents, or other evidence upon the request of any party, keeping in mind the expedited nature of the proceedings and the procedures set forth in 83 and 84. An arbitrator or steward shall not issue a subpoena for a deposition as depositions, along with formal written discovery in civil litigation, are not in keeping with the expedited nature of arbitration.

92 Inspection or Investigation

92.1 An arbitrator or steward finding it necessary to make an inspection or conduct additional investigation in connection with a proceeding shall so advise the parties. The arbitrator or steward shall set the date and time that shall not delay the procedures in Article 82 and 83 and shall notify the parties. Any party who so desires may be present at such an inspection or investigation. In the event that one or all parties are not present at the inspection or investigation, the arbitrator or steward shall make an oral or written report to the parties and afford them an opportunity to comment.

93 Interim Measures

93.1 An arbitrator or steward may take whatever interim measures they deem necessary to provide a party an immediate protection of rights.

94 Provisional Hearings

94.1 Hearings to resolve challenges to Provisional Suspensions shall be held in accordance with Article 7.4 (b). With all hearings, an arbitrator or steward may admit any evidence deemed relevant and given the weight the arbitrator or steward deems appropriate. For an avoidance of doubt, hearsay shall be admissible in a Provisional Hearing. Arbitrator or steward decisions regarding Provisional Suspensions are not subject to an interlocutory appeal.

95 Closing of Hearing for Major Infractions

95.1 The arbitrator shall declare the hearing closed at the conclusion of closing arguments unless a party demonstrates that such additional proof or witness(es) are material to the controversy and good cause exists for not providing the evidence with their pre-hearing submission. If the arbitrator agrees and the additional evidence is allowed, the adverse party then shall have the opportunity to present rebuttal evidence. No post-hearing briefs are to be filed. The hearing shall be declared closed as of the final date set by the arbitrator for the receipt of evidence or receipt of the transcript. The time limit within which the arbitrator is required to issue the reasoned award shall commence upon the closing of the hearing.

96 Reopening of Hearing for Major Infractions

96.1 To avoid manifest injustice, the hearing may be reopened on the arbitrator's initiative, or upon application of a party, at any time before the award is made. If reopening the hearing would prevent the making of the award within

the specific time required by Article 82, the matter may not be reopened unless the parties agree on an extension of time.

97 Waiver of Rules

97.1 Any party who proceeds with the adjudication under these rules after knowledge that any provision or requirement of these rules has not been complied with and who fails to state an objection in writing shall be deemed to have waived the right to object.

98 Serving of Notice

98.1 Any papers, notices, or process necessary or proper for the initiation or continuation of a proceeding under these rules, for any court action in connection therewith, or for the entry of judgment on any award made under these rules may be accomplished in accordance with Article 7.1 (b) (8), including by serving a party by mail or electronic mail addressed to the party or its representative at the last known address or by personal service in or outside the state where the arbitration is to be held.

98.2 Unless otherwise instructed by the steward, Arbitral Body, or the arbitrator, any documents submitted by any party to a steward, Arbitral Body, or arbitrator shall simultaneously be provided to the other party or parties to the proceeding.

99 Form of Award

99.1 Any award shall be in writing and signed by the arbitrator or steward. In all cases, the arbitrator or steward shall render a reasoned award.

100 Scope of Award

100.1 An arbitrator or steward may grant any remedy or relief authorized by the Protocol or the Act for the violation.

100.2 In addition to a final award, an arbitrator or steward may make other decisions, including interim, interlocutory, or partial rulings, orders, and awards.

101 Award Upon Settlement

101.1 If the parties settle their dispute during the course of the proceeding, and if the parties so request, an arbitrator or steward may set forth the terms of the settlement in a "consent award."

102 Delivery of Award to Parties

102.1 Parties shall accept as notice and delivery of the award the placing of the award or a true copy thereof in the mail addressed to the parties or their representatives at the last known addresses, personal or electronic service of the award, or the publishing of the award in accordance with the Protocol.

102.2 The award is public and shall not be considered confidential.

103 Modification of Award

103.1 Within seven days after the transmittal of an award, any party, upon notice to the other parties, may request the steward or arbitrator, through the Arbitral Body, to correct any clerical, typographical, or computational errors in the award. The arbitrator or steward is not empowered to redetermine the merits of any claim already decided. The other parties shall be given five days to respond to the request. The arbitrator or steward shall dispose of the request within five days after receipt of the request and any response thereto.

104 Release of Documents for Judicial Proceedings

104.1 The Arbitral Body and steward shall, upon the written request of a party, furnish to the party, at the party's expense, certified copies of any papers in the Arbitral Body's or steward's possession that may be required in judicial proceedings relating to the proceeding. If the matter is appealed to an administrative law judge, the Arbitral Body and steward shall furnish copies of documents to the administrative law judge requested by the administrative law judge in connection with that proceeding.

105 Appeal Rights

105.1 The award may be appealed exclusively to an administrative law judge and subject to further review as provided in the Protocol and the Act . Notwithstanding any provision set forth in these Adjudication Procedures, nothing herein shall alter the standards of review on appeal set forth in the Protocol and the Act.

106 Applications to Court and Exclusion of Liability

106.1 Arbitration is intended to be the exclusive remedy in all cases arising under the Protocol subject to appeal as described in the Protocol and the Act .

106.2 No civil action commenced by a party relating to the subject matter of the proceeding under the Adjudication Procedures shall be deemed a waiver of any party's right to adjudicate their case under the Adjudication Procedures.

106.3 Neither the Arbitral Body nor any arbitrator or steward in a proceeding under these rules is a necessary party in judicial proceedings relating to that proceeding.

106.4 Parties to a proceeding under the Adjudication Procedures shall be deemed to have consented that judgment upon an award that is not appealed may be entered in any federal or state court having jurisdiction, unless the party seeks administration review pursuant to the Protocol and the Act.

106.5 Neither the Agency, the Arbitral Body nor any arbitrator or steward shall be liable to any party for any act or omission in connection with any proceedings conducted under these rules.

107 Costs

107.1 The Arbitral Body shall prescribe filing and other administrative fees and service charges to compensate it for the cost of providing administrative services. The fees in effect when the fee or charge is incurred shall be applicable. The Arbitral Body’s filing fee and any other administrative fee or charge shall be split equally amongst the parties, and the Agency’s portion shall be paid by the Authority.

107.2 The Arbitral Body shall split the costs of the proceeding before an arbitrator (including arbitrator fees and expenses but excluding attorney, witness, and party expert fees) equally amongst the parties with the Agency’s portion being paid by the Authority. The Arbitral Body, in its discretion, may require advanced costs be paid by the parties to ensure payment is made.

107.3 A party’s failure to pay costs or advanced costs by the deadlines imposed by the Arbitral Body will, if not rectified immediately, result in a waiver of claims or defense to claims as applicable and result in imposition and publication of sanctions requested by the Agency.

107.4 The Authority shall be solely responsible for the administrative costs stemming from steward-resolved cases as described in the Adjudication Procedures.

108 Expenses

108.1 The expenses of witnesses for any party shall be paid by the party producing such witnesses. Each party shall bear their own attorneys’ fees and other expenses.

109 Arbitrator's Compensation

109.1 Arbitrators shall be compensated and reimbursed in a manner consistent with the Billing Standards.

109.2 If there is disagreement concerning the terms of compensation, the disagreement shall be resolved as described in the Billing Standards.

109.3 Any arrangement for the compensation or reimbursement of an arbitrator shall be made through the Arbitral Body and not directly between the parties and the arbitrator.

109.4 Arbitrator fees and steward fees shall be paid in accordance with 108.

110 Application of Rules

110.1 The Protocol, Standards, Policies, and Technical Documents shall be considered part of the agreement to arbitrate and that in all instances the arbitrators and stewards are required to apply the arbitration agreement and conform to its terms.

Submitted to FTC

8000 Violations, Sanctions, Hearing Procedures, and Investigatory Powers

8100 Violations

Violations under this Rule shall include:

(a) Failure to cooperate with the Authority or an agent of the Authority during any investigation;

(b) Failure to respond truthfully, to the best of a Covered Person's knowledge, to a question of the Authority or an agent of the Authority with respect to any matter under the jurisdiction of the Authority;

(c) Tampering or attempted tampering with the application of the safety, performance, or anti-doping and medication control rules or process adopted by the Authority, including:

(01) Intentional interference, or an attempt to interfere, with an official or agent of the Authority;

(02) Procurement or the provision of knowingly false information to the Authority or agent of the Authority; and

(03) The intimidation of, or an attempt to intimidate, a potential witness;

(d) Assisting, encouraging, aiding, abetting, conspiring, covering up, or any other type of intentional complicity involving a safety violation, or the violation of a period of suspension or ineligibility;

(e) Threatening or seeking to intimidate a person with the intent of discouraging the person from the good faith reporting to the Authority, an agent of the Authority or the Commission, of information that relates to:

(01) a suspected or alleged violation of a rule in the Rule 2200 Series; or

(02) a suspected or alleged noncompliance with a rule in the Rule 2200 Series;

(f) Failure to comply with a written order or ruling of the Authority or an agent of the Authority pertaining to a racing matter or investigation;

(g) Failure to register with the Authority, making a knowingly false statement or omission of information in an application for registration with the Authority, or failure to advise the Authority of material changes in the application information as required under any provision in Authority regulations;

(h) Perpetrating or attempting to perpetrate a fraud or misrepresentation in connection with the care or racing of a Covered Horse;

(i) Failure to remit fees as required under 15 USC 3052(f)(3); and

(j) Failure by a Racetrack to collect equitable allocation amounts among Covered Persons in conformity with the funding provisions of 15 USC 3052(f)(3) and any rules pertaining thereto.

8200 Schedule of Sanctions for Violations; Consent Decrees; Notice of Suspected or Actual Violation

(a) Application. This Schedule shall apply to any violation of, or failure to comply with, the Act or regulations promulgated by the Authority by a Covered Person, except for:

(01) anti-doping and medication control rule violations as established in the Rule 3000 Series; and

(02) State laws or regulations not pre-empted by 15 USC Section 3054(b).

(b) Imposition of Sanction. The Authority, the Racetrack Safety Committee, the stewards, any steward or body

of stewards selected from the National Stewards Panel, or an Arbitral Body, after any hearing required to be conducted in accordance with the Rule 7000 Series and upon finding a violation or failure to comply with the regulations of the Authority with the exceptions identified in paragraph (a), may impose one or more of the following sanctions on a Covered Person for each violation of the rules of the Authority:

(01) for a violation of Rule 2271(b) or 2272 relating to the use of Shock Wave Therapy, a violation of Rule 2280 relating to the use of the riding crop, or a violation of Rule 2273 relating to the use of other electrical or mechanical devices, impose the penalties set forth in those Sections;

(02) impose a fine upon a Covered Person in the following amounts:

(i) up to $50,000.00 for a first violation, or

(ii) from $50,000.00 to $100,000.00 for a second violation of the same or similar nature to a prior violation, or any violation that due to its nature, chronicity or severity poses an actual or potential threat of harm to the safety, health and welfare of Covered Persons, Covered Horses, or the integrity of Covered Horseraces,

(03) deny or suspend the registration of a Covered Person for a definite period, probationary period, or a period contingent on the performance of a particular act;

(04) revoke the registration of a Covered Person subject to reapplication at a specified date;

(05) impose a lifetime ban from registration with the Authority;

(06) bar a Covered Person from associating with all Covered Persons concerning any matter under the jurisdiction of the Commission and the Authority during the period of a suspension;

(07) impose a temporary or permanent cease and desist order against a Covered Person;

(08) require a Covered Person as a condition of participation in horse racing to take any remedial or other action that is consistent with the safety, welfare, and integrity of Covered Horses, Covered Persons, and Covered Horseraces;

(09) deny or require the forfeiture of purse money, disqualify a horse, or make changes to the order of finish in Covered Races as consistent with the safety, welfare, and integrity of Covered Horses, Covered Persons, and Covered Horseraces;

(10) censure a Covered Person;

(11) prohibit a Racetrack from conducting any Covered Horserace; or

(12) impose any other sanction as a condition of participation in horse racing as deemed appropriate by the Authority in keeping with the seriousness of the violation and the facts of the case, and that is consistent with the safety, welfare, and integrity of Covered Horses, Covered Persons, and Covered Horseraces.

(c) Consent Decrees. The Authority shall have the discretion to enter into a consent decree or other similar agreement with a Covered Person as necessary to promote the safety, welfare, and integrity of Covered Horses, Covered Persons, and Covered Horseraces.

(d) Notice of Suspected or Actual Violation.

(01) The Authority or the Racetrack Safety Committee may issue a Notice of Suspected or Actual Violation to a Covered Person in any case in which the Authority has reason to believe that the Covered Person has violated or has failed to comply any provision of regulations of the Authority. The notice shall:

(i) identify the provision or provisions which the Covered Person is believed to have violated;

(ii) specify with reasonably particularity the factual basis of the Authority's belief that the provision has been violated; and

(iii) provide the Covered Person at least seven (7) days to respond, or a longer period as deemed appropriate and specified in the Notice by the Authority based upon the seriousness of the violation or the imminence of risk.

(02) Upon receipt of the Notice of Suspected or Actual Violation, the Covered Person shall respond in writing to the Authority within the time period specified in the notice. The Covered Person shall include in the response:

(i) a statement by the Covered Person admitting the violation, or explaining the reasons why the Covered Person believes that a violation has not occurred;

(ii) all relevant details concerning the circumstances of the suspected or actual violation, including the results of any investigation undertaken by the Covered Person of the circumstances, and identification of any persons responsible for the circumstances; and

(iii) a detailed explanation of any remedial plan the Covered Person proposes to undertake to cure the suspected or actual violation, and the date of the expected completion of the remedial plan.

8300 Disciplinary Hearings and Accreditation Procedures

8310 Application

An alleged violation or failure to comply with the provisions of the Rule 2200 Series and any alleged violation of the rules set forth in Rule 8100 shall be adjudicated in accordance with this Rule 8300 Series, except that:

(a) An alleged violation of the anti-doping and medication control rule provisions in the Rule 3000 Series shall be adjudicated in accordance with the procedures set forth therein.

(b) This regulation shall not apply to the adjudication of violations arising under state laws, racing rules and regulations not preempted under 15 USC Section 3054(b).

8320 Adjudication of Violations of Established in the Rule 2200 Series

(a) Any ruling by the stewards finding a violation of Rule 2271(b) or 2272 relating to the use of Shock Wave Therapy, a violation of Rule 2280 relating to the use of the riding crop, or a violation of Rule 2273 relating to the use of other electrical or mechanical devices, may be appealed to the Board of the Authority under the procedures described in Rule 8330. An appeal shall be filed in writing within ten (10) days of the issuance of the ruling by the stewards.

(b) With regard to any matter involving an alleged violation of a rule in the Rule 2200 Series other than those set forth in paragraph (a) above, the Racetrack Safety Committee may, at its discretion and taking into account the seriousness of the alleged violation and the facts of the case:

(01) Refer the matter to the National Stewards Panel for adjudication in conformity with the procedures established in the Rule 7000 Series;

(02) Refer the matter to an independent Arbitral Body for adjudication in conformity with the procedures established in the Rule 7000 Series;

(03) Refer the matter to the stewards for adjudication in accordance with the procedures of the applicable state jurisdiction; or

(04) Conduct a hearing upon the matter itself, under the procedures set forth in Rule 8340.

8330 Adjudication of Rule 8100 Violations

With regard to any matter involving an alleged violation of a rule established in Rule 8100, the Board of the Authority may at its discretion and taking into account the seriousness of the violation and the facts of the case:

(a) Refer the matter to the National Stewards Panel for adjudication in conformity with the

procedures established in the Rule 7000 Series;

(b) Refer the matter to an independent Arbitral Body for adjudication in conformity with the procedures established in the Rule 7000 Series;

(c) Refer the matter to the stewards for adjudication in accordance with the procedures of the applicable state jurisdiction; or

(d) Conduct a hearing upon the matter itself, under the procedures set forth in Rule 8340.

8340 Initial Hearings Conducted Before the Racetrack Safety Committee or the Board of the Authority

(a) An initial hearing before the Board shall be conducted by a panel of three Board members. The Board chair shall appoint the panel members and shall also designate one of them as the chair of the panel.

(b) An initial hearing before the Racetrack Safety Committee shall be heard by a quorum of the Racetrack Safety Committee. The Racetrack Safety Committee chair shall act as the chair of the hearing panel unless the Chair is unavailable, in which case the Racetrack Safety Committee chair shall designate a member of the quorum to act as the chair of the panel.

(c) Persons entitled to notice of a hearing before the Board or the Racetrack Safety Committee shall be informed not less than twenty (20) days prior to the hearing of:

(01) the time, place, and nature of the hearing;

(02) the legal authority and jurisdiction under which the hearing is to be held;

(03) a description of the alleged violation, specifying by number the rule allegedly violated; and

(04) a statement of the factual basis of the alleged violation in sufficient detail to provide adequate opportunity to prepare for the hearing.

(d) At any time prior to, during, or after the hearing, the Board or the Racetrack Safety Committee in its discretion may require the submission of written briefs or other information as will assist in the hearing of the matter.

(e) All testimony in proceedings before the Board or the Racetrack Safety Committee shall be given under oath.

(f) The burden of proof shall be on the party alleging the violation to show, by a preponderance of the evidence, that the Covered Person has violated or failed to comply with a provision of or is responsible for a violation of a provision of the Authority's regulations.

(g) The Board or the Racetrack Safety Committee shall allow a full presentation of evidence and shall not be bound by the technical rules of evidence. However, the Board or the Racetrack Safety Committee may disallow evidence that is irrelevant or unduly repetitive of other evidence. The Board or the Racetrack Safety Committee shall have the authority to determine, in its sole discretion, the weight and credibility of any evidence or testimony. The Board or the Racetrack Safety Committee may admit hearsay evidence if it determines the evidence is of a type that is commonly relied on by reasonably prudent people. Any applicable rule of privilege shall apply in hearings before the Board or the Committee.

(h) A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such limited cross-examination as may be required for a full and true disclosure of the facts.

(i) The Board or the Racetrack Safety Committee shall issue to all parties within thirty days (30) of the close of the hearing a written decision setting forth findings of fact, conclusions of law and the disposition of the matter including any penalty imposed. If the thirtieth day falls on a Saturday, Sunday, or holiday, then the written decision shall be issued on the next working day immediately following the Saturday, Sunday, or holiday.

8350 Appeal to the Board

(a) Any decision rendered by the Racetrack Safety Committee, the stewards, the National Stewards Panel, or an Arbitral Body, may be appealed on the record to the Board. The decision may be appealed by a party to the decision, or the decision may be reviewed upon the Board's own initiative and at its discretion.

(b) Any decision rendered by an initial Board hearing panel may be appealed on the record to the Board, to be heard by a quorum of the Board which shall not include the Board members who were on the panel in the initial hearing. The decision may be appealed by a party to the decision, or the decision may be reviewed upon the Board's own initiative and at its discretion.

(c) An appeal shall not automatically stay the decision. A party may request the Board to stay the decision. The Board shall order a stay for good cause shown.

(d) A party to the decision may appeal to the Board by filing with the Board a written request for an appeal within ten days after receiving a written order. The appeal request shall contain the following information:

(01) the name, address, and telephone number, if any, of the appellant;

(02) a description of the objections to the decision;

(03) a statement of the relief sought; and

(04) whether the appellant desires to be present in person at the hearing of the appeal.

(e) The Board shall set a date, time, and place for the hearing. Notice shall be given to the appellant in writing and shall set out the date, time, and place of the hearing, and shall be served personally or sent by electronic or U.S. mail to the last known address of the appellant. If the appellant objects to the date of the hearing, the appellant may obtain a continuance, but the continuance shall not automatically stay imposition of a sanction or prolong a stay issued by the Board.

(f) Upon review of the decision which is the subject of the appeal, the Board shall uphold the decision unless it is clearly erroneous or not supported by the evidence or applicable law.

(g) Upon completing its review, the Board may:

(01) Accept the decision;

(02) Reject or modify the decision, in whole or in part;

(03) Remand the matter, in whole or in part, to the stewards, Racetrack Safety Committee, the National Stewards Panel, or an Arbitral Body, as the case may be, for further proceedings as appropriate; or

(04) Conduct further proceedings on the matter as appropriate, including but not limited to requiring the submission of written briefs or, in extraordinary circumstances and at the Board's discretion, the taking of additional testimony before the Board under oath.

(h) The Board shall issue its written decision based on the record and any further proceedings or testimony. A copy of the Board's decision shall be served upon all parties by first class mail, electronic mail, or personal service.

(i) The decision of the Board shall be the final decision of the Authority agency decision.

8360 Accreditation Procedures

(a) Any decision issued by the Authority denying or revoking racetrack accreditation may:

(01) Be appealed within ten (10) days by the Racetrack to the Authority for a de novo hearing reviewing the Authority's decision; or

(02) Reviewed by the Authority on its own initiative.

(b) The Authority's order revoking accreditation shall be stayed automatically pending review of the decision by the Authority.

(c) At its discretion, the Authority may request and consider any additional information from any source that may assist in the review.

(d) The Racetrack may request to make a presentation before the Authority concerning racetrack safety and any remedial efforts proposed to be undertaken by the Racetrack. At its discretion, the Authority may permit the Racetrack to make such presentation.

(e) In conducting its review, that Authority may consider all factors that it deems appropriate, including but not limited to:

(01) The extent and magnitude of any deficiencies in racetrack operations conducted at the Racetrack;

(02) The threat posed by the deficiencies to the safety and integrity of horse racing conducted at the Racetrack;

(03) The adequacy of the efforts the Racetrack proposes to undertake or has undertaken to remedy all deficiencies at the Racetrack;

(04) The likelihood and timeframe within which compliance will be achieved by the Racetrack, given the resources available to the Racetrack and the past record of the Racetrack in achieving and maintaining compliance with the rules of the Authority; and

(05) Any other factors the Authority deems relevant to its review.

(f) Upon completing its review, the Authority may take one or more of the following actions:

(01) Order that the Racetrack's accreditation be denied or revoked, upon a vote in favor of denial or revocation by two-thirds (2/3) of a quorum of the members of the Authority;

(02) Reinstate accreditation subject to any requirements the Authority deems necessary to ensure that horse racing will be conducted in a manner consistent with racetrack safety and integrity. The Authority may also impose a fine upon reinstatement in amount not to exceed $50,000.00. The Authority may require the Racetrack to report at prescribed intervals on the status of racetrack safety operations and remedial efforts to improve safety pursuant to the Authority's racetrack safety rules; or

(03) Prohibit a Racetrack from conducting any Covered Horserace.

8370 Final Civil Sanction

Any decision rendered by the Board of the Authority under Rule 8350, or the Authority under Rule 8360, shall constitute a final civil sanction subject to appeal and review in accordance with the provisions of 15 USC 3058.

8400 Investigatory Powers

(a) The Commission, the Authority or their designees:

(01) Shall have free access to the books, records, offices, racetrack facilities, and other places of business of Covered Persons that are used in the care, treatment, training, and racing of Covered Horses, and to the books, records, offices, facilities, and other places of business of any person who owns a Covered Horse or performs services on a Covered Horse; and

(02) May seize any medication, drug, substance, paraphernalia, object, or device in violation or suspected violation of any provision of 15 USC Chapter 57A or the regulations of the Authority.

(b) A Covered Person shall:

(01) Cooperate with the Commission, the Authority or their designees during any investigation; and

(02) Respond truthfully to the best of the Covered Person's knowledge if questioned by the Commission, the Authority, or their designees about a racing matter.

(c) A Covered Person or any officer, employee or agent of a Covered Person shall not hinder a person who is conducting an investigation under or attempting to enforce or administer any provision of 15 USC Chapter 57A or the regulations of the Authority.

(d) The Commission or the Authority may issue subpoenas for the attendance of witnesses in proceedings within their jurisdiction, and for the production of documents, records, papers, books, supplies, devices, equipment, and all other instrumentalities related to matters within the jurisdiction of the Commission or the Authority.

(e) Failure to comply with a subpoena or with the other provisions of this Rule may be penalized by the imposition of one or more penalties set forth in Rule 8200.

(f) The Commission or the Authority may administer oaths to witnesses and require witnesses to testify under oath in matters within the jurisdiction of the Commission or the Authority.

8500 Methodology for Determining Assessments.

8510 Definitions.

For purposes of this Rule 8500 Series:

(a) Annual Covered Racing Starts means, for the following calendar year, the sum of: (i) fifty percent (50%) of the number of Projected Starts; plus (ii) fifty percent (50%) of the number of Projected Purse Starts.

(b) Covered Horseraces has the meaning set forth in 15 USC 3051(5).

(c) Projected Starts means the number of starters in covered horseraces in the previous twelve (12) months as reported by Equibase, after taking into consideration alterations in the racing calendar of the relevant State(s) for the following calendar year.

(d) Projected Purse Starts means: (i) the total amount of purses for covered horseraces as reported by Equibase, after taking into consideration alterations in purses for the relevant State(s) for the following calendar year; divided by (ii) the Projected Starts for the following calendar year.

(e) Racetrack has the meaning set forth in 15 USC 3051(15).

8520 Annual Calculation of Amounts Required.

(a) If a State racing commission elects to remit fees pursuant to 15 USC 3052(f)(2), the State Racing Commission shall notify the Authority in writing on or before May 2, 2022 of its decision to elect to remit fees.

(b) Not later than April 1, 2022 and not later than November 1 of each year thereafter, the Authority shall determine and provide to each State Racing Commission the estimated amount required from each State pursuant to the calculation set forth in Rule 8520(c) below.

(c) Upon the approval of the budget for the following calendar year by the Board of the Authority, and after taking into account other sources of Authority revenue, the Authority shall allocate the calculation due from each State pursuant to 15 USC 3052(C)(i) proportionally by each State's respective percentage of the Annual Covered Racing Starts. Provided however, that no State's allocation shall exceed ten percent (10%) of the total amount of purses for covered horseraces as reported by Equibase in the State. All amounts in excess of the ten percent (10%) maximum shall be allocated proportionally to all States that do not exceed the maximum, based on each State's respective percentage of the Annual Covered Racing Starts.

(d) Pursuant to 15 USC 3052(f)(2)(B), a State racing commission that elects to remit fees, shall remit fees on a monthly basis and each payment shall equal one-twelfth (1/12) of the estimated annual amount required from the State for the following year.

(e) If a State racing commission does not elect to remit fees pursuant to 15 USC 3052(f)(2):

(01) The Authority shall on a monthly basis calculate and notify each Racetrack in the State of the applicable fee per racing start for the next month based upon the following calculations:

(i) Calculate the amount due from the State as if the State had elected to remit fees pursuant to 15 USC 3052(f)(2) (the “Annual Calculation”).

(ii) Calculate the number of starters in covered horseraces in the previous twelve months as reported by Equibase (the “Total Starts”).

(iii) Calculate the number of starters in covered horseraces in the previous month as reported by Equibase (the “Monthly Starts”).

(iv) The applicable fee per racing start shall equal (i) the quotient of Monthly Starts divided by Total Starts; (ii) multiplied by the Annual Calculation.

(02) The Authority shall on a monthly basis calculate and notify each Racetrack in the jurisdiction of the following calculations:

(i) Multiply the number of starters in covered horseraces in the previous month by the applicable fee per racing start calculated pursuant to paragraph (e)(1)(iv) above.

(ii) The calculation set forth in 15 USC 3052(f)(3)(A) shall be equal to the amount calculated pursuant to paragraph (e)(2)(i) (the “Assessment Calculation”).

(03) The Authority shall allocate the monthly Assessment Calculation proportionally based on each Racetrack’s proportionate share in the total purses in covered horseraces in the State over the next month and shall notify each Racetrack in the jurisdiction of the amount required from the Racetrack. Each Racetrack shall pay its share of the Assessment Calculation to the Authority within thirty (30) days of the end of the monthly period.

(04) Not later than May 1, 2022 and not later than November 1 each year thereafter, each Racetrack in the State shall submit to the Authority its proposal for the allocation of the Assessment Calculation among covered persons involved with covered horseraces (the “Covered Persons Allocation”). On or before thirty (30) days from the receipt of the Covered Persons Allocation from the Racetrack, the Authority shall determine whether the Covered Persons Allocation has been allocated equitably in accordance with 15 USC 3052(f)(3)(B) and if so, the Authority shall notify the Racetrack that the Covered Persons Allocation is approved. If a Racetrack fails to submit its proposed Covered Person Allocation in accordance with the deadlines set forth in this paragraph, or if the Authority has not approved the Covered Persons Allocation in accordance with this paragraph, the Authority shall determine the Covered Persons Allocation for the Racetrack. Upon the approval of or the determination by the Authority of the Covered Persons Allocation, the Racetrack shall collect the Covered Person Allocation from the covered persons involved with covered horseraces.

(f) All notices required to be given to the Authority pursuant to the Act and these regulations shall be in writing and shall be mailed to 401 West Main Street, Suite 222, Lexington, Kentucky 40507 and emailed to feedback@hisaus.org.