*****TENDERED TO FTC BY HISA FOR CONSIDERATION*****

AGENCY: Federal Trade Commission

ACTION: Proposed Rule

SUMMARY: As directed by the "Horseracing Integrity and Safety Act of 2020", the Federal Trade Commission ("FTC" or "Commission") issues a set of proposed rules related to a formula or methodology for determining assessments described in 15 USC § 3052(f).

DATES: The effective date of this proposed rule is January 1, 2023.

The deadline for comments is _____.

ADDRESSES:

FOR FURTHER INFORMATION CONTACT:

SUPPLEMENTARY INFORMATION:

Pursuant to Section 3053(a) of the Horseracing Integrity and Safety Act of 2020¹ (the "Act") and Rule 1.142 thereunder,² on August 17, 2022, the Horseracing Integrity and Safety Authority ("HISA" or the "Authority") filed with the Commission the proposed rules described herein, which Items have been prepared by HISA. The Commission has published notice of the proposed rule submitted by HISA and has solicited comments on the proposed rules from interested persons.

¹ Pub. L. 116–260, div. FF, title XII, §1201, Dec. 27, 2020, 134 Stat. 3252, codified at 15 USC Ch. 57A §§3051-3060

² 16 CFR Part 1 Subpart S § 1.142

RULE SERIES 5000

EQUINE TESTING AND INVESTIGATIONS STANDARDS

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5000. EQUINE TESTING AND INVESTIGATIONS STANDARDS

5010. Purpose

(a) The Equine Testing and Investigations Standards have been developed pursuant to the Act and the Protocol.

(b) The first purpose of the Testing and Investigations Standards is to plan for intelligent and effective Testing, both in- 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 Sample collection, to the point the Samples are delivered to a Laboratory for analysis. To that end, these Testing and Investigations Standards establish protocols for test planning, notification of a Covered Horse's selection for Sample collection, preparing for and conducting Sample collection, security/post-test administration of Samples and documentation, and transport of Samples to Laboratories for analysis.

(c) 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.

5020. Definitions

Unless specified otherwise, capitalized terms used in these Testing and Investigations Standards have the meanings given to them in Rule 1020.

5100. STANDARDS FOR TESTING

5110. Planning effective Testing

(a) The Agency is required to plan and implement intelligent and effective Testing on Covered Horses over which it has authority, and that is proportionate to the risk of doping and the misuse of medication, and effective to detect and to deter such practices. The objective of this Rule is to explain the steps that form part of a Risk Assessment to inform Testing plans in a way that best ensures clean competition and protects the health and welfare of Covered Horses.

(b) 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 Sample collection.

(c) The Agency should monitor, evaluate, and update its Risk Assessment during the year or cycle in light of changing circumstances and in implementing its Testing plans.

5120. Risk Assessment

The Risk Assessment shall be conducted in good faith, reviewed and updated as required (at the discretion of the Agency), and should take into account (if available) the following information:

(a) discipline and individual factors that may result in a higher potential for adopting doping behavior and/or misuse of medication;

(b) available statistics and research on doping trends and/or misuse of medication, practices, and methods;

(c) reliable information received and intelligence developed on possible doping practices and/or misuse of medication;

(d) outcomes of previous test planning cycles, including past testing strategies;

(e) optimal times to apply specific test types (including analysis) to maximize opportunities for detecting and deterring doping;

(f) given the structure of the racing season (including generic racing schedules and training patterns), the time during the year a horse is most likely to be administered Banned Substances or be subjected to Banned Methods (to enhance or impair performance or impact welfare and/or soundness); and

(g) any Risk Assessment carried out by a State Racing Commission or racing authority in another country and provided to the Agency for the purposes of enhancing its Risk Assessment.

5130. Prioritizing between Covered Horses, types of Testing, and Samples

(a) 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.

(b) Factors relevant to determining which Covered Horses should be the subject of Target Testing may include, but are not limited to, the following:

(1) Covered Horses serving a period of Ineligibility or a Provisional Suspension;

(2) Covered Horses who were high priority for Testing before retirement and are now returning from retirement to active participation;

(3) Covered Horses' testing history, including any abnormal Sample data (e.g., an Atypical Finding reported by a Laboratory);

(4) Covered Persons' prior anti-doping and medication control rule violations and testing history, including any abnormal Sample data (e.g., an Atypical Finding reported by a Laboratory);

(5) performance history, performance pattern, and/or high performance (e.g., Trainer strike rate) without a commensurate testing record;

(6) repeated failure to meet whereabouts requirements;

(7) suspicious whereabouts filing patterns;

(8) moving to or training in a remote location;

(9) suspicious withdrawal or absence from expected Covered Horserace(s);

(10) association with a third party (such as a Trainer, Veterinarian, or Owner) with a history of involvement in doping and/or misuse of medication;

(11) injury;

(12) age and stage of career;

(13) financial incentives for improved or degraded performance, such as purse size, unusual betting patterns, or upcoming Claiming Race; and/or

(14) reliable information from a third party, or intelligence developed by or shared with the Agency.

(c) 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 may be tested at any time and at any place where they are located (e.g., Racetrack, Training Facility, private facility). The Protocol does not impose any reasonable suspicion or probable cause requirement for Target Testing or Testing.

(d) Testing that 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 testing (where Covered Horses are ranked using pre-determined criteria to increase or decrease the chances of selection) or random testing (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 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.

(e) 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 effectively detect and deter doping and misuse of medication within the sport:

- (1) TCO2 and Post-Race Sample collection on Race Day;
- (2) Post-Work Sample collection following Timed and Reported Workouts;
- (3) Out-of-competition Sample collection;
- (4) Sample matrices to be considered:
 - (i) urine;
 - (ii) hair;
 - (iii) blood; and/or
 - (iv) other matrices or methodologies, as available.

5140. Sample analysis, retention strategy, and Further Analysis

(a) Laboratories shall analyze Samples for an Analytical Testing menu directed by the Agency. The Agency may also consider undertaking more extensive Sample analysis for Prohibited Substances or Prohibited Methods based on the assessed risk or any intelligence that the Agency may receive (e.g., specific Prohibited Substances, gene doping).

(b) The Agency should develop a system for retention of Samples and related documentation to enable the Further Analysis of such Samples at a later date in accordance with Rule 3138. Such a system should comply with the requirements of the Laboratory Standards and should take into account the purposes of Sample analysis set out in Rule 3137, as well as (without limitation) the following elements:

(1) Laboratory recommendations (when available);

(2) new relevant detection methods to be introduced in the future;

(3) collected Samples that meet some or all of the criteria set out at Rule 5130; and/or

(4) the Agency determining based on available information or random selection that long-term storage or Further Analysis of the Samples is appropriate.

5150. Coordinating with State Racing Commissions and other entities

(a) In accordance with Rule 3132, the Agency may delegate Testing (or aspects thereof) to State Racing Commissions, subject to the applicable State Racing Commission electing to enter into an agreement with the Agency. For example, the Agency may utilize Sample Collection Personnel employed or designated by a State Racing Commission to collect Samples. Any state rule, law, or regulation preventing sample collection personnel employed or designated by a State Racing Commission from contracting with the Agency to collect Samples is pre-empted by this rule, which expressly permits such arrangements. Regardless of who collects a Sample, only the Agency shall receive the results of Sample analysis directly from the Laboratory.

(b) The Agency may delegate Testing (or aspects thereof) to qualified third parties, e.g., by contracting a third-party sample collection service provider to collect Samples on behalf of the Agency.

(c) State Racing Commissions, Racetracks, Race Organizers, and other third parties may (at their own cost) contract with the Agency to collect additional Samples on Covered Horses in a manner that is consistent with the Act and the Protocol.

5200. NOTIFICATION

5210. Requirements prior to notification

(a) Testing without advance notice should be the method for Sample collection except in circumstances where advance notice is required to facilitate the Testing. 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 without advance notice 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.

(b) The Agency shall appoint DCOs, BCOs, Chaperones, and other Sample Collection Personnel sufficient to facilitate Testing without advance notice and to ensure continuous observation of the Covered Horse and confirmation that the Covered Horse is in a secure location (a stall, for example) throughout the Sample collection process. Sample Collection Personnel must be trained for their assigned responsibilities, must not have a conflict of interest with respect to the performance or outcome of the Sample collection, and must be eighteen (18) or older. See Rule 5450 for more information on Sample Collection Personnel requirements.

(c) Sample Collection Personnel shall have official documentation provided by the Agency, evidencing their authority to collect a Sample from the Covered Horse.

(d) Information provided in the Covered Horse's whereabouts filing and registration with the Authority, or other equally reliable form of identification, 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.

(e) The DCO and/or BCO 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., Covered Horserace, Timed and Reported Workout, Vets' List Workout).

5220. Requirements for notification

(a) Out-of-competition Sample collection

(1) The Sample Collection Personnel will seek to locate the Covered Horse based on available data regarding Racetracks and Training Facilities and/or based on whereabouts information.

(2) If the Sample Collection Personnel are able to locate the Covered Horse, notification of out-ofcompetition Sample collection shall ordinarily take place in person, but may, if necessary, take place by telephone, text message, and/or email using the contact details provided by the Responsible Person upon registration with the Authority.

(3) If the Sample Collection Personnel are not able to locate the Covered Horse based on available data or whereabouts information, notification of out-of-competition Sample collection shall take place by telephone, text message, and/or email, using the contact details provided by the Responsible Person upon registration with the Authority.

(4) In accordance with Rule 3215, the Responsible Person shall ensure that the Covered Horse is produced for Sample collection immediately upon notification by a duly authorized person in accordance with the Agency's procedures if the Covered Horse is present at the location where notification is attempted. If the Covered Horse is not present at the location where notification is attempted (including due to a Whereabouts Failure), the Responsible Person shall ensure that the Covered Horse is produced for Sample collection within six (6) hours of notification by a duly authorized Person in accordance with the Agency's procedures, except that the Agency may extend the six (6) hour period if it considers that extenuating circumstances justify doing so.

(5) At the time of notification, the Sample Collection Personnel shall inform the Responsible Person or Nominated Person:

(i) that the Covered Horse is required to undergo Sample collection;

(ii) that immediate access to the Covered Horse shall be granted, and (if that is not possible because the Covered Horse is not present at the location), the Responsible Person has six (6) hours to produce the Covered Horse for Sample collection, failing which significant Consequences may apply in accordance with Rule 3215;

(iii) that the Sample collection process shall start immediately, unless there are valid reasons for a delay (as determined by the DCO or BCO);

(iv) that the Sample collection process shall take place in a secure location determined suitable

by the DCO or BCO (e.g., the horse's stall);

(v) of the responsibilities of the Responsible Person or Nominated Person with respect to the Covered Horse, including the requirement to:

(A) ensure that the Covered Horse remains under continuous observation of Sample Collection Personnel at all times until the completion of the Sample collection procedure;

(B) not leave the Covered Horse unattended once the Responsible Person or Nominated Person is notified and contact is made with the Covered Horse until the completion of the Sample collection procedure;

(C) produce on request identification for himself or herself and the Covered Horse. Identification for the Responsible Person or Nominated Person should include his or her Authority registration number or (if not available) valid photo identification. The Sample Collection Personnel may take photographs of the individual(s) and the Covered Horse if identification is not provided;

(D) comply and cooperate with Sample collection procedures and processes (the Responsible Person or Nominated Person should also be advised of the possible Consequences of failure to comply, including pursuant to Rule 3215 and 3510); and

(E) ensure that the Covered Horse is not administered any medications or supplements from notification of Sample collection until completion of Sample collection, unless there is a medical emergency, as determined by a Regulatory Veterinarian or (if not available) a Veterinarian.

(6) The Sample Collection Personnel shall have the Responsible Person or Nominated Person sign an appropriate form to acknowledge and accept the notification of Sample collection. If the Responsible Person or Nominated Person refuses to sign the form, or evades notification, the Sample Collection Personnel should, 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 or BCO. When possible, the Sample Collection Personnel shall continue the Sample collection. The DCO shall document the facts in a detailed report and report the circumstances to the Agency.

(7) A Nominated Person may be replaced by another Nominated Person during the Sample collection process upon reasonable request to the Sample Collection Personnel so long as the new Nominated Person (i) falls within the scope of the definition of Nominated Person, (ii) completes the relevant portions of the Sample collection paperwork, and (iii) 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.

(b) Post-Race Sample collection

(1) Pursuant to Rule 1020, a Post-Race Sample includes any Sample collected by or on behalf of the Agency from a Covered Horse where notification of such Sample collection takes place no more than one (1) hour after the end of a Covered Horserace in which a Covered Horse participates or is entered, or the end of a Vet's List Workout in which a Covered Horse participates.

(2) A member of the Sample Collection Personnel will tag or otherwise identify a Covered Horse selected for Sample collection (ordinarily in the unsaddling area) within one (1) hour of the end of the Covered Horserace or Vets' List Workout and chaperone the Covered Horse from the point of tagging/notification until the end of the Sample collection process. Such notification should inform the Responsible Person or Nominated Person:

(i) that the Covered Horse is required to undergo Sample collection;

(ii) that the Covered Horse must immediately be brought to the Test Barn, unless there are valid reasons for a delay (as determined by the DCO or BCO);

(iii) of the location of the Test Barn;

(iv) of the responsibilities of the Responsible Person or Nominated Person with respect to the Covered Horse, including the requirement to:

(A) ensure that the Covered Horse remains under continuous observation of Sample Collection Personnel at all times until the completion of the Sample collection procedure;

(B) not leave the Covered Horse unattended once the Responsible Person or Nominated Person is notified and contact is made with the Covered Horse until the Sample collection procedure is completed;

(C) produce on request identification for himself or herself (which shall include his or her Authority registration number) and the Covered Horse. The Sample Collection Personnel may take photographs of the individual(s) and the Covered Horse if no identification is provided;

(D) comply and cooperate with Sample collection procedures and processes (the Responsible Person or Nominated Person should be advised of the possible Consequences of a failure to comply, including pursuant to Rule 3215 and 3510);

(E) ensure that the Covered Horse is not administered any medications or supplements (or similar items) from notification of Sample collection until completion of Sample collection, unless there is a medical emergency, as determined by the Test Barn Veterinarian or a Regulatory Veterinarian; and

(F) confirm that the water bucket of the Covered Horse is clean and acceptable and ensure that it is only used for that Covered Horse during the Sample collection process.

(3) 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 or through such other reasonable and appropriate measure under the circumstances), 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 the form, or evades the notification, the Sample Collection Personnel should, 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 or BCO) shall immediately report all relevant facts to the DCO or BCO. When possible, the Sample Collection Personnel shall continue the

Sample collection. The DCO or BCO shall document the facts in a detailed report and report the circumstances to the Agency.

(4) From the time that a Covered Horse is tagged or identified for Sample collection until the end of the Sample collection process, 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).

(5) A Nominated Person may be replaced by another Nominated Person during the Sample collection process upon reasonable request to the Sample Collection Personnel, so long as the new Nominated Person (i) falls within the scope of the definition of Nominated Person, (ii) completes the relevant portions of the Sample collection paperwork, and (iii) 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.

(c) Pre-race Sample collection

Blood samples may be collected before a Covered Horserace or Vets' List Workout for purposes of TCO2 testing in accordance with Rule 5430. Sample Collection Personnel shall provide notification of Sample collection in accordance with paragraph (a) or (b) above depending on the circumstances.

(d) Post-Work Sample collection

Samples may be collected after a Timed and Reported Workout in accordance with Rule 5400. All Banned Substances and any Controlled Medication Substances specifically identified on the Prohibited List as prohibited during Timed and Reported Workouts are prohibited from being present in a Post-Work Sample. Sample Collection Personnel shall provide notification of Sample collection in accordance with paragraph (a) and (b) above depending on the circumstances.

5230. Requests for delay

(a) The DCO or BCO may consider any reasonable request from the Responsible Person or Nominated Person or third party for permission to delay beginning the Sample collection process following acknowledgment and acceptance of notification. The DCO or BCO may grant such permission only if the Covered Horse can remain under continuous observation of Sample Collection Personnel at all times until the completion of the Sample collection procedure. The DCO or BCO shall otherwise reject a request for delay, unless there is a medical emergency (as determined by a Test Barn Veterinarian or Regulatory Veterinarian or, if not available for an out-of-competition Sample collection, a Veterinarian) or other circumstances so require it (as determined by the DCO or BCO).

(b) For Race Day Sample collection, delayed reporting to the Test Barn may be permitted in accordance with paragraph (a) on account of:

(1) participation in the winner's circle;

(2) obtaining necessary medical treatment if there is a medical emergency, as determined by a Regulatory Veterinarian or Test Barn Veterinarian; or

(3) any other reasonable circumstances, as determined by the DCO or BCO, taking into account any instructions of the Agency.

(c) For out-of-competition Sample collection, delayed reporting for Sample collection may be permitted in accordance with paragraph (a) on account of:

(1) completing a training session or a cool down;

(2) receiving necessary medical treatment if there is a medical emergency, as determined by a Regulatory Veterinarian or (if not available) a Veterinarian; or

(3) any other reasonable circumstances, as determined by the DCO or BCO, taking into account any instructions of the Agency.

(d) Sample Collection Personnel shall document any reasons for delay in reporting for Sample collection.

(e) If immediate access to the Covered Horse is not granted, the DCO or BCO shall report to the Agency a possible failure to comply. If at all possible, the DCO or BCO shall proceed with collecting a Sample.

5300. PREPARING FOR THE SAMPLE COLLECTION SESSION

5310. General requirements

(a) The Agency should establish a system for obtaining all of the information necessary to ensure that the Sample Collection Session can be conducted effectively.

(b) For Race Day Sample collection, a Test Barn should be used that, where possible, is used solely as a Test Barn for the duration of all Sample Collection Sessions. Unauthorized persons should not be permitted access to the Test Barn. Should the DCO or BCO determine the Test Barn is unsuitable, he or she shall seek an alternative location.

(1) Unless otherwise approved by the Agency, the Test Barn should be equipped with:

(i) an enclosed 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;

(ii) sufficient enclosed stalls for the number of Sample collections that permit observation of the collection process and provide for the protection of Covered Horses undergoing Sample collection and space for Sample Collection Personnel and up to two (2) Covered Persons per Covered Horse;

(iii) facilities and equipment for the collection, identification, and storage of Samples, including one (1) refrigerator or cooler that can be locked or otherwise secured, and one (1) freezer that can be locked or otherwise secured;

(iv) an area and appropriate facilities for a Covered Horse to be bathed;

(v) a table or other suitable surface;

(vi) access to hot and cold running water;

(vii) clean water buckets for each Covered Horse; and

(viii) a security officer to ensure no unauthorized person is permitted in the Test Barn.

(2) The Test Barn Veterinarian shall be responsible for managing horse welfare in the Test Barn. For example, this includes determining when and how to manage congestion in the Test Barn, when to release Covered Horses from the Test Barn, and whether (if necessary) to permit treatment of a Covered Horse. A Covered Horse in the Test Barn may receive medical treatment only with the prior authorization of the Test Barn Veterinarian or a Regulatory Veterinarian.

(c) For out-of-competition Sample collection, the DCO or BCO 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.

5320. Sample Collection Equipment

(a) *General*. Sample Collection Personnel should ensure that they have and use Sample Collection Equipment provided by or approved by the Agency.

(b) *Minimum requirements*. Sample Collection Equipment should, at a minimum:

(1) have a unique numbering system for all bottles, containers, tubes, security bags, bar code labels, or other items used to seal and transport the Samples;

(2) have a Tamper Evident sealing system;

(3) not reveal the identities of the Responsible Person and Covered Horse on the equipment (i.e., only the unique numbering system shall be used on the equipment);

(4) be clean and sealed prior to use;

(5) be constructed of a material and sealing system approved by the Agency that should:

(i) be 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 storage;

(ii) maintain the integrity (chemical and physical properties) of the Sample for Laboratory analysis;

(iii) if the Sample will be transported and/or stored frozen, withstand temperatures of up to - 80 °C and a minimum of three (3) freeze/thaw cycles;

(iv) be transparent or translucent so the Sample is visible;

(v) have a sealing system that allows verification by the Responsible Person or Nominated Person and the DCO or BCO that the Sample is correctly sealed in the bottles or containers;

(vi) be designed to prevent leakage during transportation (including by air);

(vii) have been manufactured under the internationally recognized ISO 9001 certified process which includes quality control management systems; and

(viii) 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 and Further Analysis; and

(6) include a transport device and/or packaging that is suitable to the Sample at issue.

(c) *Additional requirements applicable to urine Samples.* In addition to the requirements of paragraph (b) of this Rule 5320, Sample Collection Equipment used in the collection of urine Samples shall include:

(1) a collection vessel with the capacity to contain a minimum of 50 mL volume of urine;

(2) A and B bottles with the capacity to contain a minimum 25 mL volume of urine; and

(3) visual markings on the A and B bottles and the collection vessel, indicating the minimum volume of urine required and the maximum volume levels that allow for expansion when frozen without compromising the bottle, container, or sealing system.

(d) *Specific requirements applicable to blood Samples*. In addition to the requirements of paragraph (b) of this Rule 5320, Sample Collection Equipment used in the collection of blood Samples shall include:

(1) a needle for blood sampling; and

(2) three (3) blood collection tubes, each with a capacity to contain a minimum of 8 mL of blood, to ensure a minimum total of 24 mL of blood is collected (except for TCO2 testing, where a lesser volume may be collected at the discretion of the Agency).

(e) *Specific requirements applicable to Hair Samples and other Samples.* Sample Collection Personnel should ensure that they have the necessary equipment for hair Sample collection and any other approved Testing matrices or methodologies, in accordance with any procedures or guidance issued by the Agency.

5400. CONDUCTING THE SAMPLE COLLECTION SESSION

5410. Collection of Samples

(a) The Agency shall be responsible for the overall conduct of the Sample Collection Session, with specific responsibilities delegated to the DCO or BCO. Sample collection may be performed only by Sample Collection Personnel approved by the Agency. The Agency may issue supplemental procedures and/or guidance regarding Sample collection procedures as it considers necessary.

(b) The following Persons may be authorized and/or required to be present during the Sample Collection Session:

(1) Sample Collection Personnel sufficient to notify, chaperone, and collect the required Samples must be present during the Sample Collection Session;

(2) the Responsible Person or Nominated Person should be present during the Sample Collection Session. If the Responsible Person or Nominated Person is not present, this will be documented by the DCO or BCO;

(3) no more than two (2) Covered Persons (including the Responsible Person and/or Nominated Person) may be present during the Sample collection for a Covered Horse, except in exceptional circumstances, as determined by the DCO or BCO; and

(4) any Person authorized by the Agency (e.g., a person who is involved in the training or supervision of Sample Collection Personnel) may be present during the Sample Collection Session.

(c) The Sample Collection Personnel will coordinate with the Test Barn security officer to ensure that no unauthorized person is permitted in the Test Barn.

(d) For Race Day Sample collection, the Covered Horse shall remain in the Test Barn through to the end of the Sample collection when the Covered Horse is released from the Test Barn by the DCO.

(e) Samples shall be collected in a manner that ensures:

(1) the Sample is of a quality and quantity that meets the relevant Sample suitability and analytical requirements;

(2) the Sample has not been contaminated or otherwise tampered with in any way at the time of collection;

(3) the Sample is clearly and accurately identified; and

(4) the Sample is securely sealed in a Tamper Evident kit.

(f) 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:

(1) Rule 5420: Collection of urine Samples;

(2) Rule 5430: Collection of blood Samples; and

(3) Rule 5440: Collection of hair Samples.

(g) Except for Samples collected for TCO2 testing (see Rule 5430(p) below), each Sample collected shall be split into an A and a B Sample at the time of collection.

(h) In general, the relevant Sample Collection Personnel should wear a new pair of disposable gloves when handling the Sample collection vessel/tubes and when sealing Samples.

(i) The following information shall be recorded at a minimum on the Sample collection documentation for a Sample Collection Session:

(1) date and time of notification, and name and signature of notifying Sample Collection Personnel;

(2) the arrival time of the Covered Horse to the Test Barn (for Race Day Sample collection) or secure location (for out-of-competition Sample collection);

(3) the name of the Responsible Person and Nominated Person;

(4) any changes in the Nominated Person during the Sample Collection Session;

(5) the contact information of the Responsible Person or Nominated Person(s), if requested;

(6) the name of the Covered Horse;

(7) the sex of the Covered Horse (intact male, mare, gelding);

(8) the color of the Covered Horse;

(9) the means by which the Covered Horse's identity is validated (e.g., microchip number, and/or branding);

(10) the name and signature of the Sample Collection Personnel involved in the Sample collection process for the Covered Horse;

(11) the name of additional Covered Persons (if any) present during the Sample Collection Session;

(12) the Sample code number(s);

(13) the date and time of sealing of each Sample collected and date and time of completion of entire Sample Collection Session;

(14) the location at which the Sample Collection Session took place;

(15) the type of the Sample collected (e.g., urine, blood, hair);

(16) the type of test, e.g., Race Day (TCO2 or Post-Race Sample), Post-Work, or out-of-competition;

(17) whether furosemide was administered to the Covered Horse within 48 hours before Post-Time;

(18) any required Laboratory information on the Sample (e.g., for urine or blood Sample, its volume; for hair Sample, mane/tail and pulled/cut);

(19) for a blood Sample, the information to be recorded by the DCO or BCO as outlined in Rule 5430;

(20) any irregularities in procedures (e.g., if advance notice was provided, if there were any delays in arriving to the Test Barn or secure location, or any anomalous behavior by those present at the collection);

(21) any comments or concerns from the Responsible Person or Nominated Person regarding the conduct of the Sample Collection Session; and

(22) acknowledgement by the Responsible Person or Nominated Person of the processing of Sample collection data and a description of such processing.

(j) At the conclusion of the Sample Collection Session the Responsible Person or Nominated Person and DCO or BCO shall sign appropriate documentation to indicate their satisfaction (or otherwise) that the documentation accurately reflects the details of the Covered Horse's Sample Collection Session. The DCO (or BCO) shall also provide the Responsible Person or Nominated Person the opportunity to document any concerns he or she may have concerning the manner in which Sample Collection Session was conducted.

(k) The Agency may require the Sample Collection Personnel to complete supplemental documentation regarding the Sample Collection Session. For example, any anomalous behavior by the Responsible Person, Nominated Person, and/or other Covered Persons or Persons associated with the

Covered Horse or Responsible Person, or behavior with the potential to compromise the Sample collection shall be recorded in detail by the Sample Collection Personnel. If the Covered Horse requires any emergency medical treatment, that shall be recorded in detail by the Sample Collection Personnel.

(1) Only the DCO or BCO is authorized to end a Sample Collection Session and so release a Covered Horse from the Test Barn or Sample collection location. Only the DCO or BCO, in consultation with the Test Barn Veterinarian for any Race Day Sample collection, is authorized to temporarily release a Covered Horse from the Test Barn or Sample collection location.

(m) Subject to Rule 5200, no photography or audio or video recording of the Sample Collection Session is permitted. Instead, the Sample collection documentation will be the definitive record of the Sample Collection Session, and any comments regarding the Sample Collection Session must be recorded on the Sample collection documentation. If a Covered Person insists on photographing or recording the Sample Collection Session (in whole or in part) in violation of this Rule, the Sample Collection Session should continue, but a case may be brought against the Covered Person under Rule 3510. If the conduct of the Covered Person results in the Sample Collection Session being discontinued, a case may be brought against the Covered Person (on its own or in the alternative) for an Anti-Doping Rule Violation under Rule 3215 and/or Rule 3216. For the avoidance of doubt, any conduct by a Nominated Person or other Person or employee, agent, or associate of the Responsible Person in relation to a Sample Collection Session may in appropriate circumstances be imputed to the Responsible Person for these purposes.

(n) If the Agency collects any Sample(s) from a deceased horse:

(i) Sample collection shall not interfere with any life-saving treatment.

(ii) Sample(s) should ordinarily be collected from the Covered Horse before it is removed from the relevant venue where it suffered a fatal condition, but otherwise may be collected at the location where the Covered Horse is transported to (e.g., veterinary clinic).

(iii) The Agency shall afford the Responsible Person and Nominated Person the opportunity to waive attendance at the Sample collection if such attendance would cause undue distress.

(iv) The Sample collection shall proceed in accordance with the applicable Sample collection procedures, amended as necessary to account for the specific circumstances.

5420. Collection of urine Samples

(a) Urine Samples may be collected and analyzed for any anti-doping analytical matrix or methodology, as determined by the Agency, and in accordance with the Prohibited List and related Technical Documents.

(b) The relevant Sample Collection Personnel will retain control of the Sample collection vessel.

(c) The Responsible Person or Nominated Person will be instructed to examine the Sample collection vessel to ensure that it will not affect the integrity of the urine Sample.

(d) The relevant Sample Collection Personnel will then open and use the selected Sample collection vessel to collect the urine Sample.

(e) The relevant Sample Collection Personnel shall ensure as unobstructed a 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.

(f) When the Covered Horse passes urine, the collection vessel should be positioned to collect as much urine as possible.

(g) The volume of urine required for a full Sample is a minimum of 25 mL for each of the A Sample and B Sample (minimum of 50 mL in total). If during the initial attempt less than 50 mL is obtained, the relevant Sample Collection Personnel should try to collect additional urine.

(h) The Test Barn Veterinarian (or a Regulatory Veterinarian), in consultation with the DCO, shall determine if a Covered Horse is intractable, and (if so) when the urine Sample Collection Session should be terminated. If a urine Sample is not collected because the Covered Horse is intractable, a blood Sample should be collected (in addition to any other Sample, e.g., hair). The Sample Collection Personnel should record the reasons for terminating any Sample collection on the Sample collection documentation.

(i) 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.

(j) 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 to confirm the same.

(k) If the Responsible Person or Nominated Person is not satisfied with the chosen Sample Collection Equipment, this shall be recorded by the DCO. If the DCO does not agree with the Responsible Person or Nominated Person that the equipment is unsatisfactory, the DCO shall inform the Responsible Person or Nominated Person or

(1) Once the Sample collection kit has been selected, the relevant Sample Collection Personnel will pour and split the urine Sample into A and B Sample collection bottles within the view of the Responsible Person or Nominated Person.

(m) The relevant Sample Collection Personnel will seal the A and B bottles within the view of the Responsible Person or Nominated Person. Once closed, the relevant Sample Collection Personnel will check that the bottles have been properly sealed.

(n) The DCO will complete all the required Sample collection documentation and provide the Responsible Person a copy for his or her records.

(o) 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.

5430. Collection of blood Samples

(a) Blood collection shall be conducted by the BCO.

(b) Blood Samples may be collected and analyzed for any anti-doping analytical matrix or methodology, as determined by the Agency, and in accordance with the Prohibited List and related Technical Documents.

(c) The DCO or BCO will select a Sample collection kit containing three blood collection tubes (two of which will be paired together as the A Sample, and the third of which will constitute the B Sample), and the other necessary equipment needed to collect a blood Sample.

(d) If the Responsible Person or Nominated Person is not satisfied with the chosen Sample Collection Equipment, this shall be recorded by the DCO or BCO. If the DCO or BCO does not agree with the Responsible Person or Nominated Person that the equipment is unsatisfactory, the DCO or BCO shall inform the Responsible Person or Nominated Person that the Sample Collection Session is proceeding. If the DCO or BCO agrees with the Responsible Person or Nominated Person or Nominated Person or Nominated Person that the equipment the the equipment is unsatisfactory, the DCO or BCO shall use other available equipment that the DCO or BCO determines is satisfactory. If no such equipment is available, the DCO or BCO shall terminate the Sample Collection Session, and this termination and its specific reason shall be recorded by the DCO or BCO.

(e) Once the Sample collection kit has been selected, the BCO or DCO will open, inspect, and confirm Sample codes numbers within the kit match and ask the Responsible Person or Nominated Person to confirm the same.

(f) The BCO will determine the most suitable location of venipuncture;

(g) The BCO shall safely dispose of used blood sampling equipment not required to complete the Sample Collection Session.

(h) Subject to paragraph (l) below, the 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 24 mL whole blood, plasma, or serum, with each collection tube containing a minimum of 8 mL.

(i) If the amount of blood that can be removed from the Covered Horse at the first attempt is insufficient, the BCO shall repeat as necessary and appropriate (taking horse welfare into account) to try to obtain the minimum total volume for a blood Sample. If the BCO is unable to collect a sufficient amount of blood, the BCO or DCO may terminate the blood Sample Collection Session and record the reasons for such termination. Other matrices should be considered for collection.

(j) Once a complete blood Sample is obtained, the BCO or DCO will properly seal the A and B tubes.

(k) The BCO or DCO will complete all the required Sample collection documentation and provide the Responsible Person a copy for his or her records.

(1) Total carbon dioxide (TCO2):

(1) In addition to the collection of a Post-Race Sample, blood Sample(s) may also be collected from a Covered Horse prior to a Covered Horserace or Vets' List Workout for the purpose of testing for TCO2. The Prohibited List specifies the TCO2 levels that will be considered *prima facie*

evidence of alkalinization or administration of an alkalinizing agent, i.e., a Controlled Medication Method.

(2) A blood Sample collected for TCO2 analysis may have a total volume below 24 mL, at the Agency's discretion. Any volume of blood collected for TCO2 analysis will be transported to the Laboratory.

(3) The Responsible Person or Owner of a Covered Horse selected for TCO2 testing may request that a duplicate Sample be taken. Such request must be made prior to the collection of the official Sample. The costs related to obtaining, handling, shipping, and analyzing the duplicate Sample shall be the responsibility of the Responsible Person or Owner who requested such Sample.

(4) The duplicate sample shall not constitute a B Sample. Accordingly:

(i) the provisions in the Protocol addressing the splitting of Samples for analysis purposes shall not apply to blood samples collected for TCO2 testing.

(ii) the provisions of Rule 5430 apply to blood Samples collected for TCO2 testing, except that any references to A and B Samples or tubes shall not apply, as there shall be only one official Sample.

(5) The official Sample and any duplicate Sample shall be analyzed by the same Laboratory. If the Agency, in its discretion, determines that the duplicate Sample cannot be analyzed within five (5) days after the Sample is collected, the findings of the official Sample shall be final.

(6) Blood Samples collected for TCO2 testing may be subject to Further Analysis if a Post-Race Sample collected from the same Covered Horse returns an Atypical Finding or an Adverse Analytical Finding.

5440. Collection of hair Samples

Sample Collection Personnel should collect hair Samples in accordance with the following requirements:

(a) hair should (to the extent possible) be completely dry and free of visible dirt, debris, or foreign substances;

(b) mane hair should be collected unless tail hair is specifically requested. If, for a particular reason, a mane Sample cannot be obtained (e.g., due to a hogged mane), tail hair may be collected;

(c) an adequate Sample of hair should be obtained for each of the A and B Samples;

(d) if the mane is less than 10 cm, an additional Sample of hair may be required to ensure a suitable volume is obtained for analysis;

(e) 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

(f) hair shafts should remain aligned so that the hair does not become knotted.

5450. Sample Collection Personnel requirements

(a) *Minimum requirements*. The Agency shall establish the necessary eligibility and qualification requirements for the positions of DCO, BCO, and Chaperone. At a minimum:

(1) Sample Collection Personnel shall be eighteen (18) years or older;

(2) Sample Collection Personnel shall agree to undergo screening required by the Agency (e.g., background checks, conflicts of interest); and

(3) The BCO shall be a Veterinarian or veterinary technician with the practical skills and knowledge to perform blood collection from a vein on a horse.

(b) Conflicts

(1) The Agency may require all Sample Collection Personnel to sign an agreement regarding conflicts of interest, confidentiality, and an appropriate code of conduct.

(2) The Agency shall not assign any Sample Collection Personnel to a Sample Collection Session where they have an interest in the performance or outcome of the Sample collection process. At a minimum, Sample Collection Personnel are deemed to have such an interest if they:

(i) are related to, employed or otherwise engaged by, or otherwise affiliated with any Equine Constituencies, excluding State Racing Commissions;

(ii) have a financial interest in or are involved in any way with the care or training or ownership of the Covered Horse at issue;

(iii) are engaged in business with, have a financial interest in, or have a personal stake in a Covered Horserace; and/or

(iv) 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.

(c) *Training*

(1) The Agency shall establish or approve written training materials for Sample Collection Personnel that outline their respective responsibilities and that provide adequate training for their roles.

(2) The Agency shall ensure that DCOs and BCOs have completed the necessary training program and are familiar with the requirements before issuing them a credential or other authorization documentation.

(3) The training program for DCOs and BCOs should include, at a minimum:

(i) comprehensive theoretical training in the activities relevant to the DCO or BCO position (as applicable);

(ii) observation of the activities that are the responsibility of the DCO or BCO as set out in these Testing and Investigations Standards, preferably on-site; and

(iii) the satisfactory performance of one (1) complete Sample Collection Session on-site under observation by a qualified DCO, BCO, or similar personnel.

(4) The training program for Sample Collection Personnel responsible for the collection of blood Samples shall also include standard precautions in veterinary settings.

(5) 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.

(d) *Credentialing*

(1) The Agency shall establish a system for credentialing and re-credentialing DCOs and BCOs. DCOs and BCOs shall have either a credential including 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 or authorization documentation to require for other Sample Collection Personnel.

(2) Only Sample Collection Personnel who have been authorized by the Agency are permitted to conduct Doping Control and Medication Control activities on behalf of the Agency.

(3) DCO and BCO credentials shall be valid for a maximum of two (2) years. DCOs and BCOs should be subject to an assessment (theoretical and/or practical) before being re-credentialed.

(4) The Agency will take steps to develop a system to monitor the performance of DCOs and BCOs.

(5) The Agency will maintain records of conflicts of interest and training of all Sample Collection Personnel.

5500. STORAGE AND TRANSPORTATION

5510. Storage and custody of Samples prior to analysis

(a) After Sample collection, the DCO or BCO shall store Samples in a manner that protects the integrity, identity, and security, prior to transport to the Laboratory.

(b) If a urine or blood Sample is not transported to the Laboratory on the day of collection:

(1) the DCO shall store the urine Sample in a secure freezer; and

(2) the DCO or BCO shall store the blood Sample in a secure refrigerator;

(3) and, in each case, shall document in the Chain of Custody the location and time in and time out of the urine or blood Sample.

(c) The DCO or BCO shall document who has custody of the Samples and/or who is permitted access to the Samples.

(d) 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.

5520. Transport of Samples and documentation

(a) Samples should be transported to the Laboratory as soon as reasonably practicable after the conclusion of the Sample Collection Session. Samples collected on a weekend or over consecutive days may be stored and shipped together in batches (e.g., Samples collected on a race weekend may be stored and sent to the Laboratory on the next Monday), provided that the Samples are stored in accordance with the requirements of these Testing and Investigations Standards.

(b) Samples shall be transported securely via a transportation or shipping service authorized by the Agency. The Agency shall authorize a transport system that ensures Samples and related documentation are transported in a manner that protects their integrity, identity, and security, and which minimizes the potential for Sample degradation due to factors such as delays and extreme temperature variations. Blood samples must be transported in a manner that maintains a cool and constant environment.

(c) State Racing Commissions may select a Laboratory at which the A Samples (or official TCO2 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 Agency 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 (as determined by the Agency).

(d) A and B Samples (and official and duplicate TCO2 Samples) will be shipped together to the Laboratory conducting the A Sample analysis. If the B sample analysis is requested, the B Sample will be shipped to the B Sample Laboratory selected by the Agency.

(e) The Agency will have the ability to confirm, if necessary, that Samples and related documentation arrived at the Laboratory. The Laboratory shall report any irregularities to the Agency with respect to the condition of Samples upon arrival in accordance with the Laboratory Standards.

(f) 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, including whether long-term storage is required.

(g) 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.

(h) If the Samples or related documentation are not received by the Laboratory, or if a Sample's integrity or identity was compromised during transport, the Agency will consider whether the Samples should be voided. The decision to void a Sample is in the sole discretion of the Agency.

5530. Ownership and retention of Samples and retention of documentation

(a) Samples collected from a Covered Horse are owned by the Authority. Samples shall be retained by Laboratories in accordance with the requirements of Rule 6319.

(b) Documentation related to a Sample Collection Session and/or an Anti-Doping Rule Violation or Controlled Medication Rule Violation shall be stored by the Agency in accordance with the Agency's record retention policy.

5600. STANDARDS FOR INTELLIGENCE GATHERING

5610. Purpose

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 misuse of medication and inform effective, intelligent, and proportionate test planning; plan Target Testing; and conduct investigations as required by the Protocol. The objective of this Rule is to establish standards for the efficient and effective gathering, assessment, and processing of such intelligence for these purposes.

5620. Gathering intelligence

(a) The Agency should make every reasonable effort to ensure that it is able to obtain or receive antidoping and medication control intelligence from all available sources, including, but not limited to: Covered Persons, including through Substantial Assistance; members of the public (e.g., by means of a confidential whistleblower platform); Sample Collection Personnel (whether via mission reports, incident reports, or otherwise); Laboratories; pharmaceutical companies; the Authority; law enforcement (authorized by any government, including federal, state, or international); State Racing Commissions; Racetracks; Race Organizers; anti-doping organizations; equine regulatory bodies; other relevant regulatory or disciplinary authorities; and the media (in all its forms).

(b) The Agency shall ensure that anti-doping and medication control intelligence obtained 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 in a matter intended to be confidential is processed, used, and disclosed only for any legitimate legal, law enforcement, regulatory, anti-doping, medication control, integrity, disciplinary, horse welfare, and/or safety purposes.

(c) The Agency shall facilitate, encourage, and seek to protect whistleblowers.

(d) The Agency may consult and/or coordinate with the Authority, law enforcement (authorized by any government, including federal, state, or international), State Racing Commissions, Racetracks, Race Organizers, Training Facilities, anti-doping organizations, equine regulatory bodies, and/or other relevant regulatory or disciplinary authorities in obtaining, developing, and/or sharing information and intelligence that may be useful for the implementation or enforcement of the Protocol or the Act and/or for any legitimate legal, law enforcement, regulatory, anti-doping, medication control, integrity, disciplinary, horse welfare, and/or safety purposes (e.g., the Agency may share information with other entities investigating the possible commission of a crime, regulatory offense, or breach of other rules of conduct; in particular, for example, the Agency may share the results of Sample analyses with the Authority for purposes of enforcing the Racetrack Safety Program).

5630. Assessment and analysis of intelligence

(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.

(b) All relevant anti-doping and medication control intelligence obtained 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 in determining (where the intelligence relates to a particular case) whether there is reasonable suspicion that an Anti-Doping Rule Violation or Controlled Medication Rule Violation may have been committed, such that further investigation is warranted.

5640. Intelligence outcomes

Anti-doping and medication control intelligence may be used for the following purposes (without limitation):

- (a) developing, reviewing, and revising test distribution planning;
- (b) determining when to conduct Target Testing; and/or
- (c) creating targeted intelligence files to be referred for investigation.

5700. STANDARDS FOR INVESTIGATIONS

5710. Purpose

(a) The objective of this Rule is to establish standards for the efficient and effective conduct of investigations under the Protocol, including, but not limited to:

(1) the investigation of Sample abnormalities reported by Laboratories;

(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 Rule Violation or Controlled Medication Rule Violation may have been committed;

(3) the investigation of the circumstances surrounding and/or arising from an Adverse Analytical Finding to gain further intelligence concerning the Responsible Person or other Covered Persons associated with the Covered Horse whose Sample is the subject of the Adverse Analytical Finding, including to determine if any other methods are involved in doping or medication abuse; and

(4) where a Covered Person is alleged to have committed an Anti-Doping Rule Violation or Controlled Medication Rule Violation, the investigation into whether any other Covered Persons were complicit or otherwise involved in that violation.

(b) In each case, the purpose of the investigation is to achieve one of the following:

(1) to rule out a possible violation or involvement in an Anti-Doping Rule Violation or Controlled Medication Rule Violation;

(2) to develop evidence that supports an Anti-Doping Rule Violation or Controlled Medication Rule Violation proceeding or the initiation of such a proceeding in accordance with the Protocol; or

(3) to provide evidence of a violation of any other provisions of the Protocol or related Rule Series, or applicable law or regulation.

5720. Investigating possible violations

(a) The Agency shall conduct, direct, and manage all investigations under the Protocol, unless it specifically delegates an investigation (or aspects of an investigation) to a State Racing Commission (subject to the applicable State Racing Commission electing to enter into an agreement with the Agency).

(b) The Agency and any State Racing Commission to which the Agency delegates investigatory tasks shall ensure that investigations are conducted confidentially.

(c) The Agency will seek to investigate any analytical or non-analytical information or intelligence that indicates (i) there is reasonable suspicion that an Anti-Doping Rule Violation or Controlled Medication Rule Violation may have been committed, or (ii) further inquiry might lead to the discovery of admissible evidence of such violation.

(d) The Agency should gather and record all relevant information and documentation as soon as possible.

(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.

(f) Covered Persons are required under the Protocol to cooperate with investigations conducted by the Agency (or a State Racing Commission, if the investigation is delegated by the Agency). If they fail to do so, the Agency may bring proceedings against them for failure to cooperate (in accordance with Rule 3510(b)). If their conduct amounts to subversion of the investigative 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 the Anti-Doping Rule Violation of Tampering or Attempted Tampering.

(g) It shall not be a defense in a proceeding involving an Anti-Doping Rule Violation or Controlled Medication Rule Violation that an investigation should have been conducted more quickly or that any aspect of the Testing and Investigations Standards was not followed by the Agency or State Racing Commission, except as provided in Rule 3122.

5730. Obtaining investigative information

(a) *General.* The Agency should make use of all investigative resources reasonably available to it to conduct its investigation. These resources may include: obtaining information and assistance from other entities pursuant to Rule 5620(d); 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 the Protocol. Without limitation, the Agency may utilize the investigative tools set forth in paragraphs (b) through (f) of this Rule in relation to investigations and inquiries of possible violations of the Protocol.

(b) Inspection, examination and seizure

(1) The Agency shall have 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/or racing of Covered Horses.

(2) The Agency may seize any medication, drug, substance, or paraphernalia in violation or suspected violation of any provision of the Act or any rules approved by the Commission pursuant to the Act, and any object or device reasonably believed to have been used in furtherance of the violation or suspected violation.

(c) *Return of seized property*. Upon final resolution of a violation, the Agency shall return seized property, including, but not limited to, phones, computers and other repositories of electronic data, the possession of which is not specifically prohibited by the Act or the rules of the Authority.

(d) Production of documents and information

(1) The Agency may require a Covered Person to provide any information, documents, or records in such form as the Agency may require, which are held by the Covered Person or are within his or her power to obtain, and that are used in the care, treatment, training, and/or racing of Covered Horses.

(2) The Agency may 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, and that are used in the care, treatment, training, and/or racing of Covered Horses.

(e) *Subpoenas*. The Agency may request that 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; produce designated evidence by a specific time; or permit the Agency to inspect premises 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 being conducted. Additionally, the arbitrator(s), IAP member(s), administrative law judge, or Commission considering a case arising under the Protocol may draw 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.

(1) This issuance of a subpoena and compliance therewith is independent of the Agency's powers to inspect and obtain evidence without a subpoena and a 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 the arbitrator(s), IAP member(s), administrative law judge, or Commission.

(2) The following considerations should be taken into account by the Agency in determining whether a subpoena should be requested to be issued by the Authority:

(i) the availability of, and success in, using alternative methods for obtaining the information in a timely manner;

(ii) the indispensability of the information to the success of the investigation or establishing a violation; and

(iii) the need to protect against the destruction of records or information that may be necessary to investigate and prosecute violations of the Protocol.

(f) Interviews

(1) Covered Persons shall comply with a request to be interviewed by the Agency.

(2) If the Agency requires a Covered Person to submit to an interview under oath, the Covered Person may request a delay of the interview to seek legal advice. However, such delay shall only encompass the time reasonably necessary to contact and retain legal counsel and shall in no case exceed seven (7) days, unless agreed otherwise by the Agency.

(3) An authorized Person may administer an oath or affirmation to a Covered Person appearing for an interview under oath.

(4) The only basis for refusing to answer a question in an interview is an assertion of the attorneyclient privilege or the Fifth Amendment privilege against self-incrimination.

5740. Investigation outcomes

(a) The Agency shall determine without undue delay whether proceedings should be initiated against a Covered Person and/or Responsible Person in relation to a Covered Horse for an Anti-Doping Rule Violation or Controlled Medication Rule Violation.

(b) If the Agency concludes based on the results of its investigation that proceedings should be initiated against a Covered Person or a Responsible Person independently or in relation to a Covered Horse, asserting commission of an Anti-Doping Rule Violation or Controlled Medication Rule Violation, it shall give notice of that decision in the manner set out in the Protocol.

(c) If the Agency concludes, based on the results of its investigation, that proceedings asserting commission of an Anti-Doping Rule Violation or Controlled Medication Rule Violation should not be initiated against a Covered Person or a Responsible Person independently or in relation to a Covered Horse, the Agency shall consider whether any of the intelligence obtained and/or lessons learned during the investigation should be used for test distribution planning, Target Testing, and/or whether it should be shared with any other Person or included in any report in accordance with these Testing and Investigations Standards.

(d) 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.